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PART 1/19

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT

Accompanying the document

Proposal for a COUNCIL REGULATION establishing the Joint Undertakings under Horizon Europe

EU-Africa Global Health Partnership

{COM(2021) 87 final} - {SEC(2021) 100 final} - {SWD(2021) 38 final}

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Acronyms

AMR Anti-Microbial Resistance
CD Communicable disease

CSA Coordination and Support Action
DIS Dedicated Implementation Structure

EC European Commission

EDCTP European and Developing Countries Clinical Trials Partnership

EIT European Institute of Innovation & Technology

EU European Union

ERA European Research Area
FTE Full Time Equivalent
GA EDCTP General Assembly

GHIT Global Health Innovative Technology Fund

H2020 Horizon 2020 - EU Framework Programme of Research and Innovation -

2014-2020

HE Horizon Europe - EU Framework Programme for Research and Innovation

2021-2027

HIV/AIDS Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome

ID Infectious disease

IHI Innovative Health InitiativeIMI Innovative Medicines Initiative

JU Joint Undertaking

LMIC Low and Middle-Income Countries
MDG Millennium Development Goals
MOU Memorandum of Understanding

MS EU Member States

NCD Non-Communicable DiseasesNGO Non-Governmental OrganisationsNTD Neglected Tropical Diseases

OPC Open Public Consultation

PDP Product Development Partnership

PRND Poverty Related and Neglected Disease

R&D Research and Development R&I Research and Innovation

RIA Research and Innovation Action SDG Sustainable Development Goals

SME Small- and Medium-Size Enterprises

SRIA Strategic Research and Innovation Agenda

SSA Sub-Saharan Africa

TFEU Treaty of Functioning of the European Union

TMA Training and Mobility Actions
WHO World Health Organisation

Definitions

For the purposes of the GHP/EDCTP3 impact assessment, the following definitions apply:

Clinical trial: Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials may also be referred to as interventional trials. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc.¹

Disease outbreak: The occurrence of disease cases in excess of normal expectancy. The number of cases varies according to the disease-causing agent, and the size and type of previous and existing exposure to the agent. Disease outbreaks are usually caused by an infection, transmitted through person-to-person contact, animal-to-person contact, or from the environment or other media.²

Health technology: The application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives.³

Health intervention: An act performed for, with or on behalf of a person or population whose purpose is to assess, improve, maintain, promote or modify health, functioning or health conditions.⁴

Infectious diseases: Those diseases caused by pathogenic microorganisms, such as bacteria, viruses, parasites or fungi; the diseases can be spread, directly or indirectly, from one person to another.⁵

Phases of a clinical trial: A trial of experimental drug, treatment, device or behavioural intervention may proceed through four phases:⁶

- Phase I Clinical trials test a new biomedical intervention in a small group of people (e.g., 20-80) for the first time to evaluate safety (e.g., to determine a safe dosage range and to identify side effects).
- Phase II Clinical trials study the biomedical or behavioural intervention in a larger group of people (several hundred) to determine efficacy and to further evaluate its safety.
- Phase III Studies investigate the efficacy of the biomedical or behavioural intervention in large groups of human subjects (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the intervention to be used safely.

https://www.who.int/ictrp/en/

² https://www.who.int/environmental_health_emergencies/disease_outbreaks/en/#:~:text=A% 20disease%20outbreak% 20is%20the,or%20to%20radioactive%20materials

³ https://www.who.int/health-technology-assessment/about/healthtechnology/en/

⁴ https://www.who.int/classifications/ichi/en/

https://www.who.int/topics/infectious_diseases/en/

⁶ https://www.who.int/ictrp/glossary/en/#TrialPhase

• Phase IV Studies are conducted after the intervention has been marketed. These studies are designed to monitor effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.

Zoonotic diseases: Infectious diseases of animals that can cause disease when transmitted to humans. 7

⁷ https://www.who.int/topics/infectious_diseases/en/

PART 1 - COMMON FOR ALL CANDIDATE INSTITUTIONALISED EUROPEAN PARTNERSHIPS

1. BACKGROUND AND CONTEXT TO EUROPEAN PARTNERSHIPS IN HORIZON EUROPE AND FOCUS OF THE IMPACT ASSESSMENT—WHAT IS DECIDED

1.1. Focus and objectives of the impact assessment

This impact assessment accompanies the Commission proposal for Institutionalised European Partnerships to be funded under Horizon Europe, the 2021-2027 Framework Programme for EU Research and Innovation (R&I).⁸ It sets out to help decide in a coordinated manner the right form of implementation for specific candidate initiatives based on a common approach and methodology according to individual assessments⁹. It also provides an horizontal perspective on the portfolio of candidate European Partnerships to identify further efficiency and coherence gains for more impact.

European Partnerships are initiatives where the Union, together with private and/or public partners (such as industry, public bodies or philanthropies) commit to support jointly the development and implementation of an integrated programme of R&I activities. The rationale for establishing such initiatives is to achieve the objectives of Horizon Europe more effectively than what can be attained by other activities of the Horizon Europe programme. ¹⁰

Based on the Horizon Europe Regulation, European Partnerships may be set up using **three different forms**: "Co-funded", "Co-programmed" and "Institutionalised". The setting-up of **Institutionalised Partnerships** involves new EU legislation and the establishment of dedicated implementing structures based on Article 185 or 187 of the Treaty on the Functioning of the EU (TFEU). This requires an impact assessment to be performed.

The Horizon Europe Regulation defines **eight priority areas**, scoping the domains in which Institutionalised Partnerships could be proposed¹¹. Across these priority areas, **13 initiatives** have been identified **as suitable candidate initiatives** for Institutionalised Partnerships because of their objectives and scope. This impact assessment aims to identify whether 12 of these initiatives¹² need to be implemented through this form of implementation and would not deliver equally well with traditional calls of Horizon Europe or other lighter forms of European Partnerships under Horizon Europe. This means assessing whether each of these initiatives meets the necessity test set in the **selection criteria** for European Partnerships in the Horizon Europe Regulation, Annex III.

This assessment is done **without any budgetary consideration**, as the overall budget of the Multiannual Financial Framework of the EU – and hence of Horizon Europe – for the next financing period is not known at this stage. ¹³

11 Set out in the Annex Va of the Horizon Europe Regulation (common understanding). https://data.consilium.europa.eu/doc/document/ST-7942-2019-INIT/en/pdf

⁸ Horizon Europe Regulation (common understanding), https://data.consilium.europa.eu/doc/document/ST-7942-2019-INIT/en/pdf

⁹ Based on the European Commission Better Regulation framework (SWD (2017) 350) and supported by an external study coordinated by Technopolis Group (to be published in 2020).

¹⁰ For further details on these points, see below Section 1.2.2.

Only 12 are subject to this impact assessment, as one initiative on High Performance Computing has already been subject to an impact assessment in 2017 (SEC(2018) 47).

¹³ EU budget commitments to the European Partnership candidates can only be discussed and decided following the political agreement on the overall Multiannual Financial Framework and Horizon Europe budgetary envelopes. The level of EU contribution for individual partnerships should be determined once there are agreed objectives, and clear commitments from partners. Importantly, there is a ceiling to the partnership budgets in Pillar II of Horizon Europe (the legal proposal specifies that the majority of the budget in pillar II shall be allocated to actions outside of European Partnerships).

1.2. The political and legal context

1.2.1. Shift in EU priorities and Horizon Europe framework

European priorities have evolved in the last decades, and reflect the social, economic, and environmental challenges for the EU in the face of global developments. In her Political Guidelines for the new European Commission 2019 – 2024¹⁴, the new Commission President put forward six overarching priorities, which reach well beyond 2024 in scope¹⁵. Together with the Sustainable Development Goals (SDGs), these priorities will shape future EU policy responses to the challenges Europe faces, and thus also give direction to EU research and innovation.

As part of the Multi-annual Financial Framework (MFF) 2021-27 the new EU Framework Programme for Research and Innovation Horizon Europe will play a pivotal role for Europe to lead the social, economic, and environmental transitions needed to achieve these European policy priorities. It will be more impact driven with a strong focus on delivering European added value, but also be more effective and efficient in its implementation. ¹⁶ Horizon Europe finds its rationale in the daunting challenges that the EU is facing, which call for "a radical new approach to developing and deploying new technologies and innovative solutions for citizens and the planet on a scale and at a speed never achieved before, and to adapting our policy and economic framework to turn global threats into new opportunities for our society and economy, citizens and businesses." While Horizon Europe continues the efforts of strengthening the scientific and technological bases of the Union and foster competitiveness, a more strategic and impact-based approach to EU R&I investment is taken. Consequently, the **objectives of Horizon Europe** highlight the need to deliver on the Union strategic priorities and contribute to the realisation of EU objectives and policies, contribute to tackling global challenges, including the Sustainable Development Goals by following the principles of the Agenda 2030 and the Paris Agreement. ¹⁷

In this context, at least 35 % of the expenditure from actions under the Horizon Europe Programme will have to contribute to climate action. Furthermore, a Strategic Plan is codesigned with stakeholders to identify key strategic orientations for R&I support for 2021-2024 in line with the EU priorities. In the Orientations towards the first Strategic Plan for Horizon Europe, the need to strategically prioritise and "direct a substantial part of the funds towards the areas where we believe they will matter the most" is emphasised. The Orientations specify, that actions under Pillar II of Horizon Europe "Global Challenges and European Industrial Competitiveness" will target only selected themes of especially high impact that significantly contribute to delivering on the political priorities of the Union. Most of the candidate European Partnerships fall under this Pillar.

1.2.2. Key evolutions in the approach to partnerships in Horizon Europe

Since their start in 1984 the successive set of Framework Programmes uses a variety of instruments and approaches to support R&I activities, address global challenges and industrial competitiveness. Collaborative, competition-based and excellence-driven R&I projects funded through Work Programmes are the most traditional and long-standing approach for implementation. Since 2002, available tools also include **partnerships**, whereby

15 I.A European Green Deal; An economy that works for people; A Europe fit for the Digital Age; Promoting our European way of life; A Stronger Europe in the World; and 6.A New push for European Democracy

¹⁴ https://ec.europa.eu/info/strategy/priorities-2019-2024_en

¹⁶ EC (2018) A Modern Budget for a Union that Protects, Empowers and Defends. The Multiannual Financial Framework for 2021-2027. Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, COM(2018) 321 final

¹⁷ Article 3, Common understanding regarding the proposal for Horizon Europe Framework Programme.

the Union together with private and/or public partners commit to jointly support the development and implementation of a R&I programme. These were introduced as part of creating the European Research Area (ERA) to align national strategies and overcome fragmentation of research effort towards an increased scientific, managerial and financial integration of European research and innovation. Interoperable and integrated national research systems would allow for better flows of knowledge, technology and people. Since then, the core activities of the partnerships consist of building critical mass mainly through collaborative projects, jointly developing visions, and setting strategic agendas.

As analysed in the interim evaluation of Horizon 2020¹⁸, a considerable repertoire of partnership initiatives have been introduced over time, with 8 forms of implementation ¹⁹ and close to 120 partnership initiatives running under Horizon 2020 - without clear exit strategies and concerns about their degree of coherence, openness and transparency. Even if it is recognised that these initiatives allow setting long-term agendas, structuring R&I cooperation between otherwise dispersed actors, and leveraging additional investments, the evaluation points to the complexity generated by the proliferation of instruments and initiatives, and their insufficient contribution to policies at EU and national level.

Box 1 Key lessons from the interim evaluation of Horizon 2020 and R&I partnerships

- The Horizon 2020 Interim Evaluation concludes that the overall partnership landscape has become overly complex and fragmented. It identifies the need for rationalisation, improve their openness and transparency, and link them with future EU R&I missions and strategic priorities.
- The Article 185 evaluation finds that these public-public partnerships have scientific quality, global visibility and networking/structuring effects, but should in the future focus more on the achievement of policy impacts. From a systemic point of view, it found that the EU public-topublic cooperation (P2P) landscape has become crowded, with insufficient coherence.
- The Article 187 evaluation points out that Public-Private Partnership (PPP) activities need to be brought more in line with EU, national and regional policies, and calls for a revision of the Key Performance Indicators. As regards the contractual PPPs (cPPPs) their reviews identified challenges of coherence among cPPPs and the need to develop collaborations and synergies with other relevant initiatives and programmes at EU, national and regional level.

Over 80% of respondents to the Open Public Consultation (OPC) indicated that a significant contribution by future European Partnerships is 'fully needed' to achieve climate-related goals, to develop and effectively deploy technology, and for EU global competitiveness in specific sectors/domains. Views converged across all categories of respondents, including citizens,

19 E.g. initiatives based on Article 187 (Joint Technology Initiatives), Article 185 TFEU, Contractual Public-Private Partnerships (cPPPs), Knowledge & Innovation Communities of the European Institute of Innovation & Technology (EIT-KICs), ERA-NETs, European Joint

Programmes, Joint Programming Initiatives.

¹⁸ Interim evaluation of Horizon 2020, Commission Staff Working Document, SWD(2017)221 and 222 Interim evaluation of the Joint Undertakings operating under Horizon 2020 (Commission Staff Working Document, SWD(2017) 339); Evaluation of the Participation of the EU in research and development programmes undertaken by several Member States based on Article 185 of the TFEU, Commission Staff Working Document, SWD (2017)340)

The impact assessment of Horizon Europe identifies therefore the need to rationalise the EU R&I funding landscape, in particular with respect to partnerships, as well as to re-orient partnerships towards more impact and delivery on EU priorities. To address these concerns and to realise the higher ambition for European investments, Horizon Europe puts forward a major simplification and reform for the Commission's policy on R&I partnerships²⁰. Reflecting its pronounced systemic nature aimed at contributing to EU-wide 'transformations' towards the sustainability objectives, Horizon Europe indeed intends to make a more effective use of these partnerships with a more strategic, coherent and impact-driven approach. Key related changes that apply to all forms of European

Box 2 Key features of the revised policy approach to R&I partnerships under Horizon Europe based on its impact assessment

- ✓ **Simpler architecture & toolbox** by streamlining 8 partnership instruments into 3 implementation forms (Co-Funded, Co-Programmed, Institutionalised), under the umbrella 'European Partnerships'
- More systematic and transparent approach to selecting, implementing, monitoring, evaluating and phasing out all forms of partnerships (criteria for European Partnerships):
 - The selection of Partnerships is embedded in the strategic planning of Horizon Europe, thereby ensuring coherence with the EU priorities. The selection criteria require that partnerships are established with stronger ex-ante commitment and higher ambition.
 - The implementation criteria stipulate that initiatives adopt a systemic approach in achieving impacts, including broad engagement of stakeholders in agenda-setting and synergies with other relevant initiatives to promote the take-up of R&I results.
 - A harmonised monitoring & evaluation system will be implemented, and ensures that progress is analysed in the wider context of achieving Horizon Europe objectives and EU priorities.
 - All partnerships need to develop an exit strategy from Framework Programme funding. This new approach is underpinned by principles of openness, coherence and EU added value.

✓ Reinforced impact orientation:

- Partnerships are established only if there is evidence they support achieving EU policy objectives
 more effectively than other Horizon Europe actions, by demonstrating a clear vision and targets
 (directionality) and corresponding long-term commitments from partners (additionality).
- European Partnerships are expected to provide mechanisms based on a concrete roadmap to join up R&I efforts between a broad range of actors towards the development and uptake of innovative solutions in line with EU priorities, serving the economy and society, as well as scientific progress.
- They are expected to develop close synergies with national and regional initiatives, acting as dynamic change agents, strengthening linkages within their respective ecosystems and along the value chains, as well as pooling resources and efforts towards the common EU objectives.

Partnerships encapsulated in Horizon Regulation are summarised in the Box below.

Under Horizon Europe, a 'European Partnership'²¹ is defined as "an initiative where the Union, prepared with early involvement of Member States and/or Associated Countries, together with private and/or public partners (such as industry, universities, research organisations, bodies with a public service mission at local, regional, national or international level or civil society organisations including philanthropies and NGOs), commit to jointly support the development and implementation of a programme of research and innovation activities, including those related to market, regulatory or policy uptake."

The Regulation further specifies that European Partnerships shall adhere to the "principles of Union added value, transparency, openness, impact within and for Europe, strong leverage effect on sufficient scale, long-term commitments of all the involved parties, flexibility in implementation, coherence, coordination and complementarity with Union, local, regional, national and, where relevant, international initiatives or other partnerships and missions."

²¹ Article 8 and Annex III of the Horizon Europe Regulation (common understanding)

²⁰ Impact assessment of Horizon Europe, Commission Staff Working Document, SWD(2018)307.

1.3. Why should the EU act

1.3.1. Legal basis

Proposals for Institutionalised European Partnerships are based on:

- 1) Article 185 TFEU which allows the Union to make provision, in agreement with the Member States concerned, for participation in research and development programmes undertaken by several Member States, including participation in the structures created for the execution of those programmes; or
- 2) Article 187 TFEU according to which the Union may set up joint undertakings or any other structure necessary for the efficient execution of Union research, technological development and demonstration programmes.²²

1.3.2. Subsidiarity

The EU should act only in areas where there is demonstrable advantage that the action at EU level is more effective than action taken at national, regional or local level. Research is a shared competence between the EU and its Member States according to the TFEU. Article 4 (3) specifies that in the areas of research, technological development and space, the EU can carry out specific activities, including defining and implementing programmes, without prejudice to the Member States' freedom to act in the same areas. The candidate initiatives focus on areas where there is a demonstrable value added in acting at the EU level due to the scale, speed and scope of the efforts needed for the EU to meet its long-term Treaty objectives and deliver on its strategic policy priorities and commitments. In addition, the proposed initiatives should be seen as complementary and reinforcing national and subnational activities in the same area. Overall European Partnerships find their **rationale in addressing a set of systemic failures**²³:

- Their primary function is to create a platform for a strengthened **collaboration** and knowledge exchange between various actors in the European R&I system and an enhanced **coordination** of strategic research agendas and/or R&I funding programmes. They aim to address **transformational failures** to better align agendas and policies of public and private funders, pool available resources, create critical mass, avoid unnecessary duplication of efforts, and leverage sufficiently large investments where needed but hardly achievable by single countries.
- The concentration of efforts and pooling of knowledge on common priorities to solve multi-faceted societal and economic challenges is at the core of these initiatives. Specifically, enhanced cross-disciplinary and cross-sectoral collaboration and an improved integration of value chains and ecosystems are among the key objectives of these instruments. In the light of Horizon Europe, the aim is to **drive system transitions and transformations towards EU priorities**.
- Especially in fast-growing technologies and sectors such as ICT, there is a need to **react to emerging opportunities** and address systemic failures such as shortage in skills or critical mass or cross-sectoral cooperation along the value chains that would hamper attainment of future European leadership and/or strategic autonomy.
- They also aim to address **market failures** predominantly to enhancing industry investments thanks to the sharing of risks.

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²² Both Articles are under Title XIX of the TFEU - Research and Technological Development and Space.

²³ The Interim Evaluation of Horizon 2020 and the impact assessment of Horizon Europe provide qualitative and quantitative evidence on these points. Sections 1 and 2 of each impact assessment on candidate European Partnerships include more detail on the necessity to act at EU level in specific thematic areas.

2. THE CANDIDATE EUROPEAN PARTNERSHIPS – WHAT NEEDS TO BE DECIDED

2.1. Portfolio of candidates for Institutionalised European Partnerships

The new approach for more objective-driven and impactful European Partnerships is reflected in the way candidate Partnerships have been identified. It involved a co-design exercise aiming to better align these initiatives with societal needs and policy priorities, while broadening the range of actors involved. Taking into account the 8 areas for Institutionalised European Partnerships set out in the Horizon Europe Regulation²⁴, a co-design exercise as part of the Strategic Planning process of Horizon Europe lead to the identification of 49 candidates for Co-funded, Co-programmed or Institutionalised European Partnerships²⁵. Out of these, 13 were identified as suitable candidate Institutionalised Partnerships because of their objectives and scope²⁶. Whilst the Co-Funded and Co-Programmed Partnerships are linked to the comitology procedure (including the adoption of the Strategic Plan and the Horizon Europe Work Programmes), Institutionalised Partnerships require the adoption of legislation and are subject to an impact assessment. The Figure below gives an overview of all candidate European Partnerships according to their primary relevance to Commission priorities for 2019-2024.

Figure 1 - Overview of the candidates for Co-Funded, Co-Programmed and Institutionalised European Partnerships according to Horizon Europe structure

Horizon Europe	Pillar II - Global challenges & I	European industrial competitivene	ess		
Cluster 1: Health	Cluster 4: Digital, Industry & Space	Cluster. 5: Climate, Energy & Mobility	Cluster 6: Food, Bioeconomy, Agriculture,		
Innovative	Key digital technologies	Clean Hydrogen	Circular Bio-based Europe		
Health Initiative	Smart networks & services	Safe & automated road transport	Safe & sustainable food		
EU-Africa Global Health	High-Performance Computing	Transforming EU's rail system	system		
Large-scale	European Metrology	Clean Aviation	Climate-neutral, sustainable & productive blue bio-		
innovation & transformation of	AI-Data-Robotics	Integrated Air Traffic Management	economy		
health systems	Photonics	European industrial battery value	Animal Health		
Personalised	Made in Europe	chain	Water4All		
Medicine	Clean steel – low-carbon	Zero-emission waterborne transport	Accelerating farming systems transitions Environmental observations for sustainable agriculture		
ERA for Health	steelmaking	Zero-emission road transport			
Rare diseases	Carbon neutral & circular industry	Built environment & construction			
One-Health Anti Microbial	Global competitive space systems	Clean energy transition	Rescuing biodiversity		
Resistance Chemicals risk	Geological Service for Europe	Sustainable, smart & inclusive cities & communities	EIT Food		
assessment	EIT Digital	EIT Climate	Cluster 2: Culture, Creativity		
EIT Health	EIT Manufacturing	EIT InnoEnergy	& Inclusive Society		
			EIT Cultural and Creative Industries		
Horizon Europe l Innovative Europ	(roce_Dilla	ırs			
Innovative SMEs	European Op	pen Science Cloud			
	Candidate Institution	alised Partnerships EIT KIC Co-Program	med Co-Funded CP or CF		

• Source: Technpolis group (2020)

 $^{\rm 24}$ Horizon Europe Regulation (common understanding), Annex Va.

²⁵ Shadow configuration of Strategic Programme Committee for Horizon Europe. The list of candidate European Partnerships is described in "Orientations towards the Strategic Plan of Horizon Europe" - Annex 7

²⁶ Only 12 are subject to this impact assessment, as one initiative on High Performance Computing has already been subject to an impact assessment in 2017 (SEC(2018) 47)

- There are only three partnerships for which implementation as an Institutionalised Partnership under Article 185 is an option, i.e. European Metrology, the EU-Africa Global Health partnership, and Innovative SMEs. Ten partnerships are candidates for Institutionalised Partnerships under Article 187. Overall the initiatives can be categorised into 'horizontal' partnerships and 'vertical' partnerships.
- The 'horizontal' partnerships have a central position in the overall portfolio, as they are expected to develop methodologies and technologies for application in the other priority areas, ultimately supporting European strategic autonomy in these areas as well as technological sovereignty. These 'horizontal' partnerships are typically proposed as Institutionalised or Co-programmed Partnerships, in addition to a number of EIT KICs, they cover mainly the digital field in addition to space, creative industries and manufacturing, but also the initiative related to Innovative SMEs. 'Vertical' partnerships are focused on the needs and development of specific application areas, and are primarily expected to support enhanced environmental sustainability thereby addressing Green Deal related objectives. They also deliver on policies for more people centred economy, through improved wellbeing of EU citizen and the economy, like health related candidate European Partnerships.

2.2. Assessing the necessity of a European Partnership and possible options for implementation

Horizon Europe Regulation Article 8 stipulates that Institutionalised European Partnerships based on Article 185 and 187 TFEU shall be implemented only where other parts of the Horizon Europe programme, including other forms of European Partnerships would not achieve the objectives or would not generate the necessary expected impacts, and if justified by a long-term perspective and high degree of integration. At the core of this impact assessment is therefore the need to demonstrate that the impacts generated through a Partnership approach go beyond what could be achieved with traditional calls under the Framework Programme – the Baseline Option. Secondly, it needs to assess if using the Institutionalised form of a Partnership is justified for addressing the priority.

For all candidate Institutionalised European Partnerships the options considered in this impact assessment are the same, i.e.:

- Option 0 Baseline option Traditional calls under the Framework Programme
- Option 1 Co-programmed European Partnership
- Option 2 Co-funded European Partnership
- Option 3 Institutionalised Partnership
 - Sub-option 3a Institutionalised Partnerships based on Art 185 TFEU
 - Sub-option 3b Institutionalised Partnerships based on Art 187 TFEU

2.2.1. Option 0 - Baseline option - Traditional calls

Under this option, strategic programming for R&I in the priority area will be done through the mainstream channels of Horizon Europe. The related priorities will be implemented through **traditional calls** of Horizon Europe covering a range of actions, mainly R&I and/or innovation actions but also coordination and support actions, prizes or procurement. Most actions involve consortia of public and/or private actors in ad hoc combinations, while some actions are single actor (mono-beneficiary). There will be no dedicated implementation structure and no support other than what is foreseen in the related Horizon Europe Work Programme. This means that discontinuation costs/benefits of predecessor initiatives should be factored in for capturing the baseline situation when relevant.

Under this option, strategic planning mechanisms in the Framework Programme will allow for a high level of flexibility in the ability of traditional calls to respond to particular needs over time, building upon additional input in co-creation from stakeholders and programme committees involving Member States. The Union contribution to addressing the priority covers the full duration of the initiative, during the lifetime of Horizon Europe. Without a formal EU partnership mechanism, it is less likely that the stakeholders will develop a joint Strategic Research Agenda and commit to its implementation or agree on mutual commitments and contributions outside their participation in funded projects.

2.2.2. European Partnerships

Under this set of options, three different forms of implementation are assessed: Co-funded, Co-Programmed, Institutionalised European Partnerships. These have **commonalities that cannot serve as a distinguishing factor in the impact assessment process**. They are all based on agreed objectives and expected impacts and underpinned by Strategic Research and Innovation Agendas / roadmaps that are shared and committed to by all partners in the partnership. They all have to follow the same set of criteria along their lifecycle, as defined in the Horizon Europe Regulation (Annex III), including ex ante commitment from partners to mobilise and contribute resources and investments. The Union contribution is defined for the full duration of the initiative for all European Partnerships. The Horizon Europe legal act introduces few additional requirements for Institutionalised Partnerships, e.g. the need for long-term perspective, strong integration of R&I agendas, and financial contributions.

Figure 2 - Key differences in preparation and implementation of European Partnerships

Type	Legal form	Implementation				
Co-Programmed	Contractual arrangement /	Division of labour, whereby Union contribution is				
	MoU	implemented through Framework programme and				
		partners' contributions under their responsibility.				
Co-Funded	Grant Agreement	Union provides co-funding for an integrated				
		programme with distributed implementation by				
		entities managing and/or funding national research				
	and innovation programmes					
Institutionalised	Basic act (Council regulation,	Integrated programme with centralised				
based on Article	Decision by European	implementation				
185/187 TFEU	¥ 1 1					

The main differences between the different forms of European Partnerships are in their preparation and in the way they function, as well as in the overall impact they can trigger. The Co-Programmed form is assessed as the simplest, and the Institutionalised the most complex to prepare and implement. The functionalities of the different form of Partnerships – compared to the baseline option – are presented in Figure 3. They relate to the types of actors Partnerships can involve and their degree of openness, the types of activities they can perform and their degree of flexibility, the degree of commitment of partners and the priority setting system, and their ability to work with their external environment (coherence), etc. These key distinguishing factors will be at the basis of the comparison of each option to determine their overall capacity to deliver what is needed at a minimised cost.

Figure 3 Overview of the functionalities provided by each form of European Partnerships, compared to the traditional calls of Horizon Europe (baseline)

Baseline: Horizon	Option 1: Co-	Option 2: Co-Funded	_	Option 3b:
Europe calls	Programmed		nalised Art 185	Institutionalised Art 187
1.7	of actors (including openn		D . 37 . 1	D
Partners: N.A., no common set of actors that engage in planning and	Partners: Suitable for all types: private and/or public partners, philanthropies	Partners: core of national funding bodies or govern-mental research organisations	Partners: National funding bodies or governmental research organisation	Partners: Suitable for all types: private and/or public partners, philanthropies
implementation Priority setting: open to all, part of Horizon Europe Strategic planning Participation in R&I activities: fully open in line with Horizon Europe rules	Priority setting: Driven by partners, open stakeholder consultation, MS in comitology Participation in R&I activities: fully open in line with Horizon Europe rules	Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: limited, according to national rules of partner countries	Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: fully open in line with Horizon Europe rules, but possible derogations	Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: fully open in line with Horizon Europe rules, but possible derogations
*	rities (including additions		-	
**	vities (including additiona	•		
Activities: Horizon Europe standards that allow broad range of individual actions Additionality: no additional activities and investments outside the	Activities: Horizon Europe standard actions that allow broad range of individual actions, support to market, regulatory or policy/ societal uptake	Activities: Broad, according to rules/programmes of participating States, State-aid rules, support to regulatory or policy/ societal uptake	Activities: Horizon Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to	Activities: Horizon Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to systemic
funded projects <u>Limitations:</u> No systemic approach beyond individual actions	Additionality: Activities/investments of partners, National funding Limitations: Limited systemic approach beyond individual actions	Additionality: National funding Limitations: Scale & scope depend on participating programmes, often smaller in scale	systemic approach Additionality: National funding	approach (portfolios of projects, scaling up of results, synergies with other funds. Additionality: Activities/investments of partners/ national funding
Priority-setting proces				
Priority-setting: Strategic Plan and annual work programmes, covering max. 4 years. Limitations: Fully taking into account existing or to be developed SRIA/ roadmap	Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Input to FP annual work programme drafted by partners, finalised by EC (comitology) Objectives & commitments set in contractual arrangement	Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Annual work programme drafted by partners, approved by EC Objectives & commitments set in Grant Agreement	Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Annual work programme drafted by partners, approved by EC Objectives & commitments set in legal act	Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Annual work programme drafted by partners, approved by EC (vetoright in governance) Objectives & commitments set in legal act
Coherence: internal (H	lorizon Europe) & externa	ıl (other Union program	mes, national program	mes, industrial strategies)
Internal: Coherence between different parts of the FP Annual Work programme can be ensured by EC External: Limited for other Union programmes, no synergies with national/regional programmes & activities	Internal: Coherence among partnerships & with parts of the FP Annual Work programme can be ensured by partners & EC External: Limited synergies with other Union programmes & industrial strategies. If MS participate, with national/regional	Internal: Coherence among partnerships & with parts of the FP Annual Work programme can be ensured by partners & EC External: Synergies with national/ regional programmes & activities	Internal: Coherence among partnerships & with parts of the FP Annual Work programme can be ensured by partners & EC External: Synergies with national/regional programmes & activities	Internal: Coherence among partnerships & with parts of the FP Annual Work programme can be ensured by partners & EC External: Synergies with other Union programmes and industrial strategies If MS participate, with national/ regional programmes & activities
	programmes & activities	14		

2.2.3. Option 1 - Co-programmed European Partnership

This form of European Partnership is **based upon a Memorandum of Understanding or a Contractual Arrangement** signed by the Commission and the private and/or public partners. Private partners are represented by industry associations, which also support the daily management of the partnership. This type of partnership would allow for a large degree of flexibility for the activities, partners and priorities to continuously evolve. The commitments of partners are political efforts described in the contractual arrangement and the contributions from partners are provided in-kind more than financially. The priorities for the calls, proposed by the Partnership's members for integration in the Horizon Europe's Work Programmes, are subject to further input from Member States (comitology) and Commission services. The Union contribution is implemented within the executive agency managing Horizon Europe calls for research and innovation projects proposals. The full array of Horizon Europe instruments can be used, ranging from research and innovation (RIA) types of actions to coordination and support actions (CSA) and including grants, prizes, and procurement.

2.2.4. *Option 2 – Co-funded European Partnership*

The Co-funded European Partnership is **based on a Grant Agreement** between the Commission and a consortium of partners, resulting from a specific call in the Horizon Europe Work Programme. This form of implementation only allows to address public partners at its core. Typically these provide co-funding to a common programme of activities established and/or implemented by entities managing and/or funding national R&I programmes. The recipients of the EU co-funding implement the initiative under their responsibility, with national funding/resources pooled to implement the programme with co-funding from the Union. The expectation is that these entities would cover most if not all EU Member States. Calls and evaluations would be organised centrally, beneficiaries in selected projects would be funded at national level, following national funding rules.

2.2.5. *Option 3 – Institutionalised European Partnership*

This type of Partnership is the most complex and high-effort arrangement, and requires meeting additional requirements. Institutionalised European Partnership are based on a Council Regulation (Article 187 TFEU or a Decision by the European Parliament and Council (Article 185 TFEU) and are implemented by dedicated structures created for that purpose. These regulatory needs limit the flexibility for a change in the core objectives, partners, and/or commitments as these would require amending legislation. The basic rationale for this type of partnership is the need for a strong integration of R&I agendas in the private and/or public sectors in the EU in order to address a strategic challenge. It is therefore necessary to demonstrate that other forms of implementation would not achieve the objectives or would not generate the necessary expected impacts, and that a long-term perspective and high degree of integration is needed. For both Article 187 and 185 initiatives, contributions from partners can be in the form of financial and in-kind contributions. Eligibility for participation and funding follows by default the rules of Horizon Europe, unless a derogation is introduced in the basic act.

Option 3a - Institutionalised Partnerships based on Article 185 TFEU

Article 185 of the TFEU allows the Union to participate in programmes jointly undertaken by Member States and limits therefore the scope to **public partners** which are Member States and Associated Third Countries. This type of Institutionalised Partnership aims therefore at reaching the greatest possible impact through the integration of national and EU funding,

aligning national strategies in order to optimise the use of public resources and overcome fragmentation of the public research effort. It brings together R&I governance bodies of most if not all EU Member States (legal requirement: at least 40% of Member States) as well as Associated Third Countries that designate a legal entity (Dedicated Implementation Structure) of their choice for the implementation. By default, participation of non-associated Third Countries is not foreseen. Such participation is possible only if it is foreseen in the basic act and subject to conclusion of an international agreement.

Option 3b - Institutionalised Partnerships based on Article 187 TFEU

Article 187 of the TFEU allows the Union to set up joint undertakings or any other structure necessary for the efficient execution of EU research, technological development and demonstration programmes. This type of Institutionalised Partnership brings together a stable set of **public and private partners** with a strong commitment to taking a more integrated approach and requires the set-up of a dedicated legal entity (Union body, Joint Undertaking (JU)) that carries full responsibility for the management of the Partnership and implementation of the calls. Different configurations are possible:

- Partnerships focused on creating strategic industrial partnerships where, most often, the partner organisations are represented by one or more industry associations, or in some cases individual private partners;
- Partnerships coordinating national ministries, public funding agencies, and governmental research organisations in the Member States and Associated Countries;
- Or a combination of the two: the so-called tripartite model.

Participation of non-associated Third Countries is only possible if foreseen in the basic act and subject to conclusion of an international agreement.

2.3. Overview of the methodology adopted for the impact assessment

The methodology for each impact assessment is based on the Commission Better Regulation Guidelines²⁷ to evaluate and compare options with regards to their **efficiency**, **effectiveness** and coherence. This also integrates key selection criteria for European Partnerships.

Box 2 Summary of European Partnerships selection criteria²⁸

- *Effectiveness* in achieving the related objectives and impacts of the Programme;
- Coherence and synergies of the European Partnership within the EU R&I landscape;
- *Transparency* & *openness* as regards the identification of priorities and objectives and the involvement of partners & stakeholders from the entire value chain, backgrounds & disciplines;
- Ex-ante demonstration of *additionality* and *directionality*;
- Ex-ante demonstration of the partners' *long-term commitment*.

2.3.1. Overview of the methodologies employed

In terms of **methods and evidence used**, the impact assessments draw on an external study covering all candidate Institutionalised European Partnerships in parallel to ensure a high level of coherence and comparability of analysis, in addition to an horizontal analysis.²⁹ For all initiatives, the understanding of the overall context of the candidate institutionalised European Partnerships relied on desk research, including among others the lessons learned from previous partnerships. This was complemented by the analysis of a range of quantitative

²⁸ For a comprehensive overview of the selection criteria for European Partnerships, see Annex 6.

²⁷ European Commission (2017), Better Regulation Guidelines (SWD (2017) 350)

²⁹ Technopolis Group (2020), Impact Assessment Study for Institutionalised European Partnerships under Horizon Europe, Final Report, Study for the European Commission, DG Research & Innovation

and qualitative evidence, including evaluations of past and ongoing initiatives; foresight studies; statistical analyses of Framework Programmes application and participation data, and Community Innovation Survey data; analyses of science, technology and innovation indicators; reviews of academic literature; sectoral competitiveness studies and expert hearings. The analyses included a portfolio analysis, a stakeholder and social network analysis in order to profile the actors involved as well as their co-operation patterns, and an assessment of the partnerships' outputs (bibliometrics and patent analysis). A cost modelling exercise was performed in order to feed into the efficiency assessments of the partnership options, as described below. Public consultations (both open and targeted) supported the comparative assessment of the policy options. For each initiative, up to 50 relevant stakeholders were interviewed by the external contractor (policymakers, business including SMEs and business associations, research institutes and universities, and civil organisations, among others). In addition, the analysis was informed by the results of the Open Public Consultation run between September and November 2019, the consultation of Member States through the Strategic Programme Committee and the online feedback received on the Inception Impact Assessments of the set of initiatives.

A more detailed description of the methodology and evidence base that were mobilised, completed by thematic specific methodologies, is provided in Annexes 4 and 6.

2.3.2. *Method for identifying the preferred option*

The first step of the assessments consisted in scoping the problems that the initiatives are expected to solve given the overall economic, technological, scientific and social context, including the lessons to be learned from past and ongoing partnerships on what worked well and less well. This supported the identification of the objectives of the initiative in the medium and long-term with the underlying intervention logic – showing how to get there.

Given the focus of the impact assessment on comparing different forms of implementation, the Better Regulation framework has then been adapted to introduce "key functionalities needed" - making the transition between the definition of the objectives and what would be crucial to achieve them in terms of implementation. The identification of "key functionalities needed" for each initiative as an additional step in the impact assessment is based on the distinguishing factors between the different options (see Section 2.2.1). In practical terms, each option is assessed on the basis of the degree to which it would allow for the key needed functionalities to be covered, as regards e.g. the type and composition of actors that can be involved ('openness'), the range of activities that can be performed (including additionality and level of integration), the level of directionality and integration of R&I strategies; the possibilities offered for coherence and synergies with other components of Horizon Europe, including other Partnerships (internal coherence), and the coherence with the wider policy environments, including with the relevant regulatory and standardisation framework (external coherence). This approach guides the identification of discarded options while allowing at the same time a structured comparison of the options not only as regards their effectiveness, efficiency and coherence, but also against a set of other key selection criteria for European Partnerships (openness, transparency, directionality)³⁰.

In line with the Better Regulation Framework, the assessment of the effectiveness, efficiency and coherence of each option is made compared to the baseline. Therefore, for each of these aspects the performance of using traditional calls under Horizon Europe is first estimated and scored 0 to serve as a reference point. This includes the discontinuation costs/benefits of existing implementation structures when relevant. The policy options are then scored

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³⁰ The criterion on the ex-ante demonstration of partners' long-term commitment depends on a series of factors that are unknown at this stage, and thus fall outside the scope of the analysis.

compared to the baseline with a + and - system with a two-point scale, to show a slightly or highly additional/lower performance compared to the baseline. A scoring of 0 of a policy option means that it would deliver as much as the baseline option.

On the basis of the evidence collected, the intervention logic of each initiative and the key functionalities needed, the impact assessments first evaluate the **effectiveness** of the various policy options to deliver on their objectives. To be in line with the Horizon Europe impact framework, the fulfilment of the specific objectives of the initiative is translated into 'expected impacts' - how success would look like -, differentiating between scientific, economic/ technological, and societal (including environmental) impacts. Each impact assessment considers to which extent the different policy options provides the 'key functionalities needed' to achieve the intended objectives. The effectiveness assessment does not use a compound score but shows how the options would deliver on the different types of expected impacts. This is done to increase transparency and accuracy in the assessment of options³¹.

A similar approach is followed to evaluate the coherence of options with the overarching objectives of the EU's R&I policy, and distinguishes between **internal** and **external coherence**. Specifically, internal coherence covers the consistency of the activities that could be implemented with the rest of Horizon Europe, including European Partnerships (any type). External coherence refers to the potential for synergies and/or complementarities (including risks of overlaps/gaps) of the initiative with its external environment, including with other programmes under the MFF 2021-27, but also the framework conditions at European, national or regional level (incl. regulatory aspects, standardisation).

To compare the expected costs and benefits of each option (efficiency), the thematic impact assessments broadly follow a cost-effectiveness approach³² to establish to which extent the intended objectives can be achieved for a given cost. A preliminary step in this process is to obtain a measure of the expected costs of the policy options, to be used in the thematic assessments. As the options correspond to different implementation modes, relevant cost categories generally include the costs of setting-up and running an initiative. For instance, setup costs includes items such as the preparation of a European Partnership proposal and the preparation of an implementation structure. The running costs include the annual work programme preparation costs. Where a Partnership already exists, discontinuation costs and cost-savings are also taken into account³³. The table below provides an overview of the cost categories used in the impact assessment and a qualitative scoring of their intensity when compared to the baseline option (traditional calls). Providing a monetised value for these average static costs would have been misleading, because of the different features and needs of each candidate initiative.³⁴ The table shows the overall administrative, operational and coordination costs of the various options. These costs are then put into context in the impact assessments to reflect the expected co-financing rates and the total budget available for each of the policy options, assuming a common Union contribution (cost-efficiency):

• The costs related to the baseline scenario (traditional calls under Horizon Europe) are

³¹ In the thematic impact assessments, scores are justified in a detailed manner to avoid arbitrariness and spurious accuracy. A qualitative or even quantitative explanation is provided of why certain scores were given to specific impacts, and why one option scores better or worse than others

³² For further details, see Better Regulation Toolbox # 57.

Discontinuation costs will bear winding down and social discontinuation costs and vary depending on e.g. the number of full-time-equivalent (FTEs) staff concerned, the type of contract (staff category and duration) and applicable rules on termination (e.g. contracts under Belgian law or other). If buildings are being rented, the cost of rental termination also apply. As rental contracts are normally tied to the expected duration of the current initiatives, these termination costs are likely to be very limited. In parallel, there would also be financial cost-savings related to the closing of the structure, related to operations, staff and coordination costs in particular. This is developed further in the individual efficiency assessments.

³⁴ A complete presentation of the methodology developed to assess costs as well as the sources used is described in the external study supporting this impact assessment (Technopolis Group, 2020).

- pre-dominantly the costs of implementing the respective Union contribution via calls and project, managed by the executive agencies (around 4%, efficiency of 96% for the overall investment).
- For a Co-Programmed partnership the costs of preparation and implementation increase only marginally compared to the baseline (<1%), but lead to an additional R&I investment of at least the same amount than the Union contribution³⁵ (efficiency of 98% for the overall investment).
- For a Co-Funded partnership the additional R&I investment by Member States accounts for 2,3 times the Union contribution³⁶. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the national programmes, can be estimated at 6% of the Union contribution (efficiency of 98% related to the overall investment).
- For an Article 185 initiative the additional R&I investment by Member States is equal to the Union contribution³⁷. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the dedicated implementation structure, can be estimated at 7% of the Union contribution (efficiency of 96% related to the overall investment).
- For an Article 187 initiative the additional R&I investment by partners is equal to the Union contribution³⁸. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the dedicated implementation structure, can be estimated at 9% of the Union contribution (efficiency of 94% related to the overall investment).

Figure 4 - Intensity of additional costs compared with Horizon Europe Calls (for Partners, stakeholders, public and EU)

Cost items	Baseline: traditional calls	Option 1: Coprogrammed	Option 2 Co-funded	Option 3a - Art. 185	Option 3b -Art. 187			
Preparation and set-up costs								
Preparation of a partnership proposal (partners and EC)	0							
Set-up of a dedicated implementation structure		0 Existing New: ↑						
Preparation of the SRIA / roadmap	0		$\uparrow \uparrow$					
Ex-ante Impact Assessment for partnership		0		$\uparrow \uparrow \uparrow$				
Preparation of EC proposal and negotiation		0	$\uparrow \uparrow \uparrow$					
Running costs (Annual cycle of implementation)								
Annual Work Programme preparation	0	↑						
Call and project implementation	0	0 In case of MS contributions: ↑	↑	↑	\uparrow			
Cost to applicants	Comparable, oversubscript	unless there are	strong argumen	ts of major di	ifferences in			
Partners costs not covered by the above	0	\uparrow	0	↑	↑			
Additional EC costs (e.g. supervision)	0	\uparrow		↑	$\uparrow \uparrow$			
Winding down costs								
EC	0				$\uparrow \uparrow \uparrow$			
Partners	0	\uparrow	0	↑	↑			

Notes: 0: no additional costs, as compared with the baseline; \uparrow : minor additional costs, as compared with the baseline; $\uparrow \uparrow$: medium additional costs, as compared with the baseline; $\uparrow \uparrow \uparrow$: higher costs, as compared with the baseline.

³⁵ Minimum contributions from partners equal to the Union contribution

³⁶ Based on the default funding rate for programme co-fund actions of 30%, partners contribute with 70% of the total investment.

³⁷ Based on the minimum requirement in the legal basis that partners contribute at least 50% of the budget.

³⁸ Based on the minimum requirement in the legal basis that partners contribute at least 50% of the budget.

The cost categories estimated for the common model are then used to develop a scorecard analysis and further refine the assessment of options for each of the 12 candidate Institutionalised Partnerships. Specifically, the scores related to the set-up and implementation costs are used in the thematic impact assessments to consider the scale of the expected benefits and thereby allow a simple "value for money" analysis (cost-effectiveness)³⁹. In carrying out the scoring of options, the results of fieldwork, desk research and stakeholder consultation undertaken and taken into account.

For the **identification of the preferred option**, the scorecard analysis builds a hierarchy of the options by individual criterion and overall in order to identify a single preferred policy option or in case of an inconclusive comparison of options, a number of 'retained' options or hybrid. This exercise supports the systematic appraisal of alternative options across multiple types of monetary, non-monetary and qualitative dimensions. It also allows for easy visualisation of the pros and cons of each option. Each option is attributed a score of the adjudged performance against each criterion with the three broad appraisal dimensions of effectiveness, efficiency and coherence.

As a last step, the alignment of the preferred option with key criteria for the selection of European Partnerships is described, reflecting the outcomes of the 'necessity test'. ⁴⁰ The monitoring and evaluation arrangements are concluding the assessment, with an identification of the key indicators to track progress towards the objectives over time.

2.4. Horizontal perspective on candidate Institutionalised European Partnerships

2.4.1. Overall impact orientation, coherence and efficiency needs

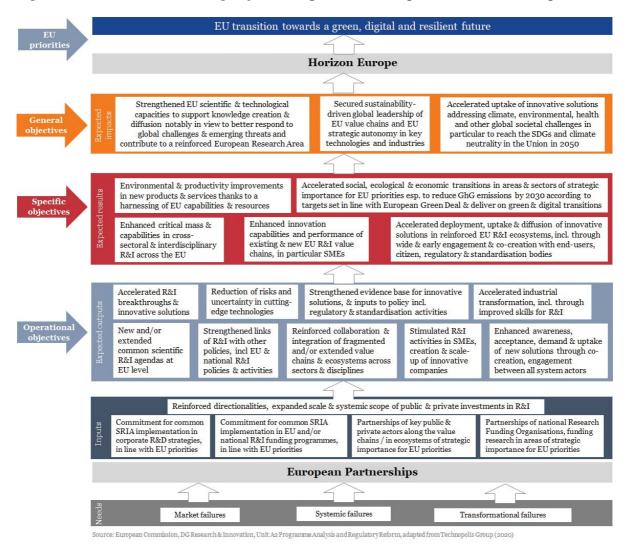
The consolidated **intervention logic** for the set of candidate Institutionalised European Partnerships in the Figure below builds upon the objectives as reported in the individual impact assessments.

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³⁹ More details on the methodology can be found in Annex 4.

⁴⁰ Certain aspects of the selection criteria will be further addressed/ developed at later stages, notably in the context of preparing basic acts (e.g. Openness and Transparency; Coherence and Synergies), in the Strategic Research and Innovation Agendas (e.g. Directionality and Additionality), and by collecting formal commitments (Ex-ante demonstration of partners' long-term commitment).

Figure 5 – Overall intervention logic of the European Partnerships under Horizon Europe



When analysed as a package the 12 candidate Institutionalised European Partnerships are expected to support the achievement of the European policy priorities targeted by Horizon Europe by pursuing the following joint general objectives:

- Strengthening and integrating EU scientific and technological capacities to support knowledge creation and diffusion notably in view to better respond to global challenges and emerging threats and contribute to a reinforced European Research Area;
- b) Securing sustainability-driven global leadership of EU value chains and EU strategic autonomy in key technologies and industries; and
- c) Accelerate the uptake of innovative solutions addressing climate, environmental, health and other global societal challenges contributing to Union strategic priorities, in particular to reach the Sustainable Development Goals and climate neutrality in the Union in 2050.

In terms of specific objectives, they jointly aim to:

- a) Enhance the critical mass and scientific capabilities in cross-sectoral and interdisciplinary research and innovation across the Union;
- b) Accelerate the social, ecological and economic transitions in areas and sectors of strategic importance for Union priorities, in particular to reduce greenhouse gas emissions by 2030 according to the targets set in line with the European Green Deal, and deliver on the green and digital transition;

- c) Enhance the innovation capabilities and performance of existing and new European research and innovation value chains, in particular SMEs;
- d) Accelerate the deployment, uptake and diffusion of innovative solutions in reinforced European R&I ecosystems, including through wide and early engagement and cocreation with end-users, citizen and regulatory and standardisation bodies;
- e) Deliver environmental and productivity improvements in new products and services thanks to a harnessing of EU capabilities and resources.

In terms of their operations, taking an horizontal perspective on all initiatives allows for the identification of further possible collective efficiency and coherence gains for more impact:

- Coherence for impact: The extent and speed by which the expected results and impacts will be reached, will depend on the scale of the R&I efforts triggered, the profile of the partners involved, the strength of their commitments, and the scope of the R&I activities funded. To be fully effective it comes out clearly that future partnerships need to operate over their whole life cycle in full coherence with their environment, including potential end users, regulators and standardisation bodies. This relates also to the alignment with relevant EU, national or regional policies and synergies with R&I programmes. This needs to be factored in as of the design stage to ensure a wide take-up and/or deployment of the solutions developed, including their interoperability.
- Collaboration for impact: Effectiveness could also be improved collectively through enhanced cross-disciplinary and cross-sectoral collaboration and an improved integration of value chains and ecosystems. An adequate governance structure appears in particular necessary to ensure cross-fertilisation between all European Partnerships. This applies not only to initiatives where similar R&I topics are covered and/or the same stakeholders involved or targeted, but also to the interconnections needed between the 'thematic' and the 'vertical' Partnerships, as these are expected to develop methodologies and technologies for application in EU priority areas. Already at very early stages of preparing new initiatives, Strategic Research and Innovation Agendas and roadmaps need to be aligned, particularly for partnerships that develop enabling technologies that are needed in other Partnerships. The goal should be to achieve greater impacts jointly in light of common challenges.
- Efficiency for impact: Potential efficiency gains could also be achieved by joining up the operational functions of Joint Undertakings that do not have a strong context dependency and providing them through a common back-office⁴¹. A number of operational activities of the Joint Undertakings are of a technical or administrative nature (e.g. financial management of contracts), or procured from external service providers (e.g. IT, communication activities, recruitment services, auditing) by each Joint Undertaking separately. If better streamlined this could create a win-win situation for all partners leading to better harmonization, economies of scales, and less complexity in supervision and support by the Commission services.
 - 2.4.2. Analysis of coherence of the overall portfolio of candidate initiatives at the thematic level

Looking at the coherence of the set of initiatives at the thematic level, the "digital centric" initiatives have a strong focus on supporting the digital competitiveness of the EU ecosystem. Their activities are expected to improve alignment and coordination with Member States and industry for the development of world-competitive EU strategic digital technology value chains and associated expertise. Addressing the Key Digital Technologies, the 5G and 6G

⁴¹ See Annex 6 for an overview of key functions/roles that could be provided by a common back office.

connectivity needs as part of a Smart Networks and Services initiative and the underlying supercomputing capacities through a European High Performance Computing initiative present potential for synergies that can be addressed through cooperative actions (e.g. joint calls, coordinated support activities, etc.). They may as well profit from and contribute to Partnerships envisaged for Photonics, AI, data, robotics, Global competitive space system and Made in Europe, together with the EIT Digital. Synergies between these initiatives and several programmes (Digital Europe and Connecting Europe as well as cohesion programmes) are needed in areas where EU industry has to develop leadership and competitiveness in the global digital economy. They are expected to impact critical value chains including on sectors where digital is a strong enabler of transformation (health, industrial manufacturing, mobility/transport, etc.).

The **transport** sector face systemic changes linked to decarbonisation and digitalisation. Large scale R&I actions are needed to prepare the transition of these complex sectors to provide clean, safer, digital and economically viable services for citizens and businesses. Past decades have shown that developing and implementing change is difficult in transport due to its systemic nature, many stakeholders involved, long planning cycles and large investments needed. A systemic change of the air traffic network through an Integrated Air Traffic Management initiative should ensure safety and sustainability of aviation, while a Clean Aviation initiative should focus on the competitiveness of tomorrow's clean aircrafts made in Europe. The initiative for Transforming Europe's rail system would comprehensively address the rail sector to make it a cornerstone in tomorrow's clean and efficient door-to-door transport services, affordable for every citizen as well as the most climate-friendly mode of transport for freight. Connected and Automated Mobility is the future of road transport, but Europe is threatened to fall behind other global regions with strong players and large harmonised markets. The initiative Safe and Automated Road Transport would bring stakeholders together, creating joint momentum in digitalising road transport and developing new user-based services. Stronger links and joint actions will be established between initiatives to enable common progress wherever possible. The Clean Hydrogen initiative would be fundamental to that regard. Synergies would also be sought with partnerships driving the digital technological developments.

To deliver a deep decarbonisation of highly emitting industrial sectors such as the steel, transport and chemical industries would require the production, distribution and storage of **hydrogen** at scale. The candidate hydrogen initiative would have a central positioning in terms of providing solutions to the challenges for sustainable mobility and energy, but also is expected to operate in synergies with other industry related initiatives. The initiative would interact in particular with initiatives on the zero emission road and water transport, transforming Europe's railway system, clean aviation, batteries, circular industry, clean steel and built environment partnerships. There are many opportunities for collaboration for the delivery and end-use of hydrogen. However, the Clean Hydrogen initiative would be the only partnership focused on addressing hydrogen production technologies.

Metrology, the science of measurement, is an enabler across all domains of R&I. It supports the monitoring of the Emissions Trading System, smart grids and pollution, but also contributes to meeting demands for measurement techniques from emerging digital technologies and applications. More generally, emerging technologies across a wide range of fields from biotechnologies, new materials, health diagnostics or low carbon technologies are giving rise to demands requiring a world-leading EU metrology system.

The initiative for a Circular Bio-based Europe is intended to solve a shortage of industry investments in the development of bio-based products whose markets do not have yet certain long-term prospects. The Innovative Health Initiative and EU-Africa Global Health

address the lack of investments in the development of solutions to specific health challenges. The initiative on **Innovative SMEs** supports innovation-driven SMEs in participating in international, collaborative R&I projects with other innovative firms and research-intensive partners. As a horizontal initiative it is expected to help innovative SMEs to grow and to be successfully embedded in global value chains by developing methodologies and technologies for potential application in the other partnership areas or further development by the instruments of the European Innovation Council.

The description of the interconnections between all initiatives for each Horizon Europe cluster is provided in the policy context of each impact assessment and further assessed in the coherence assessment for each option.

PART 2 - THE CANDIDATE EUROPEAN PARTNERSHIP ON EU-AFRICA GLOBAL HEALTH

1. INTRODUCTION: POLITICAL AND LEGAL CONTEXT

The death toll from infectious diseases is spread disproportionally around the world, with low- and middle- income countries being most affected, particularly sub-Saharan Africa. Infectious diseases, such as lower respiratory infections, HIV/AIDS, diarrhoeal diseases, malaria and tuberculosis, remain the main cause of death, disability, and ill-health in sub-Saharan Africa. 44

The current Sars-CoV-2, also called COVID-19, pandemic is a clear reminder, that due to increased global connectivity through world trade and tourism, infectious diseases spread rapidly around the globe causing huge human and also economic suffering in many countries, including Europe. Therefore research into health technologies to detect, treat and prevent infectious diseases will not only protect people's right to health worldwide, but might also contribute to halt the spread of emerging epidemics.

Medical and technological research and innovation are needed to accelerate the production of key interventions such as precise diagnostics tests, therapeutic treatments and preventive vaccines to alleviate the burden of infectious diseases and ensure a healthy and productive life, especially in the most vulnerable and affected region such as sub-Saharan Africa. The successful development and deployment of such interventions needs to take into account the environmental and social context, including the capacities of the health systems, of countries in which these diseases are prevalent. In addition, the development of health technologies, especially at the late stage of clinical development, is an expensive process with high costs and a long timeframe, hence it requires large scale and especially coordinated funding.

This document focuses on assessing the most effective, efficient and coherent way of implementing an initiative under Horizon Europe, which would focus on joint research and innovation activities to accelerate the development of suitable, effective, safe, accessible and affordable health technologies to fight infectious diseases affecting sub-Saharan Africa. The assessment will help to decide on which of the following different policy options should be pursued in order to legally establish and financially support this partnership:

- Option 0: Traditional Framework Programme calls
- Option 1: Co-funded partnership, based on a grant agreement
- Option 2: Co-programmed partnership, based on a memorandum of understanding;
- Option 3a: Institutionalised partnership, based on a decision of European Parliament and Council under Article 185 TFEU;
- Option 3b: Institutionalised partnership, based on a Council regulation under Article 187 TFEU.

https://www.who.int/healthinfo/global_burden_disease/estimates/en/index1.html

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⁴² Bhutta ZA, Sommerfeld J, Lassi ZS, Salam RA, Das JK (2014). Global burden, distribution, and interventions for infectious diseases of poverty. Infectious Diseases of Poverty 3(21)

⁴³ von Philipsborn P, Steinbeis F, Bender M, Regmi S, Tinnemann P (2015). Poverty-related and neglected diseases: An economic and epidemiological analysis of poverty relatedness and neglect in research and development. Global Health Action 8, 25818.

1.1. Emerging challenges in the field

The World is undergoing rapid population growth with more than 9.7 billion people by 2050,⁴⁵ whereby Africa is accounting for more than half of the projected global population growth.⁴⁶ Climate and environmental changes such as hotter summers, warmer winters or increased annual rainfalls, potentially introduce diseases to new areas,⁴⁷ and increase the disease burden of many tropical and neglected diseases.⁴⁸

Antimicrobials agents or antibiotics are crucial in the treatment of many infectious diseases, but the spread of drug-resistance, or **antimicrobial resistance** (AMR), could undermine the progress made to date. Although, due to lack of monitoring, ⁴⁹ the precise levels of AMR in the African region are not recorded, available data suggest that the African region follows the global trend of rising AMR prevalence, with significant resistance, found for numerous treatments against tuberculosis, malaria, HIV/AIDS, cholera, and dysentery. ⁵⁰ Apart from increasing the level of mortality and morbidity in the region, drug-resistance puts a financial burden on health systems as it increases the costs of treatment.

In addition to the burden posed by well-recognised diseases such as HIV, malaria and tuberculosis, as well as neglected tropical diseases, the world is seeing an increasing number of outbreaks of **emerging infectious diseases**, which may be further exacerbated by climate change. Emerging infectious diseases can be caused by newly identified infectious pathogens which cause public health problems either locally or internationally such as Ebola or the new corona viruses. Pathogens may also remerge with new characteristics, such as multidrug-resistance, or in different places, to cause new epidemics. Outbreaks of emerging infectious diseases have the potential to cause enormous social and economic damage globally and particularly in already heavily constrained health systems in Africa. Outbreaks can also discourage use of healthcare, indirectly leading to greater morbidity, mortality and financial costs.

Moreover, previously unknown or new strains of virus can emerge due to close contact with animals, spread by modern transportation⁵⁹ or crowded urban environments,⁶⁰ causing epidemics, such as the current COVID-19 pandemic.⁶¹ This is a global health

⁴⁵ https://www.worldometers.info/world-population/, Accessed on 16 March 2020

⁴⁶ Data from https://www.un.org/en/sections/issues-depth/population/, Accessed 29 August 2019

⁴⁷ Data from https://ecdc.europa.eu/en/climate-change/climate-change-europe

⁴⁸ WHO (2003). A.J. McMichael, et al Climate change and human health - risks and responses.

⁴⁹ Antimicrobial resistance in the WHO African region: current status and roadmap for action https://academic.oup.com/jpubhealth/article/39/1/8/3065721

WHO African Health Monitor (2013). J. B. Ndihokubwayo et al "Antimicrobial resistance in the African Region: Issues, challenges and actions proposed". https://www.afro.who.int/publications/antimicrobial-resistance-african-region-issues-challenges-and-actions-proposed

⁵¹ Smith KF, Goldberg M, Rosenthal S, Carlson L, Chen J, Chen C, Ramachandran S. (2014) Global rise in human infectious disease outbreaks. J R Soc Interface. 1(101):20140950.

⁵² World Health Day (1997). Emerging infectious diseases. Available at: https://www.who.int/docstore/world-health-day/en/documents1997/whd01.pdf

The Ebola outbreak, 2013–2016: old lessons for new epidemics https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5394636/

⁵⁴ Van Doorn HR (2014). Emerging infectious diseases. Medicine (Abingdon). 42(1): 60–63.

⁵⁵ If COVID-19 is not beaten in Africa it will return to haunt us all. Only a global victory can end this pandemic, not a temporary rich countries' win. Financial Times 25 March 2020 https://www.ft.com/content/c12a09c8-6db6-11ea-89df-41bea055720b

⁵⁶ Looming threat of COVID-19 infection in Africa: act collectively, and fast

https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)30464-5/fulltext?dgcid=raven_jbs_etoc_email
⁵⁷ Smith, K. M., Machalaba, C. C., Seifman, R., Feferholtz, Y., & Karesh, W. B. (2019). Infectious disease and economics: The case for considering multi-sectoral impacts. One health (Amsterdam, Netherlands), 7, 100080. doi:10.1016/j.onehlt.2018.100080

Wilhelm JA, Helleringer S. Utilization of non-Ebola health care services during Ebola outbreaks: a systematic review and meta-analysis. J Glob Health. 2019;9(1):010406. doi: 10.7189/jogh.09.010406.

⁵⁹ Zaheer Ahmad Nasir et al. Airborne biological hazards and urban transport infrastructure: current challenges and future directions (2016)

⁶⁰ Duane J. Gluber Dengue, Urbanization and Globalization: The Unholy Trinity of the 21st Century (2011)

 $^{^{61} \, \}underline{\text{https://unsdg.un.org/sites/default/files/2020-03/SG-Report-Socio-Economic-Impact-of-Covid 19.pdf} \\$

crisis unlike any in the last 75 years history, killing people, spreading human suffering, and upending people's lives. ⁶² Previously other recent known outbreaks have been: SARS in 2002–2003, H1N1 in 2009 or MERS in 2014, ⁶³ Zika in 2016 ⁶⁴ and Ebola in 2014 and 2016. ⁶⁵

Preparedness and response research, that can provide an evidence base to increase individual and community resilience, facilitate operational readiness, improve decision-making during emergency response, and speed the recovery of public health and healthcare systems and communities, remain the preferred path to contain epidemics and pandemics, and early public health interventions are the second and essential line of attack.

A further important challenge is the **rise of chronic non-communicable diseases** (NCDs), such as cardiovascular disease, diabetes and cancer also in Africa. ⁶⁶ Along with the unresolved epidemic of infectious diseases, this presents Africa with an unwelcome double burden of disease. Diabetes patients are over three times more likely to become infected with tuberculosis, ⁶⁷ while COVID-19 infection is more severe in patients with high blood pressure, heart disease, lung disease, cancer or diabetes. ⁶⁸ The resulting increased levels of comorbidity are likely to create new challenges for the development and use of effective treatment strategies, in particular in sub-Saharan Africa, overstretching the already strained health systems. ⁶⁹

Encouragingly, over the past decade, there have been significant **scientific and technological advances** in the development of health technologies, such as those in the areas of DNA sequencing and genome editing that are opening up new avenues, to prevent, diagnose and treat infectious diseases.

In addition, since the Ebola crisis in West Africa, the **industry** seems to be gaining interest in global health projects targeting priority R&D gaps. ⁷⁰ Some of them have created integrated global health R&D units. Moreover, large **philanthropic foundations** have found the challenges of global health as too big to tackle on their own, and therefore are more willing than before to join forces and collaborate with public organisations to fund research & innovation in the field of infectious diseases. ⁷¹

Noteworthy is furthermore the **digitalisation of Africa** and the increasing use of mobile technologies.⁷² Digital technology has the potential to accelerate and transform health research and product development, as well as the delivery of healthcare itself. For instance, it can be used to improve the collection, analysis and sharing of high-quality

⁶² https://www.nzma.org.nz/journal-articles/covid-19-another-infectious-disease-emerging-at-the-animal-human-interface

⁶³ http://www.euro.who.int/en/health-topics/health-emergencies/coronavirus-covid-19/news/news/2020/3/who-announces-covid-19-outbreak-a-pandemic

⁶⁴ https://web.archive.org/web/20160804185858/http://www.who.int/mediacentre/news/statements/2016/emergency-committee-zika-microcephaly/en/

⁶⁵ https://www.who.int/csr/disease/ebola/en/

⁶⁶ World Health Organization (2016). Burden of non-communicable diseases on the rise.

⁶⁷ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6029598/

⁶⁸ https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(20)30116-8/fulltext

⁶⁹ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3600620/

⁷⁰ G-FINDER Report 2019 Neglected Diseases Research and Development: Uneven Progress

⁷¹ https://www.gatesnotes.com/2020-Annual-Letter

⁷² Biarritz Declaration for a G7 and Africa Partnership: Digital transformation in Africa (2019).

research data. It can also change the way services are delivered in hard-to-reach areas, for instance, using digital diagnostics or drones. ^{73,74}

1.2. EU relative positioning in the field

Europe has been traditionally strong in tropical diseases research⁷⁵ and during the last two decades the EU has provided support to research and innovation on infectious diseases through the different EU Framework Programmes FP6 (2002-2006), FP7 (2007-2013) and Horizon 2020 (2014-2020). This funding has covered all the phases of the research and innovation pathway from pre-clinical discovery to clinical trials for diagnostics, vaccines, therapeutics, as well as microbicides and vector control. ^{76,77,78}

The strength of European research has not been so much in the quantity of investment, but rather in the way funding is addressing the needs of the research community and the impacts on shaping the environment for research. There has been a strong focus on collaboration between researchers from different countries, sectors and disciplines. This has helped to build wide networks of scientists who can cover the entire innovation cycle, from basic research to implementation in order to support crucial discoveries, as well as drive economic growth and job creation.

In 2018, the EU was the third largest public funder of neglected infectious diseases with USD 113 million.⁷⁹ This funding also includes the EU funding to the European and Developing Countries Clinical Trials Partnership (EDCTP).

Table 1: Public R&D funders 2018 on poverty related & neglected infectious diseases

	JS\$ Imilia	msl								25	18% of	
ountry	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018		
United States of America	1,798	1,706	1,672	1,769	1,574	1,583	1,516	1,615	1,631	1,779	68	
United Kingdom	131	144	116	81	111	116	95	105	197	230	8.8	
EC	123	96	115	99	118	116	141	85	125	134	5.2	
Germany	35	38	33	56	46	50	56	50	70	73	2.8	
India	28	43	48	48	56	43	48	55	76	66	2.6	
France	49	41	62	55	81	66	66	52	50	44	1.7	
Australia	26	29	36	46	24	36	21	23	25	36	1.4	
Japan	6.2	9.4	3.5	2.6	11	11	14	17	18	33	1.3	
Netherlands	28	19	25	16	24	19	5.4	25	25	21	0.8	
Switzerland	8.7	15	15	17	17	19	21	19	18	17	0.7	
Canada	18	9.5	9.6	18	20	13	10	7.1	13	15	0.6	
South Africa	7.3	7.8	7.1	5.7	13	4.4	6.9	12	15	13	0.5	
Subtotal of top 12^	2,319	2,176	2,163	2,242	2,100	2,082	2,007	2,075	2,264	2,462	95	
Total public funding	2,444	2,320	2,289	2,348	2,219	2,166	2,102	2,200	2,385	2,599	100	

⁷³ Mumley J, Thakker AN (2018). Africa leading way in healthcare tech: the continent is ahead of the game in cutting-edge drone use. HealthManagement 18(3)..

⁷⁴ Marketwatch (2019). Ghana: Zipline Drone Makes Delivery of Sickle Cell Medication

⁷⁵ Watson M: African Highway: The Battle for Health in Central Africa London: John Murray; 1953.

⁷⁶ A. Holtel et all EU-funded malaria research under the 6 and 7 Framework Programmes for research and technological development

⁷⁷ Tuberculosis research in the European Union: Past achievements and future challenges. https://www.sciencedirect.com/science/article/pii/S1472979209000882

⁷⁸ Increasing European Support for Neglected Infectious Disease Research https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5294741/

⁷⁹ G-FINDER 2019 Neglected Disease Research and Development: Uneven Progress

The European and Developing Countries Clinical Trials Partnership, was launched in 2003 to accelerate the development of medical interventions to prevent, control and treat HIV/AIDS, malaria and tuberculosis contributing to reduce the economic burden caused by these diseases in sub-Saharan Africa. Under the second EDCTP programme this scope was extended in 2014 to include the neglected infectious diseases. Currently it is a partnership of 16 African and 14 European member countries, assembled around the EDCTP Association (established under Dutch law), and the European Union. The EU financial contribution to the second EDCTP programme (2014-2020), up to EUR 683 million, comes from the H2020 framework programme, based on the decision of the European Parliament and the Council under Article 185 of the Treaty.

The new partnership, the EU-Africa Global Health Partnership under Horizon Europe, builds on the first and second EDCTP programmes and aims to advance the clinical development of suitable, effective, safe, accessible and affordable health technologies (e.g. diagnostics, treatments and vaccines) to help reduce the burden of infectious diseases in sub-Saharan Africa and strengthen capacities to improve the R&I response to (re-)emerging infectious diseases.

EDCTP has delivered, since 2003, more than 800 scientific peer-reviewed publications, built ethical review panels, regulatory capacity and networks of scientists for exchange high-quality clinical research, generating data with a significant impact on global and national health policy and practice. Moreover, since 2014, EDCTP has integrated the global health Participating States Initiated Activities in the EDCTP work annual plans, providing alignment of the European countries research efforts in this area.

During 2014-2019, EDCTP2 has awarded EUR 605 million in grant funding, supporting 83 clinical trials and other clinical research activities conducted by European-Africa consortia, 130 fellowships in career development of researchers from sub-Saharan Africa, and 57 grants to strengthen the enabling environment for conducting clinical trials and clinical research in Africa. As result, nearly 7,500 people in Africa have participated in training and workshops on study protocol, specimen collection, research administration, good clinical practice and epidemics preparedness, etc. EDCTP-funded studies have made vital contributions to the development of HIV antiretroviral drug formulations tailored to children; EDCTP has also supported the evaluation of the Xpert MTB/RIF diagnostic technology for the detection of drug-resistant tuberculosis bacteria, now recommended by the WHO and implemented globally. EDCTP studies have generated key evidence on malaria treatments for pregnant women, who are particularly susceptible to malaria, among other examples.

Thus, EDCTP is already a well-branded global health initiative that has made vital contributions to the development of treatments against diseases like AIDS, tuberculosis, malaria and neglected infectious diseases. It has strengthened capacity in sub-Saharan Africa and fostered strong research collaboration between the EU and Africa.

29

⁸⁰ Decision No 1209/2003/EC of the European Parliament and of the Council of 16 June 2003 on Community participation in a research and development programme aimed at developing new clinical interventions to combat HIV/AIDS, malaria and tuberculosis through a long-term partnership between Europe and developing countries, undertaken by several Member States https://eur-lex.europa.eu/LexUriServ.do?uri=OJ:L:2003:169:0001:0005:EN:PDF

⁸¹ Decision No 556/2014/EU of the European Parliament and of the Council of 15 May 2014 on the participation of the Union in a second European and Developing Countries Clinical Trials Partnership Programme (EDCTP2) jointly undertaken by several Member States https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014D0556

⁸² Burkina Faso, Cameroon, Congo, Ethiopia, Gabon, The Gambia, Ghana, Mali, Mozambique, Niger, Nigeria, Senegal, South Africa, Tanzania, Uganda and Zambia

⁸³ Austria, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, and the United Kingdom

The global spreading of COVID-19, in a pandemic of unprecedented global scale, could not be avoided despite existing knowledge about other coronaviruses of earlier epidemics. This means that the GHP candidate becomes even more relevant to addressing explicitly the research preparedness and response in case of emerging epidemics and in its role of coordinating research and innovation support with other funders. Therefore, the proposed EU-Africa Global Health partnership will explicitly address strengthening capacities to improve the R&I response to (re-)emerging infectious diseases.

The scope of the new partnership should also be extended to better cover the threat of antimicrobial resistance (AMR) and emerging infectious diseases with the potential to cause pandemics. This widened scope would also be reflected in the goal of the GHP, also called EDCTP3. The name 'EU-Africa Global Health Partnership' was proposed to give an indication of ambition. However, dialogue with Member States and African countries revealed that they would in a first stage prefer to focus on sub-Saharan Africa, as that is where the main burden of infectious diseases lies.

In the **evaluation of all the EU partnerships of Horizon 2020 based on Article 185** carried out in 2017, the Commission has underscored that 'the topics addressed by [...] EDCTP2 are to a large extent not tackled with other Horizon 2020 actions'.

Moreover, the thematic **EDCTP2** independent Interim Evaluation panel highlighted the invaluable and unique contribution of the programme to sub-Saharan Africa and that that EDCTP had 'made important inroads in strengthening cooperation and partnership between European and sub-Saharan African countries and developing clinical trial capacity and scientific career development in Africa'. It also noted that, because of the long timescales associated with new healthcare product development and implementation, achieving EDCTP's ambitious goals will require long-term commitment and investment.

An impact assessment study on the EU funding on poverty related and neglected infectious diseases⁸⁴ concluded that to ensure that innovations can be adopted, more health systems and implementation research is needed; as well as to include the low and middle income countries at different stages of the health research and innovation pathway. Overall, there is a need for more 'pull' policy incentives to help bridge research and impacts, as well as to increase awareness of EU funding efforts for better coordination with other funders.

A **SWOT** analysis (strengths, weaknesses, opportunities, threats) of the first two EDCTP programmes carried out by EDCTP, drawing on the independent Evaluations and impact assessments, as well as the insights of Scientific Advisory Committee members and other key stakeholders, suggested that EDCTP has established itself as an important contributor to health research in sub-Saharan Africa, with a distinct niche in the funding landscape – particularly through its progressive commitment to **later-stage trials** and to **under-served groups** with unmet medical needs. The analysis further showed that the partnership's integration of capacity-building activities into EDCTP projects, as well as its dedicated capacity-building funding, through the regional networks and fellowship programme in sub-Saharan Africa, was a notable feature of the partnership's work (details in Annex 6).

1.3. EU policy context beyond 2021

The European Commission is committed to the United Nations 2030 Agenda for Sustainable Development, with a set of Sustainable Development Goals directly related to global health: (SDG3), calling to 'ensure healthy lives and promote well-being for all

⁸⁴ EDCTP-funded clinical studies for medical interventions 2003-2018 http://www.edctp.org/web/app/uploads/2018/09/Tackling-infectious-disease-in-sub-Saharan-Africa EDCTP-funded-clinical-studies-for-medical-interventions-2003-2018-4.pdf

at all ages' and SDG1 'to end poverty in all its forms everywhere'. Supporting global health is also related to SDG 9 'Build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation' and SDG17 'Strengthen the means of implementation and revitalize the global partnership for sustainable development'.

The Commission reflection paper *Towards a Sustainable Europe by 2030*, adopted in January 2019, outlines three scenarios on how best to progress on the SDGs: 1) an overarching EU SDGs strategy to guide all actions by the EU and Member States; 2) continued mainstreaming of the SDGs in all relevant EU policies by the Commission, but not enforcing Member States' action; and 3) putting enhanced focus on external action while consolidating current sustainability ambition at EU level. It emphasizes the continuous need to face persisting or novel challenges in science, society and policy for achieving a sustainable Europe by 2030. In this context health research and related innovation actions play a significant role in improving productivity, health care systems and the functioning of its industries.⁸⁵

The proposed initiative is fully in line with the recent Communication on the *Global EU* response to *COVID-19*⁸⁶ that asks for 'Stepping up the preparation with EU Member States and third countries of the Global Health Partnership' and the Commission's comprehensive Africa Strategy 'Towards a comprehensive Strategy with Africa'⁸⁷ adopted in March 2020. It is also in line with the 'EU-Africa Alliance for Sustainable Investments and Jobs'⁸⁸ of September 2018, where the EU is committed to increase access to quality education, skills, research, innovation, health and social rights, and to reinforce Africa as a partner in trade, in foreign investment and in development, and to tackle together the green and digital transformations, as well as promoting sustainable investments and jobs.

In December 2019, when the new Commission took office, it presented its new priorities for the upcoming years, including the 'A European Green Deal', 'A people-centred economy' and 'A Digital Europe', which are particularly relevant for health research and innovation. In her letter to the Commissioner for Innovation, Research, Culture, Education and Youth, Mariya Gabriel, the President of the European Commission, Ursula von der Leyen requests the maximisation 'of the potential of the EC exchange programmes to foster international cooperation in education, research and innovation'. Moreover, to the Commissioner for International Partnerships, Jutta Urpilainen, she asks to 'make the most of the political, economic and investment opportunities that Africa offers, with its growing economies, populations and digital innovations, and to work on a new comprehensive strategy for Africa creating a partnership of equals and mutual interest'. 91

Under Horizon Europe, the GHP/EDCTP3 would be part of R&I activities funded under Pillar II Cluster 1 Health, which is one of the six Horizon Europe clusters. Pillar II addresses global challenges and industrial competitiveness. Cluster Health is supporting

⁸⁵ Data from Sustainable Europe 2030. Available at:

https://ec.europa.eu/commission/sites/beta-political/files/rp_sustainable_europe_30-01_en_web.pdf

https://ec.europa.eu/international-partnerships/system/files/joint-comm-2020-eu-global-response_en.pdf https://eur-lex.europa.eu/legal-content/FR/TXT/?qid=1583753318333&uri=JOIN:2020:4:FIN

⁸⁸ Progress factsheet Africa-Europe Sustainable investments and Jobs Alliance (2018). Available at: https://ec.europa.eu/commission/africaeuropealliance_en

⁸⁹ https://ec.europa.eu/commission/sites/beta-political/files/political-guidelines-next-commission_en.pdf

⁹⁰ European Commission (2019). Mariya Gabriel: Commissioner-designate for Innovation and Youth. Mission letter: https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-mariya-gabriel-2019_en.pdf

gen European Commission (2019). Jutta Urpilainen: Commissioner-designate for International Partnerships. Mission letter: https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-jutta-urpilainen en.pdf

the Sustainable Development Goals, notably SDG 3 'Ensure healthy lives and promote well-being for all at all ages'. The potential inter-connections between partnership initiatives in the Health cluster of Horizon Europe and other EU policies and priorities are presented in Figure 6.

SDG SDG 3: Ensure healthy lives and promote well-being for all at all ages EU priorities A digital Europe European Green Deal A people-centred economy EU Strategic 2030 Agenda for EU policies / The future 8th European European Framework on Health Pillar of Social Sustainable policy frameworks Environment and Environment Action and Safety at Work Development Health Process (EHP) Rights Programme R&I Staying Living and Tackling Ensuring access Unlocking the full Maintaining an orientations / challenges healthy in a working in a to innovative, potential of new diseases and innovative sustainable & sustainable and rapidly healthreducing tools, technologies globally and digital promoting high-quality changing disease society health care in solutions for a competitive health environment burden the EU healthy society industry Areas of Health Environmental Non-Infectious Health Tools, Technologies intervention communicable throughout and Social Diseases and Digital Solutions under the Life Health and rare for Health and Care Systems Horizon Course Determinants diseases Europe Rare Envisaged EIT Chemicals Personalised Large-scale Health risk Diseases global health Medicine innovation and Health partnerships assessment transformation of Initiative health systems ERA for Health One-Health AMR Institutionalised Faster development and safer use of health innovations for European patients, and global health Partnerships Area Technopolis Group

Figure 6: Potential inter-connections between the Health cluster of Horizon Europe and EU policies and priorities.

2. PROBLEM DEFINITION

Taken into consideration the scale of the challenges ahead for addressing infectious diseases threats globally and the current scientific, technological and economic positioning of Europe, as well as the overarching EU policy context, a set of problems have been identified where EU research and innovation in the field of Global Health would have a specific role to play.

This has been summarised in a problem tree presented in Figure 7 portraying the identified problems, their drivers and potential consequences if the problems are not addressed. The lack of robust health technologies and the insufficient clinical research capacity for tackling infectious diseases in sub-Saharan Africa are due largely to a number of problem drivers: insufficient knowledge of the pathogens causing the diseases; fragmentation of public and private research efforts to tackle infectious diseases affecting sub-Saharan Africa, insufficient number of trained scientists in sub-Saharan Africa and the insufficient capacity of national health systems in sub-Saharan Africa to detect, diagnose and monitor (re) emerging infectious diseases

As well as impacts on population, these factors undermine economic development in the region and increase the risk of global dissemination of novel pathogens. In order to

address these problems and their drivers, it is important to establish a partnership structure that is most suitable for the needed actions. Let us first look at the problems and their drivers in more detail in order to understand what kind of partnership is needed.

Insufficient Fragmentation of public Insufficient capacity of national Insufficient number of trained scientists in sub-Saharan Africa knowledge of the and private research health systems to detect, efforts to tackle infectious diagnose and monitor (re-) diseases affecting subthe infectious emerging infectious diseases in haran Africa and globall Problem drivers Lack of health technologies to tackle Insufficient clinical research capacity in sub-Saharan infectious diseases in sub-Saharan Africa Africa and insufficient collaboration with EU Problems High morbidity and mortality Poverty and limited Increase of outbreaks and potential for economic from infectious diseases in transmission of infectious Sub-Saharan Africa growth in Sub-Saharan Africa diseases worldwide Consequences

Figure 7: Problem tree behind an initiative for European R&I on EU-Africa Global Health

2.1. What are the problems?

The main problem the partnership aims to address is the lack of suitable diagnostics, treatments and vaccines, the so-called health technologies, to address infectious diseases, such as HIV, malaria, tuberculosis but also leishmaniosis that are prevalent in Africa, especially in sub-Saharan Africa. One of the lessons learnt, also now with the COVID-19 pandemic, is that with the increased connectivity of different regions in the world, through world trade and tourism, infectious diseases in one part of the world do not stay there but can rapidly affect other regions. Therefore, developing these health technologies in sub-Saharan Africa is the starting point to contain infectious diseases in this region and protect the health of the citizens in the concerned countries and globally, including in Europe.

1. Lack of health technologies or interventions for tackling infectious diseases in sub-Saharan Africa

Although important strides have been made in combating infectious diseases, much still needs to be done at scientific level. For instance, although the development of antiretroviral therapy in the fight against HIV has been a major game changer, ⁹² there still is no effective vaccine to prevent HIV infection. ⁹³ Likewise, whilst there are numerous treatments against tuberculosis, the increasing threat of (multi-)drug-resistant forms of the disease increase the urgency for the development of new vaccines with greater efficacy and broader application, as well as for continued development of new (combination) treatments. ⁹⁴ For other diseases, such as Dengue – a mosquito-borne viral

⁹⁴ McShane, Helen. Insights and challenges in tuberculosis vaccine development The Lancet Respiratory Medicine, Volume 7, Issue 9, 810 - 819

⁹² Broder S. (2010). The development of antiretroviral therapy and its impact on the HIV-1/AIDS pandemic. Antiviral research, 85(1), 1–18. doi:10.1016/j.antiviral.2009.10.002

⁹³ HIV vaccine: better to start together? Felber, Barbara K et al. The Lancet HIV, Volume 6, Issue 11, e724 - e725

infection affecting around 390 million people annually –, there is no effective treatment. 95

Moreover, the progress made in combatting infectious diseases is being increasingly challenged by the rising levels of drug resistance or antimicrobial resistance. For instance, whilst chloroquine has long been used as a malaria treatment, there now is widespread resistance against it in most areas of the world. ⁹⁶

Intensified research efforts aiming at introduction of new modern health technologies in sub-Saharan Africa would have a major effect on the infectious disease burden in this region.

2. Insufficient clinical research capacity for tackling infectious diseases in sub-Saharan Africa associated with insufficient knowledge exchange and research collaboration with EU

Even where suitable health technologies are available, there often is a challenge in getting them to where they are most needed and ensuring that they are used to optimal effect. Most sub-Saharan African countries are faced with weak, under-resourced health systems. As a result, health technologies that have proven efficacious in trial environments may show reduced effectiveness in real-world settings, when they are not used correctly, or if they are used only intermittently as a result of insufficient availability.

While development aid and local capacity development activities have led to some progress in the delivery of existing health technologies such as diagnostics, vaccines and therapeutics to the region, much remains to be achieved to ensure that new health technologies are available and accessible to the people in need, calling also for implementation research. ⁹⁷

In many disease-endemic countries in Africa, there is insufficient capacity for conducting health research and clinical trials. This concerns the equipment and tools needed to support trials (e.g. laboratory equipment, computers), as well as the human resources (e.g. health care workers, technicians, researchers) and the broader enabling research environment (e.g. ethical review boards, and national medicines regulatory authorities). There is also an insufficient capacity to harness and package available local, regional and global evidence to inform health policies and practice. In line with this challenge is the growing importance of implementation research to achieve the Sustainable Development Goals.

As discussed, research and product development to combat infectious diseases require a multi-stakeholder approach and a common research agenda that brings together different forms of expertise. Crucially, this also demands strong involvement from funders and

⁹⁵ Data from https://www.who.int/en/news-room/fact-sheets/detail/dengue-and-severe-dengue, Accessed 1 Sept 2019.

⁹⁶ D'Alessandro U, Buttiëns H (2001). History and importance of antimalarial drug resistance. Trop Med Int Health 6(11):845-8

⁹⁷ WHO Regional Office for Africa (2018). The state of health in the WHO African Region: an analysis of the status of health, health services and health systems in the context of the Sustainable Development Goals.

⁹⁸ Whitworth JA, Kokwaro G, Kinyanjui S, et al. (2008). Strengthening capacity for health research in Africa. Lancet. 372(9649):1590–1593

⁹⁹ Ndebele P, Wassenaar D, Benatar S, Fleischer T, Kruger M, Adebamowo C, Kass N, Hyder AA, Meslin EM. (2014). Research ethics capacity building in Sub-Saharan Africa: a review of NIH Fogarty-funded programs 2000–2012, J Empir Res Hum Res Ethics, 9(2):24-40

Edwards, A., Zweigenthal, V. & Olivier, J. Evidence map of knowledge translation strategies, outcomes, facilitators and barriers in African health systems. Health Res Policy Sys 17, 16 (2019). https://doi.org/10.1186/s12961-019-0419-0

Alonge O, Rodriguez DC, Brandes N, et al. How is implementation research applied to advance health in low-income and middle-income countries? BMJ Glob Health 2019;4:e001257. doi:10.1136/bmjgh-2018-001257

stakeholders, including researchers from disease-endemic countries, ¹⁰² as these are best placed to understand the specific needs of the populations and how research is expected to serve. This includes increasing attention for principles of fair research, ¹⁰³ needed to ensure that African researchers can play a full and equitable role in research collaborations.

2.2. What are the key problem drivers?

The key causes of the problems from the R&I perspective, are the following:

1. Insufficient knowledge of the pathogens causing infectious diseases that have high capacity to evade immune responses and develop resistance to treatment.

The most prevalent pathogens that are predominantly affecting low- and middle-income countries, such as HIV, the causative agent of tuberculosis Mycobacterium tuberculosis and the malaria parasite Plasmodium, have shown tremendous resilience against control measures against them. One of the main reasons is the insufficient knowledge about host-pathogen interaction and about the mechanism on how they cause disease and escape human immune system. ¹⁰⁴ This has made the search for new vaccines and treatment a slow process, emphasizing the need to conduct clinical trials in many different target populations and settings. ¹⁰⁵

Clinical trials are essential to know how pathogens react to medical interventions and to determining the efficacy and safety of such interventions. While valuable safety and efficacy data can be drawn from studies in high-income countries, often studies need to be conducted within sub-Saharan Africa itself. This may be because the infections are found only in this region, or particular strains of pathogen are found mainly in sub-Saharan Africa. In addition, responses to drugs or vaccines may be different in various populations, because of genetic differences or environmental factors. For example, particular genetic variations found in Africa affect responses to some antiretroviral drugs, while responses to rotavirus vaccine are generally lower in sub-Saharan Africa than in high-income countries.

Importantly, for later-stage and post registration trials and implementation studies, the nature of local health systems is a crucial factor, central to study design. Given their high degree of local relevance, these studies generally deliver the evidence most useful to national policymakers. A collaborative approach is required to develop and evaluate vaccines, drugs and other tools needed to control these diseases. Partnerships across a wide range of actors are needed to chaperone new interventions through complex evaluations in disease-endemic settings, regulatory pathways, and implementation into health systems. Collaboration between public and private funders, together with research institutes, product development partnerships and national health authorities, is therefore key to further progress.

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¹⁰² Lansang MA, Dennis R (2004) Building capacity in health research in developing World Bull World Health Organ 2004 82(10):764-70

Musolino N, Lazdins J, Toohey J, IJsselmuiden C (2015). COHRED Fairness Index for international collaborative partnerships, The Lancet 385(9975):1293-1294

¹⁰⁴ DeRycker, M., Baragana, B., Duce, S.I. & Gilbert, I.H. (2018). Challenges and recent progress in drug discovery for tropical diseases. Nature 559: 498-506. https://doi.org/10.1038/s41586-018-0327-4

¹⁰⁵ Rappuoli, R. & Aderem, A. (2011) A 2020 vision for vaccines against HIV, tuberculosis and malaria. Nature 473: 463-469. Doi:10.1038/nature10124

2. Fragmentation of public and private research efforts to tackle infectious diseases affecting sub-Saharan Africa.

There are few economic incentives for companies to invest in interventions for diseases that predominantly affect low-resource settings. Development of vaccines and drugs is both costly and high risk, and the lack of financial resources in countries in sub-Saharan Africa inevitably makes them an unattractive market for commercial organisations. The low commercial potential for achieving enough return on investment has led the industry to show, until recently, limited interest to invest in R&I for infectious diseases, especially those that are prevalent in LMICs.

For devices such as diagnostics, a further challenge is the need for products that are affordable, reliable, easy to use, and robust enough for challenging environmental settings. This demanding set of criteria deters investment when the potential to achieve a reasonable return on investment is highly uncertain.

As a result, the product development pipeline for infectious diseases is poorly stocked, and the progress has been slow. For instance, in 2019, there were only 129 active clinical studies/trials on poverty related neglected diseases, compared to 3,499 oncology studies/trials. The 2018 Access to Medicines Index showed that in the pipelines of the 20 largest pharmaceutical companies, out of 1,314 R&D projects, only 298 targeted priority gaps products 107 for infectious diseases. 108

Most of the support to R&I in this area in sub-Saharan Africa has been provided through public sources. Europe has a long history of supporting medical research in sub-Saharan Africa, often being based on informal contacts between researchers and institutions, and bilateral arrangements that reflect long-standing geopolitical legacies. While excellent research has been carried out, clinical evaluation of medical interventions requires systematic investment in infrastructure, generally across several countries, which can be challenging to achieve through bilateral or project-based initiatives.

Tackling infectious diseases affecting sub-Saharan Africa with modern technology tools requires the involvement of a large set of actors. These range from academic researchers to international development agencies, philanthropies and pharmaceutical companies. As each of these actors have their own priorities and focus areas, ¹⁰⁹ one of the main challenges is uniting such diverse actors around a common strategic agenda and roadmaps, in order to use resources effectively and efficiently.

Although Member States have shown willingness to align and coordinate their national programmes for R&D infectious diseases around a common strategic research agenda, these efforts are hindered by national political priorities for international cooperation and development, which often follow political international agreements with different criteria than the research and innovation agenda efforts.

Individual funders, both public and private, including industry, and scientists often address a scientific problem in infectious diseases with a single hypothesis or theory. In

WHO Global Observatory on Health R&D, data from July 2019. Available at: https://www.who.int/research-observatory/monitoring/processes/health_products/en/

Priority product gaps are indicated: Policy Cures Research G-FINDER neglected diseases, products and technologies (2017); Policy Cures G-FINDER reproductive health areas, products and technologies (2014); WHO R&D Blueprint (2017), WHO Initiative for Vaccine Research gaps (2017), WHO priority pathogens list for R&D of new antibiotics (2017)

Access to Medicines Foundation. Access to Medicines Index 2018. Available at:

https://accesstomedicinefoundation.org/media/uploads/downloads/5d25b3dd5f128_5cb9b00e8190a_Access-to-Medicine-Index-2018.pdf

¹⁰⁹ Sridhar D (2012) Who sets the global health research agenda? The challenge of multi-bi financing. PLoS Med. 9(9)

case of complex diseases and circumstances, it would be advantageous to combine the knowledge and hypothesis of several groups and get a comprehensive understanding of the disease process. Infectious diseases that represent the most sophisticated mechanisms of evasion and escape from our defences, require a collaborative approach to tackle them, and partnerships with a wide range of actors have the best chances of finding the vaccines and drugs against these diseases. Communication between public and private funders together with scientists and scientists is one of the keys of finding comprehensive solutions.

3. Insufficient number of trained scientists on infectious diseases clinical research in sub-Saharan Africa (medical doctors, researchers)

Sub-Saharan Africa is faced with a lack of adequate research infrastructure and established researchers capable of initiating and maintaining competitive research outputs. Despite the many gains over the last few years, sub-Saharan Africa is still faced with a dearth of recognised researchers capable of maintaining competitive research outputs. Many researchers are working in isolation and engaging in activities that may have short-term economic advantages but are often not relevant to clinical research. Partnership-centered networks are needed to train scientists and build clinical research capacity so that more African scientists become experts of clinical research.

Clinical studies are governed by stringent international regulations, covering areas such as the conduct of trials, ethical approvals and the quality of laboratory analyses. Studies therefore require sufficient infrastructure and an appropriately trained workforce in order to carry out studies generating data consistent with the standards imposed by national and international regulatory agencies.

Furthermore, as well as shortcomings in institutional and individual capacity, many countries also have limited capabilities to ensure effective oversight and governance of research. This includes the capacity to oversee ethical approvals and ensure compliance with national and international regulatory standards.

To conduct high-quality clinical trials and implementation research in sub-Saharan Africa, consistent with fundamental ethical principles and recognised international regulatory standards, good participatory practices as well as to perform research effectively, efficiently, and in a sustainable manner, complementary fellowship training programmes are also necessary.

Many resolutions of the World Health Assembly and the WHO Regional Committee for Africa have called upon African countries and their development partners to make the required investments in National Health Research Systems (NHRS) to generate knowledge and promote its use in dealing with priority public health challenges. Implementation of these resolutions is critical to achieving the Sustainable Development Goals. Recent review of the NHRS in Africa has observed that despite an improvement in the average NHRS Barometers scores from 43% in 2014 to 61% in 2018, a number of challenges remain. These include lengthy ethical clearance processes; weak research coordination mechanisms, weak enforcement of research laws and regulation, inadequate infrastructure, limited resource mobilisation skills and donor dependence. This underscores the need to continue to strengthen the NHRS in order to

¹¹¹ Rusakaniko, S., Makanga, M., Ota, M.O. et al. Strengthening national health research systems in the WHO African Region – progress towards universal health coverage. Global Health 15, 50 (2019). https://doi.org/10.1186/s12992-019-0492-8

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Kirigia, J.M., Ota, M.O., Motari, M. et al. National health research systems in the WHO African Region: current status and the way forward. Health Res Policy Sys 13, 61 (2015). https://doi.org/10.1186/s12961-015-0054-3

not only strengthen clinical research capacity but to also facilitate knowledge translation and implementation science in general. This strategy would help reduce the knowledge-practice gap that persists in many LMICs.

4. Insufficient capacity of national health systems to detect, diagnose and monitor (re-) emerging infectious diseases in sub-Saharan Africa and globally.

As mentioned before, due to increased globalisation and migration, with overpopulated urban environments, climate change and closer contact with wild animals in certain areas of the world, the potential for infectious diseases to rapidly spread around the world has increased.

Early detection and diagnosis are vital to responding and limiting the number of new infections in case of an outbreak. This can be particularly challenging in sub-Saharan Africa where systems for detection, diagnosis and monitoring are inadequate. In its first annual report, *A World at Risk*, published in September 2019, 112 the Global Preparedness Monitoring Board concluded that the world is poorly prepared to respond to new global threats. It suggested that global actions are still dominated by responses to outbreaks, with too little investment in preparedness. This is well illustrated by the current COVID-19 outbreak. 113

Compared to many other countries, the health systems in sub-Saharan Africa show limited capacity for research and innovation. This low research capacity not only impedes the achievement of health SDGs, but causes a slow response to emerging infectious disease threats and insufficient preparedness to epidemics. This leads to less than optimal control of outbreaks, and the potential for further spread to populations at risk and international dissemination. Low level of domestic funding makes it further challenging for health systems to control infectious diseases.

It is critical that African countries are involved in rapid and responsive clinical research to develop diagnostics, treatment regimens, vaccines and other health solutions during a public health emergency. Rapid and responsive research during a public health emergency should also be extended to socio-behavioural research, medical anthropology research as well as applied and translational research. The Ebola and other outbreaks left a legacy that research should take a centre stage and become the norm in responding to a public health emergency, especially when the cause is unknown or novel.

The emergency epidemic infectious diseases such as COVID-19 makes it even more imperative to have both strong and resilient health systems and strong NHRS. The latter is critical to coordinate and facilitate rapid generation of evidence as well as facilitating utilization of that evidence. The COVID-19 pandemic has re-emphasized to the global community the importance of research and innovation and the need to invest more in Research and Development (R&D); as both finding a cure and a vaccine have remained elusive, while both the public health and economic impacts escalate. R&D cannot progress without a functioning NHRS just as Universal Health Coverage would remain a pipedream without strong and resilient National Health Systems. Lastly, this EU-Africa Global Health Partnership rightly places great emphasis on Global Health Security which would be impossible to achieve without strengthening R&D and the NHRS.

113 https://www.ecdc.europa.eu/sites/default/files/documents/RRA-sixth-update-Outbreak-of-novel-coronavirus-disease-2019-COVID-19.pdf

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¹¹² Global Preparedness Monitoring Board. A World at Risk: Annual Report on global preparedness for health emergencies. 2019. Geneva: WHO. Available at https://apps.who.int/gpmb/annual_report.html

African leadership is essential in examining how governments should engage to improve health systems, a critical step in improving population health. African governments should make an effort to assess the return of investment of different health sector interventions, and to improve data and understand the costs, effectiveness and long-term effects of the investment on both health and economic outcomes.

2.3. How will the problems evolve?

The nature of infectious disease threats is constantly changing, with varying consequences for morbidity and mortality, as well as for social and economic outcomes. However, the major infectious diseases, such as HIV/AIDS, tuberculosis and malaria, are likely to continue causing the greatest disease burden in sub-Saharan Africa also in the near future. Infectious diseases can be combatted with different responses, ranging from clean water provision to new biomedical countermeasures. The rise of new antimicrobial resistance mechanisms is reducing the impact of previously effective treatments 112,113,114 and the climate crisis will only worsen the situation.

Emerging and re-emerging infections present major challenges and represent a grave threat to global health security. As the current global health system is called into question by the current corona virus COVID-19 pandemic, and before by other outbreaks such as the Ebola outbreak, the need for diagnostics, vaccines and drugs for key infectious diseases, as well as novel approaches for rapid detection and effective response to infectious diseases outbreaks, including surveillance and control, remains as pressing as ever.

3. WHY SHOULD THE EU ACT?

3.1. Subsidiarity: Necessity of EU action

Technologies and tools for tackling infectious diseases remain insufficiently available, while there still is a significant disease burden. The EU's commitment to the Sustainable Development Agenda calls for a dedicated approach to support the achievement of SDG3, thus including support for the research and development of vaccines and medicines for infectious diseases that affect developing countries, as well as the European Member States. In the 2019 Eurostat report on the progress towards the SDGs in an EU context, it is noted that while the number of deaths due to HIV, malaria and tuberculosis decreased in the EU, deaths due to other infectious and parasitic diseases rose. In light of the EU's commitment to achieving SDG3, an initiative to advance a collaborative effort for global health research is deemed necessary, and it should be based on legal structure that would be most effective in reaching its objectives.

¹¹⁴ Bloom DE, Cadarette D (2019) Infectious Disease Threats in the Twenty-First Century: Strengthening the Global Response. Frontiers in Immunology, 10, 549.

Tadesse, B. T., Ashley, E. A., Ongarello, S., Havumaki, J., Wijegoonewardena, M., González, I. J., & Dittrich, S. (2017).
Antimicrobial resistance in Africa: a systematic review. BMC infectious diseases, 17(1), 616. doi:10.1186/s12879-017-2713-1

¹¹³ WHO. Antimicrobial resistance. Available at: https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance

¹¹⁴ WHO African Health Monitor (2013). J. B. Ndihokubwayo et al "Antimicrobial resistance in the African Region: Issues, challenges and actions proposed".

¹¹⁵ Data from https://ecdc.europa.eu/en/climate-change/climate-change-europe

¹¹⁶ Wu X, Lu Y, Zhou S, Chen L, Xu B (2016) Impact of climate change on human infectious diseases: Empirical evidence and human adaptation. Environ Int, 86:14-23.

¹¹⁷ Eurostat (2019). Sustainable development in the European Union Monitoring report on progress towards the SDGs in an EU context.

The development of health technologies, especially at the late stage of clinical development, is an expensive process with **high costs and a long timeframe**, which requires large scale funding. In addition, much of the research on infectious diseases, including clinical trials, needs to be conducted in the areas where a disease is most prevalent taking into account the environmental and social context, including the capacities of the **health systems**. An underdeveloped health infrastructure does not allow vulnerable populations to benefit from newly developed health technologies, especially if they are not adapted to local circumstances and need.

The **low commercial potential** of the research and development on infectious diseases affecting sub-Saharan has discouraged private **pharmaceutical companies** to invest in this area, as their investments are based on the purchasing power of potential clients or health systems. This means that most of the support, also to cover access and capabilities, needs to be provided through **public sources**, which are very scarce in the sub-Saharan region. Moreover, this lack of investment hinders the development of the scientific leadership of African researchers.

Funding from public sources or philanthropies acting separately is not always sufficient and more international development cooperation is needed. It is crucial to **pool enough funding** for the development of these technologies among public funders in different countries and private philanthropies. There is a strong need of economies of scale, better coordination of efforts, avoiding duplications and generating synergies between public and private funders. In addition, more coordination is needed between European governments. The EU has supported the first and second EDCTP programmes that have helped to conduct clinical trials and to develop research capacity in Africa. Most importantly, they have demonstrated that working in partnership delivers. The results have shown that European and African governments can join forces with the EU around common objectives, and create an enabling environment to obtain results that individual countries, or the EU framework programme alone, could not have achieved.

For instance, in the CHAPAS consortium, five research organisations from Zambia, United Kingdom, Ireland, Spain and India, worked on combination antiretroviral formulations for first-line treatment of HIV-infected children. The consortium provided important data on first-line treatment of HIV-infected children in Africa and data to support the current WHO guidelines for first-line paediatric antiretroviral therapy. The results led to licensed combinations for treatment of children. Other type of results are those stemming from the support and coordination actions funding the four Networks of Excellence that address disparities between countries in terms of clinical research capacity. The East Africa Consortium for Clinical Research (EACCR) includes 23 research organisations from Kenya, Sudan, Ethiopia, Tanzania and Uganda. This network has achieved success in terms of capacity building, staff training and research outputs, playing a pivotal role in supporting South-South cooperation in Africa (e.g. training 281 clinicians, 33 Master students, 5 PhD, 5 Post Docs, 8 training courses, and producing 15 scientific publications).

Recent EDCTP2 support to clinical development of tuberculosis vaccines gives another example. Three Phase II multi-site clinical trials were funded. This has helped to build capacity for late stage clinical development. The next step would be a Phase III trial, which costs more than EUR 100 million. This requires even more pooling of resources from several funders and capacity for multi-centre trials. In addition, many of the diseases that the new partnership would be addressing are not only affecting sub-Saharan Africa, but also other parts of the world. In Europe, the most important problem with

tuberculosis is the high rate of antimicrobial resistance, making the infection very difficult and expensive to cure. The clinical trials conducted in sub-Saharan Africa can provide new efficient drugs and vaccines for tuberculosis that can be globally used, also in Europe.

The EDCTP2 programme has also supported more than 50 projects to strengthen the enabling environment for clinical trials and research in sub-Saharan Africa, including health systems strengthening, pharmacovigilance activities and the translation of research results into policy and practice, and supporting the establishment of functional regulatory systems and capacities for ethical review of clinical research. EDCTP is also a member of the African Medicines Regulatory Harmonisation Partnership Platform, which aims to improve coordination of regulatory systems strengthening and harmonisation activities in Africa. Moreover, EDCTP has established a long-term working relationship with WHO-AFRO, which hosts the African Vaccine Regulatory Forum (AVAREF).

It is important to continue public support to a stable, long-term cooperation that only an institutionalised partnership can offer, in order to address a market failure and the low commercial potential for the private sector to develop health technologies that are appropriate for use also in Africa. The **EU** has an important role to play in the funding and facilitating coordination of funders in this area. The strong and long-term support of the EU can provide a sustainable and well-defined funding stream, around a strategic research and innovation agenda, which would encourage Member States, sub-Saharan countries, pharmaceutical industry and other private funders to invest in this area. Therefore the intervention at EU level is necessary with an initiative that would encourage both public and private sector to invest in this area.

Around three quarters of respondents to the **structured consultation of Member States** agreed that a partnership would be more effective in achieving the objectives and delivering clear impacts for the EU and its citizens, underlying the necessity for EU action.

Among respondents to the **open public consultation**, 34 out of 47 respondents indicated that a European partnership of this kind was fully needed to be more responsive towards societal needs and to make a significant contribution to achieving the SDGs.

Interviewees across all stakeholder groups expressed similar opinions on the importance of EU action. A number of **interviewees** furthermore expressly highlighted the EU's moral responsibility to support LMICs, sometimes referring to European values of solidarity. Some interviewees also stressed the need to support Africa as an emerging economy, and an economic partner to the EU. Furthermore, interviewees regularly indicated that EU action is necessary to ensure the continuity of EU investment efforts in R&I for infectious diseases.

3.2. Subsidiarity: Added value of EU action

Coordinated and coherent EU action would help overcome the current fragmentation of research and help to put together a critical mass of organisations and the investment required to address this important global health challenge. Coordinated action will increase the impact and cost-effectiveness of European activities and investments. Moreover, the high application rate to the EU Framework Programmes¹¹⁸ shows the relevance and attractiveness of the EU support to R&I and the capacity of the EU to convene stakeholders, also in the area of infectious diseases.

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¹¹⁸ Interim Evaluation of Horizon 2020, Commission Staff Working Document, SWD (2017)221 and 222

The Interim Evaluation¹¹⁹ of EDCTP2 indicated that EDCTP provides an important mechanism for joint discussions and planning, and identified that the co-leadership provided by European and African Participating States is critical to success.

The candidate initiative would facilitate collaboration and strategic response to existing and emerging infectious diseases by acting as a go-between and knowledge broker in a way that would be difficult to achieve for any national actor or initiative. Moreover, because of the strong role that EDCTP has already played in the global health research arena since its establishment in 2003, 120 the new initiative would have a competitive advantage by building upon the success of EDCTP.

During EDCTP2 several European Participating States have contributed to calls for proposals launched by EDCTP with EU funding, increasing the number of projects that could be financed and the chances to better tackle the challenges. However, pooling of funding across participating states has been one of the weaker areas until now. The new initiative will revise the mechanism to facilitate alignment of funding around a strategic research and innovation agenda.

The Interim Evaluation found uneven leadership and gaps in joint leadership among European Participating States, and has recommended that additional efforts need to be done. The Participating States Initiated Activities, initially intended to provide a mechanism for synergistic activities among European Participating States, however to be more effective, this mechanism should be revised.

Sub-Saharan African countries are strong stakeholders of EDCTP, and the new initiative would offer a good platform for better pooling of resources and deepened interaction between the European and African countries.

The Interim Evaluation identified efforts and successes to exploit synergies with other EU policy directions. However, the Panel advised that the EDCTP Strategic Research Agenda should include explicit strategic direction with respect to collaborative partnerships that would purposefully exploit synergies with other EU policies. To achieve value-add of EDCTP2 and to align efforts of EDCTP2 with other significant global funders and with politically driven goals and directions, the EDCTP2 Interim Evaluation Panel recommended that EDCTP should develop a strategic policy plan and catalyse the development and strengthening of national health research plans especially for African Participating States.

Interviewees almost unanimously stress the added value of EU investments because of the ability to support large-scale activities, going beyond the remits of national research funders. In addition, some interviewees note that having a dedicated initiative can incentivise additional funding for infectious disease research from national funders and other funding bodies (such as charitable foundations).

4. OBJECTIVES: WHAT IS TO BE ACHIEVED?

4.1. General objectives of the initiative

Based on the problems described in Section 2, the following general objectives have been identified for an initiative supporting an EU-Africa Global Health partnership:

http://ec.europa.eu/research/evaluations/pdf/edctp2_evaluation_experts_report_2017.pdf

https://ec.europa.eu/research/evaluations/pdf/edctp2_evaluation_experts_report_2017.pdf

- To reduce the socio-economic burden of infectious diseases in sub-Saharan Africa through the development and uptake of new or improved health technologies against infectious diseases;
- To increase health security in sub-Saharan Africa and globally by strengthening the R&I-based capacities for preparedness and response to control infectious diseases.

These general objectives are directly aligned with SDG3.3 'By 2030, end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other infectious diseases' and SDG3.B 'Support the research and development of vaccines and medicines for the communicable [...] diseases that primarily affect developing countries, [...]'. Likewise, these objectives need to be interpreted in the context of resilience and health systems strengthening. Ultimately, they also support the general objectives of Horizon Europe, in particular that of tackling global challenges, including the SDGs.

An initiative in this area would mainly focus on conducting clinical trials in the field of infectious diseases and building clinical research capacity in sub-Saharan Africa.

Both in the structured open consultation of Member States and in the dedicated interviews performed for the study supporting this impact assessment, 121 some respondents have argued that whilst a focus on diseases affecting sub-Saharan Africa is appropriate, this should not exclude the possibility of supporting activities that are outside of the region when they are relevant to sub-Saharan Africa. This could include the ability to support large multi-centre clinical trials, with some of the trial sites located both in Africa and, for example, in Asia or Latin America. This concerns also the objective to contribute to the control of (re-)emerging infectious diseases, of relevance in sub-Saharan Africa, with global impacts.

The large majority of **interviewees**, regardless of the stakeholder group they represent, support the outlined general objectives for the candidate initiative. Interviewees also acknowledge the rise of non-communicable diseases in Africa and see many ways in which the candidate initiative could address them. However, they also state that maintaining the focus on infectious diseases is essential to ensure that research funding is adequate and can lead to substantial progress.

The specific consultation of African countries reflected that for the African countries the most important objectives of the current EDCTP2 were: increasing the number of new or improved medical interventions for HIV/AIDS, tuberculosis, malaria and other poverty-related diseases, including neglected ones; and strengthening cooperation with sub-Saharan African countries, in particular on building their capacity for conducting and interpreting clinical trials. The study also reflected the importance of contributing to the regional and global health research agenda and informing about the most appropriate products and interventions for health security.

4.2. Specific objectives

In order to achieve the general objectives, four specific objectives, which respond to each of the problem drivers discussed in Section 2.2, have been identified together with indicative targets: 122

¹²¹ Technopolis Group (2020), Impact Assessment Study for Institutionalised European Partnerships under Horizon Europe, Final Report, Study for the European Commission, DG Research & Innovation

¹²² Indicative targets based on the experience of the EDCTP2 programmes and if the initiative could have a similar budget size as of the EDCTP2 programme.

- 1. Advance the development and use of new or improved health technologies for tackling infectious diseases by supporting the conduct of clinical trials in sub-Saharan Africa.
 - Target: by the end of the initiative to have progressed to license at least two new or improved health technologies in the field of infectious diseases; to deliver evidence to be able to issue 30 guidelines for improved or extended use of existing health technologies; and to have progressed the clinical development of approximately 30 candidate health technologies.
- 2. Facilitate better alignment of R&I funders around a common strategic research and innovation agenda to increase the cost-effectiveness of European public investments.
 - Target: by the end of the initiative to have launched joint actions with other public and private funders, and increased the budget of the joint actions to at least EUR 500 million compared to EUR 300 million under EDCTP2.
- 3. Strengthen research and innovation capacity and the national health research systems ¹²³ in sub-Saharan Africa for tackling infectious diseases.
 - Target: by the end of the initiative to have supported at least 50 coordination and support actions and at least 250 fellowships, reinforcing the environment for conducting clinical trials in sub-Saharan countries, and in compliance with fundamental ethical principles and relevant national, Union and international legislation.
- 4. Strengthen capacity in sub-Saharan Africa for epidemic preparedness through effective and rapid research response to develop essential diagnostics, vaccines and therapeutics for early detection and control of (re-)emerging diseases of epidemic potential.
 - Target: by the end of the initiative to have strengthened the preparedness of 100 research institutes in at least 30 sub-Saharan countries for an effective and rapid research response to develop essential diagnostics, vaccines and therapeutics to tackle re-emerging epidemics in accordance to international health regulations.

The research priorities should be established in an objective-orientated manner in order to accelerate results and contribute to the control and eradication of poverty- related diseases, including neglected ones, (re-)emerging epidemics, antimicrobial resistance and co-morbidities in sub-Saharan Africa.

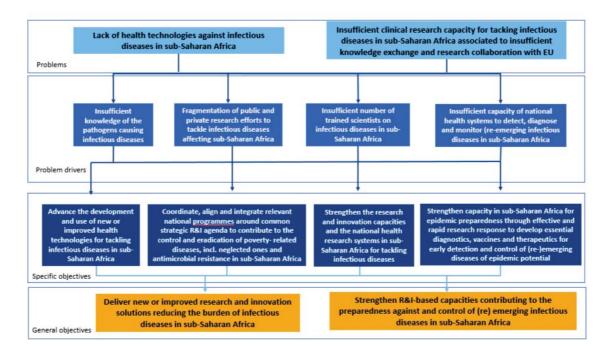
4.3. Intervention logic of the initiative

The relationship between the general and specific objectives of the potential initiative is shown in Figure 8.

Figure 8: Intervention logic for the initiative EU-Africa Global Health

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¹²³ Following the WHO-AFRO Research for Health: a Strategy for the African Region, 2016-2025 https://www.afro.who.int/publications/research-health-strategy-african-region-2016-2025



The lack of health technologies, the fragmentation of the research efforts, the insufficient research capacity for tackling infectious diseases in sub-Saharan Africa, and the insufficient capacity of the sub-Saharan Africa national health systems to detect, diagnose, and monitor emerging infectious diseases, are to a large extent consequence of the insufficient knowledge of the pathogens causing the diseases, the fragmentation of the research funding efforts, the insufficient number of trained scientists in sub-Saharan Africa, and the insufficient R&I capacity of the national health systems in these countries.

The partnership will address the problem drivers by advancing the development of new or improved health technologies in sub-Saharan Africa, facilitating the alignment of the different R&I funders in the region, strengthening the R&I capacities of the national health research systems in sub-Saharan Africa and the preparedness capacity for a rapid R&I response to develop essential diagnostics, vaccines and therapeutics for early detection and control epidemics, which are the specific objectives of the initiative. To reach such ambitious objectives the partnership will need to involve as many partners as possible, from both, public and private sectors, and that all of the partners can commit for a long period of time.

How would success look like?

Should the initiative deliver on its specific objectives, it is expected that it would translate into practise the following impacts:

Scientific impacts

If successful, the initiative is expected to demonstrate various types of scientific impacts:

- Strengthened EU scientific excellence in clinical research for infectious diseases;
- Increased scientific leadership of sub-Saharan Africa in the infectious diseases field:
- Increased research response capacity to control of (re-)emerging epidemics in sub-Saharan Africa:

• Increased evidence base for national and international health policy-making (bridging the gap between science and policy for health).

Economic/technological impacts

If successful, the initiative is expected to demonstrate a set of economic/technological impacts:

- Increased research capacity of institutions in sub-Saharan Africa to design, conduct and manage infectious disease research projects;
- Higher capacity of the research institutions to attract funding;
- Increased industry participation in research projects in sub-Saharan Africa;
- Increased number of employed researchers in sub-Saharan Africa.

Societal impacts

If successful, the initiative is expected to demonstrate a set of societal impacts:

- Higher retention of scientific talent in sub-Saharan Africa;
- Increased uptake of new or improved health technologies;
- Increased gender equality (Tropical diseases can disproportionally affect and disadvantage women), 124 increasing the protection of the fundamental rights.

The initiative can contribute to better living conditions in sub-Saharan Africa, particularly by increasing and building the capacity of the health research systems and addressing issues affecting vulnerable populations (e.g. women and children).

As the initiative is expected to contribute to reduce disease burden in sub-Saharan Africa and increase employment opportunities, these will also have an impact on poverty reduction and will have a direct effect on an individual's quality of life and social opportunities.

Because it is intended to accelerate the development and production of new health technologies, including pharmaceutical products, the initiative has the potential for negative environmental impacts resulting from pharmaceutical production. Pharmaceutical pollution forms a significant threat to population health and ecosystems globally. On the other hand, this risk would be mitigated with the aim of the new initiative to use new appropriate technologies with a reduced risk to the environment.

Interviewees across different stakeholder groups expect that the Initiative will have the ability to create impact in the societal domains, particularly through improving access to medicines, reducing disease burden, and encouraging development of the African scientific leadership.

¹²⁴ Uniting to Combat Neglected Tropical Diseases (2016). Neglected tropical diseases: women and girls in focus. Summary report of meeting held on July 27-28, 2016 in London, UK. Available at: https://unitingtocombatntds.org/wp-content/uploads/2017/11/women_and_girls_in_focus_english.pdf

¹²⁵ Maghear A, Milkowska M (2018) The environmental impact of pharmaceutical manufacturing: how does industry address its own waste? Health Care Without Harm, Belgium. Available at: https://noharm-europe.org/sites/default/files/documents-files/5731/2018 PharmaceuticalIndustryReport WEB.pdf

4.4. What is needed to achieve the objectives – Key functionalities needed

Given the focus of the impact assessment on comparing different forms of implementation, the identification of "key functionalities needed" allows making the transition between the definition of the objectives and what would be crucial to achieve them in terms of implementation. These functionalities relate to the type and composition of actors that have to be involved, the type of range of activities that should be performed, the degree of directionality needed and the linkages needed with the external environment. These functionalities have an important influence on the type of partnership that will be selected from a number of options.

Type and composition of the actors to be involved

The partnership will harness the investments of the EU, the EU Member States and Associated States to the Framework Programme and African countries. In addition, for specific trials or diseases, philanthropies, industry and other third countries will join and contribute to the partnership.

The motivation for the EU, European and African countries comes mainly from the successes of EDCTP and EDCTP2 partnerships. These partnerships have shown that European and African governments can join forces with the EU around common objectives, creating an environment within which results were achieved that individual countries or the EU research framework programme alone, would not have managed to obtain. The governance of EDCTP2 is based on an EDCTP Association that provides meaningful participation and involvement of the sub-Saharan countries in the decision-making, essential for tackling the burden of diseases in sub-Saharan countries.

For example, EDCTP PREGACT studies have generated key evidence on malaria treatments for pregnant women who are particularly susceptible to malaria. These studies involved several countries in Africa: Burkina Faso, Ghana, Malawi and Zambia, (to be able to better study exposure) and several partners in Europe: Austria, Belgium, The Netherlands and United Kingdom, harnessing the necessary multidisciplinary teams to study such a complex disease as malaria and transfer knowledge to African scientists.

In addition, to further leverage larger and sustained funding and to play a stronger global health leadership than the current EDCTP2, the candidate partnership should be able to answer to the emerging infectious diseases threats, exacerbated by the COVID-19 pandemic, and to the ever increasing problem of antimicrobial resistance and comorbidities with non-communicable diseases, requiring to coordinate with other funders¹²⁶ and to speed up research by harnessing different investments. Therefore, the initiative should include other international research funders, such as the philanthropies and pharma industry as contributors that will contribute to the partnership on *ad hoc basis*. Based on this ambition, the new global health partnership should evolve from EDCTP2 framework to be more inclusive and to have a broader base of funding from partners, which the EU funding can also match.

Philanthropies, such as the Bill and Melinda Gates Foundation or Wellcome Trust, have realised that alone they cannot bear the costs of late stage clinical trials for the development of medicines or vaccine for poverty related diseases (e.g. phase IV of the

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As recommended by the Evaluation of the impact of the European Union's research funding for poverty-related and neglected diseases – Lessons from EU research funding (1998-2013) https://op.europa.eu/en/publication-detail/-/publication/1f324128-a4c1-11e7-837e-01aa75ed71a1/language-en

RTS,S malaria vaccine candidate) and they are therefore seeking partners to join forces with. These philanthropies have flexibility in their investments and can act speedily when new developments emerge or in the case of a public health emergency.

The Ebola epidemics in West Africa and the Democratic Republic of Congo have contributed to raise the interest of the pharma industry and vaccine in investing in infectious diseases threats affecting Africa and they are actively reaching out to potential partners. Also, for some of these industries, investing in research that is relevant to Africa is part of their corporate social responsibility (e.g. Johnson & Johnson, 127 GSK 128) with a commitment to fair pricing. Including pharma industry in the partnership will also allow to produce at scale and cover the whole value chain. While industry has already taken part in some projects under EDCTP2, the limitations were that it was done on an ad hoc basis for a specific disease, and no forward looking dialogue to plan for potential further investments. The industry that would participate in this partnership, is the industry that has a research agenda that is relevant to infectious diseases in low and middle income countries. This is to be seen in contrast to the proposed Innovative Health Initiative partnership that focuses on research on 'integrated' product development that will help transform health systems in Europe, explicitly integrating the pharma, med tech and digital industries.

The current COVID-19 pandemic and the ongoing EU led Coronavirus Global Response pledge¹²⁹ illustrate the need for the public sector, philanthropies and the industry to join forces to combat infectious threats effectively. All these partners working around the same strategic research agenda are seeking partners for cooperation so that they jointly can support larger clinical trials as well as fund research capacity building more efficiently, therefore achieving greater the impact.

Other essential stakeholders such as researchers, scientific leaders and clinical product development experts, product development partnerships, that have often been crucial for ensuring the final development of products and their delivery of to the market, 130 and national and international institutions focused on infectious disease research (e.g. WHO-TDR, GHIT¹³¹), etc., will also participate but through calls for proposals, projects, consultative groups, etc.

The Interim Evaluation of EDCTP2 recommended that, based on a thorough analysis of existing programmes and active international funders, EDCTP and the EC should jointly explore the opportunities where synergies can be leveraged, and complementary programmes aligned for greater impact and reach. Furthermore it recommended that EDCTP should develop and/or mobilize a mechanism to attain strategic partnerships.

The EDCTP2 Interim Evaluation Panel recommended that in order to reach its full potential and ambitious goals, EDCTP should assume a position as a proactive key strategic player and change agent in sub-Saharan Africa. This effort will require a reinvigorated strategic approach not only by EDCTP management but also by the Participating States and the EC. The Participating States should enhance the executive and political level of EDCTP General Assembly representatives and ensure that representatives are clear on their responsibility to report

¹²⁷ https://www.jnj.com/responsibility/

https://www.gsk.com/en-gb/responsibility/

¹²⁹ https://global-response.europa.eu/index_en

The Initiative on Public-Private Partnerships for Health, Global Forum for Health Research (2004). Combating Diseases Associated with Poverty - Financing Strategies for Product Development and the Potential Role of Public-Private Partnerships. Available at: http://www.who.int/intellectualproperty/topics/ppp/en/CombatingDiseases-Abridged.pdf

The Global Health Innovative Technology (GHIT) Fund focuses on investments in the discovery and development of medicines, diagnostics and vaccines (referred to as health technologies) for TB, malaria, NTDs and other diseases. The GHIT Fund supports partnerships and identifies global opportunities for collaboration with Japanese organizations involved in the R&D of global health technologies.

back to their respective government agencies that have the mandate to deliver on their governments' commitment to EDCTP.

In the **specific consultation of African countries**, 94 (81.7%) of the 115 responders indicated that EDCTP3/GHP can benefit from extending membership to the private sector including industry and foundations. However, the majority of the responders thought it was a highly risky venture. The main risks identified relate to conflicts of interest and loss of control.

Type and range of activities needed

The candidate initiative should first and foremost be an instrument for funding collaborative research and innovation actions, in particular, those focused on the clinical development of health technologies for prevention, diagnosis and treatment of infectious diseases affecting sub-Saharan Africa, as well as supporting the portfolio approach.

The candidate initiative should also play a significant role in the strengthening of research capacity in sub-Saharan Africa. For this, it needs to fund **coordination and support actions** that allow for, among other things, creation and strengthening of networks of excellence, supporting the **career development and scientific leadership** of African researchers, actions to support **knowledge dissemination**.

All stakeholders indicate that funding and implementation of research and innovation actions should be the primary focus of the initiative. Stakeholders view late-stage clinical trials as the primary area, where initiative can deliver direct impacts, while lower, in financial terms, share of the investment should be directed at capacity building activities.

The **EDCTP2 Interim Evaluation Panel** recommended adopting a portfolio approach in order to use its funding instruments (including competitive calls) more strategically, to enhance the value-add of EDCTP and maximize impact. The Panel viewed the EDCTP regional networks as a critical element of institutional capacity in sub-Saharan Africa. The strategic role of the EDCTP regional networks should be broadened and clearly defined. To support the networks in achieving this next phase of their evolution, the level of funding for networks should increase.

The **EDCTP2 Interim Evaluation Panel** recommended to adopt a more comprehensive and catalytic funding approach for supporting the career path of young talented African investigators and to build African scientific leadership. Particular attention should be paid to gender balance, and assess opportunities in this area to strategically align with other funders and programmes on career development.

The **specific consultation of African countries** revealed that clinical epidemiology activities should also be included in the follow up programme. This consultation also stressed the lessons learned from the COVID-19 pandemic with the critical role played by the regional entities, like Africa CDC and WHO-AFRO as well as the EDCTP Regional Networks of Excellence, for managing public health emergencies.

Directionality and additionality required

Directionality

One of the drivers for the current lack of health technologies for tackling infectious disease is the fragmentation of research and innovation efforts in this field. A jointly agreed **strategic research and innovation agenda** is therefore needed so that the shared vision aligns with the individual goals of the members of the partnership, and so that all actors have a clear understanding of how the various elements of the initiative will fit

together in a coherent manner, building commitment and trust and contributing to reaching the jointly agreed objective and thus impacts. The strategic vision should be shared and implemented as much as possible by the key stakeholders along the whole value chain.

The candidate initiative thus has an important role to play in bringing together different actors and aligning their efforts around a common strategic vision and research agenda, reducing duplication of efforts. To be able to do so, there is the need to have a credible and strong position within the stakeholder landscape. EDCTP is already widely recognized as a key player, as confirmed by various stakeholders throughout the consultation and evident in the substantial research output to which it has contributed. Therefore, a new initiative, building on EDCTP2 would have real potential to further focus and strengthen the measures of various countries and organisations towards common global health goals.

Although EDCTP has positioned itself as a key research funder and contributor to the global health research agenda, it could better align its partners' national efforts. Most of the contributions by the Participating States have been delivered in-kind, through Participating States' Initiated Activities. At present, these activities need to be in line with the overarching objectives of EDCTP, to be included in the EDCTP2 Annual Work Plans and, once they are executed, to be formally approved by the EC, before their value can be matched from the EU budget. As currently there is no compulsory requirement for the Participating States to align each other's activities, as a result there have been problems in terms of directionality and duplications of efforts from the national funding schemes. Therefore in the future partnership, the Participating States would need to demonstrate upfront the added value of being part of the initiative for their activities to be eligible for matching the EU funding.

The **EDCTP2 Interim Evaluation Panel** recommended that a strategic policy plan needs to be urgently developed. As a high priority, EDCTP should catalyse the development and strengthening of national health research plans especially for African Participating States.

Additionality

Being part of the partnership must be viewed as an added value by the countries. As even countries that are not part of the EDCTP Association have been able to participate in all EDCTP-supported activities, there has been limited incentive for formal commitment and alignment of national activities. Therefore, the establishment of an effective partnership arrangement among Participating States to incentivise participation needs to be further developed. Targeted or restricted calls for specific challenges should be further explored.

As a potential incentive, the **Interim Evaluation** suggested that EDCTP country membership should be a requirement for their legal entities applying to EDCTP calls.

The EU contribution is expected to mobilise an additional (at least 100%) funding from Member States and Associated States to the Framework programme, as well as third countries, private funders and industry contribution (in-kind or financial). This type of commitment to pool resources only happens beyond the scope of individual projects and requires long-term predictability and commitment to the jointly accepted strategic research agenda. Thanks to these additional resources, the initiative will ensure the

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¹³² EDCTP Annual Report 2019 http://www.edctp.org/publication/edctp-annual-report-2019/

necessary leverage to be able to successfully tackle its objectives and deliver on its impacts.

To be able to set up the partnership and reach the expected impact, it will be necessary to reach a level of financing similar to the one under the current EDCTP2. The EU contribution should be at least EUR 700 million with contribution from the partners at least at the same level.

The future partnership with its proposed additional focus on (re) emerging infectious diseases is extremely relevant, also post COVID-19 pandemic, as epidemics are likely to occur more and more often. ¹³⁴ There is of course a certain level of uncertainty around Member States and African countries, philanthropies and industry's capacity to commit sizeable amounts, seeing the economic impact of the COVID-19 pandemic. Should fewer resources become available, strategic prioritisation will need to be made on the thematic scope and coverage. This would happen at the level of the annual work programme to be co-developed with the stakeholders.

A number of **interviewees** have pointed out the importance of ensuring alignment with other initiatives and programmes in the field of global health and infectious disease. However, they do so mostly in rather general terms rather than by singling out specific areas or initiatives.

Interviewees questioned what can be done to increase the incentives to participate and to increase the leveraging effect for the candidate partnership. Some have suggested that certain activities should be accessible only to active participants in the partnership. The Interim Evaluation Panel suggested that only legal entities in participating countries should be eligible for funding.

The **EDCTP2 Interim Evaluation** recommended that EDCTP will need to understand the goals and priorities of Participating States and work with them to align EDCTP strategy and programmes. EDCTP should thus actively support the Participating States in developing their own national research agendas.

The Interim Evaluation also found that the capacity for active participation in the EDCTP program varies significantly across sub-Saharan Africa. It is important to ensure a more equitable distribution of EDCTP activities and investments so the benefits of EDCTP impact weaker institutions and regions. A strategy must be developed to incentivise wealthier African Participating States to engage with less resourceful African nations in all EDCTP activities.

Moreover, EDCTP should initiate a process for in-depth analysis of the outcome of the activities initiated by the Participating States in order to identify synergies, gaps and overlaps. These activities should be prospectively and strategically integrated with EDCTP programmes and calls in order to minimize gaps. In addition, they should be strategically integrated among themselves to efficiently maximize their impact. EDCTP and the EC should jointly modify the entire process around the Participating States Initiated Activities (which are the countries' in-kind contributions to the partnership) to improve efficiency and to enhance impact. The aims of these activities must be articulated with consideration given to how they can be used to enhance strategic value-add of both EDCTP and the Participating States. A more efficient way to bring in the Participating States' engagement in EDCTP, and to effectively obtain the co-funding that is conditional to the EU co-funding, should be developed.

¹³³ At present EDCTP2 has the EU contribution of €683M plus the same amount €683M from the Participating States.

https://www.ncbi.nlm.nih.gov/pubmed/27318484 Nazir et al. Airborne biological hazards and urban transport infrastructure: current challenges and future directions (2016); Duane J. Gluber Dengue, Urbanization and Globalization: The Unholy Trinity of the 21st Century (2011)

Coherence needed with the internal and external environment

Due to its versatility and cross-sectoral integration, the candidate EU-Africa Global Health Partnership should be managed through close collaboration with other programmes and initiatives to create synergies and limit duplications. It is essential to design administrative mechanisms to appropriately address these synergies and complementarities.

The initiative, that promotes clinical research on infectious diseases in sub-Saharan Africa, would have some areas of common interest, with Horizon Europe work programmes and other EU initiatives or programmes with shared objectives to enable effective prevention, diagnosis and treatment of diseases and to facilitate the uptake of new interventions, in the field of infectious diseases.

In Horizon Europe, health is one of the six Horizon Europe clusters under the Pillar II addressing global challenges and industrial competitiveness through targeted funding of collaborative R&I projects. Cross-cluster research on antimicrobial resistance is expected with the future partnership on One Health Antimicrobial Resistance, focused on animal health and its interaction with human health. 135 Within Cluster Health, a very relevant candidate partnership is the One Health AMR, which aims at facilitating the fight against the rise of antimicrobial resistance by coordinating activities and facilitate national coherence between different services and ministries with responsibility for the various aspects of AMR (e.g. human and animal health, agriculture, environment, industry, finances, etc).

In addition, the Innovative Health Initiative, 136 is expected to contribute to advance the development and uptake of health care technologies and innovations to help transform health systems, mainly in Europe. Some solutions developed under IHI, for example those related to novel health technologies to address infectious diseases or new and validated methods for conducting clinical trials, could be relevant for the EU-Africa Global Health partnership. In addition, methods developed under the candidate publicpublic partnership on Health and Care Systems Transformation, aiming to facilitate the uptake of those solutions into health care systems 137 might be appropriate for sub-Saharan Africa.

Beyond Cluster Health, the proposed partnership on Key Digital Technologies (successor of ECSEL JU¹³⁸), could provide access to the latest digital technologies and data-driven tools, applicable to several fields. Some of them could prove essential for IHI and GHP/EDCTP3 due to the key role of health data for innovative, integrated health technologies. Another instrument with shared interests in infectious diseases is the InnovFinID¹³⁹ and the future EuropeInvest of the European Investment Bank that foresee support through loans in the infectious diseases area.

https://ec.europa.eu/health/amr/antimicrobial-resistance_en
https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/11906-European-Partnership-for-innovative-health

¹³⁷ It is important to emphasise that solutions proposed by IHI would be concrete goods or services (e.g. medicines, diagnostics, medical devices incl. digital tools etc) rather than organisational solutions. Organisational processes will be in the remit of health care authorities/organisations to consider whether and how these could be deployed in the best way.

¹³⁸ https://www.ecsel.eu/

https://www.eib.org/en/products/blending/innovfin/products/infectious-diseases.htm

Potential initiatives in the Health cluster, where complementarities and interconnections are expected, both in terms of research topics covered and stakeholders involved are shown in the Figure 9 below.

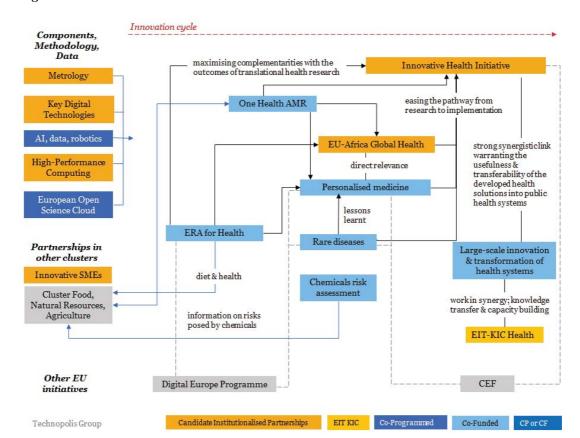


Figure 9: EU initiatives related to the SDG 3

The problems that the candidate initiative would address are highly complex and are set in the context of weak health systems and institutions for the delivery of health care. This was particularly evident in the devastating 2014–2016 Ebola Virus Epidemic in West Africa. ¹⁴⁰

The candidate partnership aims to support the research and the strengthening of the health research systems in sub-Saharan Africa, and will need to seek for synergies with the EU programmes and initiatives that aim to build resilient and responsive health systems and to implement the International Health Regulations in the region, so that health innovations can be accessible to the poorest populations. The development aid is to be provided through the EU instruments of the Development Cooperation and External Action, the future European Neighbourhood, Development and International Cooperation Instrument, the Universal Health Coverage Partnership and other initiatives in the region, including the support to global initiatives such as The Global Fund, GAVI the Vaccine Alliance Alliance 144 and the Global Financing Facility.

These instruments also support health systems in case of public health emergencies by fast-tracking approval and subsidizing their delivery in countries once a health

¹⁴⁰ WHO. 2020. Ebola virus disease. https://www.afro.who.int/health-topics/ebola-virus-disease

https://ec.europa.eu/commission/publications/neighbourhood-and-world_en

https://www.uhcpartnership.net/

https://www.theglobalfund.org/en/

https://www.gavi.org/

https://www.globalfinancingfacility.org/

technology is available, strengthening regional health security organisations and supporting epidemiological surveillance. The EU Emergency Trust Funds, ¹⁴⁶ provides emergency medical assistance and support in basic health services to irregular migration and displaced persons in Africa.

The support will be done in a coordinated fashion with the European Centre for Disease Prevention and Control (ECDC) and the African CDC (ACDC), both in human capital (doctors, nurses, community health workers, technicians etc.) and in infrastructures (hospitals, equipment, vehicles etc.), which are necessary. In case of outbreaks, the initiative will also contribute and take into account the recommendations of GloPID-R, the unique international network of the major research funding organizations to facilitate a rapid and effective research response.

Whilst development of new health technologies is essential, they cannot be used unless they are authorized for use where they are needed. The regulatory capacity in Africa for assessment and approval of medicines, as well as for conducting post-authorisation pharmacovigilance is still weak. Here, the recently established African Medicines Agency (AMA) will have an important role to play and the initiative will contribute to it through the regulatory capacity building and through interactions with AMA and other agencies, such as the European Medicines Agency (EMA) and the US Food and Drug Administration (US FDA).

The candidate initiative will need to actively pursue synergies through consultative mechanisms or partnering on ad-hoc basis with other initiatives or programmes taken by other funders with shared objectives to enable effective prevention, diagnosis and treatment of diseases and to facilitate the uptake of new interventions (Figure 10). Therefore, it is important to position the candidate initiative clearly in the global health spectrum to avoid duplications. This initiative will be focused on clinical development and uptake of health technologies addressing infectious diseases affecting sub-Saharan Africa.

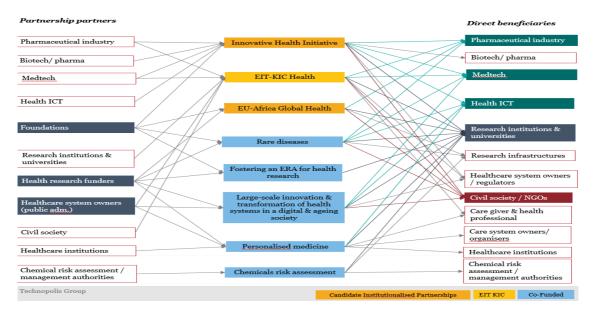
The **EDCTP2 Interim Evaluation Panel** recommended that the EU would benefit by having a high level strategy across programmes and policies to facilitate alignment, coordination and collaboration where opportunities exist. This approach would be most effective with the appointment of a specific coordinator responsible for coherence among EU initiatives and policies. The communication role within EDCTP will require considerable networking and coordination across Participating States to identify synergies and to achieve better alignment and coordination with their clinical research activities in sub-Saharan Africa.

https://www.glopid-r.org/

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 $[\]underline{^{146}\ https://ec.europa.eu/trustfundforafrica/index_en}$

Figure 10: Potential synergies with the stakeholders of the EU-Africa Global Health Partnership candidate



As in the case of internal coherence, **interviewees widely agree** that the candidate partnership should coordinate its efforts with other key stakeholders in the field, often without being specific. Some have noted a proliferation of initiatives, some of which appear to share focal areas with the candidate partnership. In addition to EU programmes and initiatives, specific examples include the Coalition for Epidemic Preparedness Innovations, and the Bill & Melinda Gates Foundation. These interviewees indicated that it will be important for the candidate partnership to clearly position itself in relation to these other initiatives and funders and, where applicable, coordinate activities.

The **EDCTP2 Interim Evaluation** recommended that EDCTP and the EC should jointly explore the opportunities where synergies can be leveraged, and complementary programmes aligned for greater impact and reach. In addition, EDCTP should develop and/or mobilize a mechanism to attain strategic partnerships and current communication strategy to become more focused on building relationships and dialogue with Participating States governments and European and International funders and stakeholders.

The **EDCTP2 Interim Evaluation** also recommended that the function of strategic communication and advocacy within EDCTP should be elevated to the highest level of leadership. Closer coordination and planning between the EC leadership and the EDCTP Secretariat and General Assembly will also help to achieve the level of communication and advocacy needed. These coordinated leadership roles will require a mind-set change across organizations and individual leaders.

5. WHAT ARE THE AVAILABLE POLICY OPTIONS?

This section describes the specific functionalities that could be provided under the baseline scenario of traditional calls and the different options of different types of European partnerships.

5.1. What is the baseline from which options are assessed?

Baseline: Traditional calls under the Framework Programme

The baseline scenario used in this impact assessment is a situation without a Partnership, where traditional calls under the Framework Programme, Horizon Europe, are the means

to award grants. Given that there is a predecessor Partnership, the current EDCTP, as well as other funders in the area, most probably will continue collaborations, even if to a lesser extent, generating outputs and results of relevance even in the absence of a new Partnership. It is expected that these already existing initiatives will still have an impact on the burden of infectious diseases. This is taken into account in the effectiveness assessment of the baseline.

In parallel, the baseline option means that the current implementation structure of the Article 185 would be closed, which bears winding down and social discontinuation costs. Traditional calls would represent financial cost-savings related to the closing of the structure, related to operations, staff and coordination costs in particular. This is taken into account in the efficiency assessment.

The closing down of the current EDCTP2 programme is shown in Figure 11. The last EDCTP2 calls, launched during 2020, take into consideration the need to wind down, asking for a shorter duration of projects.

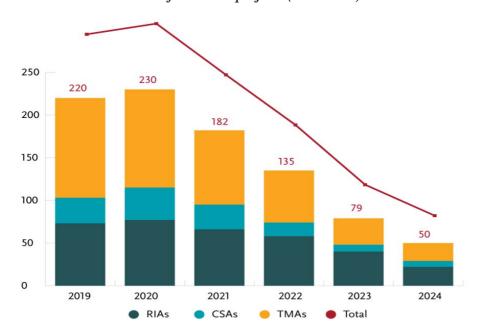


Figure 11: Predicted attrition of EDCTP2 projects (2019-2024)

Notes: RIA: Research and Innovation Actions; CSA: Coordination and Support Actions; TMA: Training and Mobility Actions.

It will be important to take into consideration in this projection another consequence of COVID-19 pandemic and its confinement measures: many of these projects will be obliged to extend their duration by half a year in order to be able to execute them as planned.

Table 2: Key characteristics of the baseline - Traditional calls

Functionalities of option	Key characteristics of Traditional calls
Enabling appropriate profile of participation	Partners: There are no partners, and no common set of actors that engage in planning and implementation Priority setting: open to all, part of Horizon Europe Strategic planning. Given the broad range of activities, the Commission would need to consult with a large group of stakeholders, both from Europe and Africa, to develop the Horizon Europe annual work programmes.

	Participation in R&I activities: fully open in line with standard Horizon Europe rules No common set of actors that engage in planning and implementation. Participation in traditional calls is open to any Horizon Europe eligible legal entity within a consortium. This includes research organisations in Africa, although these are not automatically eligible for funding.
Supporting implementation of R&I agenda	Activities: Horizon Europe standards that allow broad range of individual actions. Calls for proposals would be published in the work programmes of Horizon Europe. No additional activities and investments outside the funded projects. Implementation would rely on standard infrastructure underpinning the open calls procedure, drawing on resources of the Commission or relevant executive agency and Commission IT systems No systemic approach beyond individual actions. Transparency and open publication of results would ensure their availability to all interested parties.
Ensuring alignment with R&I agenda	Priority setting: Strategic Plan and annual work programmes, covering max. 4 years. Strategic programming and the research agenda would be defined by the European Commission via co-creation, with the support of an advisory group and the programme committee. Work programmes would need to reflect the requirement for R&I activity across the health technologies clinical development, with input from representatives of all relevant stakeholders. Limitations: Fully taking into account existing or to be developed SRIA/ roadmap
Securing effective leveraging of resources	Internal coherence between different parts of the Annual Work programme can be ensured by the Commission. This option does not require upfront determination of a budgetary EU envelope. External coherence limited for other Union programmes, no synergies with national/regional programmes and activities.
Key differences compared to the current situation	Under the current EDCTP2 programme, which is based on Article 185, the EU contributes for ten years to a programme gathering Member States and African countries in an EDCTP Association, where all the countries have voting rights, around a common strategic agenda. A dedicated structure based on the Association and a Secretariat implements the programme and aligns the national activities under the scope of the programme. The EU is matching the European Participating States contributions to the EDCTP2 Programme.
	With traditional calls under Horizon Europe, there is no common set of actors nor a long-term commitment as the maximum duration of a SRIA or roadmap would be 4 years. The baseline does not foresee a dedicated implementing structure to help leveraging resources.

5.2. Description of the European Partnership policy options

Option 1 – Co-programmed European Partnership

The co-programmed partnership is based on a Memorandum of Understanding of the partners (the EU, Member and Associated States, African countries and/or other Third countries), or another non-legally binding contractual agreement, around a common strategic research and innovation agenda. The contributions may be financial or in-kind, and any financial risks would be covered by the parties' own contributions to the partnership. The EU calls would be published through the Horizon Europe Work Programme. A co-programmed partnership does not require a separate legislative procedure, and the EU budget is managed by the EC or an EC executive agency.

Table 3: Key characteristics of Option 1 – Co-programmed

Functionalities	Key characteristics of Option 1 – Co-programmed
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of option	
Enabling appropriate profile of participation	Partners: Suitable for all types: private and/or public partners, philanthropies. Based on a declaration of intentions, the co-programmed option enables participation from any kind of partner; EU Member States and Associated States to the Framework Programme, as well as African countries, charitable foundations and the pharmaceutical industry. The composition of partners can change over time, allowing for flexibility and adaptation to emerging needs and priorities in the global health arena Priority setting: Driven by partners, open stakeholder consultation, MS in comitology Participation in R&I activities: fully open in line with standard Horizon Europe rules; the relationships built under the current EDCTP can be maintained.
Supporting implementation of R&I agenda	Activities: Horizon Europe standard actions that allow broad range of individual actions, support to market, regulatory or policy/ societal uptake. The co-programmed partnership allows the Commission to launch collaborative R&I actions, coordination and support actions, and training actions towards a common strategic agenda launched through the Horizon Europe annual work programme Additionality: Activities/investments of partners and national funding. Limitations: Limited systemic approach beyond individual actions. Other partners would have limited control over the precise definition of the EU calls, limiting the extent to which calls can be adapted to the specific needs of certain partners. This may hinder the possibility to issue <i>ad hoc</i> joint calls with other parties.
Ensuring alignment with R&I agenda	Priority setting: Strategic R&I agenda/ roadmap agreed between partners and EC, covering usually 7 years, including allocation of Union contribution. Input to FP annual work programme drafted by partners, finalised by EC (comitology). Under the co-programmed option, a strategic roadmap is agreed between the EC and the partners involved. All partners can contribute to the development of the work programme, but not to the implementation of the calls and actions themselves. Objectives and commitments are set in the contractual arrangement or Memorandum of Understanding. The alignment with other initiatives and parties outside of the partnership would be the responsibility of the EC, or EC Agency, in charge of the programme implementation
Securing effective leveraging of resources	Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM. This option allows an upfront EU budgetary envelope. Commitments by partners only represent political/best efforts, but these are usually honoured. External: Limited synergies with other Union programmes and industrial strategies as well as with national/ regional programmes and activities. This option allows for the creation of a dedicated small office to manage the coordination of the partners contributions and alignment with the R&I agenda. Under the Co-programmed option, both cash and in-kind contributions can be leveraged for increased impact.
Key differences compared to the current situation	 Under the current EDCTP2 programme, which is based on Article 185, the EU contributes for ten years to a programme gathering Member States and African countries in an EDCTP Association, where all the countries have voting rights, around a common strategic agenda. A dedicated structure based on the Association and a Secretariat implements the programme and aligns the national activities under the scope of the programme. The EU is matching the European Participating States contributions to the EDCTP2 Programme. With Co-Programmed option, there is a limited systemic approach beyond individual actions. Other partners would have limited control over the precise definition of the EU calls, limiting the extent to which calls can be adapted to the specific needs of certain partners.

Option 2 – Co-Funded European Partnership

A Co-Funded partnership is based on a Grant Agreement between the Commission and a consortium of public partners (particularly research funders), with a certain degree of flexibility for the involvement of philanthropies and international partners. Whilst public

sector partners can make contributions and formal commitments to the partnership, industry can only apply to calls for proposals. Partner contributions are often financial contributions used for calls for proposals but can also be in-kind.

Table 4: Key characteristics of Option 2 – Co-Funded European Partnership

Functionalities of option	Key characteristics of Option 2 – Co-Funded European Partnership
Enabling appropriate profile of participation	Partners: core of national funding bodies or governmental research organisations. A Co-Funded partnership would be mainly limited to public sector parties and possibly philanthropies. Industry parties would not be able to contribute to the partnership but could be involved in activities (projects). Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: limited, according to national rules of partner countries. Under national rules, Member States could issue calls open only to legal entities from countries that are part of the partnership. This form of implementation requires partners (Member States, Associated States, but also charities, product development partnerships, international organisations, among others) to sign a Grant Agreement. Collaborations built under EDCTP, including those with African countries under the EDCTP Association, could be largely maintained, although the type of involvement of parties would be different than under EDCTP.
Supporting implementation of R&I agenda	Activities: Broad, according to rules/programmes of participating States, State-aid rules, support to regulatory or policy/ societal uptake. Based on a EU Horizon Europe Grant Agreement between the Commission and the consortium of participating partners, this option would allow for the support of a broad range of R&I activities, coordination and support actions and training of researchers and technical clinical support, around a strategic R&I agenda. Additionality: National funding Limitations: Scale and scope depend on the participating programmes, often smaller in scale. Other partners would have limited control over the precise definition of the calls, limiting the extent to which calls can be adapted to the specific needs of certain partners. This may hinder the possibility to issue ad hoc joint calls with other parties.
Ensuring alignment with R&I agenda	Priority setting: Strategic R&I agenda/ roadmap agreed between partners and EC. A Co-Funded partnership will have a strategic R&I agenda/roadmap, to be agreed between partners and the EC, and the joint drafting of an annual work programme covering usually 7 years, including allocation of Union contribution Annual work programme drafted by partners, approved by COM Objectives and commitments are set in the Grant Agreement. A large number of parties (Member States, Associated States, Third countries, private funders, product development partnerships, etc.) would likely need to be included in the Grant Agreement.
Securing effective leveraging of resources	Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Synergies with national/ regional programmes and activities. The Co-Funded partnership option allows for leveraging the commitments made by partners from the EU budget. This includes both financial and in-kind contributions. This form of partnership represents a high degree of political commitment from partners as the funding is committed upfront. This option allows for the creation of a dedicated 'programme office', within one of the beneficiary organisations, to manage the coordination of the partners contributions and alignment with the R&I agenda.
Key differences compared to the current situation	Under the current EDCTP2 programme, which is based on Article 185, the EU contributes for ten years to a programme gathering Member States and African countries in an EDCTP Association, where all the countries have voting rights, around a common strategic agenda. A dedicated structure based on the Association and a Secretariat implements the programme and aligns the national activities under the scope of the programme. The EU is matching the European Participating States contributions to the EDCTP2 Programme.

With Co-Funded option, there is the limitation in the participation to only public organisations and philanthropies. Member States could issue calls open only to legal entities from countries that are part of the partnership.

Option 3a and 3b - Institutionalised European Partnerships

The institutionalised European partnerships are subject to implementation under Article 185 or Article 187 of the Treaty on the Functioning of the European Union (TFEU). Both types of initiatives are governed through separately established entities, with partners tied through legally binding commitments. The flexibility of these partnerships is limited since the composition of partners cannot be changed easily, and the strategic priorities and goals are set in advance. The implementation of activities is set up through a specifically created entity (Dedicated Implementation Structures (DIS) or Joint Undertaking (JU) respectively) with a mandate to launch calls and distribute grants based on the annual work programmes, which are approved by the EC.

For both partnership types, contributions from partners can be in-kind and financial, while EU financial contributions are implemented through matching mechanisms and are distributed through the dedicated entity. In both cases, the financial risk at the project level would be covered by the Mutual Insurance Mechanism of Horizon Europe (the former Participant guarantee funds).

The below paragraphs outline the key differences between these two types of institutionalised partnership in relation to the candidate EU-Africa Global Health Partnership.

Option 3a – Institutionalised European Partnership under Article 185 TFEU

Article 185 of the TFEU allows the Union to participate in programmes jointly undertaken by Member States and Associated Countries, aimed at achieving the greatest possible impact through the integration of national and EU funding, aligning national strategies in order to optimise the use of public resources and overcome fragmentation of public research investments. Involvement is limited to Member States and Associated States. Non-associated countries can only participate if foreseen in the basic act, and their participation is subject to concluding individual international agreements. Under EDCTP2, African countries can take part indirectly in the partnership through their involvement in the EDCTP Association, a private association under Dutch law. Private sector actors or charitable foundations cannot formally join the partnership and, whilst they can be partners in specific activities, their contributions cannot be matched from the EU budget. This form of partnership requires participation of at least 40% of all EU Member States.

Table 5: Key characteristics of Option 3a – Institutionalised European Partnership – Article 185 TFEU

Functionalities of option	Key characteristics of Option 3a – Article 185 TFEU
Enabling appropriate profile of	Partners: National funding bodies or governmental research organisation. This form of partnership is open only to Member States and Associated States, represented by public sector organisations. Third countries, private sector organisations and charitable foundations can be involved indirectly, through the partnership's projects, and their

participation (actors involved)	contributions cannot be matched from the EU budget. Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: fully open in line with standard Horizon Europe rules, but possible derogations. EU funding is open to legal entities in all Member States and Associated States, as well as third countries if eligible for funding under Horizon Europe.
Supporting implementation of R&I agenda (activities)	Activities: Horizon Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to systemic approach. Implementation of activities would be responsibility of the Dedicated Implementing Structure, the existing EDCTP Association, which will publish the calls for proposals. Additionality: EU plus national funding.
Ensuring alignment with R&I agenda (directionality)	Strategic R&I agenda/ roadmap agreed between partners and EC, covering usually 7 years, including allocation of Union contribution. By participating in the development of a common strategic agenda, partners are encouraged to improve their alignment and transnational cooperation. Annual work programme drafted by partners, approved by EC Objectives and commitments are set in the legal base.
Securing leveraging effects (additionality)	Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Synergies with national/ regional programmes and activities. National R&I activities can be integrated into the programme, and can then be matched from the EU budget to increase the synergies and promote transnational cooperation. Legally binding funding requirements would be clearly defined at the outset, with partners other than the EU expected to provide between 50% and up to 75% of partnership resources through in-kind and/or financial commitments. This form of partnership comes with very high visibility and political commitment from partners with upfront commitments. A Dedicated Implementation Structure (DIS) would be responsible for implementing the programme and aligning partners around a shared strategic agenda jointly prepared with the EC. The DIS would also look for synergies between EU and national/regional programmes and activities, as well as with other EU and international programmes or initiatives.
Key differences compared to the current situation	Article 185 option is the current situation. No difference.

Option 3b – Institutionalised European Partnership – Article 187

Whilst the Institutionalised Partnership under Art. 187 shares many characteristics with that under Art. 185, a key difference lies in the possibility of involvement of partners beyond the Member States and Associated States. Under Art. 187 private sector actors and charitable foundations can be included in the partnership and their contributions can be matched from the EU budget. Similar to the Art. 185 option, participation of non-associated countries is possible if foreseen in the basic act. The implementation of the programme is usually managed by a Joint Undertaking, with the European Commission being fully involved in the governance. In comparison with Option 3a under Article 185, which is a Member State led programme where the Commission acts as an observer in the Board, in an Article 187, the Commission will have co-ownership of the programme and will be sitting in the Board, thus participating fully in the decision-making process.

Table 6: Key characteristics of Option 3b – Institutionalised European Partnership under Article 187 TFEU

Functionalities of option	Key characteristics of Option 3b – Article 187
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Enabling	
appropriate	
profile	of
participation	
(actors involve	d)

Partners: Suitable for all types: private and/or public partners, philanthropies. This form of partnership would enable participation by the key global health stakeholders, contributing to the development and execution of the strategic R&I agenda. It is open to Member States and Associated States, represented by public sector organisations, as well as private sector organisations and charitable foundations. Third countries can participate if foreseen in the basic act.

Priority setting: Driven by partners, open stakeholder consultation
Participation in R&I activities: fully open in line with standard Horizon Europe rules, but
possible derogations. EU funding would be open to legal entities in all Member States and
Associated States, as well as third countries if eligible for funding under Horizon Europe.
Funding is not limited to institutions from countries in the partnership.

Supporting implementation of R&I agenda (activities)

Activities: Horizon Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to systemic approach (portfolios of projects, scaling up of results, synergies with other funds. Implementation of activities would be the responsibility of a Joint Undertaking. This form of partnership allows for funding of R&I activities, as well as coordination and support actions and capacity building. This full mix of activities is foreseen as needed for the fulfilment of the candidate partnership's objectives.

Additionality: Activities/investments of partners including national funding.

Ensuring alignment with R&I agenda (directionality)

Priority setting: Strategic R&I agenda/ roadmap agreed between partners and EC, covering usually 7 years, including allocation of Union contribution. By participation in the development of a strategic agenda, partners are encouraged to improve their alignment and transnational cooperation.

Annual work programme drafted by partners, approved by EC (veto-right in governance). Objectives and commitments are set in the legal base.

Securing leveraging effects (additionality)

Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and EC.

External: Synergies with other Union programmes, industrial strategies, philanthropies and Member States with national/regional programmes and activities. National R&I activities can be integrated into the programme, which can then be matched from the EU budget to increase the synergies and promote transnational cooperation. Legally binding funding requirements would be clearly defined at the outset, with partners other than the EU expected to provide between 50% and up to 75% of partnership resources through in-kind and/or financial commitments. Each partner's contribution can be matched from the EU budget.

Key differences compared to the current situation

Under the current EDCTP2 programme, which is based on Article 185, the EU contributes for ten years to a programme gathering Member States and African countries in an EDCTP Association, where all the countries have voting rights, around a common strategic agenda. A dedicated structure based on the Association and a Secretariat implements the programme and aligns the national activities under the scope of the programme. The EU is matching the European Participating States contributions to the EDCTP2 Programme.

With an Article 187 option, in addition to Member States and Associated States, other key global players would be able to join the initiative, and also contribute to the partnership. These are philanthropies (BMGF, Wellcome Trust, etc.), industry (EFPIA, etc.) and other third countries (e.g. United Kingdom, Japan, etc.) and they can participate on ad-hoc basis. Moreover, all these partners contributions would be able to be matched by the EU contribution, increasing the leveraging effect and the coherence of the initiative.

5.3. Option discarded at an early stage

The Co-Funded partnership is unlikely to be feasible for the EU-Africa Global Health Partnership because this form of implementation only allows for public partners (mainly EU Member States and sub-Saharan countries) to participate in the partnership. Industry, which is a key player in the global health area, would not be able to contribute to the partnership, but could only be involved in specific activities (projects). In addition, only

legal entities from countries that are part of the partnership can apply to calls. This means that institutions from non-participating countries would not be able to receive funding. This could hinder access of certain sub-Saharan African countries that are unable to participate in the partnership. Moreover, it is also very unlikely that this form of partnership would be able to raise the amount of funding needed to have a significant impact. This option has thus hereafter been discarded from further assessment.

Although the option of Article 185 also has the disadvantage that key partners, such as industry, can only participate at project level, we have included the assessment of the Article 185 option, since it is the current set up of EDCTP2.

6. HOW DO THE DIFFERENT POLICY OPTIONS COMPARE TO ACHIEVE THE EXPECTED IMPACTS?

Based on the objectives pursued by the initiative and the key functionalities of each option, each policy option for implementation is assessed in terms of effectiveness, efficiency and coherence compared to the baseline scenario of traditional calls. The analysis is primarily based on the degree to which the different options would cater for the key needed functionalities. All options are compared to the baseline situation of traditional calls, which is thus consistently scored at 0 to serve as reference point.

6.1. Effectiveness

To be in line with the Horizon Europe impact framework, ¹⁴⁸ the achievement of the initiative's specific objectives is translated to 'expected impacts' – i.e. how success would look like -, differentiating between scientific, economic/ technological, and societal (including environmental) impacts. This section considers to which extent the different policy options would allow in **delivering these expected impacts** – confronting what is needed (functionalities) with what each form of implementation can provide in practice. The assessments in this section set the basis for the comprehensive comparative assessment of all retained options against all dimensions in Section 6.4, based on a scoring system.

In line with the Better Regulation guidelines, ¹⁴⁹ the baseline has a score of 0 and is used as a basis for comparison for the other options. The other options receive a score of 0 if they have the same potential as the baseline, a score of (+) if they have a *good* potential compared to the baseline and a score of (++) if they have a *high* potential compared to the baseline.

Scientific impacts

Baseline: Horizon Europe traditional calls

Under the baseline option, calls for proposals launched under the Horizon Europe Health Cluster could focus on: the development of new or improved health technologies to strengthen the EU's scientific excellence in clinical research on infectious diseases

 $[\]underline{\text{https://ec.europa.eu/info/publications/horizon-europe-impact-assessment-staff-working-document_en}\\$

¹⁴⁹ https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how/better-regulation-guidelines-and-toolbox en

relevant to sub-Saharan Africa, increasing the scientific leadership of African researchers, increasing the capacity of the research response to effectively control (re) emerging epidemics in sub-Saharan Africa, and increasing evidence base for national and international health policy-making (bridging the gap between science and policy for health).

Horizon Europe calls are expected to lead to scientific discoveries that are of a precursory and exploratory nature and that lead to the elucidation of the underlying mechanisms of health and disease conditions. Therefore under this option there would be a potential to establish new scientific paradigms providing the foundation for innovative health technologies. However, by themselves, these calls would likely not be focused on long-term clinical development, nor would they deliver implementable solutions. For that to happen, a more strategic approach is needed, with a 'portfolio-level' thinking, directionality towards common objectives, alignment of individual projects and the joint participation of key partners.

Under this option, the initiative's objective of reducing the risk of spread of (re) emerging infectious diseases would be possible, by supporting networks to promote knowledge exchange between disease control institutions and countries, since these activities are typically less resource-intensive than large-scale clinical trials.

However, as this option does not allow for the pooling of additional resources from countries and for cooperation with additional stakeholders around a common strategic agenda, support long-term, multisite and international clinical trials would be difficult. Moreover, the baseline option does not have a dedicated implementing structure that can effectively coordinate the key partners around a common strategic agenda.

In addition, under the baseline option, neither the Commission nor the partners make an upfront budgetary commitment. This implies less political commitment and reduced visibility to the field compared to under a partnership approach. The existing collaboration built under the first and second EDCTP programmes, between the EU, European countries and African countries, would not be maintained at the level that it is currently. Additionally, the scientific leadership and ownership by sub-Saharan African countries would be reduced, as well as the potential to bridge the gap between science and policy for health or evidence base health policy-making.

Even under the current COVID-19 crisis, the baseline scenario is still a valid baseline for the different options. However, if due to the consequences of the pandemic there was a delay in the process for the adoption of the partnerships under Horizon Europe, or a reduced expected budget availability, this option might become the only option, at least for the starting year (2021).

All interviewed stakeholders, from all stakeholder groups, agree that the baseline option is undesirable and would result in a near-complete loss of the momentum that EDCTP has been able to generate. It is thus seen as a major step backwards.

Option 1: Co-Programmed European Partnership

Under a co-programmed option, compared to the baseline option, the partnership is more likely to support late-stage clinical trials, because of the ability of partners to actively align activities around a common research agenda. Therefore it has an increased chance

of contributing to successful product development, thus receiving a score of +, i.e. a *good* potential compared to the baseline.

Under this option, the initiative's objective of reducing the risk of spread of (re) emerging infectious diseases would also be possible, by supporting networks to promote knowledge exchange between disease control institutions and countries, since these activities are typically less resource-intensive than large-scale clinical trials.

However, in all other aspects, the co-programmed option has similar drawbacks as the baseline option. As in the baseline option, there will no dedicated implementing structure, which will reduce the capacity to effectively coordinate countries and other key partners around the common strategic agenda.

Option 3a: Institutionalised European Partnership under Article 185

This form of institutionalised partnership would bring together Member States and Associated States and their contributions would be matched from the EU budget. Other stakeholders could participate indirectly in the partnership. This is the current form of the EDCTP2 programme. This option would generate sufficient financial space to support mid- to late-stage clinical research, where the costs are highest. Additionally, the institutionalised partnership approach encourages partners to come together to commit budget to a common strategic research vision and to plan their activities accordingly.

Since it has the same legal basis as the current EDCPT2, under the Article 185 option, the candidate EU-Africa Global Health Partnership would be able to retain the current programme office, knowledge and know-how of sub-Saharan clinical trials management, and relations with key stakeholders in the region. However, under an Article 185, the EU would not be able to match the contributions from third countries nor from philanthropies or industry.

Compared to the baseline option, this option would have significantly better prospects to reach a high scientific impact. This option has therefore received a score of ++, i.e. a *high* potential compared to the baseline.

Option 3b: Institutionalised European Partnership under Article 187

This option would allow to bring together EU Member States and Associated States, as well as third countries, philanthropies, industry and international organisations around a strategic research and innovation agenda. It would also foresee a long-term budgetary commitment from all parties, which could be matched by the EU budget. A Joint Undertaking would implement the programme under full control of the Commission, which would have a seat in the governing board. The greater number of partners and the possibility for the EU budget to match third parties' contributions, in addition to the Member and Associated States' contributions, would represent greater budget commitments and a greater pooling of resources around a common objective.

In terms of scientific impact, an Article 187 institutionalised partnership appears to be the best option to mobilise the resources needed to support a sustained and coordinated response to infectious diseases in sub-Saharan Africa, as well as to have a significant impact by strengthening the knowledge of clinical research on infectious diseases relevant to sub-Saharan Africa, increasing the scientific leadership of African

researchers, the capacity to control (re) emerging epidemics in sub-Saharan Africa and to have evidence-based national and international health policy making. This option has therefore received a score of +++, i.e. a very high potential compared to the baseline.

Interviewees unanimously express a strong preference for an institutionalised partnership approach. Opinions are, however, divided on whether this should take the form of an Article 185 partnership or an Article 187 partnership. Many acknowledge the advantages an Art.187 set-up would bring to the partnership, arguing that it allows for more meaningful inclusion of a greater range of stakeholders, creates more financial certainty, and would allow for a leaner and more efficient organisational structure. Others, however, have concerns about what this would mean for the relationships built with and between current EDCTP members and for the level of control that the EC would have over the partnership.

Numerous interviewees have expressed varying degrees of concern that countries that cannot substantially contribute to the partnership financially will be left out of the decision-making. Not all stakeholders fully understand the advantages and disadvantages of these two options and question why a change from one to the other would even be under consideration.

In the responses to the **open public consultation**, 26 out of 41 respondents indicated that an institutionalised partnership would be the preferred option, emphasising in particular the need for strong (financial and political) commitment and long-term stability. The consultation, however, did not allow respondents to distinguish between the two individual forms of institutionalised partnership. Among those who expressed a preference for a Co-Funded or Co-Programmed option, the reasons given related to a need for flexibility, inclusiveness of the partnership, and lower costs. Similar to the case among interviewees, however, the open comments provided in response to the consultation clearly show that many respondents struggle to fully understand the details of different forms of partnership.

While consulted non-government stakeholders indicated their preference for an institutional partnership, many of them could not position themselves in favour of Article 185 or Article 187, leaving it to the Commission and the Member States to decide which form of implementation was best suited. The governmental stakeholders consulted for the GHP/EDCTP3 have the experience with an Article 185 for EDCTP2 and an Article 187 for the Innovative Medicine Initiative (IMI), which is a public–private partnership with industry. Consulted governmental stakeholders indicated their preference for an Article 187, since it would allow philanthropies and the industry to join. They highlighted the importance of transparency on industry participation and its contribution, to safeguard public interests.

Summary

Table 7 lists the scores for each of the policy options as regards to the effectiveness criteria for scientific impacts, based on the assessments above, as well as taking into account the support expressed by the different stakeholders.

Table 7: Overview of the options' effectiveness compared to the baseline - Scientific impacts

	Option 0:	Option 1:	Option 3a:	Option 3b:
Scientific Impacts	Horizon Europe calls	Co- programmed	Institutionalised Art 185	Institutionalised Art 187
Strengthened EU scientific excellence	0	+	++	+++

Scientific Impacts	Option 0: Horizon Europe calls	Option 1: Co- programmed	Option 3a: Institutionalised Art 185	Option 3b: Institutionalised Art 187
in clinical research for infectious diseases				
Increased scientific leadership of sub- Saharan Africa in the infectious diseases field	0	0	++	+++
Increased research response capacity to control of (re-)emerging epidemics in sub-Saharan Africa	+	+	++	+++
Increased evidence base for national and international health policy-making (bridging the gap between science and policy for health)	0	0	++	+++

Notes: Score +++: Option presenting a *very high* potential compared to baseline; Score ++: Option presenting *high* potential compared to baseline; Score +: Option presenting a *good* potential compared to baseline; Score 0: Potential of the baseline.

Economic/Technological impacts

Baseline: Horizon Europe traditional calls

The lack of commitment to a strategic research and innovation agenda would likely result in a much-reduced ability to support end-of-pipeline product development. This means a lower impact on the capacity of institutions in sub-Saharan to design, conduct and manage infectious diseases research projects, on the number of employed researchers in sub-Saharan Africa, and lower capacity to attract funding in the region. On the other hand, the lack of long-term commitment would discourage industry from participation in research projects in sub-Saharan Africa.

Option 1: Co-Programmed European Partnership

Economic impacts are tied to the increased ability to reduce health care related expenditure, increase the number of employed researchers, and strengthen the capacity in sub-Saharan Africa to manage research projects and attract funding, all resulting in a more attractive environment for industry to participate in research projects in the region. Economic impacts depend not only on the implementation of research results, but also on the level of funding and alignment. In a co-programme partnership, the engagement of all the actors around a strategic research agenda would provide a directionality for all the partners, thus having a higher impact than the baseline option. This option has received a score of + compared to the baseline.

Option 3a and 3b: Partnership under Article 185 and Article 187

The economic and technological impacts are largely dependent on the attainment of scientific results and impacts. With its greater possibility to focus on clinical research and product development and the higher level of budgetary commitments, the institutionalised partnerships have a higher chance to develop technologies ready for their production, distribution and uptake.

The extent of the economic impact resulting from increases in the skills of researchers and research activity depend on the scale as well as on the focus of the initiative. Under an institutionalised partnership, irrespective of whether this takes the form of an Article

185 or an Article 187 partnership, there will be greater opportunities for capacity strengthening in the area of clinical research than under the baseline option. In light of the above, the two institutionalised options have been scored with ++ compared to the baseline.

Summary

Table 8 lists the scores assigned to each of the policy options as regards to the effectiveness criteria for economic / technological impacts, based on the assessments above, as well as taking into account the support expressed by the different stakeholders.

Table 8: Overview of the options' effectiveness compared to the baseline – Economic / technological impacts

Economic/Technological impacts	Option 0: Horizon Europe calls	Option 1: Co- programmed	Option 3a: Institutionalised Art 185	Option 3b: Institutionalised Art 187
Increased research capacity of institutions in sub-Saharan Africa to design, conduct and manage infectious disease research projects	0	+	++	++
Higher capacity of the research institutions to attract funding	0	+	++	++
Increased industry participation in research projects in sub-Saharan Africa	0	+	++	++
Increased number of employed researchers in sub-Saharan Africa	0	+	++	++

Notes: Score +++: Option presenting a *very high* potential compared to baseline; Score ++: Option presenting *high* potential compared to baseline; Score +: Option presenting a *good* potential compared to baseline; Score 0: Potential of the baseline.

Societal impacts (including environmental, social and fundamental rights)

Baseline: Horizon Europe traditional calls

The achievement of societal impacts, in particular those impacts directly associated with the health status of people, depend on the increased availability and uptake of new or improved health technologies.

The baseline scenario is likely to have some societal and environmental impact stemming from the funded projects, increasing the higher retention of scientific talent in sub-Saharan Africa. However, it is likely to lack a comprehensive strategic approach. Research focusing on developing and improving health technologies may reduce morbidity and mortality due to infectious diseases in sub-Saharan Africa, as well reduce antimicrobial resistance and the risks of (re-)emerging infectious diseases. To some extent, coordination and support actions could help to communicate and disseminate research results and increase the uptake of the results in the region. Similarly, supporting the training of researchers in sub-Saharan Africa could offer increased chances for their career development and retention in the country, and increase the capacity of the research institutions to manage clinical research, leading to an increased focus on unmet medical needs.

On the other hand, the capacity of the research institutions to provide safe medical interventions would be reduced, as well as the uptake of the health technologies in the

region, leading to a smaller chance of alleviating the infectious diseases burden in sub-Saharan Africa.

Whilst strengthening of research capacity in sub-Saharan Africa through Horizon Europe calls would be possible, it is difficult to foresee to what extent this would be translated into an increase in long-term employment opportunities for researchers and higher retention of scientific talent in the region. Additionally, project funding alone cannot influence nor stimulate the much-needed involvement of other stakeholders.

In the absence of a partnership, the baseline option would struggle to integrate research and innovation efforts to tackle the infectious diseases burden in sub-Saharan Africa.

Option 1: Co-Programmed European Partnership

Whilst a co-programmed partnership does not require formal commitments, it can be expected to leverage sufficient resources to support the research and innovation activities of the candidate partnership. As it would have better strategic vision, it would have greater likelihood of achieving the societal impacts, than the baseline option. This option has therefore received a score of + compared to the baseline.

Option 3a and 3b: Partnership under Article 185 / Article 187

Under the institutionalised partnership option, there would be a more strategic approach and vison, as well as a better integration. Greater emphasis would be placed on supporting the kind of research that is required to produce and deliver health technologies. An institutionalised partnership also has a more strategic approach and stronger impact on the uptake of the new or improved health technologies. As consequence this type of partnerships have higher capacity to reduce morbidity and mortality associated with infectious diseases in sub-Saharan Africa, as well reducing antimicrobial resistance and the risks of (re) emerging infectious diseases.

However, as previously mentioned, in the Article 185 option the EU budget can only match Member and Associated States' contributions, reducing significantly the possibility of leveraging enough resources and therefore reducing the expected impacts. This option has therefore received a score of ++ compared to the baseline. On the other hand, the Art. 187 option would allow the EU budget to match, in addition to the partners under an Art. 185, the contributions from sub-Saharan Africa countries, as well as private charitable funders, industry and other third countries, leveraging substantial and sustainable funding and integrating them around a common agenda. An institutionalised partnership under Art. 187 has the strongest chance to deliver the highest societal impacts, compared to the baseline, the co-programmed and the Art. 185 options. In light of the above, the Art. 187 option has been scored +++ compared to the baseline.

Summary

Table 9, below, lists the scores assigned to each of the policy options as regards the effectiveness criteria for societal impact, based upon the assessments above, as well as taking into account the opinion of the different stakeholders.

Table 9: Overview of the options' effectiveness compared to the baseline – Societal impacts

Societal impacts	Option 0:	Option 1: Co-	Option 3a:	Option 3b:
	Horizon	programmed	Institutionalised	Institutionalised
	Europe calls	European Partnership	Art 185	Art 187

Societal impacts	Option 0: Horizon Europe calls	Option 1: Co- programmed European Partnership	Option 3a: Institutionalised Art 185	Option 3b: Institutionalised Art 187
Higher retention of scientific talent in sub-Saharan Africa	0	+	++	+++
Better uptake of new or improved health technologies	0	+	++	+++
Better (gender) equality	0	+	++	+++

Notes: Score +++: Option presenting a *very high* potential compared to baseline; Score ++: Option presenting *high* potential compared to baseline; Score +: Option presenting a *good* potential compared to baseline; Score 0: Potential of the baseline.

6.2. Efficiency

In order to compare the policy options consistently in terms of their efficiency, a standard cost model was developed for the external study supporting the impact assessment for the set of candidate Institutionalised Partnerships. The model and the underlying assumptions and analyses are set out in the Common Part of this impact assessment, Section 2.3.2 and in the Methodology Annex 4. A dedicated Annex 3 also provides more information on who is affected and how by this specific initiative in line with the Better Regulation framework. The scores related to the costs set out in this context allow for a "value for money" analysis (cost-effectiveness) in the final scorecard analysis in Section 6.4.

On this basis, the scores for the costs of the different options range from a value of 0, in case an option does not entail any additional costs compared to the baseline, to a score of (-) when an option introduces limited additional costs when compared to the baseline and a score of (-)(-) when substantial additional costs are expected in comparison with the baseline. In case the scores are lower than for the baseline scenario, (+) and (+)(+) are used.

For this specific initiative under the **baseline scenario** of traditional calls, there would be winding down and social discontinuation costs for the existing implementation structure of the current Article 185 initiative. There would also be longer term financial cost-savings related to the closing of the structure, related to operations, staff and coordination costs in particular. These can be estimated at EUR 1.5 million per year of operation. Overall, it is estimated that the overall longer term cost savings from using traditional calls, instead of an existing Article 185 initiative, would considerably exceed the costs incurred for winding down operations. This overall situation is set as the starting point for the comparison of options. The score of this baseline scenario (traditional Horizon Europe calls) is set to 0 to be used as a reference point.

The overall administrative, operational and coordination costs of Option 3a (Article 185 Partnership) would be close to those of the existing initiative EDCTP2, e.g. the EDCTP Secretariat, which has implemented efficiently the EDCTP2, ensuring that programme's administrative costs do not exceed 6% of the European Union's financial contribution of EUR 683 million (i.e. EUR 41 million for the period 2014-2024). These costs can be estimated at EUR 4.1 million per year. In this option, the initiative would benefit from the experience of the existing organisation/structure already in place.

Finally, Option 3b (an Article 187 Partnership) would imply a change of legal basis from the current situation. The change of legal basis would generate some limited additional

costs to set up the Joint Undertaking from the EDCTP Secretariat. These would include an indicative one-off administrative expenditure to set up the Joint Undertaking of a maximum EUR 0.3 million for the new structure and a recurring annual cost of a maximum EUR 5.5 million depending on the size of the partnership. Further details are provided in Annex 3. It is worth noting, however, that these limited additional costs would be compensated by the yearly recurring costs savings from the simplification of procedures, as the Commission will be part of the decision Board of the Joint Undertaking. This would simplify the adoption of the annual work programmes and provide the JU with the possibility to benefit from the common support office of Horizon Europe for proposal submission, evaluation and selection, and other common services. An important consideration in this respect is the necessity of a mechanism to keep the knowledge generated during the implementation of EDCTP1 and 2 of the current programme office staff. This would require devising a proper solution to preserve this experience in the new partnership, including the expertise in clinical research projects in sub-Saharan Africa and building up relationships with key stakeholders in the region.

It is considered that while there is a clear gradation in the overall costs of the policy options, the cost differentials are less marked when one takes into account the expected co-financing rates and the total budget available for each of the policy options, assuming a common Union contribution. From this perspective, there are only one or two percentage points that split the most cost-efficient policy options – the baseline (traditional calls) and the Co-Programmed policy options – and the least cost-efficient – the Institutionalised Partnership options. Indeed, in terms of cost-efficiency, the Co-Programmed Partnership (Option 1) is two percentage points more efficient than the baseline; an Article 185 Institutionalised Partnership somewhat less cost-efficient than the baseline, and an Article 187 Partnership is two percentage points less cost-efficient than the baseline.

A score of + is therefore assigned for **cost-efficiency** to the Co-Programmed options and a score of (-) for the Institutionalised Partnerships policy option. ¹⁵⁰ It is worth noting that the adjusted cost scoring for the Article 185 in the case of the EU-Africa Global Health Partnership departs from the common approach adopted to cost-efficiency. ¹⁵¹ Indeed, Option 3a is scored (-) instead of (0). This is to reflect the specificity of this Partnership, involving an important number of third countries, which makes the Article 185 coordination costs higher than in other cases and thus potentially closer to the costs of an Article 187. The scoring for all the other options is in line with the common approach.

Table 10: Matrix on 'overall costs' and 'adjusted cost scoring'

	Baseline: Horizon Europe calls	Option 1: Co- programmed	Option 3a: Institutionalised Article 185 TFEU	Option 3b: Institutionalised Article 187 TFEU
Administrative, operational and coordination costs	0	(0)	(-)(-)	(-)(-)
Adjusted administrative, operational and coordination costs per expected co-funding (i.e. cost-efficiency)	0	(+)	(-)	(-)

¹⁵⁰ The baseline (traditional calls) is scored 0, as explained above.

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¹⁵¹ Under the common approach to assess efficiency (see Annex 4, p. 51), Options 3a and 3b (Institutionalised Partnerships under Article 185 and 187 respectively) score overall (-)(-) for total administrative/operational/coordination costs. Once these scores are adjusted to better reflect the expected co-financing rates and the total budget available for each option (cost-efficiency), the adjusted score for the Article 185 Partnership becomes 0 (equal to the baseline), while the adjusted score for the Article 187 Partnership becomes (-).

Notes: Score 0 = same costs as for the baseline; score (-) = limited additional costs compared with the baseline; score (-)(-) = substantial additional costs compared with the baseline.

The Interim Evaluation of the EDCTP2 programme of 2017 assessed how competently and economically the activities had been executed under an Article 185 in relation to the objectives and indicators during the first two years of the programme implementation, 2014-2016. This evaluation recommended that, in order to ensure more efficient progression, EDCTP should understand the goals and priorities of Participating States and work with them to align EDCTP strategy and programmes, and that EDCTP should thus actively support the Participating States in developing their own national research agendas. The EDCTP2 Interim Evaluation Panel recommended that in addition to the 6% eligible administrative costs, and to reach the ambitious objectives of the partnership, EDCTP be allowed to use the financial contribution from the EU to cover programmatic costs, e.g. costs for analysis and policy-related actions.

6.3. Coherence

Internal coherence

This section assesses the extent to which the policy options could ensure and maximise coherence with other actions, programmes and initiatives under Horizon Europe, in particular European Partnerships (internal coherence).

For the initiative to deliver on its ambitious specific objectives, it needs to show a high degree of internal coherence, from developing a research agenda and coordination of stakeholders to developing linkages to other initiatives within Horizon Europe.

Baseline: Horizon Europe traditional calls

Traditional Horizon Europe calls may create opportunities to exploit synergies within the Health cluster to deliver on health-related challenges for the EU, as well as with other clusters although Coordination and Support Actions could catalyse some opportunities to identify linkages, opportunities for coordination and communication, with other stakeholders. However, it would be challenging for individual Research and Innovation Actions to make steady progress on advancing the development of diagnostics, vaccines, treatments and enabling the environment for the uptake of health innovation in sub-Saharan Africa, from the actions' limited budget, and without a long-term commitment and a dedicated implementing structure.

Work programmes would need to reflect the requirement for R&I activity across the health technologies clinical development, with input from representatives of all relevant stakeholders.

In the absence of a dedicated implementing structure, traditional calls cannot ensure alignment with other key initiatives and organisations in the global health arena.

Option 1: Co-Programmed European Partnership

Through a co-programmed European partnership, the partners can aim to achieve a certain coherence with other partners and with the Annual Work Programme of Horizon Europe, and implementing Coordination and Support Actions to facilitate relationships with European and African governments, funders, industry, academics, policy-makers and regulators. However, its decentralised management structure is not likely to

effectively support the building of strong and sustained integrated relationships with other organisations or initiatives keeping coherent linkages with other initiatives within Horizon Europe, which would be needed for this initiative. This option has therefore received a score of + compared to the baseline.

Option 3a and 3b: Partnership under Article 185 / Article 187

A clear coherence is required between the different types of activities to attain the initiative's objectives. The institutionalised form of implementation would be better placed to deliver this than the baseline option because it can take a more dedicated approach in the criteria of the calls for proposals.

The Article 185 Institutionalised European Partnership supports the widest possible participation of governments, and has a dedicated implementing structure that can facilitate new and deepen existing relationships with policy-makers, academics, industry, regulators, etc. It is also likely to reach a higher level of alignment and coordination of national budgets. It can also provide support to finding synergies with other parts of the Horizon Europe Work Programmes and other Partnerships, as well as with national development agencies and other stakeholders. This option has therefore received a score of ++ compared to the baseline.

An Article 187 Institutionalised European Partnership provides a Joint Undertaking with the capacity to be a single point of access to partners, not only EU Member States and States Associated to the Framework Programme and sub-Saharan countries but also other third countries, industry and private funders, policy makers, regulators, academia and other stakeholders, within the context of Horizon Europe. This can better ensure that synergies are maximised across the Horizon Europe Work Programmes and Horizon Europe Partnerships. This option has therefore received a score of +++ compared to the baseline.

Respondents to the **Open Public Consultation**, as well as a number of interviewees, have pointed out the importance of ensuring alignment with other initiatives and programmes in the field of global health and infectious disease. However, they do so mostly in rather general terms rather than by singling out specific areas or initiatives.

A few **interviewed stakeholders**, including those from within the EC, have indicated that there is space for improved coordination across different Directorate-Generals within the EC. In particular, this relates to the role of DG DEVCO in health systems strengthening and to DG ECHO and DG SANTE in the field of epidemic preparedness.

External coherence

In this section we assess the extent to which the policy options could ensure and maximise coherence with their external environment, including EU-level programmes and initiatives beyond the Framework Programme and/or national and international programmes and initiatives, but as well as with overarching framework conditions, such as regulation, standardisation, etc. (external coherence).

Baseline: Horizon Europe traditional calls

To have an impact it is necessary to strategically share areas of common interest with other initiatives, organisations and research funders. It is important to coordinate and, where necessary, align activities to optimize synergy and minimize duplication. This can be done, for instance, through joint funding calls or collaborative activities. Under

EDCTP, for instance, joint calls have been issued with organisations such as the Bill & Melinda Gates Foundation, WHO-TDR, the Special Programme for Research and Training in Tropical Diseases.

Under traditional calls, the options for structured engagement with actors such as public health, institutions and regulatory authorities, as well as with philanthropies are limited. The baseline option offers few opportunities for regular and continued coordination. Participation in traditional calls is open to any Horizon Europe eligible legal entity within a consortium. This includes research organisations in Africa, although these are not automatically eligible for funding.

Under the baseline option there are no explicit incentives for Member States to increase or maintain their investments in research and innovation to combat infectious diseases as there is no matching of national contributions from the EU budget.

With the discontinuation of the dedicated implementing structure, it will not be possible to effectively facilitate the alignment of national and other funders' programmes around a strategic agenda and the knowledge and know-how of the current EDCTP implementing structure would be lost.

In addition, the current decision-making capacity of sub-Saharan countries within the EDCTP Association will not exist, losing the countries' trust and their buy-in, necessary for the local uptake of the potential innovations resulting from the Horizon Europe projects.

Option 1: Co-Programmed European Partnership

The ability for a co-programmed partnership to interact with other programmes or initiatives is similar to the baseline option. A co-programmed partnership, through the Horizon Europe Work Programme, can provide some opportunities to engage with other initiatives, organisations and research funders through collaborative research projects and coordination and support actions. In addition, individual partners may at a national level have the ability to improve coherence between activities supported within the partnership and those outside of it. However, alignment with globally operating initiatives would be difficult in the absence of a dedicated implementing structure. This option has therefore received a score of + compared to the baseline.

Option 3a and 3b: Partnership under Art. 185 / Art. 187

The institutionalised partnerships have the capacity to include many types of partners in the partnership. Under an Article 185 the EU can contribute to Member States programmes. Moreover, the dedicated implementing structure would engage with other initiatives, organisations, research funders, national development agencies, ¹⁵² EU Delegations in sub-Saharan Africa, and would manage such relations. In addition, an institutionalised partnership would have the capacity to launch calls within its own Work Plan to further engage with additional collaborations and to coordinate them. Therefore, the institutionalised partnership option under Article 185 offers greater ability to engage with other relevant actors, including those outside of the partnership increasing the coherence of the EU investment. This option has therefore received a score of +++ compared to the baseline.

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¹⁵² Under the current EDCTP2 programme, several national development agencies, (e.g. SIDA from Sweden, DLR from Germany), are already involved in the partnership, contributing to the programme and participating in the decision-making as part of the EDCTP Association.

Furthermore, under Article 187 the EU could set up a joint undertaking (JU) or any other structure necessary for the efficient execution of EU research, technological development and demonstration programmes with additional partners that would be more integrated and with a programme office that would ensure external coherence. Therefore this option has received a score of +++ compared with the baseline option.

As in the case of internal coherence, **interviewees** widely agree that the candidate partnership should coordinate its efforts with other key stakeholders in the field, often without being specific. Some have noted a proliferation of initiatives, some of which appear to share focal areas with the candidate partnership. In addition to EU programmes and initiatives, specific examples include the Coalition for Epidemic Preparedness Innovations, and funders such as the Bill & Melinda Gates Foundation.

These interviewees indicated that it will be important for the candidate partnership to clearly position itself in relation to these other initiatives and funders and, where applicable, coordinate activities.

Summary

Table 11, below, lists the scores we assigned to each of the policy options as regards the internal and external coherence criteria, based upon the assessments above, as well as taking into account the support expressed by the different stakeholders.

Table 11: Overview of the options' potential for ensuring and maximizing coherence

	Option 0: Horizon Europe calls	Option 1: Co- programmed	Option 3 a Art 185	Option 3b Art 187
Internal coherence	0	+	++	+++
External coherence	0	+	++	+++

Notes: Score +++: Option presenting a *very high* potential compared to baseline; Score ++: Option presenting *high* potential compared to baseline; Score +: Option presenting a *good* potential compared to baseline; Score 0: Potential of the baseline

6.4. Tabular comparison of options and identification of preferred option

The scorecard below provides an overview of the assessment made of each option under each of the criteria based on the performed analysis.

Table 12: Comparison - Ranking the policy options

	Criteria	Option 0: Horizon Europe calls	Option 1: Co- programmed	Option 3a: Art. 185	Option 3b: Art. 187
Effectiveness	Scientific impacts	0	+	++	+++
	Economic/technological impacts	0	+	++	+++
	Societal impacts	0	+	++	+++
Efficie	Administrative, operational and coordination costs	0	(0)	(-)(-)	(-)(-)

	Adjusted administrative, operational and coordination costs per expected co-funding (i.e. cost-efficiency)	0	(+)	(-)	(-)
Coherence	Internal coherence	0	+	++	+++
	External coherence	0	+	++	+++

The scorecard shows that the baseline performs less well against all dimensions and criteria compared to Co-programmed and Institutionalised Partnership options. Even though it has a higher score in the efficiency criteria, this does not weigh up against its lower performance in the effectiveness and coherence criteria.

Without long-term commitment, the traditional calls would not be able to attract funders and facilitate alignment between programmes of key initiatives and organisations active in the global health arena and they will not have a significant leveraging effect. As a consequence the traditional calls would have lower scientific, economic/technological and societal impacts.

A co-programmed partnership based on a memorandum of understanding between the Commission and the already established EDCTP Association would be simple to establish, however, it would have a lower level of commitment and integration than the current EDCTP2. In addition, the participation from the African countries in the decision-making would be reduced in comparison to EDCTP2. African countries could perceive this as a step backwards.

An institutionalised partnership based on Article 185, based on a decision of the European Parliament and the Council for an EU contribution to a Member States programme, would represent a continuity with the current EDCTP2. This form of partnership would allow the EDCTP Association to continue to function as it is, with a similar set of actors, roles and responsibilities. The EDCTP Association allows for participation of African countries in strategic discussions and decision-making. However, this option would be only possible if at least 40% of the Member States become members of the GHP/EDCTP3. In this option, only contributions from Member States and countries associated to Horizon Europe can be matched by the EU contribution. Other third parties, such as third countries, philanthropies or industry, could contribute at the level of call for proposals or in projects, but their contributions would not able to be considered for the matching of EU contribution. There is a certain level of uncertainty around Member States' capacity to commit sizeable amounts, seeing the economic impact of the COVID-19 pandemic. This could make an Article 185 partnership even less likely seeing the requirement to have budgetary commitments from 40% of the Member States. This would reduce the size of the budget and therefore the level of ambition for and the potential impact of the partnership.

The scorecard also shows that benefits are clearly maximised under the Institutionalised Partnership Art. 187 option. In particular, compared with the other options, option 3b would:

• Provide greater effectiveness by maximising leverage effects, allowing for greater strategic alignment among partners, and supporting a broader range of activities in research and innovation.

• Improve coherence by enhancing collaboration and alignment with the other key stakeholders in the area of combatting infectious diseases and strengthening research capacity in sub-Saharan Africa.

The lower scores of the Art. 185 assessment option are based on the fact that the EU can only match the European countries contributions, and not the third countries, nor the private founders or industry, reducing largely the leverage effect of the partnership. The size of the initiative would be smaller than in an Art. 187, and thus the impact reduced.

The conclusion of the assessment is that the **Institutionalised European Partnership** based on Article 187 TFEU is the preferred option, showing a better cost-effectiveness than the other options and in light of the need to strengthen the partnership through increased participation in comparison to the current EDCTP2.

7. THE PREFERRED OPTION – HOW WILL ACTUAL IMPACTS BE MONITORED AND EVALUATED?

7.1. The preferred option

Based on the comprehensive analysis of the available data, this study concludes that the preferred option for the candidate EU-Africa Global Health Partnership is that of an Institutionalised Partnership under Art. 187. This option would also allow the EU budget to match, the sub-Saharan Africa countries contributions as well as the private charitable funders, industry and other third countries contributions, leveraging substantial and sustainable funding around a common agenda. This type of institutionalised partnership is the most likely option to deliver the targeted impacts, and offers the greatest potential for alignment of partners around shared strategic objectives.

Table 13 shows the alignment of the preferred option with the selection criteria for European Partnerships defined in Annex III of the Horizon Europe Regulation. Considering that the design process of the candidate Institutionalised Partnerships is not yet concluded and several of the related topics are still under discussion at the time of writing, the criteria of additionality/directionality and long-term commitment are covered in terms of expectations rather than ex-ante demonstration.

The COVID-19 crisis does not fundamentally change the foreseen Partnership and confirms the relevance of the proposed initiative. An Article 187 Institutionalised Partnership scores significantly higher overall than the baseline option (traditional calls under Horizon Europe) and Option 1 (Co-Programmed Partnership) in terms of effectiveness. The preferred option remains the Article 187 with the highest capacity to coordinate and generate impact in research preparedness and response research, to provide an evidence base to increase individual and community resilience, facilitate operational readiness, and improve decision-making during emergency response.

Table 13: Alignment with the selection criteria for European Partnerships

Criterion	Alignment of the preferred option
Higher level of	As an Institutionalised Partnership based on Art. 187, provides the closest integration
effectiveness	of key stakeholder groups across the value chain to ensure that the initiative can
	respond to ambitious objectives corresponding to scientific, technological/economic
	and societal impacts. This mode of implementation will ensure a sufficient scale,
	commitment, leverage and long-term vision for the accelerated development and
	deployment of health innovations in sub-Saharan Africa. The EU-Africa Global

Criterion	Alignment of the preferred option
	Health Partnership is expected to generate highly competitive knowledge and scientific, economic/technological, and societal impacts in partnership with sub-Saharan Africa countries, as well as to contribute to the integration of research resources, secure sustainability, and strengthen the European Research and Innovation Area.
Coherence and synergies	The preferred option will be able to fulfil a unique position with the EU and global health research and innovation landscape to ensure coordination and complementarity with the EU programmes, as well as with national and international initiatives. Coherence and synergies will be achieved by maintaining a clear focus on infectious diseases affecting sub-Saharan Africa and contributing to the EU international commitments.
Transparency and openness	Under an Art. 187 the Partnership will work around common priorities under a strategic research and innovation agenda. Partners and stakeholders from across the whole clinical development process of health technologies, and from different sectors, backgrounds and disciplines, including international ones, will participate in the initiative. The Partnership will promote principles of research fairness and transparency as well as promote the dissemination and exploitation of results. It will be able as well to design exit-strategy and measures for phasing-out from the Programme.
Additionality and directionality	The financial or in-kind contributions from governments and private partners other than the EU will be between 50% and 75% of the aggregated Partnership budgetary commitments, working towards the common strategic vision and achieving the expected impacts. The partnership will also be able to set up the appropriate approaches to ensure flexibility of implementation of a strategic research and innovation agenda and to adjust to changing policy, societal, market needs and/or scientific advances, and to increase policy coherence between regional, national and EU level, resulting in better health for all (SDG3).
Long-term commitment	The Partnership under the Art. 187 option offers the possibility of a long-term commitment and would cover the whole duration of Horizon Europe.

The main added value of the partnership based on an Article 187 of the Treaty of the European Union is that the African countries' contribution can count towards matching the EU contribution. This new approach provides a strong recognition of the political and the operational importance of the African countries in the partnership. In addition, Article 187 provides the framework within which philanthropies, industry and other third countries can also join and contribute to the partnership, allowing the EU to collaborate with different key global health players. Moreover, under an Article 187, the EU is a full partner and co-owner in the endeavour. This means that the Commission is an active actor in the policy dialogue and the governance mechanism of the partnership and not only an observer, as is the case in the current partnership. In this partnership, based on the Article 185, the EU participates under the H2020 Framework Programme, in a programme jointly undertaken by several Member States (the EDCTP2 programme) and the legal base foresees the Commission's role as an observer.

With its broader, multi-stakeholder partnership, an Article 187 partnership would be a powerful actor to address global health and it would be able to deliver at the necessary speed and scale, with the Commission having a clear role in its governance that ensures that public interests are at the core of the partnership.

While consulted non-government stakeholders clearly indicated their preference for an institutional partnership, many of them could not position themselves in favour of Article 185

and Article 187, leaving it to the Commission and the Member States to decide which form of implementation was best suited.

Consulted governmental stakeholders, who have the experience with both an Article 185 (through EDCTP2) and an Article 187 (through IMI2) partnership, have indicated their preference for an Article 187, embracing the idea that it would allow also public funds to join forces with philanthropies and the industry. However, they highlighted the importance to safeguard transparency and public interests when considering industry participation.

A partnership under Article 187 would attract the widest range of actors, leveraging and pooling resources: the EU, Member States and countries associated to Horizon Europe, third countries, ¹⁵³ philanthropies (e.g. Bill and Melinda Gates Foundation, the Wellcome Trust) and pharma industry. One example of this is, as mentioned above, the response to the COVID-19 pandemic, bringing public, industry/private sector and philanthropies together to address the problem.

An institutionalised partnership based on Article 187 would require a Council regulation to set up a new structure or joint undertaking. While it would be more demanding in the set-up, it would however offer a long-term perspective, a strong political commitment as well as leveraging and pooling resources from the EU. The EU would become a full partner and the EDCTP Association would become its counterpart, representing its members (EU member states, countries associated to Horizon Europe, third countries from sub-Saharan Africa and any other third country). Any third party could participate as 'associated partners' on an ad hoc basis. This option would allow the EU to match contributions from the EDCTP Association and its members as well as from the other 'associated partners'. In turn, it would leverage budgetary commitments and coordination. It would also allow maintaining inclusive governance with African countries, as part of the EDCTP Association, which has proven to work. This option has a higher chance of obtaining higher impact, greater visibility of EU investment and positions the partnership as a stronger global player.

The Interim Evaluation of EDCTP2 specified that to improve the efficiency and effectiveness of EDCTP, the partnership should be strengthening the links to policymakers in African Participating States. EDCTP needs to better understand the goals and priorities of Participating States and further work with them to align EDCTP strategy and programmes; EDCTP should thus actively support the Participating States in developing their own national research agendas. An additional emphasis should be on strategic alliances, and a strong focus on developing African scientific leadership. Opportunities to extend the range of partners were also noted, including organisations working in related areas such as antimicrobial resistance and global health security.

As indicated previously, **interviewees** strongly favour an institutionalised partnership approach to the Candidate Initiative, whereas among respondents to the **open public consultation** just over half (26 out of 41) view the institutionalised partnership approach as the best way to address the identified problems. Respondents to the **open public consultation** furthermore see the relevance of a specific dedicated structure to govern the initiative in many different aspects. In particular, they see such a structure as relevant or even very relevant to the Candidate Initiative's ability to implement activities more effectively (35 out of 45 respondents) and transparently (32 out of 45).

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¹⁵³ African countries, United Kingdom, Japan, etc.

All **interviewees** agree that, to achieve impact, the Candidate Initiative needs to encompass a broad range of stakeholders, including European and African countries, research institutions, industry, charitable and international organisations. The extent of participation, particularly stakeholders' involvement in a General Assembly, voting rights and funding decisions have been widely discussed among interviewees but there appears to be no consensus on the best format of participation.

Interviewed representatives of national governments stress the importance of European and African country participation, and their ability to "steer the processes". All interviewees encourage third party participation, in the form of private entities, associated countries, and charitable foundations. In case of industry participation, many interviewees welcome their inclusion but express a need for transparency in their participation and contributions, as well as limited mandate in order to ensure that public interests are at the core of the partnership.

The need for ensuring involvement of a broad range of partners is confirmed also by respondents to the **open public consultation**: 17 out of 47 deemed it relevant, and 25 out of 47 very relevant. Parties that are considered relevant for pooling and leveraging resources include in particular Member States, Associated Countries and African countries. Most respondents also agree on the need to include industry, academia, philanthropies and NGOs in the partnership, although some respondents expressed some reluctance about doing so.

Interviewees widely agree that funding and implementation of research and innovation actions should be the primary focus of the Candidate Initiative. Interviewees with whom the optimal positioning for the Candidate Initiative was explored in more depth, mostly viewed late-stage clinical trials as the primary area where the Candidate Initiative could deliver direct impacts. Nonetheless, among all interviewees there was a large degree of consensus that investments in research and innovation actions should be done alongside investments in research capacity development activities.

Respondents to the **open public consultation** hold similar views on how best to allocate resources to different types of activities. A large majority are strongly supportive of investment in collaborative R&I projects (35 out of 45 respondents) and in co-creation of solutions with endusers (30 out of 45). These respondents were not explicitly asked to indicate their support for investment in research capacity development, nor did the question allow for open comments.

Among **interviewees**, some representatives of the EC as well as current members of the EDCTP Association agreed that EDCTP has played an important role in maintaining national commitments to combating infectious diseases but felt that this has not necessarily resulted in increased national investments.

Box 2 Comparison between the preferred option & the current partnership existing in the area taking into account lessons from past evaluations

What continues	What is different
The current scientific scope covering HIV/AIDS, tuberculosis, malaria and neglected infectious diseases, but it will be enlarged.	The scientific scope will be enlarged to include (re-)emerging epidemics, antimicrobial resistance and co-morbidities of infectious diseases with non-communicable diseases, affecting sub-Saharan Africa.
Geographical focus in sub-Saharan Africa. EU Member States, Associated States to the Framework Programme and sub-Saharan States will part of the EDCTP3, through the EDCTP Association, under Dutch law, enabling all Participating States, also the sub-Saharan countries, to be part in the decision-making.	Additional key global players such as philanthropies (BMGF, Wellcome Trust, etc.), industry (EFPIA, etc.) and other third countries (e.g. United Kingdom, Japan, etc.) would be able to join the initiative, and contribute to the partnership on ad-hoc basis, and their funds would be able to be matched by the EU contribution, increasing the leveraging effect and the coherence of the initiative.

One particular issue raised by **representatives of EDCTP Participating States** in regard to the current EDCTP2 programme, is that even legal entities whose countries are not part of the EDCTP Association, are able to participate in all EDCTP2-supported activities, meaning there has been limited incentive for formal commitment and alignment of activities. Under these conditions, some countries, in particular from the sub-Saharan region, would not see the benefit in committing to the partnership. They question what can be done to increase the leveraging effect for the Candidate Initiative. To encourage countries to participate in the initiative, it is proposed to consider the introduction of provisions that would limit eligibility for funding for certain activities.

7.2. Objectives and corresponding monitoring indicators

Operational objectives

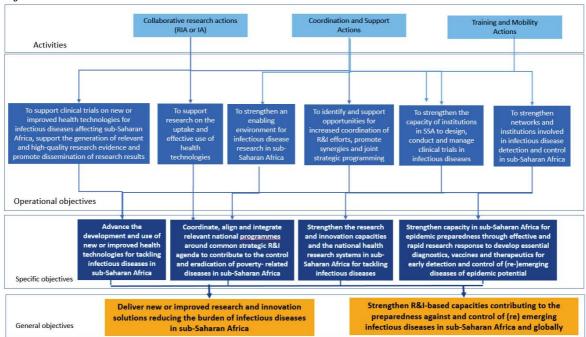
Figure 12 below lists a range of actions and activities to be carried out, which go also beyond the R&I activities that can be implemented under Horizon Europe. This reflects the definition of European Partnerships in the Horizon Europe regulation as initiatives where the Union and its partners "commit to jointly support the development and implementation of a programme of research and innovation activities, including those related to market, regulatory or policy uptake." This figure also shows the links between the actions, operational objectives and the specific and general objectives of the initiative.

A set of six operational objectives have been developed for the initiative, which feed into the previously identified specific objectives, subsequently feeding into the general objectives. These operational objectives are:

- To support clinical trials on new or improved health technologies for infectious diseases affecting sub-Saharan Africa, generating relevant and high-quality research evidence and to promote dissemination of research results;
- To support research on the uptake and effective use of new or improved health technologies

- To identify and support opportunities for increased coordination of research and innovation efforts, promote synergies and joint strategic programming, and the dissemination of research results
- To strengthen the capacity of institutions in sub-Saharan Africa to design, conduct and manage clinical trials in infectious diseases
- To strengthen an enabling environment for infectious disease research in sub-Saharan Africa
- To strengthen networks and institutions involved in infectious disease detection and control in sub-Saharan Africa.

Figure 12: Operational objectives of the candidate in relation to the specific and general objectives



Monitoring indicators

In addition to Key Impact Pathways indicators set centrally in the Regulation of Horizon Europe, additional monitoring indicators have been identified to enable the tracking of progress of the partnership towards meeting its objectives. Whenever possible these indicators will be reported in relation to the initial baseline at country level.

In the medical sector, the timelines for development are long, taking up to 12-15 years on average for the development of a new drug, and approximately 2-8 years for the development of a new medical device. The necessary regulatory acceptance/approval and implementation process can add an additional 5 years. Therefore, the attainment of some of the initiative's objectives would not be appreciated until long after the projects have finished.

Table 14: Monitoring indicators in addition to the Horizon Europe key impact pathway indicators

	Short-term (typically as of year 1+)	Medium-term (typically as of year 3+)	Long-term (typically as of year 5+)
Scientific impacts	Launching calls to pursue EU-Africa	Generating high quality R&I scientific knowledge of relevance	Advancing development of diagnostic kits, candidate vaccines and treatment products

	Short-term (typically as of year 1+)	Medium-term (typically as of year 3+)	Long-term (typically as of year 5+)
	Global health partnership (# of calls launched and projects funded in each scheme (RIA, TMA, CSA), and € invested. Engaging stakeholders to promote generation of high quality scientific knowledge of relevance to EU-Africa GH priorities (Outcomes of stakeholders' consultative meetings (# of topics informing future calls for proposals)	to EU-Africa GH priorities (# of peer-reviewed international publications generated by the partnership projects). Increased cooperation and additional joint actions with other public and private funders, including WHO initiatives and increased aligned strategy with key global players including development agencies (# of new or strengthened international networks sharing good practice, extending capacity, and creating platforms for multicentre trials). Building South-South and North-South networks to facilitate (rapid) decisions, actions and information exchange for making (urgently needed) clinical resources and products available (# of countries and institutions participating in Regional Networks,# of countries and institutions participating in projects addressing epidemic preparedness (# of clinical resources and products on track to gather information for regulatory approval)	for addressing infectious diseases related challenges of relevance to EU and Africa (# of new or improved health technologies progressed to licence; # of new or improved health technologies (diagnostics, vaccines, drug candidates, etc.) having progressed through key milestones Improving R&D preparedness for diseases that might lead to epidemics (surveillance, response and health capacity) and readiness to promptly conduct R&D during an emergency (#of projects resulting in, e.g. guidance and good practices, response mechanisms and other tools facilitating a coordinated response in case of epidemics, # of projects with activities/ deliverables oriented towards "twinning" between stronger and weaker regions/sites # of robust early warning systems in place; effectiveness of investments in building preparedness capacity as judged by independent evaluations)
Economic/ Technological impacts	Supporting studies into cost-effectiveness and economic benefits of products (# of projects addressing improved efficiency of research resources) Facilitating industry and private foundations participation in EU-Africa GHP to speed up R&I process (# of projects with industry and/or private foundations participation)	Leveraging investments in R&I and developing partnerships to support joint working and minimising duplication (€ leveraged though partnerships with other public and private funders, # of public - private publications) More closely aligned national research programmes and activities on poverty-related diseases, at scientific, management, and financial levels Improving coordination of national PSs investments (Participating States' budget in centrally funded activities and in joint activities with other Participating States.)	Driving forward advancements in GH R&I through innovative public-private collaborations (# of new or improved health technologies (diagnostics, vaccines, drug candidates # of new or improved health technologies submitted to standardisation or regulatory approval, or in use in at least one country, etc.) having progressed through key milestones) Increased number of co-funding programs and co-funded activities in Europe (# of new co-funded health technologies activities between Participating States programmes)
Societal impacts Incl. Environmental / sustainability impact	Supporting human capital in R&I through training and mobility schemes (# of TMA calls launched, # of TMA projects supported by gender) Supporting enabling environment for	Addressing through research specific needs of more vulnerable groups (# of clinical studies targeting vulnerable populations: women, children, adolescents, etc.) Building and sustaining engagement and co-ownership	Pursing effective and sustainable investments into and retention of human capital in R&I (number of trainees retained by gender, career advancement and professional recognition of researchers following funding Increased clinical research capacity and scientific leadership, including
	conducting clinical studies in sub-Saharan countries, compliance with fundamental ethical principles and relevant national, Union and international legislation (# number of Coordination and Support Action projects	EU-Africa Global health partnership and increased cooperation and additional joint actions with development partners(#of sub-Saharan Africa and European institutions and countries participating in partnership projects, # of sub- Saharan African and European countries participating in EDCTP both through ongoing activities,	advancement of women scientists. #projects completed categorised by gender, country and regional representation. Enhanced ethics and regulatory capacities and more closely aligned regulatory mechanisms across countries, with increased common regulatory reviews of new products (# of projects completed and committees created and active two years after creation - categorised by country and regional

Short-term (typically as of year 1+)	Medium-term (typically as of year 3+)	Long-term (typically as of year 5+)
funded)	and through political and financial commitment as members of the Partnership or joint undertaking) Encouraging uptake of new or improved health technologies (# of calls and projects addressing uptake of research results into policy and practice)	Increased influence on national and international policy guidelines and improved policy research uptake (# of policy changes to which EU-Africa research contributed to -e.g. citations in clinical reviews, clinical guidelines, systematic reviews or other policy documents issued by national, regional or international policymaking bodies) Enhanced implementation of evidence-based interventions (# of interventions whose implementation has been enhanced)

Evaluation framework

The evaluation of the Partnership will be done in full accordance with the provisions laid out in Horizon Europe Regulation Article 47 and Annex III, with external interim and expost evaluations feeding into the overall Horizon Europe evaluations. As set in the criteria for European Partnerships, the evaluations will include an assessment of the most effective policy intervention mode for any future action; and the positioning of any possible renewal of the Partnership in the overall European Partnerships landscape and its policy priorities. In the absence of renewal, appropriate measures will be developed to ensure phasing-out of Framework Programme funding according to conditions and timeline agreed with the legally committed partners ex-ante.



Brussels, 23.2.2021 SWD(2021) 37 final

PART 2/19

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT REPORT

Accompanying the document

Proposal for a COUNCIL REGULATION establishing the Joint Undertakings under Horizon Europe

EU- Africa Global Health Partnership

{COM(2021) 87 final} - {SEC(2021) 100 final} - {SWD(2021) 38 final}

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Annex 1 Procedural information

1. LEAD DG, DECIDE PLANNING REFERENCES

Lead DG: Directorate General Research and Innovation (RTD)

Decide number: PLAN/2019/5240

2. ORGANISATION AND TIMING

Institutionalised partnerships are foreseen in Articles 185 and 187 of the Treaty on the Functioning of the European Union (TFEU). The preliminary agreement on Horizon Europe contained a list of possible areas for institutionalised partnerships based on Article 185 and 187. For each of these areas the Commission considered 12 potential institutionalised partnerships. Their set up involves new EU legislation and the establishment of dedicated implementing structures and therefore an impact assessment for each of these initiatives.

Following political validation in June 2019, the impact assessment process started with the publication of inception impact assessments for each initiative in August 2019.

An inter-service steering group (ISSG) on research and innovation partnerships under Horizon Europe was set up in May 2019 and held 4 meetings before submission of the Staff Working Document to the Regulatory Scrutiny Board (7 May 2019, 19 June 2019, 5 December 2019, 20 January 2020). The ISSG consisted of representatives of the Secretariat-General, Directorate-General for Budget, Directorate-General for Research and Innovation Directorate-General for Communications Networks, Content and Technology, Directorate-General for Mobility and Transport, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, Directorate-General for Energy, Directorate-General for Environment, Directorate-General for Climate Action, and the Legal Service.

An online public stakeholder consultation was launched between September and November 2019, gathering 1635 replies for all 12 initiatives.

3. CONSULTATION OF THE RSB

Two upstream meetings with the Regulatory Scrutiny Board of were held on 10 July 2019 and 30 September 2019.

In accordance with the feedback received from the Regulatory Scrutiny Board on 13 May 2020 the Staff Working Document has been revised as presented in Figure 1. The impact assessment was endorsed by the Inter Service Steering Group on 20 January 2020.

On 15 May 2020 the Regulatory Scrutiny Board (RSB) gave a positive opinion with reservations to a draft version of the EU-Africa Global Health Partnership candidate impact assessment. The revision was done to ensure that the assessment relies on a solid methodology that meets the RSB standards. The Board's recommendations covered the following key aspects: (1) The report defines the problem too widely in view of what the EU-Africa health partnership aims to achieve. It does not sufficiently focus on informing the choice of form of the candidate partnership. (2) The added value of the preferred option over an alternative type of partnership is not sufficiently demonstrated. (3) The report does not

sufficiently explain which players the new partnership can attract in its upgraded form and what they will contribute to delivering on its objectives.

The core text and annexes of the EU-Africa Global Health Partnership candidate impact assessment report were adjusted following the recommendations of the RSB. In particular to focus the problems in view of what the partnership aims to achieve, and to properly inform the choice of form of the candidate partnership, demonstrating the added value of the preferred option over an alternative type of partnership and explaining in a more detailed manner which players the new partnership can attract in its upgraded form and what they will contribute to delivering on its objectives.

Figure 1 Modifications to the draft Staff Working Document based on comments received from the Regulatory Scrutiny Board

Comments from the Regulatory Scrutiny Board

The report defines the problem too widely in view of what the EU-Africa health partnership aims to achieve. It does not sufficiently focus on informing the choice of form of the candidate partnership

The logic of the intervention presented in the report should be clarified to support the analysis. It should focus on the central theme of the impact assessment, i.e. the choice of partnership form. In doing so, the report should better clarify the relationship between the problems, the 'functionalities', 'expected impacts', and the specific objectives. Impacts should be assessed with respect to the specific objectives. In the particular case of establishing a partnership for EU-Africa research health cooperation, the report should narrow down the problem definition. This should build on the experience gathered with the previous research programmes with and in African countries and focus on supporting clinical trials and enhancing research capacities.

Actions taken for the Staff Working Document

The context of the initiative has been shortened to focus on the aim of the Impact Assessment, in particular on the analysis of the types of partnerships that can be created in the specific area of research cooperation with African countries and other global partners.

The intervention logic has been revised based on a better definition for the two main problems the partnership aims to address - the lack of suitable health technologies and the emergence and spread of infectious diseases – analysing the problem drivers, their corresponding specific objectives and expected impacts.

For each policy option, the different functionalities have been detailed and assessed on the basis of the degree to which it would allow for the key needed functionalities to be covered, as regards e.g. the type and composition of actors that can be involved ('openness'); the range of activities that can be performed (including additionality and level of integration); the level of directionality and integration of R&I strategies; the possibilities offered for coherence and synergies with other components of Horizon Europe, including other Partnerships (internal coherence), and coherence with the wider policy environments, including with the relevant regulatory and standardisation framework (external coherence).

It has been highlighted that the new partnership builds on the success and experience gathered by its predecessors, the EDCTP and EDCTP2 programmes.

The added value of the preferred option over an alternative type of partnership is not sufficiently demonstrated.

The report should clarify the scoring system applied when assessing the options and explain the relative importance of the different criteria. It should remove the discrepancies between the text and the tables and correct inconsistencies in terms of expected impacts. The report should justify any deviations from the common efficiency analysis.

On this basis, the report should better the advantages explain of institutionalised Article-187 partnership over other organisational forms. This should include the prospective participation of national. international and private organisations or donors. It should also include the financial requirements and the needed time horizon of the commitment to support clinical trials and grow research capacity in sub-Saharan Africa.

The scoring system applied when assessing the options has been better explained as well as the relative importance of the different criteria and the deviations from the common efficacy analysis.

The discrepancies between the text and the tables and inconsistencies in terms of expected impacts have been corrected. The report should justify any deviations from the common efficiency analysis.

The advantages of the institutionalised Article-187 partnership over other organisational forms has been explained. The main added value of the partnership based on an Article 187 of the Treaty of the European Union is that the African countries' contribution can count towards matching the EU contribution. This new approach provides a strong recognition of the political and the operational importance of the African countries in the partnership. In addition, Article 187 provides the framework within which philanthropies, industry and other third countries can also join and contribute to the partnership, allowing the EU to collaborate with different key global health players. Moreover, under an Article 187, the EU is a full partner and co-owner in the endeavour. This means that the Commission is an active actor in the policy dialogue and the governance mechanism of the partnership. With its broader, multi stakeholder partnership, article 187 partnership would be a powerful actor to address global health and it would be able to deliver at the necessary speed and scale ensuring that public interests are at the core of the partnership.

The quantitative information on the required budget have been indicated including for the envisaged set up and running costs.

The report does not sufficiently explain which players the new partnership can

The report has been revised to better explain which players can be attracted to the

attract in its upgraded form and what they will contribute to delivering on its objectives.

The report should expand on how the preferred form of the partnership would attract private industry and donors. It should explain how it would coordinate with similar global initiatives.

partnership.

The motivation for the EU, European and African countries comes mainly from the successes of the EDCTP and EDCTP2 partnerships. These partnerships have shown that European and African governments can join forces with the EU around common objectives, creating an environment within which results were achieved that individual countries or the EU research framework programme alone, would not have managed to obtain. Philanthropies, such as the Bill and Melinda Gates Foundation or Wellcome Trust, have realised that alone they cannot bear the costs of late stage clinical trials for the development of medicines or vaccine for poverty related diseases (e.g. phase IV of the RTS,S malaria vaccine candidate) and they are therefore seeking partners to join forces with. The Ebola epidemics in West Africa and the Democratic Republic of Congo has contributed to raise the interest of the pharma industry and vaccine in investing in infectious diseases threats affecting Africa and they are actively reaching out to potential partners. Also, for some of these industries, investing in research that is relevant to Africa is part of their corporate social responsibility (e.g. Johnson & Johnson¹, GSK²) with a commitment to fair Including pharma industry in the pricing. partnership will also allow to produce at scale and cover the whole value chain. Here also a partnership under Article 187 would better harness industry's contribution as it can be matched. While industry has already taken part in some projects under EDCTP2. The industry that would participate in this partnership, is the industry that has a research agenda that is relevant to infectious diseases in low and middle income countries.

¹ https://www.jnj.com/responsibility/

² https://www.gsk.com/en-gb/responsibility/

Additional changes to the Core Impact Assessment Staff Working Document Introductory paragraphs to the Figure 6 and 7 have been added.

Following suggestions from the GHP Working Group on African Involvement additional information has been added to the problem drivers.

In the General and Specific objectives, points 4.1 and 4.2 references to the specific African countries consultation have been added.

The target to measure the objective of strengthening the capacity of sub-Saharan Africa for epidemic preparedness has been better defined.

In point 4.4, under 'Type and composition of the actors to be involved' and 'Type and range of activities needed' a reference to the specific African consultation has been added.

Under the 'Coherence needed with the internal and external environment', more information has been added to better explain Figure 9.

Under point 7.1 The preferred option, a paragraph has been adapted to avoid the repetitions.

The Table 14 on Monitoring indicators has been adapted to include additional indicators from the Draft EDCTP3 Strategic Research and Innovation Agenda.

Additional changes to the Annex of the Impact Assessment Staff Working Document

The 'Overview of costs' (Annex 3.3) has been revised based on the DG BUDG average costs to be used for the estimates on 'Human resources' in the legislative financial statements.

The 'specific African consultation on GHP/EDCTP3' has been added (Annex 6.2.7).

4. EVIDENCE, SOURCES AND QUALITY

To ensure a high level of coherence and comparability of analysis for all candidate initiatives, an external study was procured to feed into the impact assessments of the 12 candidate

institutionalised partnerships ³ (Technopolis Group, 2020). It consisted of an horizontal analysis and individual thematic analyses for each of the initiatives under review.

For all initiatives, the evidence used includes desk research partly covering the main impacts and lessons learned from previous partnerships. A range of quantitative and qualitative data sources complement the evidence base, including evaluations; foresight studies; statistical analyses of Framework Programmes application and participation data and Community Innovation Survey data; analyses of science, technology and innovation indicators; reviews of academic literature; sectoral competitiveness studies and expert hearings. The analyses included a portfolio analysis, a stakeholder and social network analysis in order to profile the actors involved as well as their co-operation patterns, and an assessment of the partnerships' outputs (bibliometrics and patent analysis).

A cost modelling exercise was performed in order to feed into the efficiency assessments of the partnership options. Public consultations (open and targeted) supported the comparative assessment of the policy options. For each initiative up to 50 relevant stakeholders were interviewed by the external contractor (policymakers, business including SMEs and business associations, research institutes and universities, and civil organisations, among others). In addition the analysis was informed by the results of the Open Public Consultation (Sep – Nov 2019), the consultation of the Member States through the Strategic Programme Committee and the online feedback received on the Inception Impact Assessments of the set of candidate Institutionalised European Partnerships.

A more detailed description of the methodology and evidence base used, completed by thematic specific methodologies, is provided in Annexes 4 and 6.

³ Technopolis Group, 2020, forthcoming.

Annex 2 Stakeholder Consultation

1. OVERVIEW FOR ALL CANDIDATE INSTITUTIONALISED EUROPEAN PARTNERSHIPS

1.1. Introduction

In line with the Better Regulation Guidelines,⁴ the stakeholders were widely consulted as part of the impact assessment process of the 12 candidates for institutionalised partnerships, including national authorities, the EU research community, industry, EU institutions and bodies, and others. These inputs were collected through different channels:

- A feedback phase on the inception impact assessments of the candidate initiatives in August 2019, gathering 350 replies for all 12 initiatives on the "Have your say" web portal during a period of 3 weeks;
- A structured consultation of Member States performed by the EC services over 2019 through the Shadow Strategic Configuration of the Programme Committee of Horizon Europe (in line with the Article 4a of the Specific Programme of Horizon Europe). This resulted in 44 possible candidates for European Partnerships identified as part of the first draft Orientations Document towards the Strategic Plan for Horizon Europe (2021-2024), taking into account the areas for possible institutionalised partnerships defined in the Regulation.
- An online public stakeholder consultation administered by the EC, based on a structured questionnaire, open between September and November 2019, gathering 1635 replies for all 12 initiatives;
- A targeted consultation run by the external study contractors with a total of 608 interviews performed as part of the thematic studies by the different study teams between August 2019 and January 2020.

1.2. Horizontal results of the Open Public Consultation

The consultation was open to everyone via the EU Survey online system.⁵ The survey contained two main parts to collect views on general issues related to European partnerships (in Part 1) and specific responses related to one or more of the 12 candidate initiatives (as selected by a participant). The survey was open from 11 September till 12 November 2019. The consultation was available in English, German and French and advertised widely through the European Commission's online channels as well as via various stakeholder organisations.

1.2.1. Profile of respondents

In total, 1635 respondents filled in the questionnaire of the open public consultation. Among them, 272 respondents (16.64%) were identified to have responded to the consultation as part of a campaign (coordinated responses). Based on the Better Regulation Guidelines, the groups of respondents where at least 10 respondents provided coordinated answers were labelled as 'campaigns', segregated and analysed separately and from other responses. In total 11 campaigns were identified, the largest of them includes 57 respondents⁶. In addition, 162

⁴ https://ec.europa.eu/info/files/better-regulation-guidelines-stakeholder-consultation_en

 $^{^{5} \}overline{\text{https://ec.europa.eu/eusurvey/runner/ConsultationPartnershipsHorizonEurope}}$

The candidate Institutionalised Partnership Clean Hydrogen has the highest number of campaigns, namely 5. A few initiatives, such as Innovative SMEs, Smart Networks and Systems, were not targeted by campaigns. Some campaign respondents decided to provide opinions about several partnerships.

respondents in the consultation also display similarities in responses but in groups smaller than 10 respondents. Hence, these respondents were not labelled as campaigns and therefore were not excluded from the general analysis.

Table 1: Country of origin of respondents (N=1635)

Country	Number of	Percentage of
Country	respondents	respondents
Germany	254	15.54%
Italy	221	13.52%
France	175	10.70%
Spain	173	10.58%
Belgium	140	8.56%
The Netherlands	86	5.26%
Austria; United Kingdom	61	3.73%
Finland	49	3.00%
Sweden	48	2.94%
Poland	45	2.75%
Portugal	32	1.96%
Switzerland	28	1.71%
Czechia	24	1.47%
Greece	23	1.41%
Norway; Romania	22	1.35%
Denmark	20	1.22%
Turkey	19	1.16%
Hungary	14	0.86%
Ireland	12	0.73%
United States	11	0.67%
Estonia; Slovakia; Slovenia	10	0.61%
Bulgaria; Latvia	9	0.55%
Bosnia and Herzegovina	7	0.43%
Lithuania	4	0.24%
Canada; Croatia; Israel	3	0.18%
China; Ghana; Iceland; Japan; Luxembourg; Morocco	2	0.12%
Bhutan; Botswana; Cyprus; Iran; Malta; Mexico; Moldova; Mongolia; Palestine; Russia; Serbia; South Africa; Tunisia; Ukraine; Uruguay	1	0.06%

As shown in Figure 2, the three biggest categories of respondents are representatives of companies and business organisations (522 respondents or 31.9%), academic and research institutions (486 respondents or 29.7%) and EU citizens (283 respondents or 17.3%). Among the group of respondents that are part of campaigns, most respondents are provided by the same groups of stakeholders, namely company and business organisations (121 respondents or 44.5%), academic and research institutions (54 respondents or 19.8%) and EU citizens (42 respondents or 15.4%).

Figure 2 Type of respondents (N=1635) - For all candidate initiatives

283 0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100% Company/business organisation Academic/research institution ≡ EU citizen Business association Public authority Other ■ Non-governmental organisation (NGO) ■ Non-EU citizen ■ Consumer organisation ■ Environmental organisation ■ Trade union

Among all consultation respondents, 1303 (79.69%) have been involved in the on-going research and innovation framework programme Horizon 2020 or the preceding Framework Programme 7, while 332 respondents (20.31%) were not. In the group of campaign respondents, the share of those who were involved in these programmes is higher (245 respondents out of 272 or 90.07%) than in the group of non-campaign respondents (1058 out of 1363 or 77.62%). When respondents that participated in the Horizon 2020 or in the preceding Framework Programme 7 were asked to indicate in which capacity they were involved in these programmes, the majority stated they were a beneficiary (1033 respondents) or applicant (852 respondents). The main stakeholder categories, e.g. companies/business organisation, academic/research institutions, etc., show a similar distribution across the capacities in which they 'have been involved in Horizon 2020 or in the Framework Programme 7' as the overall population of consultation respondents.

Among those who have been involved in Horizon 2020 or the preceding Framework Programme 7, 1035 respondents (79.43%) are/were involved in a partnership. The share of respondents from campaigns that are/were involved in a partnership is higher than for noncampaign respondents, 89.80% versus 77.03% respectively. The list of partnerships under Horizon 2020 or its predecessor Framework Programme 7 together with the numbers, percentages of participants is presented in Table 4, the table also show the key stakeholder categories for each partnership. Most consultation respondents participated in the following partnerships: Fuel Cells and Hydrogen 2 (FCH2) Joint Undertaking, Clean Sky 2 Joint Undertaking, European Metrology Programme for Innovation and Research (EMPIR) and in Bio-Based Industries Joint Undertaking. The comparison between the non-campaign and campaign groups of respondents shows that the overall distribution is quite similar. However, there are some differences. For the campaign group almost a half of respondents is/was involved in the Fuel Cells and Hydrogen 2 (FCH2) Joint Undertaking, a higher share of campaign respondents is/was participating in Clean Sky 2 Joint Undertaking and in Single European Sky Air Traffic Management Research (SESAR) Joint Undertaking.

When respondents were asked in which role(s) they participate(d) in a partnership(s), over 40% indicated that they act(ed) as partner/member/beneficiary in a partnership. The second largest group of respondents stated that they applied for funding under a partnership. The roles selected by non-campaign and campaign respondents are similar.

Table 4: Partnerships in which consultation respondents participated (N=1035)

Name of the partnership	Number and % of respondents from both groups (n=1035)	Number and % of respondents from a non-campaign group (n=815)	Academic/researc h institutions	Business associations	Company/busines s organisations	Company/busines s organisations	EU citizens	NGOs	Public authority
Fuel Cells and Hydrogen 2 (FCH2) Joint Undertaking	354 (33.33%)	247 (30.31%)	97	9	37	43	41	8	5
Clean Sky 2 Joint Undertaking	195 (18.84%)	145 (17.79%)	57	2	10	27	37	1	7
European Metrology Programme for Innovation and Research (EMPIR)	150 (14.49%)	124 (15.21%)	64	0	13	9	14	2	19
Bio-Based Industries Joint Undertaking	142 (13.72%)	122 (14.97%)	39	8	20	27	14	1	6
Shift2Rail Joint Undertaking	124 (11.98%)	101 (12.40%)	31	7	5	31	14	3	7
Electronic Components and Systems for European Leadership (ECSEL) Joint Undertaking	111 (10.72%)	88 (10.80%)	42	2	7	20	12	0	5
Single European Sky Air Traffic Management Research (SESAR) Joint Undertaking	66 (6.38%)	46 (5.64%)	10	3	3	20	3	2	3
5G (5G PPP)	53 (5.12%)	47 (5.77%)	20	1	6	14	5	0	1
Eurostrars-2 (supporting research-performing small and medium-sized enterprises)	44 (4.25%)	40 (4.91%)	17	0	6	1	7	0	6
Innovative Medicines Initiative 2 (IMI2) Joint Undertaking	37 (3.57%)	35 (4.29%)	18	2	3	3	2	4	3
Partnership for Research and Innovation in the Mediterranean Area (PRIMA)	28 (2.71%)	26 (3.19%)	15	0	3	1	2	0	2
European and Developing Countries Clinical Trials Partnership	25 (2.42%)	24 (2.94%)	12	0	1	2	3	3	2
Ambient Assisted Living (AAL 2)	22 (2.13%)	21 (2.58%)	11	2	1	1	3	0	3
European High- Performance Computing Joint Undertaking (EuroHPC)	22 (2.13%)	18 (2.21%)	6	0	2	3	5	0	2

For the remaining of the consultation respondents could provide their views on each/several of the candidate initiatives. The majority of respondents (31.4%) provided their views on the Clean Hydrogen candidate partnership. More than 45% of respondents from the campaigns selected this partnership. Around 15% provided their views for European Metrology, Clean Aviation and Circular Bio-based Europe. The share of respondents in the campaign group that chose to provide views on the Clean Aviation candidate partnership is of 20%. The smallest number of respondents provided opinions on the candidate initiative 'EU-Africa research partnership on health security to tackle infectious diseases – Global Health'.

Table 5: Candidate Institutionalised Partnerships for which consultation respondents provide responses (N=1613)

Name of the candidate Institutionalised European partnership	Number and % of respondents from both groups (n=1613)	Number and % of respondents from a non-campaign group (n=1341)		
Clean Hydrogen	506 (31.37%)	382 (28.49%)		
European Metrology	265 (16.43%)	225 (16.78%)		
Clean Aviation	246 (15.25%)	191 (14.24%)		
Circular bio-based Europe	242 (15%)	215 (16.03%)		
Transforming Europe's rail system	184 (11.41%)	151 (11.26%)		
Key Digital Technologies	182 (11.28%)	162 (12.08%)		
Innovative SMEs	111 (6.88%)	110 (8.20%)		
Innovative Health Initiative	110 (6.82%)	108 (8.05%)		
Smart Networks and Services	109 (6.76%)	107 (7.98%)		
Safe and Automated Road Transport	108 (6.70%)	102 (7.61%)		
Integrated Air Traffic Management	93 (5.77%)	66 (4.92%)		
EU-Africa research partnership on health security to tackle infectious diseases – Global Health	49 (3.04%)	47 (3.50%)		

1.2.2. Characteristics of future candidate European Partnerships

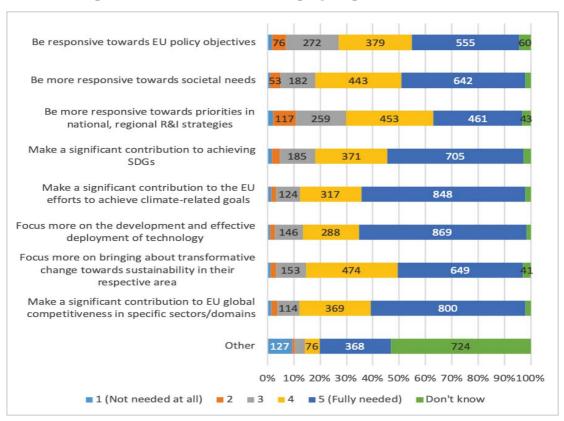
Respondents were asked to assess what areas, objectives, aspects need to be in the **focus of the future European Partnerships** under Horizon Europe and to what extent. According to Figure 6, a great number of respondents consider that a significant contribution by the future European Partnerships is 'fully needed' to achieve climate-related goals, to the development and effective deployment of technology and to EU global competitiveness in specific sectors/domains. Overall, respondents' views reflect that many aspects require attention of the Partnerships. The least attention should be paid to responding towards priorities of national, regional R&D strategies, including smart specialisation strategies, according to respondents.

Overall, only minor differences can be found between the main stakeholder categories. Academic/research institutions value the responsiveness towards EU policy objectives and focus on development and effective deployment of technology a little less than other respondents. Business associations, however, find that the future European Partnerships under Horizon Europe should focus a little bit more on the development and effective deployment of technology than other respondents. Furthermore, business associations, large companies as

well as SMEs value the role of the future European Partnerships for significant contributions to EU global competitiveness in specific sectors domains a little higher than other respondents. Finally, both NGOs and Public authorities put a little more emphasis on the role of the future European Partnerships for significant contributions to achieving the UN SDGs. The views of citizens (249, or 18.3%) do not reflect significant differences with other types of respondents. However, respondents that are/were directly involved in a partnership under Horizon 2020 or its predecessor Framework Programme 7 assign a higher importance of the future European Partnerships to be more responsive towards EU policy objectives and to make a significant contribution to achieving the UN's Sustainable Development Goals.

A qualitative analysis of the "other" answers highlights the importance of collaboration and integration of relevant stakeholders to tackle main societal challenges and to contribute to policy goals against which fragmentation of funding and research efforts across Europe should be avoided. Additionally, several respondents suggested that faster development and testing of technologies, acceleration of industrial innovation projects, science transfer and market uptake are needed. Next to that, many respondents provided answers related to the hydrogen and the energy transition, which corresponds to the high number of respondents that provided answers to the candidate initiative on this topic.

Figure 6: To what extent do you think that the future European Partnerships under Horizon Europe need to (N=1363) (non-campaign replies) For all candidate initiatives



1.2.3. Main advantages and disadvantages of Institutionalised European Partnerships

An open question asked to outline the main advantages and disadvantages of participation in an Institutionalised European Partnership (as a partner) under Horizon Europe (1551 respondents). The advantages mentioned focus on the development of technology, overall collaboration between industry and research institutions, and the long-term commitment. Disadvantages mentioned are mainly administrative burdens. An overview is provided below.

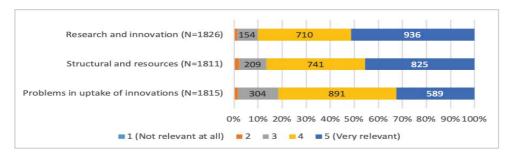
Advantages mentioned: Long term commitment, stability, and visibility in financial, legal, and strategic terms; Participation of wide range of relevant stakeholders in an ecosystem (large/small business, academics, researchers, experts, etc.); Complementarity with other (policy) initiatives at all levels EU, national, regional; Efficient and effective coordination and management; High leverage of (public) funds; Some innovative field require high levels of international coordination/standardisation (at EU/global level); Ability to scale up technology (in terms of TRL) through collaboration; Networking between members; Direct communication with EU and national authorities

Disadvantages mentioned: Slow processes; System complexity; Continuous openness to new players should be better supported as new participants often bring in new ideas/technologies that are important for innovation; Lower funding percentage compared to regular Horizon Europe projects; Cash contributions; Administrative burdens; Potential for IPR constraints.

1.2.4. Relevance of EU level to address problems in Partnerships' areas

Respondents were asked to rate the **relevance of research and innovation efforts at EU level efforts to address specific problems in the area of partnerships**. Research and innovation related problems were rated as most relevant across all candidate initiatives, followed by structural and resources problems and problems in the uptake of innovations. Overall, all three areas were deemed (very) relevant across the partnerships, as more than 80% of respondents found these challenges (very) relevant. Only minor differences were found between stakeholder categories. Research and innovation problems were found slightly more relevant by academic/research institutions, yet slight less relevant by large companies and SMEs. Structural and resource problems were indicated as slightly more relevant by NGOs, but slightly less by academic/research institutions. While both NGOs and public authorities find slightly more relevant to address problems in uptake of innovation than other respondents. The views of citizens are not differing significantly. Respondents that are/were directly involved in a current/preceding partnership find, however, the need to address problems related to the uptake of innovations slightly more relevant than other respondents.

Figure 9: To what extent do you think this is relevant for research and innovation efforts at EU level to address the following problems in relation to the candidate partnership in question? (non-campaign replies) Aggregation of responses of all candidate initiatives



1.2.5. Horizon Europe mode of intervention to address problems

Respondents were asked to indicate how these challenges could be addressed through Horizon Europe intervention. Just over 50% of all respondents indicated that institutionalised partnerships were the best fitting intervention, with relatively strong differences between stakeholder categories. The use of Institutionalised Partnership was indicated more by business associations and large companies, but less by academic/research institutions and SMEs. While academic/research institutions valued traditional calls more often, this was not the case for business associations, large companies and public authorities. Public authorities indicated a co-programmed intervention more often than other respondents. Citizens indicated slightly less often that institutionalised partnerships were the best fitting intervention. Respondents that are/were directly involved in a current/preceding partnership, selected the institutionalised partnership intervention in far higher numbers (nearly 70%).

Figure 10: In your view, how should the specific challenges described above be addressed through Horizon Europe intervention? (non-campaign replies) For all candidate initiatives



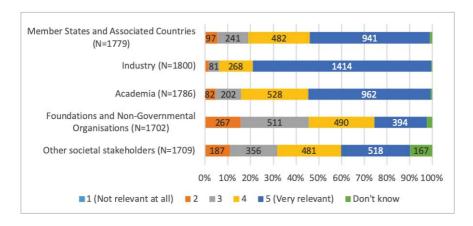
When asked to reflect on their answers, respondents that pointed to the need for using institutionalised partnership mentioned the long-term commitment of collaboration, a common and ambitious R&I strategy as well as the overall collaboration between industry and research institutions. Others shared positive experiences with other modes of interventions:

- Traditional calls, because of their flexibility and integration of a wide range of actors, as long as the evaluation panels do not deviate from the policy focus. This was mentioned by 94 participants, including companies (25), academics (26) and EU citizens (25).
- Co-funded partnership, as a mechanism to ensure that all participants take the effort seriously, while allowing business partnerships to develop. This approach was deemed suitable based on previous experiences with ERANETs. This was raised by 84 participants, 36 of them academic respondents, 18 companies and 16 EU citizens.
- Co-programmed partnerships, to tackle the need to promote and engage more intensively with the private sector. This was mentioned by 97 participants, most of them companies (34), followed by academics (22), business associations (15) and EU citizens (11).
 - 1.2.6. Relevance of a set of elements and activities to ensure that the proposed European Partnership would meet its objectives

Setting joint long-term agendas

Respondents were asked how relevant it is for the proposed European Partnerships to meet their objectives to have a strong involvement of specific stakeholder groups in setting joint long-term agenda. All respondents see stakeholders from industry as the most relevant, followed by academia and governments. The involvement of foundations and NGOs as well as other societal stakeholders were, however, still found to be (very) relevant by more than 50% of the respondents. Most respondents indicated the stakeholder group they belong to themselves or that represent them as relevant to involve.

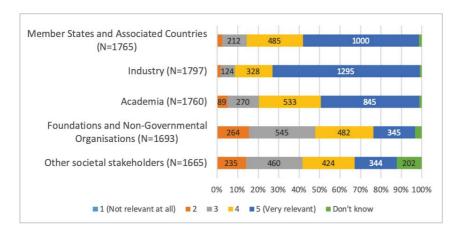
Figure 11: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives - Setting joint long-term agenda with strong involvement of: (non-campaign replies) For all candidate initiatives



Pooling and leveraging resources through coordination, alignment and integration with stakeholders

Respondents were asked how relevant it is for the proposed European Partnership to meet its objectives to pool and leverage resources (financial, infrastructure, in-kind expertise, etc.) through coordination, alignment and integration with specific groups of stakeholders. Respondents see stakeholders from industry as the most relevant, followed by academia and governments (Member States and Associated Countries). The involvement of foundations and NGOs as well as other societal stakeholders are also still found to be (very) relevant for more than 50% of the respondents. Similarly as described for the question on setting joint long-term agendas, most stakeholder categories valued their own involvement higher than other respondents – although also here differences between stakeholder categories were minor.

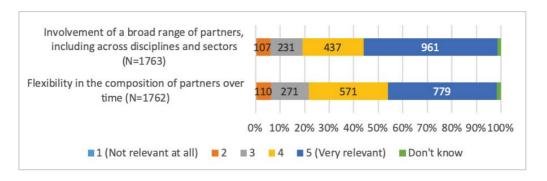
Figure 12: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives – Pooling and leveraging resources (financial, infrastructure, in-kind expertise, etc.) through coordination, alignment and integration with: (non-campaign replies) For all candidate initiatives



Composition of the partnerships

Regarding the composition of the partnership most respondents indicated that for the proposed European Partnership to meet its objectives the composition of partners needs to be flexible over time and that a broad range of partners, including across disciplines and sectors, should be involved (see Figure 13). When comparing stakeholder groups only minor differences were found. Academic/research institutions and public authorities found the involvement of a broad range of partners and flexibility in the composition of partners over time slightly more relevant than other respondents, while large companies found both less relevant. SMEs mainly found the flexibility in the composition of partners over time less relevant than other respondents, while no significant differences were found regarding the involvement of a broad range of partners. Citizens provided a similar response to noncitizens. Respondents that are/were directly involved in a current/preceding partnership, when compared to respondents not involved in a current/preceding partnership, indicated a slightly lower relevance of the involvement of a broad range of partners and flexibility in the composition of partners over time.

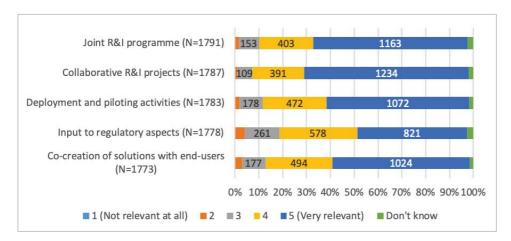
Figure 13: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives – Partnership composition (non-campaign replies) Aggregation of responses of all candidate initiatives



Implementation of activities

Most respondents indicated that implementing activities like a joint R&I programme, collaborative R&I projects, deployment and piloting activities, providing input to regulatory aspects and the co-creation of solutions with end-users are all (very) relevant for the partnerships to be able to meet its objectives. Minor differences were found between the main stakeholder categories, the differences found were in line with their profile. As such, academic/research institutions found joint R&I programme & collaborative R&I projects slightly more relevant and deployment and piloting activities, input to regulatory aspects and co-creation with end-users slightly less relevant than other respondents. For SMEs an opposite pattern is shown. Large companies, however, also found collaborative R&I projects slightly more relevant than other respondents, as well as input to regulatory aspects. The views of citizens are similar to non-citizens. Respondents that are/were directly involved in a current/preceding partnership, when compared to respondents not involved in a current/preceding partnership, show a slightly higher relevance across all activities.

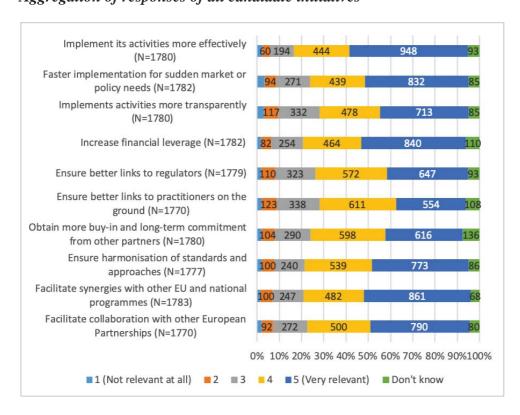
Figure 14: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives – Implementing the following activities (non-campaign replies) For all candidate initiatives



1.2.7. Relevance of setting up a legal structure (funding body) for the candidate European Partnerships to achieve improvements

Respondents were asked to reflect on the relevance of setting up a legal structure (funding body) for achieving a set of improvements, as shown in the Figure below. In general, 70%-80% of respondents find a legal structure (very) relevant for these activities. It was found most relevant for implementing activities in a more effective way and least relevant for ensuring a better link to practitioners on the ground, however differences are small.

Figure 15: In your view, how relevant is to set up a specific legal structure (funding body) for the candidate European Partnership to achieve the following? (non-campaign replies) Aggregation of responses of all candidate initiatives

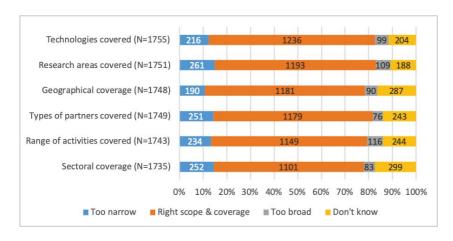


When comparing stakeholder categories there are only minor differences. Academic/research institutions indicated a slightly lower relevance for transparency, better links to regulators as well as obtaining the buy-in and long-term commitment of other partners. SMEs also indicated a lower relevance regarding obtaining the buy-in and long-term commitment of other partners. Large companies showed a slightly higher relevance for implementing activities effectively, ensure better links to regulators, obtaining the buy-in and long-term commitment of other partners, synergies with other EU/MS programmes and collaboration with other EU partnerships. NGOs find it slightly more relevant to implement activities faster for sudden market or policy needs. Public authorities, however, find it slightly less relevant to facilitate collaboration with other European Partnerships than other respondents. The views of citizens show a slightly lower relevance for a legal structure in relation to implementing activities in an effective way. Respondents that are/were directly involved in a current/preceding partnership indicated a higher relevance across all elements presented.

1.2.8. Scope and coverage of the candidate European Partnerships based on their inception impact assessments

Consulted on the scope and coverage for the partnerships, based on their inception impact assessments, the large majority feels like the scope and coverage initially proposed in the inception impact assessments is correct. However, about 11% to 15% of the respondents indicated the scope and coverage to be too narrow. About 11%-17% of respondents answered "Don't know". Overall, differences between the main stakeholder categories were found to be minor. Academic/research institutions indicated slightly more often that the research area was "too narrow" then other respondents. SMEs on the other hand indicated slightly more often that the research area and the geographical coverage were "too broad". NGOs and public authorities, however, found the geographical coverage slightly more often "too narrow". Large companies found the range of activities slightly more often "too broad" and the sectoral focus slightly more often "too narrow" when compared to other respondents. The views of citizens are the same as for other respondents. Respondents that are/were directly involved in a current/preceding partnership more often indicated that the candidate institutionalised European Partnership have the "right scope & coverage".

Figure 16: What is your view on the scope and coverage proposed for this candidate institutionalised European Partnership, based on its inception impact assessment? (non-campaign replies) Aggregation of responses of all candidate initiatives



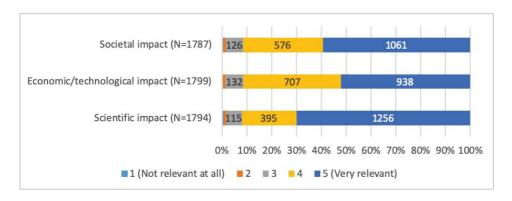
1.2.9. Scope for rationalisation and alignment of candidate European Partnerships with other initiatives

When asked whether it would be possible to rationalise a specific candidate European Institutionalised Partnership and its activities, and/or to better link with other comparable initiatives, nearly two thirds of respondents answered "Yes" (1000, or 62%), while over one third answered "No" (609, or 39%). Nearly no differences were found between stakeholder categories, only large companies and SMEs indicated slightly more often "Yes" in comparison to other respondents. The views of citizens are the same as for other respondents. Respondents that are/were directly involved in a current/preceding partnership, indicated "No" more often, the balance is about 50/50 between "Yes" and "No" for this group.

1.2.10. Relevance of European Partnerships to deliver targeted scientific, economic/technological and societal impacts

Finally, respondents were asked to rate the relevance of partnership specific impacts in three main areas: Societal; Economic/technological; and Scientific impacts. All three areas were deemed (very) relevant across the candidate partnerships. Scientific impact was indicated as the most relevant impact, more than 90% of respondents indicated that this as (very) relevant. Only minor difference between stakeholder groups were found. Academic/research institutions found scientific impacts slightly more relevant, while large companies found economic and technological impacts slightly more relevant than other respondents. NGOs found societal impact slightly more relevant, while SMEs found this slightly less important. Citizens did not a significantly different view when compared to other respondents. Respondents that are/were directly involved in a current/preceding partnership find all impacts slightly more relevant than other respondents.

Figure 17: In your view, how relevant is it for the candidate European Institutionalised Partnership to deliver on the following impacts? (non-campaign replies) Aggregation of responses of all candidate initiatives



1.3. Stakeholder consultation results for this specific initiative

1.3.1. Feedback to the inception impact assessment on candidate initiatives for Institutionalised Partnerships

Following the publication of the inception impact assessment, a feedback phase of three weeks allowed any citizen to provide feedback on the proposed initiative on the "Have your say" web portal⁷. In total 34 responses were collected for the initiative "EU-Africa Global Health", mainly from academic/research institutions, non-governmental organisations, EU and non-EU citizens, industry associations, and public authorities.⁸ Among the elements mentioned were:

- The scope of the initiative should cover late-stage clinical trials for infectious diseases, especially those poverty-related and neglected as well as emerging diseases in sub-Saharan Africa. Capacity building and education of African scientists should also be prioritised in the scope of the partnership.
- The partnership needs to guarantee a strong involvement of non-EU countries, particularly the African partners, in decision-making, strategic planning, and funding allocation.
- The partnership is expected to facilitate a coordinated scientific agenda for tackling infectious and emerging diseases.
- Funding decisions should follow public health needs in Sub-Saharan Africa, and research priority areas.
- Flexibility in funding decisions should be increased, possibly through adopting a portfolio-based funding approach.
- Efforts should be made to prevent brain-drain from Africa through strengthening local research systems and creating opportunities for researchers to continue their academic career in Africa.
- An increase (over €1.3 billion) in financial support from the EU is needed to ensure that the development of new technologies can be supported. Contributions of European and African partners need to be increased, while financial accounting needs to be simplified.
- Public-private collaboration should be boosted though stronger engagement of private partners and in-kind and financial investments. This would allow to pool adequate resources for the ambitious goals.
- The partnership should become a platform for EU science diplomacy in Africa to strengthen the ties between the continents.
- Stakeholders indicate that Institutionalised Partnership under Article 187 would allow a greater flexibility to attract a variety of stakeholders to achieve the goals of the partnership and should therefore be preferred.
 - 1.3.2. Structured consultation of the Member States on European partnerships

A structured consultation of Member States through the Shadow Strategic Configuration of the Programme Committee Horizon Europe in May/June 2019 provided early input into the

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⁷https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/11907-EU-Africa-Global-Health-Partnership/public-consultation

preparatory work for the candidate initiatives, in line with the Article 4a of the Specific Programme of Horizon Europe. For the initiative "EU-Africa Global Health" the following overall feedback was received from Member States.

Relevance and positioning in a national context

Overall the results of the Member State consultation confirm the relevance of the proposed EU-Africa partnership on health security to tackle infectious diseases, with 69% considering it relevant for national policies and priorities, and 70% for their research organisations, including universities. The proposed partnerships is considered less relevant for industry by most countries (46% relevant), see Figure 18.

100%
80%
60%
40%
20%
National Research organisations Industry policies/priorities including universities

■ Somewhat relevant ■ Neutral

■ Very relevant

■ Not very relevant
■ Not relevant at all

Figure 18: Relevance of the EU-Africa partnership on health security to tackle infectious diseases in the national context

On the question of existing national/regional R&I strategies, plans and/or programmes in support of the proposed EU-Africa Partnerships, 21 countries (70 %) report to have relevant elements in place. National R&I strategies or plans were identified most frequently (56%, BE, DE, EE, ES, HR, IT, LV, MT, PL, RO, SE, SI, UK, NO), followed by national economic, sectoral strategy and/or plan with a strong emphasis on research and/or innovation (48%, DK, EE, ES, HR, LV, NL, PL, RO, SE, SI, UK, NO) and dedicated R&I funding programmes or instruments (44%, AT, DE, ES, FR, HR, LV, PL, RO, SE, UK, NO).

Delegations identified a number of aspects that could be reinforced in the proposal for this partnership that would increase its relevance for national priorities. These are all individual comments, with few common elements, e.g. 4:

- The zoonotic origin of many tropical diseases should be strongly re-enforced and studies on vectors of tropical diseases included;
- Better definition of the role of AMR, also in relation to other partnerships candidates;
- Extension to investigating health behaviour. The fight against infectious diseases in Africa is more effective when it is approached systematically, not only from the clinical perspective;
- Increase the scope of infectious diseases covered, and geographical coverage (e.g. Latin America);
- Include major threats in terms of global burden such as diarrheal, respiratory diseases and meningitis as major causes of death for children under 5, or vector-borne diseases;

- Better alignment with policies in relation to sexual reproductive health and rights. Also, a clear gender analysis and approach;
- Increased efforts for engagement of more partners from the parts of Africa that have weak research culture (areas of greatest impact);
- Better involvement of countries that are not contributing with funding;

The majority of countries (52%) are at this stage undecided concerning their interest to participate, and 4 countries have expressed there is no national interest to participate (CY, CZ, HU, IS). At this stage 7 countries (DE, FR, IT, MT, SI, UK, NO express interest to join as a partner. National R&I programmes and governmental research organisations are identified are main potential partners or contributors. A number of countries express that their interest to participate would increase if their comments would be taken into account. While most are undecided concerning their participation, many countries (74%) expressed interest in having access to results produced in the context of the partnership.

Feedback on objectives and impacts

Overall there is a strong agreement (84%) on the use of a partnership approach in addressing health security tackling infectious diseases. There is broad agreement (76%) that the partnership is more effective in achieving the objectives and delivering clear impacts for the EU and its citizens, and only to a small degree (36%) that it would contribute to improving the coherence and synergies within the EU R&I landscape.

Countries indicate good agreement with the proposed objectives at short, medium and long term (84%) and the expected scientific, economic and societal impacts at European level (88%), with the remaining ones remaining neutral. Slightly less (72%) consider the impacts relevant in the national context. There is good agreement (80%) with the envisaged duration of the proposed partnership, but strong request for exit strategies, given that the initiative has started in 2003.

Additional comments made by individual delegations reiterate points made previously under elements to be reinforced. On the scope there are diverging views, between those that want to maintain the proposed focus, and others that want to expand the geographical and thematic scope.

Views on partners, contributions and implementation

There is no clear view between countries on the type and composition of partners, yet few comments (e.g. doubts on the inclusion of industry or foundations) are made that further elaborate their assessment. At this stage most countries (68%) would need more information on contributions and level of commitments expected from partners, while 24% agree with the proposal.

The proposed change of the implementation, from the use of Article 185 to the use of Article 187, and the establishment of a Joint Undertaking, is supported by around one third of countries (36%), while 24% disagree, with the rest expecting more details in order to be able to make an informed decision. Arguments made in relation to either implementation relate to the following:

- Article 185: Political aspects (role of the European Parliament), continuation of implementation that is considered well-working, future role of the UK (currently UK is the major contributing country in EDCTP2); positive experience with the current governance model;
- Article 187: more possibilities for private and NGO partners and reduced liability issues for Member States, need to be clear about role of industry (limitation to ad-hoc participation seems more acceptable), ensuring the programme is developed by the public domain, consideration to enhance the territorial scope beyond African countries.

1.3.3. Targeted consultation of stakeholders

The objective of this targeted consultation based on interviews was to collect stakeholder insights on the different issues. These included the functionalities of the initiative required to attain the objectives, the commitment of Member States and other stakeholders to the initiative, the costs of eventual future partnership, the leveraged R&D investments from stakeholders and the impacts and differentiators to take into account for the options assessment. The interview questions were based on the objectives, scope, type of partnership, partner engagement, governance, coherence, funding sustainability and impact.

Overview of respondents to the targeted consultation

The number of interviews with representatives in each stakeholder category, along with their percentage share is shown in Table 2. Within the category "country representatives to the EDCTP GA", a number of interviewed (European and African) representatives are affiliated with research institutions. Thus, the number of interviewed academics exceeds the number of interviews shown in the category 'academia'. Furthermore, a number of interviews were performed as group interviews with two or more participants.

1. Table 2: Number of interviews per stakeholder category

Stakeholder category	Number	Share (%)
EDCTP Secretariat and Scientific Advisory Committee	7	18.9%
Country representatives to the EDCTP General Assembly	9	24.3%
European Commission and related bodies	6	16.2%
Academia	3	8.1%
Product Development Partnerships (PDPs)	3	8.1%
Charitable foundations	2	5.4%
Industry	3	8.1%
International organisations	2	5.4%
Other	2	5.4%
TOTAL	37	100%

Political and legal context

Although no interview questions directly cover issues of political and legal context directly, interviewees were vocal in expressing their views on the subject. Interviewees discussed areas where Africa has achieved substantial progress, such as scale up of e-health technologies, and overall digitalisation of the continent. However, respondents state that, much still needs to be done. Issues of emerging infectious diseases, climate change, and antimicrobial resistance were highlighted as external factors that may shape future policy priorities for global health.

Problem definition and drivers

What are the problems? Interviewees across all categories agree that the burden of infectious disease is still high in sub-Saharan Africa. The EDCTP Secretariat, EC, PDPs, industry, and others highlighted that emerging diseases also constitute a problem that needs to be addressed. They also mention the lack of accessible and affordable technologies as a driver for this burden, as well as the limited commercial interest in the area of infectious diseases. Interviewees, from all stakeholder categories, stress that there remains a large unmet need for effective, affordable and safe treatments, vaccines and diagnostic tools to combat infectious diseases. The large majority of stakeholders across all categories believe that limited capacity of African countries to conduct clinical research for disease is a major problem driver.

Why should the EU act? Interviewees unanimously agree that there is a strong need for the EU to address the identified problems. Many stakeholders (across all stakeholder groups) believe that the Candidate Initiative is unique to address the needs. Many stakeholders (from EDCTP, country representatives, PDPs, academia, international organisations) stress the added value the initiative brings to African countries in terms of strengthened research capacity and infrastructure. Interviewees (EDCTP Secretariat and SAC, academia, other) emphasise that the partnership format is effective in promoting long-term commitments from all partners, including African countries.

Since the costs of conducting late-stage clinical trials can be extremely high, many of them (EDCTP and SAC, country representatives, EC, academia, PDPs) state that the Candidate Initiative would be essential to achieve a critical mass in terms of funding, as the expected costs are beyond the capacities of national funders. They (EDCTP and SAC, EC, academia,) also state that the Candidate Initiative could enhance coherence between national research programmes funded by EU Member States. Furthermore, some stakeholders (academia, other) believe that the large financial contributions made into EDCTP could be (partially) lost if no successor initiative is in place.

Many stakeholders (EC, country representatives, academia, product development partnerships, charities, international organisations, others) also stress the political commitment of EU to fund actions for research and innovation in Africa and the need to keep up with other international players. EU commitment to SDGs and human right principles are discussed. A few stakeholders have pointed out that supporting development of Africa is in line with European values and feel that EU has a moral obligation to do so.

Objectives: What is to be achieved?

General objectives Across all stakeholder groups, interviewees strongly favour a clear focus on diseases affecting sub-Saharan Africa, in particular on infectious diseases. It is viewed that there is still much to be done in this area and that it will be crucial to sustain and continue the progress made to date. Several interviewees – including representatives of the EC, charitable foundations, and industry – have also highlighted the rise of non-communicable diseases in Africa. However, numerous interviewees have indicated that a broadening of the scope of the Candidate Initiative, compared to that of EDCTP2, would necessitate a concomitant increase in funding.

Interviewees widely agree that the primary focus of the Candidate Initiative should be on sub-Saharan Africa. Nonetheless, some interviewees – in particular those working on emerging infectious diseases and diseases with a high prevalence in other parts of the world – have underscored that it should include other regions and collaborate with other relevant initiatives.

Specific objectives All interviewees were familiar with the type of activities that were supported under EDCTP and have expressed that the Candidate Initiative should support a similarly wide range of activities and support the development of new or improved health technologies to tackle infectious diseases. Furthermore, several interviewees – including EDCTP staff, representatives of PDPs and academics – have expressed a desire for the Candidate Initiative to increase support for implementation research, aimed at improving uptake and effective use of existing health technologies. A limited number of interviewees – in particular those working at a more overarching global health policy level – have underscored the need to promote and support integration of research efforts in the field and to convene stakeholders across the world. Interviewees also indicate the need of sustained support for capacity strengthening. At the same time, several interviewees indicate that various sub-Saharan African countries have already developed substantial capacity and now focus should be on areas where this is most needed, thus capitalising effectively on previous success and South-South networking and cooperation.

A number of stakeholders recognise emerging infectious diseases as a growing problem, affecting not only sub-Saharan Africa but also other parts of the world, including the EU. These stakeholders are in favour of bolstering capacity in the African region to timely detect and respond to such diseases, recognising that existing systems are often weak. At the same time, a number of interviewees are somewhat cautious about the extent to which the Initiative should engage in this area, where already several other initiatives are active. Whilst overall there is support among stakeholders for this specific objective, it is widely seen as one that necessitates collaboration and coordination.

Targeted impacts

Interviewees widely agree that, by supporting research in the field of infectious diseases, the Candidate Initiative has a clear and strong potential to contribute to scientific impact, in the form of new knowledge generated and new health technologies developed. Another area where the Candidate Initiative is generally expected to deliver scientific impact is in the strengthening of research capacity.

Across stakeholder groups, interviewees anticipate that any new technologies developed could have important societal impacts, by reducing the burden of infectious diseases in the African region. This is universally viewed as the ultimate goal of the Candidate Initiative. At

the same time, most interviewees have realistic expectations about the potential for the Candidate Initiative to deliver such societal impacts, recognising both the significant challenges associated with health technology development, and the broader socio-economic context of the African continent.

A number of interviewees from academia have seen first-hand what impacts EDCTP has had on career development opportunities for African researchers. They are therefore optimistic that the Candidate Initiative would likewise achieve such positive impacts if it supports a similar, or extended range, of activities.

None of the interviewees have discussed the potential for the Candidate Initiative to deliver economic impact by increasing the production, distribution and sales of health technologies for infectious diseases. That is not to say that they would not deem such impacts likely, but rather reflects the fact that this form of economic impact is not seen as a goal in itself. This similarly applies to other possible areas of economic impact, such as those on EU-Africa trade and sustainable investments, or on increased research spending in Sub-Saharan Africa. Rather, interviewees are focused on tackling the burden of infectious diseases itself, thereby reducing the associated economic burden.

Functionalities

Across the different stakeholder groups, there is unanimous recognition that to achieve impact the Candidate Initiative needs to encompass a broad range of stakeholders, including European and African countries, research institutions, industry, charitable and international organisations. The extent of participation, particularly stakeholders' involvement in the General Assembly, voting rights and funding decisions have been widely discussed among interviewees. There is no consensus on the format of participation.

Representatives of national governments stress the importance of European and African country participation, and their ability to "steer the processes". Interviewees encourage third party participation, in the form of private entities, associated countries, and charitable foundations. In case of industry participation, they welcome their involvement but express a need for transparency in their participation and contributions as well as limited mandate in order to ensure that public interests are at the core of the Candidate Initiative.

Interviewees uniformly indicate that funding and implementation of research should be the primary focus of the Candidate Initiative. In particular, they view late-stage clinical trials as the primary area where the Candidate Initiative can deliver direct impacts.

A number of interviewed representatives of the EC, as well as some members of the EDCTP Association, have expressed frustration with what they perceive as 'free riding' under EDCTP: the ability for countries that are not part of the EDCTP Association to participate in all EDCTP-supported activities. They argue that this provides limited incentive for countries to formally commit to and align activities. They thus suggest that certain activities should be accessible only to active participants in the Candidate Initiative.

Comparative assessment of policy options and preferred option

Effectiveness

All interviewees expect an institutionalised partnership approach to be most effective to achieve the objectives of the Candidate Initiative. Opinions are, however, somewhat divided

on whether this should take the form of an Article 185 partnership or an Article 187 partnership. Many acknowledge, or even embrace, the advantages an Art.187 set-up would bring to the partnership, arguing that it allows for more meaningful inclusion of a greater range of stakeholders, creates more financial certainty, and would allow for a leaner and more efficient organisational structure. Others, however, have concerns about what this would mean for the relationships built with and between current EDCTP members and for the level of control that EC would have over the partnership, possibly at the expense of the representation of current members. This group of interviewees contains in particular current representatives to the General Assembly of EDCTP, both those from Europe and those from Africa.

Among many interviewees, particular representatives from African countries, there are also concerns that countries that cannot substantially contribute to the partnership financially will be left out of the decision-making. However, several interviewees acknowledge that they do not fully understand the respective advantages and disadvantages of these two options.

Coherence

Numerous interviewees have pointed out the importance of ensuring alignment with other initiatives and programmes in the field of global health and infectious disease. However, they do so mostly in rather general terms rather than by singling out specific areas or initiatives.

A few interviewed stakeholders, including those from within the EC, have indicated that there is space for improved coordination across different Directorates-General within the EC. In particular, this relates to the role of DG DEVCO in health systems strengthening and that of DG ECHO and DG SANTE in epidemic preparedness. Other initiatives named include the Joint Programme for Anti-Microbial Resistance and the Innovative Medicines Initiative. However, these interviewees did not always seem to be fully aware of the exact focus or scope of activities supported by these activities.

Stakeholders also widely agree that the Candidate Initiative should coordinate its efforts with other key stakeholders in the field, but again often without being specific. A few suggest that there has been a proliferation of initiatives that appear to share focal areas with the Candidate Initiative. In addition to EC programmes and initiatives, specific examples include the Coalition for Epidemic Preparedness Innovations, and funders such as the Bill & Melinda Gates Foundation. These interviewees indicate that it will be important for the Candidate Initiative to clearly position itself in relation to these other initiatives and funders and, where applicable, coordinate activities

Efficiency

Few interviewees expressed any views on the comparative efficiency of the different policy options, as many lack the detailed understanding of the options to be able to comment on this meaningfully. Representatives of the EC, both in interviews and during meetings of the PSG, have expressed concerns that any change compared to the Art. 185 partnership that has been in place for EDCTP will result in loss of momentum and expertise. The main reason for this view is the fact that under any other arrangement, the current EDCTP Secretariat will

effectively cease to exist⁹. This is expected to result in important knowledge being lost, which cannot easily be found within the current EC services, and the breakdown of relationships that have been built with stakeholders and partners. Similar concerns have been voiced by members of the EDCTP Secretariat themselves.

1.3.4. Open Public Consultation

Approach to the open consultation

As part of its better regulation agenda, the Commission listens more closely to the views of citizens and stakeholders. The aim is to make evidence-based proposals of EU policies that address their needs. The consultation was open to everyone via the EU Survey online system. ¹⁰ The survey contained two main parts and an introductory identification section. The two main parts collected responses on general issues related to European partnerships (in Part 1) and specific responses related to 1 or more of the 12 candidate initiatives (as selected by a participant).

The survey contained open and closed questions. Closed questions were either multiple choice questions or matrix questions that offered a single choice per line, on a Likert-scale. Open questions were asked to clarify individual choices.

The survey was open from 11 September till 12 November 2019. The consultation was available in English, German and French. It was advertised widely through the European Commission's online channels as well as via various stakeholder organisations.

The analysis of the responses was conducted by applying descriptive statistic methods to the answers of the closed questions and text analysis techniques to the analysis of the answers of the open questions. The keyword diagrams in this report have been created by applying the following methodology: First, the open answer questions were translated into English. This was followed by cleaning of answers that did not contain relevant information, such as "NA", "None", "no comment", "not applicable", "nothing specific", "cannot think of any", etc. In a third step, common misspellings were corrected. Then, then raw open answers were tokenised (i.e. split into words), tagged into parts of speech (i.e. categorised as a noun, adjective, preposition, etc) and lemmatised (i.e. extraction of the root of each word) with a pre-trained annotation model in the English language. At this point, the second phase of manual data cleaning and correction of the automatic categorisation of words into parts of speech was performed. Finally, the frequency of appearance and co-occurrences of words and phrases were computed across the dataset and the different sub-sets (e.g. partnerships, stakeholder groups). Data visualisations were created based on that output.

The keyword graphs in the following sections have been built based on the relationships between words in the open responses of the survey participants. It features words that appear in the same answer either one after the other or with a maximum distance of two words

⁹ A change from an Article 185 into an Article 187 initiative would also affect the legal structure of the Dedicated Legal Structure

 $^{^{10}\,\}underline{\text{https://ec.europa.eu/eusurvey/runner/ConsultationPartnershipsHorizonEurope}}$

between them. Each keyword is represented as a node and each co-occurrence of a pair of words is represented as a link. The size of the nodes and the thickness of the links vary according to the number of times that keywords are mentioned and their co-occurrence, respectively. In order to facilitate the visualisation of the network, the keyword graphs have been filtered to show the 50 most common co-occurrences. Although the keywords do not aim to substitute a qualitative analysis, they assist the identification of the most important topics covered in the answers and their most important connections with other topics, for later inspection in the set of raw qualitative answers.

Open public consultation for the candidate European Partnership on EU-Africa Global Health

The chapter outlines for the candidate European Partnership on EU-Africa Global Health the type of respondents; the views on the needs of the future European Partnerships under Horizon Europe and on the advantages and disadvantages of participation in an Institutionalised European Partnership.

It also analyses the results on the views to specific questions related to: Relevance of research and innovation efforts at the EU level to address problems; Horizon Europe interventions to address these problems; Relevance of elements and activities in setting a joint long-term agenda; Pooling and leveraging resources; Partnership composition; and Implementation of activities; Setting up a specific legal structure (funding body); Proposed scope and coverage of this candidate European Partnership; Alignment of the European Partnership with other initiatives; and on Relevance of this candidate European Partnership to deliver impacts.

Profile of respondents

Only 47 respondents provided views on the EU-Africa Global Health partnership. Among them 13 respondents (27.66%) are citizens. The group is dominated by respondents from academic and research institutions (15 respondents or 31.91%), citizens and company/business organisations (7 respondents or 14.89%). The majority of respondents, namely 35 (74.47%), have been involved in the on-going research and innovation framework programme, while 31 respondents (88.57%) were directly involved in a partnership under Horizon 2020 or its predecessor Framework Programme 7.

Characteristics of future candidate EU-Africa Global Health initiative as viewed by respondents

At the beginning of the consultation, the respondents of this partnership indicated their views of the needs of the future European Partnerships under Horizon Europe. There were two options for which many respondents indicated that they were fully needed, namely be more responsive towards societal needs (34, 72,34%) and make a significant contribution to achieving SDGs (33, 70.32%). The only options where less than 30% of respondents indicated that options were fully needed, was in response to be more responsive toward priorities in national and/or regional R&I strategies and for the other category. With regard to Other, it is likely that respondents did not have a concrete idea of other needs of the future European Partnerships.

No statistical differences were found between the views of citizens and other respondents.

Be responsive towards EU policy objectives

Be more responsive towards societal needs

Be more responsive towards priorities in national, regional R&I strategies

Make a significant contribution to achieving SDGs

Make a significant contribution to the EU efforts to achieve climate-related goals

Focus more on the development and effective deployment of technology

Focus more on bringing about transformative change towards sustainability in their respective area

Figure 19: Views of respondents in regard to the needs of future European Partnerships under Horizon Europe (N=47)

The respondents also had the option to indicate other needs. The results of the analysis show that respondents have indicated needs around extensive support linkage and the development and scaling of technology.

10%

■1 (Not needed at all) ■2 ■3 ■4 ■5 (Fully needed) ■Don't know

20%

30%

40%

Main advantages and disadvantages of Institutionalised European Partnerships

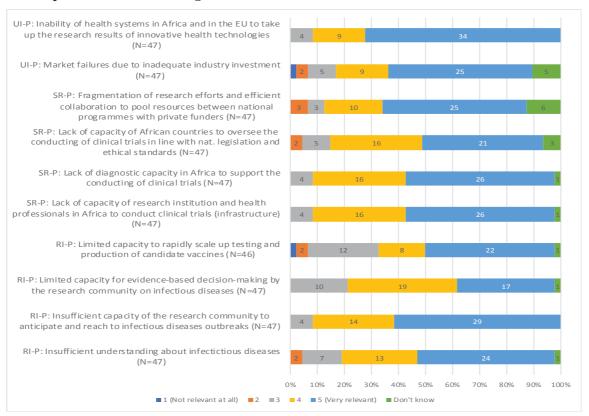
Make a significant contribution to EU global competitiveness in specific sectors/domains

The respondents were asked what they perceived to be the main advantages and disadvantages of participation in an Institutionalised European Partnership (as a partner) under Horizon Europe. The keyword analysis used for open questions showed the respondents viewed a network as the main advantage of the institutionalized partnership, as well as long term funding.

Relevance of EU level efforts to address problems in relation to Global Health

In the consultation, respondents were asked to provide their view on the relevance of research and innovation efforts at EU level to address the following problems in relation to global health, specifically on three types of problems: problems in uptake of health innovations (UI-P), structural and resource problems (SR-P) and research and innovations problems (RI-P). In Figure 20 the responses to these answers are presented.

Figure 20: Views of respondents on relevance of research and innovation efforts at the EU level to address problems in relation to global health



With regard to the uptake in innovation problems, the inability of health systems in Africa and in the EU to take up the research results of innovative health technologies was highlighted as the main area of concern (34 respondents, 72.34%, indicated it as very relevant).

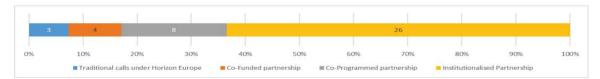
With regard to structural and resource problems, the answers are fairly similar. 26 respondents (55.32%) have indicated that both the lack of capacity of research institutions and health professionals in Africa to conduct clinical trials and the lack of diagnostic capacity in Africa to support the conducting of clinical trials are very relevant.

Last, with regard to research and innovation problems, 29 respondents have indicated that they view insufficient capacity of the research community to anticipate and react to infectious diseases outbreaks as a very relevant problem (61.70%). Limited capacity for evidence-based decision-making by the research community on infectious diseases outbreaks has received the least amount of very relevant answers out of all the problems presented, as 17 respondents have indicated that it is relevant for research and innovation efforts at the EU level to address this issue (36.17%). No statistical differences were found between the views of citizens and other respondents.

Horizon Europe mode of intervention to address problems

To the question on how the challenges could be addressed through HE intervention, just over 60% of respondents indicated that institutionalised partnerships were the best fitting intervention. No statistical differences were found between the views of citizens and other respondents.

Figure 21: Assessment of Horizon Europe intervention



The respondents were asked to justify their answers. An in-depth analysis of the open responses shows that those in favour of an institutionalised partnership viewed this as offering the greatest stability, with long-term political and financial commitments. These respondents view the institutionalised partnership as the best way to pool resources, foster collaboration between a wide range of partners and other stakeholders, with coordination and alignment of efforts. It was also noted that this partnership form best allows for a pipeline or portfolio management approach to selecting projects for funding. The small number of respondents in favour of a co-programmed partnership believe that this option would allow for inclusion of a greater range of actors, including non-EU countries and SMEs, and comes with the lowest administrative cost. The respondents opting for the co-funded partnership approach mentioned flexibility and transparency reasons. There are no significant differences between different groups of respondents.

Relevance of elements and activities to ensure meeting of objectives

Setting joint long-term agendas

To the question on how relevant the involvement of actors is in setting a joint long-term agenda to ensure that the proposed European Partnership would meet its objectives, over 90% of respondents consider that the involvement of African countries is very relevant (Figure 22). Over 60% of them suggest that the participation of Member States and Associated Countries, as well as, foundations and NGOs is very relevant. The least number of respondents (21 respondents or 44.68%) suggested that industry should be involved in setting a joint long-term agenda. No statistical differences were found between the views of citizens and other respondents.

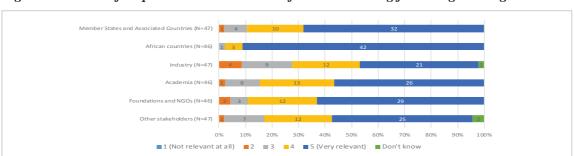


Figure 22: Views of respondents on relevance of actors in setting joint long-term agenda

Relevance of elements and activities in pooling and leveraging resources

With respect to the relevance of actors in pooling and leveraging resources, such as financial, infrastructure, and in-kind expertise to meet the candidate Partnership objectives, over 50% of respondents indicated Member States and Associated Countries, African countries, foundations and NGOs are most relevant. Based on the opinions of respondents, the role of academia is considered smaller for pooling and leveraging resources, in contrast to setting a

long-term agenda, as only 15 respondents consider that their involvement is very relevant to pool and leverage resources.

No statistical differences were found between the views of citizens and other respondents.

Figure 23: Views of respondents on relevance of actors for pooling and leveraging resources

Relevance of elements and activities for the partnership composition

Around 55% of respondents consider that both the flexibility in partners' composition and a broad range of partners (including across disciplines and sectors) are very relevant to reach the Partnership's objectives. Less than 10% of respondents consider these elements as not very relevant (Figure 24). No statistical differences were found between the views of citizens and other respondents.

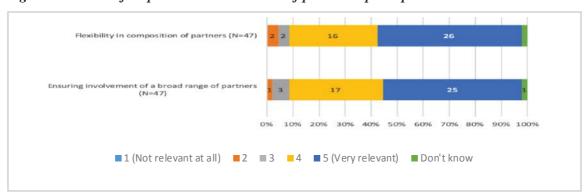
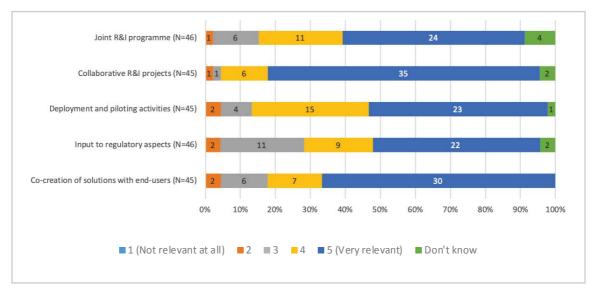


Figure 24: Views of respondents on relevance of partnership composition elements

Relevance of implementation of activities

Concerning the relevance of implementation of several activities for meeting objectives, the activities listed included: joint R&D programme, collaborative R&D projects, deployment and piloting activities, input to regulatory aspects (i.e. to developers of medicines or health technologies on approvals and pre-qualifications) and co-creation of solutions with end-users (e.g. national health systems). Out of 45 respondents, 77.8% indicated that collaborative R&D projects are very relevant. The co-creation of solutions with end-users is also considered as very relevant by a large number of respondents (66.6%). In contrast, deployment and piloting activities, and input to regulatory aspects is considered less relevant. Overall, citizens provided similar views, but found Joint R&I programme more relevant.

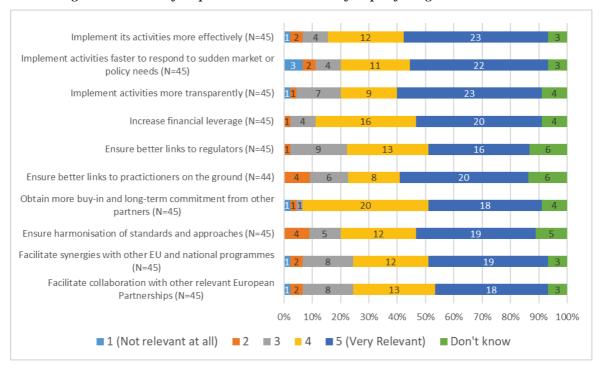
Figure 25: Views of respondents on relevance of implementation of the following activities



Relevance of setting up a legal structure (funding body) for the candidate European Partnerships to achieve improvements

Respondents were asked to assess the relevance of a specific legal structure (funding body) for the candidate European Partnership to achieve several activities. According to Figure 26, a greater number of respondents indicated that the legal structure would be needed to obtain more buy-in and long-term commitment from other partners, to increase financial leverage and to implement activities more effectively. In contrast, the least number of respondents suggest that the legal structure would assist in ensuring better links to regulators, as only 16 respondents indicated that it would be very relevant for this purpose. No statistical differences were found between the views of citizens and other respondents.

2. Figure 26: Views of respondents on relevance of a specific legal structure



Scope and coverage of the candidate European Partnerships based on their inception impact assessments

The majority of the respondents consider that the proposed scope and coverage of the Partnership is right in terms of technologies, research areas, geographical coverage, types of partners, range of activities and sectors. However, among listed areas, a higher share of respondents (14 respondents or 31.11%) indicated that the geographical coverage might be too narrow. No statistical differences were found between the views of citizens and other respondents.

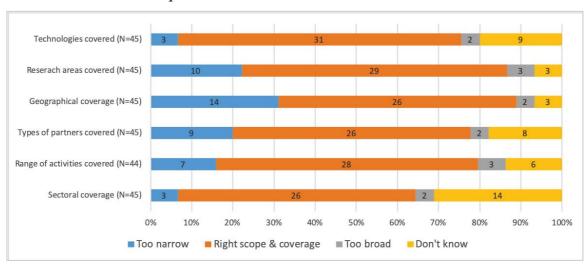


Figure 27: Views of respondents on the scope and coverage proposed for the Global Health institutionalised Partnership

Respondents were also asked to comment on the proposed scope and coverage for this candidate Institutionalised Partnership. The keyword in-depth analysis used for open questions of these responses shows that some suggested expanding the scope, compared to that proposed, to include also anti-microbial resistance and hospital-acquired infections, as well food-, water- and vector-born diseases and zoonoses. This effectively calls for inclusion of a 'One Health' approach.

Other research areas suggested for inclusion were non-communicable diseases, health systems research, and social and behavioural determinants of health. On the spectrum of research and development to be covered, comments were mixed. Whereas some suggested a full coverage from early stage research to bringing products to market, others advocated for keeping the focus on Phase I and II clinical trials. In terms of geographical scope, a small number of respondents suggested including areas other than sub-Saharan Africa, in particular the Middle East and South America.

Other respondents, however, emphasised that sub-Saharan Africa continues to carry a disproportionate burden of poverty-related infectious diseases and thus argue that this focus remains appropriate. It is furthermore cautioned that expanding the scope of the partnership, both in terms of geography and disease areas covered, would dilute resources and focus, thereby jeopardising potential impact. In all cases, the number of clarifying comments was too small and answers were too heterogeneous to determine any significant differences between different groups of respondents.

Scope for rationalisation and alignment of candidate European Partnerships with other initiatives

Among 39 respondents, 31 (79.49%) consider that it would be possible to rationalise the candidate European Institutionalised Partnership and its activities, and/or to better link it with other comparable initiatives. No statistical differences were found between the views of citizens and other respondents.

The respondents who answered affirmative, where asked which other comparable initiatives it could be linked with. The analysis of the results show that respondents mention scientific capability, infectious diseases, other programmes and new partnerships as well as clinical trials.

A more in-depth analysis of the comments shows that several respondents, mostly from academic organisations, see potential for collaboration or alignment with, in particular, WHO-TDR, the candidate 'One Health Partnership', the candidate Innovative Health Initiative, the candidate Key Digital Technologies Partnership and European vaccine development initiatives like Transvac2, as well as national initiatives (not specified). A NGOs nevertheless highlighted the need to make strategic investment decisions and to dedicate predetermined budget envelop to the development of products to heal specific diseases. A representative of the industry sector similarly reported the need to ensure the sustainability of new products by ensuring, through alignment with other initiatives, the engagement of multiple types of stakeholders.

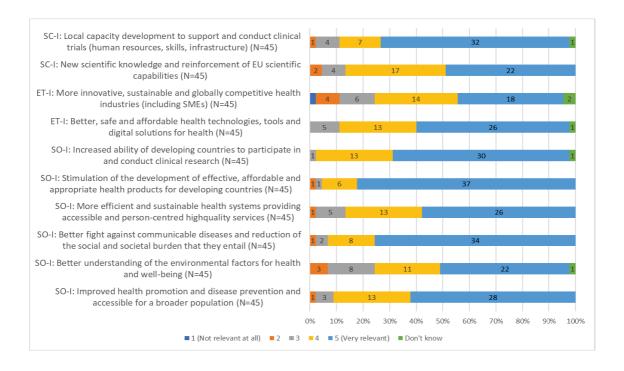
For the four respondents who answered negatively on the question, the analysis shows that they mention capacity building, broader initiatives, sufficient knowledge and specific objectives.

All respondents highlighted that the candidate partnership has very specific objectives and that, like its predecessors, it is unique, so that there should not be any risk of duplication of research and innovation efforts. A representative from the industry sector, in the same line, stated that the candidate partnership could learn from other initiatives, but it should be given the full freedom of adapting its specific objectives to the circumstances. An EU citizen added that EDCTP would not have achieved its goals if it had had broader objectives.

Relevance of the candidate to deliver targeted scientific, economic/technological and societal impacts

Respondents were asked to assess the relevance of the candidate Partnership to deliver on listed impacts. Based on results, among societal impacts, it is expected to be 'very relevant' for stimulation of the development of effective, affordable and appropriate health products for developing countries and for fighting against communicable diseases and reduction of the societal and societal burden that they entail (Figure 28). Among presented economic impacts, a greater number of respondents, namely 26 out of 45 (57.78%), indicated that the candidate Partnership would be 'very relevant' for ensuring better, safe and affordable health technologies, tools and digital solutions for health. The majority of respondents (32 out of 45, or 71.11%) suggest that the initiative would have a significant effect on local capacity development to support and conduct clinical trials. Overall, citizens provided similar views, but found the societal impact regarding 'More efficient and sustainable health systems' more relevant.

Figure 28: Views of respondents on the relevance of the candidate Partnership to various impacts



Annex 3 Who Is Affected And How?

1. Practical implications of the initiative

The ultimate beneficiaries of the EU-Africa Global Health partnership will be **people in sub-Saharan Africa who will gain access to potentially life-saving interventions**. However, the programme will also directly and indirectly deliver benefits to the EU and sub-Saharan Africa in multiple ways:

- Global leadership: The partnership will be a demonstration of the EU's commitment to the health and well-being of disadvantaged populations in sub-Saharan Africa, and its pursuit of the SDGs.
- Health security: By addressing key global threats to health such as emerging and reemerging infections and antimicrobial resistance, the partnership will help to ensure the health security of Europe as well as in sub-Saharan Africa.
- Global influence: The partnership will enable the EU to undertake activities beyond the capacity of individual countries. It will provide a powerful voice for Europe in global health research, as well as an important mechanism to promote European objectives and values, including open access to research findings.
- Industrial competitiveness: By sharing the risks of new product development with companies and product development partnerships, it is helping to create sustainable markets for products and safeguarding a strategically important industrial sector in Europe and promoting it in sub-Saharan Africa.
- Scientific competitiveness: International networking will benefit researchers in Europe and sub-Saharan Africa. Strengthening ties with sub-Sahara Africa, these networks will enable researchers, from Europe and sub-Saharan Africa, to focus their research on global priority questions and achieve greater impact.

2. Summary of benefits and costs

1. Overview of Benefits (to	tal for all provisions) – Preferred Op	nion
Description	Estimation (quantitative or qualitative)	Comments
Direct benefits		
Delivering on EU commitments to tackle global challenges	economic impact on countries (healthcare costs and lost productivity). The partnership will make an important contribution by advancing in the development of new or improved health	The initiative under 187 would be able to incorporate not only Member States and Associated States contributions but also additional contributions from the sub-Saharan countries and other third countries, private charitable foundations and the pharma industry. Some examples from the current initiative would help to understand the benefits of the proposed initiative: During the period, 2014-2019 EDCTP supported 84 large-scale clinical trials and other clinical research activities with €526 million. The PredART trial provided the first evidence of a strategy to reduce the risk of fatal complication when HIV-infected patients begin antiretroviral treatment while being treated with tuberculosis therapy. TB-NEAT consortium generated evidence on new tuberculosis diagnosis.
_	the EU's global influence within	Between 2003 and 2011, over 90% of publications from EDCTP-funded projects were published in high-impact journals. Moreover, papers from Europe-wide or Europe-sub-Saharan Africa collaborations typically have high citation rates and research impact.
Developing the evidence base for national and international health policy-making (bridging the gap between science and policy for health)	The initiative will support multiple studies that will be able to influence national and international health policy and practice.	The predecessor EDCTP, supported the WANECAM study that demonstrated the safety and efficacy of an antimalarial formulation for children, paving the way for its approval by the European Medicines Agency and recommendation by the WHO. EDCTP-UK studies contributed to Paediatric European Network for Treatment of AIDS (PENTA) guidelines. EDCTP established the Pan African Clinical Trials Registry (PACTR), which is the only WHO-endorsed primary registry in Africa, with >1,000 clinical trials registered. EDCTP is a member of the African Medicines Regulatory Harmonisation Partnership Platform, which aims to improve coordination of regulatory systems strengthening and harmonisation activities in Africa. EDCTP also has a long-term working relationship with WHO-AFRO, which hosts the African Vaccine Regulatory Forum (AVAREF). In order to boost country ownership and alignment with specific national health research needs in sub-Saharan Africa, EDCTP has been collaborating with WHO-AFRO on a National Health Research Systems (NHRS) survey project for the assessment of NHRS, informing progress towards the achievement of Universal Health Coverage.
Providing mechanisms to	Globalisation and broad access to	EDCTP has invested € 23.43 million to support preparedness

prepare for and respond international travel coupled with to respond to infectious disease outbreaks in sub-Saharan public health the emergence of African countries, including two large multidisciplinary emergencies in Africa communicable diseases highlight consortia, ALERRT and PANDORA-ID-NET, involving 22 and Europe the importance of doing local field institutions in 18 sub-Saharan African countries and 16 institutions in 6 European countries. Each consortium has research to address public health actively responded to disease outbreaks in the region (Lassa fever, Ebola, plague, monkeypox, Coronavirus) as well as redirected their research to immediately address the COVID-19 pandemic in sub-Saharan Africa, and jointly enhanced the capacity of African regions to detect, prepare, and to carry out clinical research in emergency situations. Joint calls with the World Health Organisation have developed capacity in responding to Ebola outbreaks, clinical research and implementation research. Creating and retaining a Africa's potential in science and The majority of EDCTP-funded clinical studies include a innovation is handicapped by a generation capacity-building work package that supports long- and short-African scientists shortage of trained scientists. The term training, including PhDs and Master's degrees, in partnership will contribute to the addition to improving site infrastructure and equipment. 7,488 research capacity building by people have participated in EDCTP project-related trainings and workshops to improve the capacity to conduct clinical supporting the researchers' careers Africa and strengthening trials, on topics such as study protocol, specimen collection, national health research systems. research and administration, Good Clinical Practice and epidemics preparedness. In addition a comprehensive EDCTP fellowship programme is focused on the career development of individual African researchers and already supported 126 individual fellowships (€ 31.28 million). Since its inception in 2003 the EDCTP has supported more than 500 African researchers, including fellows and MSc/PhD candidates, with 90% continuing their research career in Africa. As well as a training scientific EDCTP has supported the creation of 4 Networks of Supporting integrated building for capacity workforce and leadership, the Excellence across 63 institutions in 42 sub-Saharan African health research in Africa partnership will contribute to other institutions in 28 countries, in Central Africa CANTAM. key aspects of health research Western Africa WANETAM, Southern Africa TESA and Eastern Africa EACC, to address disparities between capacity by supporting Networks of Excellence in African regions countries in terms of clinical research capacity. EDCTP is enabling the sharing of research supporting 57 projects to strengthen the enabling environment experience, expertise for clinical trials and research in sub-Saharan Africa (EUR knowledge, and developing 51.28 million), including health systems strengthening, sustainable capabilities; and by pharmacovigilance activities and the translation of research supporting for the establishment of results into policy and practice. Moreover EDCTP is functional regulatory systems and contributing to the strengthening of national health research capacities for ethical review of systems in sub-Saharan Africa. They have received EDCTP clinical research. The partnership support for the establishment of functional regulatory systems will make efforts to address and capacities for ethical review of clinical research. gender, language and regional EDCTP is also developing innovative fellowship approaches research and related capacity disparities. (such as tandem fellowships), offering grant writing workshops in different languages (English, French and Portuguese) and project and financial management training, amongst other activities. It is also supporting the development of a standardised Financial Management Assessment Tool for assessing the financial capacity of beneficiaries and the

international standard for Good Financial Grant Practice for

EDCTP is encouraging collaboration between its Participating

States' Initiated Activities and the centrally-managed

activities in order to optimise investments in infectious

better financial governance.

The partnership will encourage

interdisciplinary and cross-disease

approaches, enabling institutions to

Developing

and African capacities in

clinical research against

European

poverty-related infectious diseases	build and diversify their expertise to combat infectious diseases and to build skills in managing global collaborative projects.	diseases R&D and maximise the impact of the limited financial resources. EDCTP also collaborates with The Global Health Network to develop online tools to facilitate open source clinical trials and data sharing. This includes a data management tool for better clinical data management; a Clinical Trial Protocol builder for open source development of clinical trial protocols; and a onestop data sharing portal called EDCTP Knowledge Hub to provide free access to a virtual research community.
Indirect benefits		
Contributing to the achievement of the African Union Agenda		
Contributing to the provision of safe medical interventions	better national pharmaco-vigilance systems as the safety of new interventions needs to be monitored when they are introduced into routine care and are	EDCTP has supported several projects building national and international expertise, from WHO international drug monitoring programme to Uppsala monitoring centre, to strengthen pharmaco-vigilance systems, to build national capacities to detect and respond to possible adverse events and to maintain public confidence. In addition EDCTP is promoting development of cooperation between academic researchers and product developers (PDPs and Pharmaceutical industry), thus matching scientific excellence with efficiency in advancing products along the product development value chain.

3. Overview of costs

II. Overview of costs – Preferred option							
		Citizens/	Consumers	s Businesses Administrations			
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Management/ Administrative	Direct costs					EUR 0.1 million ¹¹ (1FTE)	EUR 0.9-1.0 million ¹² /year
cost (a)	Indirect costs						
Personnel costs	Direct costs					EUR 0.2 million ¹³ (2FTE)	EUR 5.0-6.0 million/year (46 FTE)
	Indirect						

Notes to the administrative budget summary:

- 1. Missions: the costs budgeted under this category exclude the travel costs of expert groups (Scientific Advisory Committee and Scientific Review Committee) and for specific events, which are budgeted for under other EU-funded activities (chapter 3).
- 2. Consumables and supplies: the costs budgeted for under this category include bank charges incurred in making fund transfers to beneficiaries, postage and courier costs, office utilities, office consumables and stationery.
- 3. Service contracts (including non-recoverable taxes): the costs budgeted for under this category include annual audit fees in relation to secretariat's annual financial reports and statutory accounts, office cleaning, IT support services, office rent (for the EDCTP Association offices in The Hague and Cape Town), and other hosting costs.

REFIT Cost savings table

Not applicable for the proposed EU-Africa Global Health Partnership. The initiative would benefit from the experience of the existing organisation/structure already in place (e.g. the EDCTP Secretariat) which has implemented efficiently the EDCTP2 keeping that programme's administrative costs do not exceed 6% of the European Union's financial contribution of EUR 683 million (i.e. EUR 40.98 million). However, as there

1 1

¹¹ Indicative one-off administrative costs associated for the setting up the Joint Undertaking (logistic structures to adapt from Art 185 to Art 187)

¹² Indicative yearly figure based on draft EDCTP2 Annual Activity Report 2019 (Table 41 Comparison of actual and budget for 2019 Administrative costs). Under Article 185, the EDCTP2 administrative direct costs amount covered the expenses incurred by the EDCTP Secretariat in implementing the EDCTP2 programme. The administrative and personnel costs of the initiative will depend on several factors, including the total budget of the initiative.

¹³ Indicative one-off personnel costs associated to the setting up the Joint Undertaking (organisation of selection of personnel, etc.)
¹⁴ The EDCTP2 Interim Evaluation Panel strongly recommended that in addition to the 6% eligible administrative costs, EDCTP be allowed to use the financial contribution from the EU to cover programmatic costs, e.g. costs for analysis and policy-related actions

will be a change of partnership from an Article 185 to an Articled 187 initiative, some limited additional costs would be necessary to set up the Joint Undertaking from the EDCTP Secretariat. These limited additional costs will be compensated by the savings from the simplification of procedures, as the Commission will be part of the decision Board of the JU, which will simplify the adoption of the annual work plans and the JU will be benefiting from the common support of the Horizon Europe for proposal submission, evaluation and selection, as well as other dissemination services like Cordis. In addition, there will be also (training) savings from the possibility to recruit knowledgeable and experienced staff from the current EDCTP2 programme implementing structure that will be progressively closing down.

Annex 4 Analytical Methods

The methodology for each impact assessment is based on the Commission Better Regulation Guidelines¹⁵ to evaluate and compare options with regards to their **efficiency**, **effectiveness and coherence**. This is complemented by integrating the **conditions and selection criteria for European Partnerships**, as well as requirements for setting up Institutionalised Partnerships.¹⁶

4. Overview of the methodologies employed

In terms of **methods and evidence used**, the set of impact assessments for all candidate Institutionalised European Partnerships draw on an external study covering all initiatives in parallel to ensure a high level of coherence and comparability of analysis¹⁷.

All impact assessments mobilised a mix of qualitative and quantitative data collection and analysis methods. These methods range from desk research and interviews to the analysis of the responses to the Open Consultation, stakeholder analysis and composition/portfolio analysis, bibliometrics/patent analysis and social network analysis, and a cost-effectiveness analysis.

The first step in the impact assessment studies consisted in the definition of the context and the problems that the candidate partnerships are expected to solve in the medium term or long run. The main data source in this respect was desk research. This includes grey and academic literature to identify the main challenges in the scientific and technologic fields and in the economic sectors relevant for the candidate partnerships, as well as the review of official documentations on the policy context for each initiative.

In the assessment of the problems to address, the lessons to be learned from past and ongoing partnerships were taken into account, especially from relevant midterm or ex-post evaluations.

The description of the context of the candidate institutionalised European Partnerships required a good understanding of the corresponding research and innovation systems and their outputs already measured. Data on past and ongoing Horizon 2020 projects, including the ones implemented through Partnerships, served as basis for descriptive statistic of the numbers of projects and their respective levels of funding, the type of organisations participating (e.g. universities, RTOs, large enterprises, SMEs, public administrations, NGOs, etc.) and how the funding was distributed across them. Special attention was given to analysing the participating countries (and groups of countries, such as EU, Associated Countries, EU13 or EU15) and industrial sectors, where relevant. The sectoral analysis required enriching the eCORDA data received from the European Commission services with sector information extracted from ORBIS, using the NACE codification up to level 2. These data enabled the identification of the main and, where possible, emerging actors in the relevant systems, i.e. the organisations, countries and sectors that would need to be involved (further) in a new initiative.

¹⁵ European Commission (2017), Better Regulation Guidelines (SWD (2017) 350)

¹⁶ A pivotal element of the present analysis is the so-called two-step 'necessity test' for European Partnerships, used to establish: step 1) the need for a partnership approach in the first place, followed by step 2) a justification for the form of Institutionalised Partnership. The necessity test is described in Annex 6. This impact assessment focuses on the second step of the test.

¹⁷ Technopolis Group (2020), Impact Assessment Study for Institutionalised European Partnerships under Horizon Europe.

A Social Network Analysis was performed by the contractors using the same data. It consisted in mapping the collaboration between the participants in the projects funded under the ongoing R&I partnerships. This analysis revealed which actors – broken down per type of stakeholders or per industrial sector – collaborate the most often together, and those that are therefore the most central to the relevant research and innovation systems.

The data provided finally served a bibliometric analysis run by the contractor aimed at measuring the outputs (patents and scientific publications) of the currently EU-funded research and innovation projects. A complementary analysis of the Scopus data enabled to determine the position and excellence of the European Union on the international scene, and identify who its main competitors are, and whether the European research and innovation is leading, following or lagging behind.

A cost modelling exercise was performed in order to feed into the efficiency assessments of the partnership options.

The conclusions drawn from the data analysis were confronted to the views of experts and stakeholders collected via three means:

- The comments to the inception impact assessments of the individual candidate institutionalised European Partnerships;
- The open public consultation organised by the European Commission from September to November 2019;
- The interviews (up to 50) conducted by each impact assessment study team conducted between August 2019 and January 2020 (policymakers, business including SMEs and business associations, research institutes and universities, and civil organisations, among others).

The views of stakeholders (and experts) were particularly important for determining the basic functionalities (see further below) that the future partnerships need to demonstrate to achieve their objectives as well as their most anticipated scientific, economic and technological, and societal impacts. The interviews allowed more flexibility to ask the respondents to reflect about the different types of European Partnerships. Furthermore, as a method for targeted consultation, it was used to get insights from the actors that both the Study Teams and the European Commission were deemed the most relevant. For the comparative assessment of impacts, the external contractors confronted the outcomes of the different stakeholder consultation exercises to each other with a view of increasing the validity of their conclusions, in line with the principles of triangulation.

Annex 2 includes also the main outcomes of the stakeholder consultation exercises.

5. Method for assessing the effectiveness, efficiency and coherence of each option - The use of functionalities

Given the focus of the impact assessment on comparing different forms of implementation, the Better Regulation framework has been adapted to introduce "key functionalities needed" – so as to link the intended objectives of the candidate European Partnerships and what would be crucial to achieve them *in terms of implementation*. The identification of "key functionalities needed" for each initiative as an additional step in the impact assessment is based on the distinguishing factors between the different options (see Section 2.2.1 in the main body of the impact assessment). In practical terms, each option is assessed on the basis

of the degree to which it would allow for the key needed functionalities to be covered, as regards e.g. the type and composition of actors that can be involved ('openness'), the range of activities that can be performed (including additionality and level of integration), the level of directionality and integration of R&I strategies; the possibilities offered for coherence and synergies with other components of Horizon Europe, including other Partnerships (internal coherence), and the coherence with the wider policy environments, including with the relevant regulatory and standardisation framework (external coherence). This approach guides the identification of discarded options. It also allows for a structured comparison of the options as regards their effectiveness, efficiency and coherence, and also against a set of other key selection criteria for European Partnerships (openness, transparency, directionality)¹⁸.

Figure 29: Overview of key functionalities of each form of implementation of European Partnerships

Baseline: Horizon Europe calls	Option 1: Co- programmed	Option 2: Co- funded	Option 3.1: Institutionalised Article 185	Option 3.2: Institutionalised Article 187				
Type and composition of actors (including openness and roles)								
Partners: N.A., no common set of actors that engage in planning and implementation Priority setting: open to all, part of Horizon Europe Strategic planning Participation in R&I activities: fully open in line with standard Horizon Europe rules	Partners: Suitable for all types: private and/or public partners, foundations Priority setting: Driven by partners, open stakeholder consultation, MS in comitology Participation in R&I activities: fully open in line with standard Horizon Europe rules	Partners: core of national funding bodies or governmental research organisations Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: limited, according to national rules of partner countries	Partners: National funding bodies or governmental research organisation Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: fully open in line with standard Horizon Europe rules, but possible derogations	Partners: Suitable for all types: private and/or public partners, foundations Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: fully open in line with standard Horizon Europe rules, but possible derogations				
	ctivities (including add	 itionality and level of	 integration)	delogations				
Activities: Horizon Europe standards that allow broad range of individual actions Additionality: no additional activities and investments outside the funded projects Limitations: No systemic approach beyond individual actions Directionality	Activities: Horizon Europe standard actions that allow broad range of individual actions, support to market, regulatory or policy/ societal uptake Additionality: Activities/investment s of partners, National funding Limitations: Limited systemic approach beyond individual actions.	Activities: Broad, according to rules/programmes of participating States, State-aid rules, support to regulatory or policy/ societal uptake Additionality: National funding Limitations: Scale and scope depend on the participating programmes, often smaller in scale	Activities: Horizon Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to systemic approach Additionality: National funding	Activities: Horizon Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to systemic approach (portfolios of projects, scaling up of results, synergies with other funds. Additionality: Activities/investments of partners/ national funding				

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¹⁸ The criterion on the ex-ante demonstration of partners' long term commitment depends on a series of factors that are unknown at this stage, and thus fall outside the scope of the analysis.

Baseline: Horizon Europe calls	Option 1: Coprogrammed	Option 2: Co- funded	Option 3.1: Institutionalised Article 185	Option 3.2: Institutionalised Article 187
Priority setting: Strategic Plan and annual work programmes, covering max. 4 years. Limitations: Fully taking into account existing or to be developed SRIA/roadmap	Priority setting: Strategic R&I agenda/ roadmap agreed between partners and COM, covering usually 7 years, including allocation of Union contribution Input to FP annual work programme drafted by partners, finalised by COM (comitology) Objectives and commitments are set in the contractual arrangement.	Priority setting: Strategic R&I agenda/ roadmap agreed between partners and COM, covering usually 7 years, including allocation of Union contribution Annual work programme drafted by partners, approved by COM Objectives and commitments are set in the Grant Agreement.	Priority setting: Strategic R&I agenda/ roadmap agreed between partners and COM, covering usually 7 years, including allocation of Union contribution Annual work programme drafted by partners, approved by COM Objectives and commitments are set in the legal base.	Priority setting: Strategic R&I agenda/ roadmap agreed between partners and COM, covering usually 7 years, including allocation of Union contribution Annual work programme drafted by partners, approved by COM (veto-right in governance) Objectives and commitments are set in the legal base.
Coherence: internal industrial strategies	(Horizon Europe) and	external (other Union	programmes, national	programmes,
Internal: Between different parts of the Annual Work programme can be ensured by COM External: Limited for other Union programmes, no synergies with national/regional programmes and activities	Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Limited synergies with other Union programmes and industrial strategies If MS participate, with national/ regional programmes and activities	Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Synergies with national/ regional programmes and activities	Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Synergies with national/regional programmes and activities	Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Synergies with other Union programmes and industrial strategies If MS participate, with national/regional programmes and activities

In line with the Better Regulation Framework, the assessment of the effectiveness, efficiency and coherence of each option is made in comparison to the baseline. Therefore, for each of the above criteria, the performance of using traditional calls under Horizon Europe is first estimated and scored 0 to serve as a reference point. When relevant, this estimation also includes the costs/benefits of discontinuing existing implementation structures. The policy options are then scored compared to the baseline with a + and – system along a two-point scale, to indicate limited (+ or -) or high (++ or --) additional/lower performance compared to the baseline. When a policy option is scored 0, this means that its impact is expected to be roughly equal to the baseline option.

On the basis of the evidence collected, the intervention logic of each initiative and the key functionalities needed, the impact assessments first evaluate the **effectiveness** of the various policy options to deliver on their objectives. To be in line with the Horizon Europe impact

framework, the fulfilment of the specific objectives of the initiative is translated into 'expected impacts' - how success would look like -, differentiating between scientific, economic/ technological, and societal (including environmental) impacts. Each impact assessment considers to which extent the different policy options provides the 'key functionalities needed' to achieve the intended objectives. The effectiveness assessment does not use a compound score but shows how the options would deliver on the different types of expected impacts. This is done to increase transparency and accuracy in the assessment of options¹⁹.

A similar approach is followed to evaluate the coherence of options with the overarching objectives of the EU's R&I policy, and distinguishes between **internal** and **external coherence**. Specifically, internal coherence covers the consistency of the activities that could be implemented with the rest of Horizon Europe, including European Partnerships (any type). External coherence refers to the potential for synergies and/or complementarities (including risks of overlaps/gaps) of the initiative with its external environment, including with other programmes under the MFF 2021-27, but also the framework conditions at European, national or regional level (incl. regulatory aspects, standardisation).

To compare the expected costs and benefits of each option (efficiency), the thematic impact assessments broadly follow a cost-effectiveness approach²⁰ to establish to which extent the intended objectives can be achieved for a given cost. A preliminary step in this process is to obtain a measure of the expected costs of the policy options, to be used in the thematic assessments. As the options correspond to different implementation modes, relevant cost categories generally include the costs of setting-up and running an initiative. For instance, setup costs includes items such as the preparation of a European Partnership proposal and the preparation of an implementation structure. The running costs include the annual work programme preparation costs. Where a Partnership already exists, discontinuation costs and cost-savings are also taken into account²¹. The table below provides an overview of the cost categories used in the impact assessment and a qualitative scoring of their intensity when compared to the baseline option (traditional calls). Providing a monetised value for these average static costs would have been misleading, because of the different features and needs of each candidate initiative.²² The table shows the overall administrative, operational and coordination costs of the various options. These costs are then put into context in the impact assessments to reflect the expected co-financing rates and the total budget available for each of the policy options, assuming a common Union contribution (cost-efficiency):

• The costs related to the baseline scenario (traditional calls under Horizon Europe) are pre-dominantly the costs of implementing the respective Union contribution via calls and project, managed by the executive agencies (around 4%, efficiency of 96% for the

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¹⁹ In the thematic impact assessments, scores are justified in a detailed manner to avoid arbitrariness and spurious accuracy. A qualitative or even quantitative explanation is provided of why certain scores were given to specific impacts, and why one option scores better or worse than others.

²⁰ For further details, see Better Regulation Toolbox # 57.

²¹ Discontinuation costs will bear winding down and social discontinuation costs and vary depending on e.g. the number of full-time-equivalent (FTEs) staff concerned, the type of contract (staff category and duration) and applicable rules on termination (e.g. contracts under Belgian law or other). If buildings are being rented, the cost of rental termination also apply. As rental contracts are normally tied to the expected duration of the current initiatives, these termination costs are likely to be very limited. In parallel, there would also be financial cost-savings related to the closing of the structure, related to operations, staff and coordination costs in particular. This is developed further in the individual efficiency assessments.

²² A complete presentation of the methodology developed to assess costs as well as the sources used is described in the external study supporting this impact assessment (Technopolis Group, 2020).

- overall investment).
- For a Co-Programmed partnership the costs of preparation and implementation increase only marginally compared to the baseline (<1%),²³ but lead to an additional R&I investment of at least the same amount than the Union contribution²⁴ (efficiency of 98% for the overall investment).
- For a Co-Funded partnership the additional R&I investment by Member States accounts for 2,3 times the Union contribution²⁵. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the national programmes, can be estimated at 6% of the Union contribution (efficiency of 98% related to the overall investment).²⁶
- For an Article 185 initiative the additional R&I investment by Member States is equal to the Union contribution²⁷. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the dedicated implementation structure, can be estimated at 7% of the Union contribution (efficiency of 96% related to the overall investment).
- For an Article 187 initiative the additional R&I investment by partners is equal to the Union contribution²⁸. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the dedicated implementation structure, can be estimated at 9% of the Union contribution (efficiency of 94% related to the overall investment).

Figure 30 - Intensity of additional costs compared with Horizon Europe Calls (for Partners, stakeholders, public and EU)

Cost items	Baseline: traditional calls	Option 1: Coprogrammed	Option 2 Co-funded	Option 3a - Art. 185	Option 3b -Art. 187
Preparation and set-up costs					
Preparation of a partnership proposal (partners and EC)	0	$\uparrow \uparrow$			
Set-up of a dedicated implementation structure	0			Existing: ↑ New: ↑↑	Existing: ↑↑ New: ↑↑↑
Preparation of the SRIA / roadmap	0	$\uparrow \uparrow$			
Ex-ante Impact Assessment for partnership	0			$\uparrow \uparrow \uparrow$	
Preparation of EC proposal and negotiation	0			$\uparrow \uparrow \uparrow$	
Running costs (Annual cycle of implementa	ition)				
Annual Work Programme preparation	0	\uparrow			
Call and project implementation	0	0 In case of MS	↑	↑	↑

²³ Specifically, some additional set-up costs linked for example to the creation of a strategic research and innovation agenda (SRIA) and additional running costs linked with the partners role in the creation of the annual work programmes and the Commission's additional supervisory responsibilities. A CPP will have lower overall costs than each of the other types of European Partnership, as it will function with a smaller governance and implementation structure than will be required for a Co-Funded Partnership or an Institutionalised Partnership and – related to this – its calls will be operated through the existing HEU agencies and RDI infrastructure and systems.

²⁴ Minimum contributions from partners equal to the Union contribution.

²⁵ Based on the default funding rate for programme co-fund actions of 30%, partners contribute with 70% of the total investment.

²⁶ These costs reflect set-up costs and additional running costs for partners, and the Commission, of the distributed, multi-agency implementation model.

²⁷ Based on the minimum requirement in the legal basis that partners contribute at least 50% of the budget.

²⁸ Based on the minimum requirement in the legal basis that partners contribute at least 50% of the budget.

Cost items	Baseline: traditional calls	Option 1: Co- programmed	Option 2 Co-funded	Option 3a - Art. 185	Option 3b -Art. 187
		contributions: ↑			
Cost to applicants	Comparable, unless there are strong arguments of major differences oversubscription				fferences in
Partners costs not covered by the above	0	\uparrow	0	↑	↑
Additional EC costs (e.g. supervision)	0	\uparrow	↑	↑	$\uparrow \uparrow$
Winding down costs					
EC	0				$\uparrow\uparrow\uparrow$
Partners	0	\uparrow	0	↑	↑

Notes: 0: no additional costs, as compared with the baseline; \uparrow : minor additional costs, as compared with the baseline; $\uparrow \uparrow$: medium additional costs, as compared with the baseline; $\uparrow \uparrow \uparrow$: higher costs, as compared with the baseline.

The cost categories estimated for the common model are then used to develop a scorecard analysis and further refine the assessment of options for each of the 12 candidate Institutionalised Partnerships. Specifically, the scores related to the set-up and implementation costs are used in the thematic impact assessments to consider the scale of the expected benefits and thereby allow a simple "value for money" analysis (**cost-effectiveness**). In carrying out the scoring of options, the results of fieldwork, desk research and stakeholder consultation undertaken and taken into account.

6. Method for identifying the preferred option – The scorecard analysis

For the **identification of the preferred option**, a scorecard analysis is used to build a hierarchy of the options by individual criterion and overall in order to identify a single preferred policy option or in case of an inconclusive comparison of options, a number of 'retained' options or hybrid. This exercise supports the systematic appraisal of alternative options across multiple types of monetary, non-monetary and qualitative dimensions. It also allows for easy visualisation of the pros and cons of each option. Each option is attributed a score of the adjudged performance against each criterion with the three broad appraisal dimensions of effectiveness, efficiency and coherence.

This scorecard approach also relies on a standard cost model developed for the external study supporting the impact assessment, as illustrated in Figure 31. Specifically, the scores related to the set-up and implementation costs are used in the thematic impact assessments to consider the scale of the expected benefits and thereby allow a simple "value for money" analysis (**cost-effectiveness**). In carrying out the scoring of options, the results of fieldwork, desk research and stakeholder consultation undertaken and taken into account.

These costs essentially refer to the administrative, operational and coordination costs of the various options. The figure shows how the scoring of costs range from a value of 0, in case an option does not entail any additional costs compared to the baseline (traditional calls), to a score of (-) for options introducing limited additional costs relative to the baseline and a score of (-) when substantial additional costs are expected in comparison with the baseline. Should the costs of a policy option be lower than those of the baseline, (+) and (++) are used.

It is considered that while there is a clear gradation in the overall costs of the policy options, the cost differentials are less marked when one takes into account the expected co-financing rates and the total budget available for each of the policy options, assuming a common Union contribution. From this perspective, there are only one or two percentage points that split the most cost-efficient policy options – the baseline (traditional calls) and the Co-Programmed

policy options – and the least cost-efficient – the Institutionalised Partnership option. A score of + is therefore assigned for **cost-efficiency** to the Co-Programmed and Co-Funded options, a score of 0 to the Article 185 option and a score of (-) for the Article 187 Institutionalised Partnership policy option²⁹.

Figure 31: Matrix on 'overall costs' and 'adjusted cost scoring'

	Baseline: Horizon Europe calls	Option 1: Co- programmed	Option 2: Co- funded	Option 3a: Institutionalised 185	Option 3b: Institutionalised 187
Administrative, operational and coordination costs	0	(0)	(-)	()	()
Administrative, operational and coordination costs adjusted per expected co-funding (i.e. cost- efficiency)	0	(+)	(+)	(0)	(-)

Notes: Score 0 = same costs as for the baseline; score (-) = limited additional costs compared to baseline; score (- -) = substantial additional costs compared to baseline.; score (+) = lower costs compared to baseline

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²⁹ The baseline (traditional calls) is scored 0, as explained above.

Annex 5 Subsidiarity Grid

1. Can the Union act? What is the legal basis and competence of the Unions' intended action?

1.1 Which article(s) of the Treaty are used to support the legislative proposal or policy initiative?

This proposal is based on (1) Article 185 TFEU which stipulates that in implementing the multiannual framework programme, the Union may make provision, in agreement with the Member States concerned, for participation in research and development programmes undertaken by several Member States, including participation in the structures created for the execution of those programmes; and (2) Article 187 TFEU according to which the Union may set up joint undertakings or any other structure necessary for the efficient execution of Union research, technological development and demonstration programmes (both Articles are under Title XIX of the TFEU - Research and Technological Development and Space).

The proposal aims to implement Article 8 of the Commission proposal for Horizon Europe the future EU research and innovation (R&I) programme for 2021-2027, according to which, "European Partnerships shall be established for addressing European or global challenges only in cases where they will more effectively achieve objectives of Horizon Europe than the Union alone and when compared to other forms of support of the Framework programme". The Horizon Europe proposal has received the political agreement of the Council and the European Parliament.

1.2 Is the Union competence represented by this Treaty article exclusive, shared or supporting in nature?

Research is a shared competence between the EU and its Member States according to the TFEU. Article 4 (3) specifies that in the areas of research, technological development and space, the European Union can carry out specific activities, including defining and implementing programmes, without prejudice to the Member States' freedom to act in the same areas.

Subsidiarity does not apply for policy areas where the Union has **exclusive** competence as defined in Article 3 TFEU³⁰. It is the specific legal basis which determines whether the proposal falls under the subsidiarity control mechanism. Article 4 TFEU³¹ sets out the areas where competence is shared between the Union and the Member States. Article 6 TFEU³² sets out the areas for which the Unions has competence only to support the actions of the Member States.

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³⁰ https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12008E003&from=EN

https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12008E004&from=EN https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12008E006:EN:HTML

2. Subsidiarity Principle: Why should the EU act?

2.1 Does the proposal fulfil the procedural requirements of Protocol No. 2³³:

- Has there been a wide consultation before proposing the act?
- Is there a detailed statement with qualitative and, where possible, quantitative indicators allowing an appraisal of whether the action can best be achieved at Union level?

This proposal and the accompanying impact assessment were supported by a wide consultation of stakeholders, both during the preparation of the Horizon Europe proposal and - later on, all the candidates for European Partnerships. Member States were consulted via the Shadow Strategic configuration of the Horizon Europe Programme Committee. On candidates for institutionalised Partnerships based on Article 185/187 of the TFEU, an Open Public Consultation (OPC) was held between 11 September and 6 November 2019. Over 1 600 replies were received. In addition, targeted consultation activities were undertaken to prepare the present impact assessment. In particular, for each of the candidate partnerships, an external consultant interviewed a representative sample of stakeholders. The need for EU action as well as its added value were covered in those interviews.

The explanatory memorandum and the impact assessment (horizontal part, Section 3) contain a dedicated section on the principle of subsidiarity, as explained in question 2.2 below.

2.2 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the conformity with the principle of subsidiarity?

The impact assessment accompanying the proposal features a horizontal part on relevant common elements to all the candidate partnerships, including the conformity of the proposed initiative with the principle of subsidiarity (Section 3). Moreover, the individual assessments of each candidate partnership include additional details on subsidiarity, touching in particular on the specificities of a candidate partnership that could not be adequately reflected in the horizontal part of the impact assessment. This will also be reflected in the explanatory memorandum.

2.3 Based on the answers to the questions below, can the objectives of the proposed action be achieved sufficiently by the Member States acting alone (necessity for EU action)?

National action alone cannot achieve the scale, speed and scope of support to R&I needed for the EU to meet its long-term Treaty objectives, to deliver on the EU's strategic policy priorities (including the climate and energy goals set out in the Paris Agreement, and the European Green Deal), and to contribute to tackling global challenges and meeting the

Sustainable Development Goals (SDGs).

(a) Are there significant/appreciable transnational/cross-border aspects to the problems being tackled? Have these been quantified?

The thematic areas covered by the candidate partnerships feature a series of challenges in terms of cross-border/transnational aspects, need to pool resources, need for a critical mass to meet intended policy objectives, need to coordinate different types of actors (e.g. academia, industry, national and regional authorities) across different sectors of the economy and society, which cannot be tackled to the same degree by Member States alone. This is particularly true for the research and innovation (R&I) dimension of the proposed initiative: the importance of a multi-centre and interdisciplinary approach, cross-country data collection and research, and the need to develop and share new knowledge in a timely and coordinated manner to avoid duplication of efforts are key to achieve high quality results and impact. The Interim Evaluation of Horizon 2020 and the impact assessment of Horizon Europe provide extensive qualitative and quantitative evidence on the above points. In addition, Sections 1 and 2 of the individual impact assessments on the candidate partnerships include more detail on the necessity to act at EU-level in specific thematic areas. Finally, it is worth noting that not all Member States have the same capacity or R&I intensity to act on these challenges. As the desired policy objectives can be fully achieved only if the intended benefits are widespread across the Member States, this requires action at the EU-level.

(b) Would national action or the absence of the EU level action conflict with core objectives of the Treaty³⁴ or significantly damage the interests of other Member States?

As per Article 4(3) TFEU, national action does not conflict with core objectives of the Treaty in the area of R&I. The absence of EU level action in this area would however prevent the achievement of core objectives of the Treaty. Indeed, national action alone cannot achieve the scale, speed and scope of support to R&I needed for the EU to meet its long-term Treaty objectives on e.g. competitiveness, to deliver on the EU's strategic policy priorities, and to contribute to tackling global challenges and meet the Sustainable Development Goals (SDGs).

(c) To what extent do Member States have the ability or possibility to enact appropriate measures?

As foreseen by Article 4(3) TFEU, this proposal does not hamper Member States' ability to enact appropriate measures in the field of R&I. However, the scale and complexity of the policy objectives pursued by the present initiative cannot be fully addressed by acting at national level alone.

(d) How does the problem and its causes (e.g. negative externalities, spill-over effects)

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³⁴ https://europa.eu/european-union/about-eu/eu-in-brief en

vary across the national, regional and local levels of the EU?

As described in the horizontal part of the impact assessment accompanying the present proposal, several problems (e.g. on competitiveness, global challenges, demographic change) and their underlying causes affect the EU as a whole rather than individual Member States. Where important differences between Member States are present, these are described in Sections 1 and 2 of the individual impact assessments.

(e) Is the problem widespread across the EU or limited to a few Member States?

The problem of coordinating R&I efforts in the thematic areas covered by the candidate partnerships affects all Member States, albeit to different degrees. However, from a general EU perspective, available evidence shows that the EU as a whole needs to step up efforts and investments in thematic areas that are crucial to tackle present and future policy challenges on several fronts, e.g. ageing population, global technological trends, and climate change to name a few. The way these problems affect the EU and its Member States is described in the horizontal part of the impact assessment and in Sections 1 and 2 of the individual impact assessments.

(f) Are Member States overstretched in achieving the objectives of the planned measure?

As indicated in the horizontal part of the impact assessment and in Sections 1 and 2 of the individual assessments, the sheer scale, speed and scope of the needed support to R&I would overstretch national resources, without guaranteeing the achievement of the intended objectives. Acting at EU-level would achieve greater impact in a more effective and efficient manner.

(g) How do the views/preferred courses of action of national, regional and local authorities differ across the EU?

No specific differences between the views of national, regional and local authorities emerged from the stakeholder consultation.

2.4 Based on the answer to the questions below, can the objectives of the proposed action be better achieved at Union level by reason of scale or effects of that action (EU added value)?

EU funded R&I activities, including those covered by the present proposal, produce demonstrable benefits compared to the corresponding national and regional initiatives, due to the scale, speed and scope achievable by acting at the EU level. In addition, the proposed initiatives should be seen as complementary and reinforcing national and sub-national initiatives in the same area.

(a) Are there clear benefits from EU level action?

Quantitative and qualitative evidence of the benefits of EU level action are available in the interim evaluation of Horizon 2020 and in the impact assessment of Horizon Europe, among others. An analysis of the emerging challenges in each thematic areas, of the EU's competitive positioning, as well as feedback gathered from different types of stakeholders for the present impact assessment indicate that EU level action remains appropriate also for the present proposal. In addition, the benefits of acting at EU-level have been illustrated by the success and the impact achieved by the predecessors to the proposed initiative.

(b) Are there economies of scale? Can the objectives be met more efficiently at EU level (larger benefits per unit cost)? Will the functioning of the internal market be improved?

EU funded R&I activities, including those covered by the present proposal, produce demonstrable benefits compared to the corresponding national and regional initiatives, due to the scale, speed and scope achievable by acting at the EU level. This is the case both in terms of effectiveness in achieving intended policy objectives, but also in terms of efficiency. Positive impact is also visible in terms of competitiveness: recent data on EU funded R&I activities indicate that EU-funded teams grow 11.8% faster and are around 40% more likely to be granted patents or produce patents applications than non-EU funded teams. Efficiency gains are also visible in terms of dissemination of results to users beyond national borders, including SMEs and citizens. EU funded R&I is more effective in leveraging private investment. Finally, there are clear additionality benefits (i.e. EU R&I funding does not displace or replace national funding), as the EU focuses on projects that are unlikely to be funded at national or regional level. Overall, this is beneficial to the functioning of the internal market in several respects, including human capital reinforcement through mobility and training, the removal of barriers to cross-border activity for economic players including SMEs, easier access to finance and to relevant knowledge and research, and increased competition in the area of R&I.

(c) What are the benefits in replacing different national policies and rules with a more homogenous policy approach?

A homogeneous policy approach in the various thematic areas covered by the present proposal would reduce fragmentation and increase efficiency and effectiveness in meeting the intended policy objectives. Indeed fragmentation, persisting barriers in the internal market and differences in the resources available to Member States are some of the key problems that stand in the way of fully achieving the intended policy objectives and reaching the required critical mass to obtain tangible results. Specific detail on how these issues differ in each thematic area are illustrated in Sections 1 and 2 of the individual impact assessments, so as to reflect the specificities of each case.

(d) Do the benefits of EU-level action outweigh the loss of competence of the Member States and the local and regional authorities (beyond the costs and benefits of acting at

national, regional and local levels)?

The proposed initiative does not lead to a loss of competence of the Member States. In fact, the proposed initiative should be seen as complementary and reinforcing national and subnational initiatives in the same area. Previous quantitative and qualitative assessments of Horizon Europe and Horizon 2020 have shown that the proposed EU-level action do not displace national ones and tend to concentrate on initiatives that would not have been funded by the Member States themselves, or would not have reached the same scale and ambition without EU-level intervention, due to their complexity and trans-national nature.

(e) Will there be improved legal clarity for those having to implement the legislation?

Yes. The proposed initiatives will be implemented in line with the Horizon Europe single set of rules for participation; this will ensure increased clarity and legal certainty for end beneficiaries, other stakeholders and programme administrators. It will also reduce the administrative burden for beneficiaries, and for the Commission services. In addition, the accessibility and attractiveness of the broader Horizon Europe programme, in particular for applicants with limited resources, would be sustained.

3. Proportionality: How the EU should act

3.1 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the proportionality of the proposal and a statement allowing appraisal of the compliance of the proposal with the principle of proportionality?

The principle of proportionality underpins the entire analysis of the candidate partnerships. Specifically, the analysis included in the accompanying impact assessment is structured along the following logic: 1. Justification of the use of a partnership approach in a given area (including considerations on additionality, directionality, link with strategic priorities) instead of other forms of intervention available under Horizon Europe; 2. If the partnership approach is deemed appropriate, proportionality considerations guide the assessment of which type of partnership intervention (collaborative calls, co-programmed, co-funded or institutionalised partnership) is most effective in achieving the objectives. This will also be reflected in the explanatory memorandum.

3.2 Based on the answers to the questions below and information available from any impact assessment, the explanatory memorandum or other sources, is the proposed action an appropriate way to achieve the intended objectives?

The proposed initiative only focuses on areas where there is a demonstrable advantage in acting at the EU-level due to the scale, speed and scope of the efforts needed for the EU to meet its long-term Treaty objectives and deliver on its strategic policy priorities and commitments. In addition, the present proposal leaves full freedom to the Member States to

pursue their own actions in the policy areas concerned. This will also be reflected in the explanatory memorandum.

(a) Is the initiative limited to those aspects that Member States cannot achieve satisfactorily on their own, and where the Union can do better?

The proposed initiative only focuses on areas where there is a demonstrable advantage in acting at the EU-level due to the scale, speed and scope of the efforts needed for the EU to meet its long-term Treaty objectives and deliver on its strategic policy priorities and commitments.

(b) Is the form of Union action (choice of instrument) justified, as simple as possible, and coherent with the satisfactory achievement of, and ensuring compliance with the objectives pursued (e.g. choice between regulation, (framework) directive, recommendation, or alternative regulatory methods such as co-legislation, etc.)?

For each of the candidate partnerships, the analysis carried out in the accompanying impact assessment has explored several options for implementation. A comparative assessment of the merits of each option also included an analysis of the simplicity of the intervention, its proportionality and effectiveness in achieving the intended objectives. This is reflected in the fact that a tailored approach has been suggested for each candidate partnership, ranging from looser forms of cooperation to more institutionalised ones, depending on the intended policy objectives, specific challenges, and desired outcome identified in each case.

(c) Does the Union action leave as much scope for national decision as possible while achieving satisfactorily the objectives set? (e.g. is it possible to limit the European action to minimum standards or use a less stringent policy instrument or approach?)

The proposed approach leaves full freedom to the Member States to pursue their own actions in the policy areas covered by the present proposal.

(d) Does the initiative create financial or administrative cost for the Union, national governments, regional or local authorities, economic operators or citizens? Are these costs commensurate with the objective to be achieved?

The proposed initiatives do create financial and administrative costs for the Union, national governments and, depending on the chosen mode of implementation, for regional and local authorities. In addition, economic operators and other stakeholders potentially involved in the candidate partnerships will also incur some costs linked to implementation. The financial cost of the proposed initiative is covered under the Horizon Europe programme. Its exact amount is still subject to political decision. As regards the candidate partnerships and the different modes of implementation (co-programmed, co-funded, institutionalised), the relevant costs and benefits are assessed in the individual impact assessments covering each candidate partnership. The additional administrative costs of implementation via partnerships are

limited, when compared to the administrative costs of implementation through traditional calls. As indicated by comparable experience with previous initiatives and in feedback provided by a variety of stakeholders, these costs are expected to be fully justified by the benefits expected from the proposed initiative. Where available, additional details on costs are provided in Annex 3 of the impact assessment.

(e) While respecting the Union law, have special circumstances applying in individual Member States been taken into account?

Where relevant, differences between Member States in capacity and stage of advancement of R&I in specific thematic areas have been taken into account in the individual impact assessments.

Annex 6 Additional background information

1. BACKGROUND INFORMATION FOR ALL INITIATIVES

1.1. Selection criteria of European Partnerships

Partnerships based on Article 185 and 187 TFEU shall be implemented only where other parts of the Horizon Europe programme, including other forms of European Partnerships would not achieve the objectives or would not generate the necessary expected impacts, and if justified by a long-term perspective and high degree of integration. At the core of this impact assessment is therefore the need to demonstrate that the impacts generated through a Partnership approach go beyond what could be achieved with traditional calls under the Framework Programme – the Baseline Option. Secondly, it needs to assess if using the Institutionalised form of a Partnership is justified for addressing the priority.

The necessity test for a European Partnership (as set out in the Horizon Europe regulation) has two levels:

- 1. The justification for implementing a priority with a European Partnership to address Horizon Europe and EU priorities. This is linked to demonstrating that a European Partnership can produce added value beyond what can be achieved through other Framework Programme modalities, notably traditional calls in the work programmes (Option 0 Baseline).
- 2. The justification for the use of the form of Institutionalised Partnership: Once it has been demonstrated that a partnerships approach is justified, co-programmed and/or co-funded forms are considered for addressing the priorities as they are administratively lighter, more agile and easier to set-up (Options 1 and/or 2). As Institutionalised Partnerships require setting up a legal framework and the creation of a dedicated implementation structure, they have to justify higher set-up efforts by demonstrating that it will deliver the expected impacts in a more effective and efficient way, and that a long-term perspective and high degree of integration is required (Option 3).

The outcomes of the 'necessity test' is presented together with the preferred option.

Figure 32: Horizon Europe selection criteria for the European Partnerships

Common selection criteria & principles	Specifications
1. More effective (Union added value) clear	Delivering on global challenges and research and innovation objectives
impacts for the EU and	
its citizens	Securing sustainability
	Contributing to the strengthening of the European Research and Innovation Area
	Where relevant, contributing to international commitments
2. Coherence and	Within the EU research and innovation landscape

Common selection criteria & principles	Specifications
synergies	Coordination and complementarity with Union, local, regional, national and, where relevant, international initiatives or other partnerships and missions
3. Transparency and openness	Identification of priorities and objectives in terms of expected results and impacts
	Involvement of partners and stakeholders from across the entire value chain, from different sectors, backgrounds and disciplines, including international ones when relevant and not interfering with European competitiveness
	Clear modalities for promoting participation of smes and for disseminating and exploiting results, notably by smes, including through intermediary organisations
4. Additionality	Common strategic vision of the purpose of the European Partnership
and directionality	Approaches to ensure flexibility of implementation and to adjust to changing policy, societal and/or market needs, or scientific advances, to increase policy coherence between regional, national and EU level
	Demonstration of expected qualitative and significant quantitative leverage effects, including a method for the measurement of key performance indicators
	Exit-strategy and measures for phasing-out from the Programme
5. Long-term	A minimum share of public and/or private investments
commitment of all the involved parties	In the case of institutionalised European Partnerships, established in accordance with article 185 or 187 TFEU, the financial and/or in-kind, contributions from partners other than the Union, will at least be equal to 50% and may reach up to 75% of the aggregated European Partnership budgetary commitments

1.2. Overview of potential functions for a common back office among Joint Undertakings

Functions	Current situation	Option of joint back- office	Comments
Organising calls for grant and proposal evaluations	Each JU organises this independently.	A central organisation of evaluation, logistics, contracting evaluators, managing the data of the evaluation results Central database of potential evaluators with domain expertise in thematic areas of partnerships	The evaluations would still need to be supervised by the Scientific staff of the individual Joint Undertakings (consensus meetings of expert evaluators etc)
Human Resources related matters	Each JU has own HR policy and resources Quite some resources spent on	More generic resources and expertise for HR matters	Ensuring consistency with EC HR policies is already in place
	recruitment in some JUs Some HR facilities are procured	More consistency in HR policy	

	from external contractors Some JUs have a Service Level Agreement with COM for HR	Shared HR investment for specialised expertise (IP and legal)	
Financial management	Each JU conducts own financial contract management; differences between JUs Each JU is audited separately. Auditing at project level more frequent than in other Horizon 2020 parts and outsourced by JUs thus differences ECA: too many audits on JUs	Financial management by one core team of financial staff Would reduce the number of interfaces for audits and simplifies the auditing of the all JUs Harmonisation of project auditing	Simplifies the harmonisation of financial management across JUs in line with Horizon Europe
Communication (internal and external)	Each JU has a separate communication strategies, teams and resources	A common back-office can support activities such as event organisation, dissemination of results, setting up website communication Can help create a more visible Partnership brand	A considerable share of communication activity is partnership specific (addressing particular target groups, synthesising project results) however there are generic communication activities that can be shared Needs to avoid duplication of efforts
Data management on calls, project portfolios, information on project results	Most JUs but not all use e- Corda for project data Overall IT integration of JUs still difficult	Harmonised data management Reduction of IT systems and support that is procured	This will need to happen regardless of the common back office but will likely be more smooth if managed centrally

2. BACKGROUND INFORMATION FOR THIS SPECIFIC INITIATIVE

2.1. Implementation of the EDCTP2

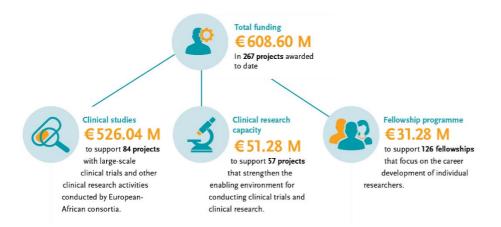
Between 2014 and 2019, the EDCTP2 programme has committed €608.6m funding (as at November 2019). A total of 347 institutions are involved in EDCTP2 projects, including 198 sub-Saharan African institutions and 137 in Europe. In addition, 147 private entities have been involved in EDCTP2 projects, receiving support of EUR 68m, while contributing matching co-funding of a higher amount in-kind through various product development services and supply of investigational products. The number of countries participating in EDCTP2-funded activities has risen to 65 − of which 37 are from Africa, 20 from Europe and eight from elsewhere. A total of 211 clinical studies have been funded, including 123 clinical trials.

The EDCTP2 European Participating States have so far contributed EUR 159.0m in cash to the EDCTP2 programme and EUR 556.3m on Participating States Initiated Activities (in-kind contributions) by the end of 2018. These national activities include 144 clinical studies as well as support for capacity development, ethics and regulatory activities, operational and implementation research, and health systems strengthening. More than 465 publications have been reported as resulting from Participating States Initiated Activities-funded research. Moreover, Participating States have also reported that these activities have resulted in significant policy change and positive influence on national or international guidelines.

EDCTP2 has so far leveraged an additional €300m funding from third parties, including global funders such as the US National Institutes of Health (NIH), philanthropic donors such as the President's Emergency Fund for AIDS Relief (PEPFAR) and the US Agency for International Development (USAID), global funders such as the Bill and Melinda Gates Foundation, Product Development Partnership, such as the TB Alliance and Medicines for Malaria Venture, and pharmaceutical companies.

EDCTP has an integrated approach to capacity development for health research in Africa as a means of ensuring sustainable development of the research environment and increasing its preparedness for conducting clinical research according to ethical principles and regulatory standards. This is done through comprehensive fellowship programmes, 126 African researchers are being supported through fellowships, and more than 6000 have benefited from training opportunities, 57 ethics and regulatory projects have been funded in 27 African countries, including health systems strengthening, pharmacovigilance activities and the translation of research results into policy and practice, also under infectious disease outbreak conditions and through collaborative research networks.

Figure 33: EDCTP2 funding (from January 2014 up to November 2019).



Joint initiatives have been launched with WHO/TDR, Fundacion Mundo Sano-Espana, African Research Excellence Fund and GlaxoSmithKline. Further joint initiatives are planned with the Coalition for Epidemic Preparedness Innovations (CEPI), the Novartis Foundation, Fondation Botnar, and the Africa Centres for Disease Control and Prevention.

EDCTP2 funding has been well spread across priority disease areas, with the greatest number of grants and funding going towards TB projects (Figure 34).

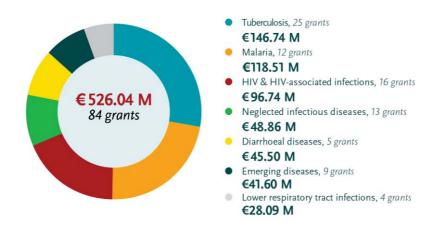


Figure 34 Allocation of EDCTP2 funding up to November 2019.

Of the clinical trials funded, 58% are phase II and III studies of drugs and vaccines, providing key data on safety and efficacy; 16% are phase IV post-licensing studies designed to inform policymaking and practice.

In terms of priority populations, 14% of projects focus on pregnant women and new-born babies, 35% involve children, and 43% adolescents.

2.2. Recommendations of the First Interim Evaluation of the EDCTP2 programme 35

Living up to the potential of EDCTP

- To reach its full potential and the ambitious goals outlined in the Strategic Business Plan, EDCTP should assume a position as a proactive key strategic player and change agent in sub-Saharan Africa. This effort will require a reinvigorated strategic approach not only by EDCTP management but also by the PSs and the EC. The Panel recommends EDCTP to develop a strategic policy plan.
- As a priority, we propose EDCTP catalyse the development and strengthening of national health research plans of African PSs.
- A change in 'mindset' will be required within EDCTP and at the heart of EDCTP, which is the PSs. The establishment of an effective partnership arrangement among PSs needs to be further developed.
- Being part of the EDCTP programme must be viewed as an added value. The Panel thus recommends that EDCTP membership should be a requirement for applying to EDCTP calls.
- EDCTP will need to understand the goals and priorities of PSs and work with them to align EDCTP strategy and programmes. EDCTP should thus actively support the PSs in developing their own national research agendas.
- The Panel views the EDCTP regional networks as a critical element of institutional capacity in sub-Saharan Africa. The strategic role of the EDCTP regional networks should be broadened and clearly defined.
- The EDCTP regional networks should develop a plan that includes a focus on its capacity building activities, with emphasis across the spectrum of scientist career development, and their support of weaker institutions and regions.
- The capacity for active participation in the EDCTP program varies significantly across sub-Saharan Africa. It is important to ensure a more equitable distribution of EDCTP activities and investments so the benefits of EDCTP impact weaker institutions and regions. A strategy must be developed to incentivise wealthier PSs to engage with less resourceful African nations in all EDCTP activities.
- To support the networks in achieving this next phase of their evolution, the level of funding for networks should increase.
- EDCTP should adopt a more comprehensive and catalytic funding approach for supporting the career path of young talented African investigators and to build African scientific leadership. Particular attention should be paid to gender balance.
- EDCTP should assess opportunities in this area to strategically align with other funders and programmes on career development.

Strengthening coherence and added value of the EDCTP programme

- Based on a thorough analysis of existing programmes and active international funders, EDCTP and the EC should jointly explore the opportunities where synergies can be leveraged, and complementary programmes aligned for greater impact and reach.
- EDCTP should develop and/or mobilize a mechanism to attain strategic partnerships.
- The EU would benefit by having a high level strategy across programmes and policies to facilitate alignment, coordination and collaboration where opportunities exist. This approach would be most effective with the appointment of a specific coordinator responsible for coherence among EU initiatives and policies
- The strategic value of the EDCTP target to obtain at least €500M in additional public or private contributions is questionable. The EU should, together with the PSs, reconsider this rather high €500M target so that EDCTP can focus on more relevant aspects of partnerships.

EDCTP visibility and advocacy

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³⁵ http://ec.europa.eu/research/evaluations/pdf/edctp2 evaluation experts report 2017.pdf

- EDCTP should put considerably more focus on external strategic communication and advocacy efforts. The current communication strategy should not only be aimed at delivering information but also become more focused on building relationships and dialogue with PSs' governments and European and International funders and stakeholders. Communication functions and strategies must better reflect the fact that EDCPT2 is a programme that PSs own collectively. Currently, this joint ownership, coordination and support of EDCTP are not evident in programmes or in advocacy and communication efforts. This lack of co-leadership weakens the overall potential and effectiveness of EDCTP2.
- To determinedly implement the communication strategy, the function of strategic communication and advocacy within EDCTP should be elevated to the highest level of leadership. This role within EDCTP will require considerable networking and coordination across PSs to identify synergies and to achieve better alignment and coordination with PSIAs. Closer coordination and planning between the EC leadership and the EDCTP Secretariat and GA will also help to achieve the level of communication and advocacy needed. These coordinated leadership roles will require a mindset change across organizations and individual leaders.
- To achieve the advocacy goals of EDCTP2 to execute the communication strategy, clear objectives, tactics, timelines, and milestones to describe how EDCTP will achieve its advocacy goals is needed. Opportunities to align messaging and programmes with PSs should be prioritized for communications and advocacy.

Improving instruments to advance research in sub-Saharan Africa

- Adopting a portfolio approach: EDCTP should take on a portfolio approach in order to use its funding instruments (including competitive calls) more strategically. This would enhance the value-add of EDCTP and maximize impact.
- EDCTP should adopt a more flexible funding approach that, after careful analysis of the current conditions, would include both broad and more specific calls. The analysis should incorporate considerations of disease burden, the potential for improving health equity and also the global funding landscape.
- Grant Funding Reference Group: In order to ensure high quality and credibility of the grant application process, EDCTP and the EC should jointly initiate an external review of the processes related to funding, including launch of calls, peer-review, evaluation and selection. EDCTP should consider establishing a 'Grant Funding Reference Group' which could mimic the approach already taken by the EC. For example, inviting Independent Observers to assess the peer review process and its implementation (e.g. 1-2 observers for each call). Alternatively, another mechanism could involve members of the research community obtaining information on how the funding strategy and funding instruments are perceived on a regular basis.
- Modifying the process of PSIAs: EDCTP and the EC should jointly modify the entire process
 around PSIAs to improve efficiency and to enhance impact. The aims of PSIAs must be
 articulated with consideration given to how they can be used to enhance strategic value-add of
 both EDCTP and the PSs. A more efficient way to bring in the Participating States' engagement
 in EDCTP, and to effectively obtain the co-funding that is conditional to the EU co-funding,
 should be developed.
- EDCTP should initiate a process for in-depth analysis of the outcome of the activities initiated by the PSs in order to identify synergies, gaps and overlaps. PSIAs should be prospectively and strategically integrated with EDCTP programmes and calls in order to minimize gaps. In addition, PSIAs should be strategically integrated among themselves to efficiently maximize their impact.
- The EC should jointly with EDCTP analyse the possible effects of the United Kingdom's decision to withdraw from the EU and develop mitigating strategies.

Governance for reaching long-term objectives and sustainability

• General Assembly (GA): The EC and EDCTP should jointly define the responsibilities and expectations for both the PSs and their General Assembly representatives.

- The PSs should enhance the executive and political level of GA representatives and ensure that representatives are clear on their responsibility to report back to their respective government agencies that have the mandate to deliver on their governments' commitment to EDCTP.
- Scientific Advisory Committee (SAC): EDCTP must further develop Scientific Advisory Committee and its critical role of providing strategic scientific advice as stated in the EDCTP Decision.
- Strategic Advisory Group: EDCTP should create a separate, Strategic Advisory Group, a high-level strategic group to advise on matters of policy, coherence and partnership to achieve value-add of EDCTP2, to align efforts of EDCTP2 with other significant global funders and with politically driven goals and directions. A strategic policy plan needs to be urgently developed. As a high priority, EDCTP should catalyse the development and strengthening of national health research plans especially for African PSs.
- 3-year work plans: EDCTP and the EC should jointly and urgently review and modify the process of approving the annual work plans so that the entire process is completed prior to the year of operation.
- The process should be changed so that EDCTP submits a 3-year work plan for approval by the EC but with annual milestones that are to be reported and evaluated on an annual basis so that timely adjustments can be made.
- Executive Director: EDCTP should further strengthen the position of the Executive Director by emphasizing his/her role to proactively initiate and implement strategic work and high-level advocacy as well as to engage in long-term planning and sustainability issues. To support the Executive Director, EDCTP should create the position of a Deputy Executive Director. The subsequent recruitment and appointment process should reflect the imperative for an improved gender balance at the high-level management.

Financial contribution

- According to the Terms of Reference, the Panel should also discuss the level of financial contribution to EDCTP2. With effectively two years of data, it is essentially impossible to evaluate this aspect of the programme. Provided that in-kind contributions stay at a level similar to today and provided that PSIAs are effectively and strategically integrated with the EDCTP programme, the current level may be appropriate.
- The Panel strongly recommends that in addition to the 6% eligible administrative costs, EDCTP be allowed to use the financial contribution from the EU to cover programmatic costs, e.g. costs for analysis and policy-related actions

2.3. Actions taken in response to the EDCTP2 Interim Evaluation Recommendations

Recommendation		Recommendation involve	Recommendation involve Actions taken (until March 2020)
Living up to the potential of EDCTP	the	Supporting development and strengthening of national health research plans of African EDCTP2 Participating States	National Health Research Systems (NHRS) assessment has been launched in collaboration with WHO-Afro to establish baseline data for guiding planning to strengthening health research capacity within sub-Saharan Africa: Survey to determine the barometer scores for NHRSs in the 17 African countries that are members of the EDCTP Association (completed, see here) Development of strategies for uptake of survey results (Consultative meeting held on 17-18 October 2019 in Brazzaville, Republic of Congo and on-going).
	1 •	Improving gender ratio and achieving more equitable distribution of activities and funding across countries/	 Improving gender ratio of EDCTP-funded activities: Workshop Enhancing networking among African and European scientists to close regional and gender disparities experienced in EDCTP1 and EDCTP2 funded health research capacity activities in subsaharan Africa (completed Nov 2019)
		regions	• Scientific Advisory Committee working group on gender (activities ongoing) initial report presented to the EDCTP General Assembly (June 2019)
			• Expansion of monitoring efforts to track and analyse gender balance (ongoing, with completed analysis on EDCTP2 Evaluation Procedures and Gender Balance)
			• Independent evaluation of Sida support to EDCTP assessing, among others, gender balance in the areas of research supported by EDCTP ³⁶ (completed)
			Achieving more equitable distribution of activities and funding across SSA countries/ regions:
			• Launch of Senior Fellowships Plus 2019 call aimed to engage less resourced African countries
			 (completed with proposal evaluation ongoing, see here) Independent evaluation of EDCTP Regional Networks activities (completed)³⁷

36 The Sida evaluation concluded that: "The gender balance across projects that have received Sida funding overall is very good. Across different capacity building programmes, the balance has an average of 43% of project staff being female (...) EDCTP are making efforts to address gender issues. This has become more visible in 2018 and 2019 with reviews being commissioned on the make-up of evaluation panels/ the gender dimensions of proposal review processes together with an evaluation of the barriers to female researchers in Africa being commissioned. The Scientific Advisory Committee (SAC) also now has a gender working group. We have not been able to investigate the degree of training given to researchers on gender equality and/or how to design research taking into account gender equality issues. However, at least one project is highly gender aware (PANDORA) and includes gender issues in its research design and evaluation."

³⁷ EDCTP Networks evaluation concluded that the EDCTP Networks are a strong brand with increasing goodwill. It was therefore recommended that in order to sustain the achievements the EDCTP Networks have made to date, it is important that EDCTP continues to financially and operationally support, and politically advocate for their sustainability. Increasing funding would strengthen

		 Three 'grant writing' workshops held in Gabon, Ivory Coast and Mozambique (targeting Portuguese-speaking and French speaking scientists) for young African scientists (completed) with a total of number of 96 participants Funding to large multi-country consortia pursuing inter and intra-regional research cooperation (ongoing projects): Four Regional Networks addressing disparities between SSA countries in terms of clinical research capacity EDCTP; Two epidemic preparedness consortia with governance and management structures organised to promote equitable decision-making and execution of research activities. An EDCTP Alumni Platform³⁸ has been launched to facilitate networking of sub-Saharan Africa researchers and to make the professional profiles of all current and past EDCTP fellows easily accessible. It facilitates reflection and collaboration among them. Working groups on HIV, tuberculosis, malaria, and neglected or emerging infectious diseases have also been established.
Strengthening (internal) coherence and added value of the EDCTP programme	Improving alignment of Participating States activities with EDCTP- centrally managed activities	 Facilitating Participating States to launch joint or aligned activities (e.g. Joint WHO-AFRO/TDR/EDCTP Small Grants Scheme for implementation research on infectious diseases of poverty-funded by Germany, Sweden and the UK Facilitating Participating States in aligning reporting and data sharing: in the UK Department Health Social Care's evidence mapping³⁹, independent evaluation of Sida funding, data sharing initiatives such as GFINDER, World RePORT, and the WHO Global Observatory on Health R&D. Creation of a dedicated webpage with the Analysis of Participating States Initiated Activities (PSIAs) and sharing of information of both centrally managed activities and PSIAs via EDCTP participating states profiles have been done to facilitate easy sharing of information⁴⁰.

clinical trials and researcher support, networking of the Networks, as well as development and implementation of digital platforms, all of which are important for data generation and sharing. Reducing funding would limit EDCTP's contribution to generation of big data and health research ecosystems capacity building broadly, which is invaluable for reducing the burden of the diseases targeted by EDCTP. Stopping the financial support towards the EDCTP Networks would reverse the gains of a model that has so far proved useful for clinical trials capacity building in Africa through North-South and South-South collaborations. Evaluation of the EDCTP Regional Networks Report: http://www.edctp.org/edctp-regional-networks-2015/

³⁸ https://edctpalumninetwork.org/

 $^{^{39}}$ https://eppi.ioe.ac.uk/cms/Default.aspx?tabid=73 $\,$

Strengthening (external) coherence and added value of the EDCTP programme	Strategic partnersh building with oth programmes and inititives	partnership with other and inititives	 Strategic partnership building Launching EDCTP Strategic grant scheme (6 calls completed as part of WPs 2015-2018 resulting in EUR 323.87 M in direct project funding from third-parties (international organisations, industry and private funders) and several collaboration agreements have been concluded with WHO-TDR Special Programme on Research and Training in Tropical Diseases, Mundo Sano Foundation, GSK, Novartis Global Health, Botnar Foundation, Leprosy Foundation. Efforts are underway to finalise a cooperation agreement with WHO-AFRO
			 Two High-level policy dialogue meetings with African States to consult on the EDCTP strategy (Dakar and Lisbon) EDCTP has contributed to strengthening national health research systems (NHRS) The report 'WHO
			(.1
			 WHO fully supports EDCTP's plans to develop a follow up programme and has nominated WHO observers to both the EDCTP Scientific Advisory Committee and General Assembly (WHO Director General's letter of 29 08 2019).
	 Coordination 	Coordination with other EU	Engagement with DG DEVCO and other EU programmes and development agencies: • Appointment of an additional observer at the EDCTP General Assembly, representing DG DEVCO.
	initiatives and na development agencies	and national agencies	• Launch of two strategic calls requiring cofounding from development cooperation agencies: Strategic actions supporting health systems/services optimisation research capacities in cooperation with
			development assistance initiatives (completed with 2 projects ongoing) and Strategic actions to maximise the impact of research on reducing disease burden, in collaboration with development cooperation initiatives (planned as part of work plan 2020)
			• Outreach through active participation events and meetings: DEVCO info point, European Development Days, side meeting at the EU Africa High Level Policy Dialogue
Visibility and advocacy	jc.	communications	• Nomination of two High Level Representatives with a strategic programme each to promote and encourage
	aimed at relationships and	building and dialogue	higher financial commitment and active participation of Participating States in Europe and sub-Saharan Africa.
	with Participating governments and E	with Participating States' governments and European	• Communications strategy has increased focus in involving Participating States' Initiated Activities in the overall EDCTP communication activities.
	and International	ional funders	• Dedicated pages for each Participating State are under preparation for the EDCTP website to presenting
	alla stancilora		their involvement under the EDC1r2 programme. More informative and user-friendly communication resources have been introduced such as: scaled in use
			of interactive online annual reports, case studies summarising ongoing activities and success stories,

⁴¹ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6660673/

			summary documents highlighting the added value of EDCTP to Europe and Africa.
Improving instruments to advance research in sub-Saharan Africa	•	Introducing portfolio funding and diversification of funding approach	 Grant to PAMAfrica consortium to support a portfolio of projects developing new treatments for malaria in the most-at-risk populations (ongoing 5-year project under portfolio funding, see here) Narrow thematic (e.g. malaria vaccine) and fairly broad (e.g. diagnostics) calls launched. There are however, limits to the flexibility of allocation of EU funding, as H2020 rules must be followed, limiting the possibilities of very targeted funding (to a specific organisation or product candidate)
	• H 4 H 0	Establishment of a grant funding reference group involving independent observers	• Involvement of independent observers in call for proposals evaluations, their reports and recommendations are followed up providing quality and transparency (ongoing)
	• I G A	Improving the process of the Participated States Initiated Activities	 Establishing a General Assembly-Scientific Advisory Group Working Group on Participating States Initiated Activities Meetings organized in 2018 and 2019 to improve efficiency and to enhance impact. Draft report presented to the General Assembly of November 2019
	• A O U U U	An in-depth analysis of the outcome of the activities initiated by the PSs to identify synergies, gaps and overlaps	 Mapping and analysis of Participating States Initiated Activities (PSIAs) to identify overlaps and opportunities for synergies with EDCTP-centrally managed activities in relation to the EDCTP2 Strategic Research Agenda (ongoing: Draft report presented to the EDCTP General Assembly Nov. 2019)
Governance for reaching long-term objectives and sustainability	•	Strengthening the role of Scientific Advisory Committee (SAC) in providing strategic (policy) advice to the General Assembly (GA)	 Secretariat restructuring in 2018 (completed) Created position of Executive Governance Officer to facilitate coordination of EDCTP constituencies Two High Level Representatives for Africa and Europe scaled up their work to support the ED on advocacy and fundraising activities The recruitment of current and future members of the SAC takes into account their dual role of providing both scientific and strategic advice The interaction between SAC and GA has been creamformed and thus facilitating the sharing of the interaction between SAC and GA has been creamformed and thus facilitating the sharing of the interaction between SAC and GA has been creamformed.
	Ш 90 δ	Executive Director and gender balance in EDCTP Senior Management	information between the two constituencies.

2.4. Strengths, Weaknesses, Opportunities and Threats of the EDCTP programmes

Strengths

ORGANISATION

- Established a presence and visibility in sub-Saharan Africa
- Covered a key gap in the funding landscape; few other private and public bodies fund large late-stage clinical trials in sub-Saharan Africa
- Supported scientific excellence, with projects generating major publications in high-profile publications
- Focused research activity on underserved populations, addressing key market failures
- · Integrated capacity-building into grants
- Developed African scientific leadership
- · Established new African networks
- Strengthened the regulatory and ethics review capabilities of multiple African countries
- Expanded the range of African countries with capacity to carry out clinical research
- · Facilitated formation of enduring global partnerships

PORTFOLIO

- Impactful HIV studies, particularly prevention of mother-to-child transmission, paediatric HIV treatment
- Influential trials on HIV co-infections, particularly HIV-TB and HIV-malaria co-infections and opportunistic infections (e.g. Cryptococcus)
- · Significant advances in TB diagnostics
- Major studies in TB drug development and vaccine evaluation, with globally important collaborations and innovative trial methodologies
- Landmark studies on malaria treatment during pregnancy, in children, and in co-infected patients
- Capacity developed in malaria vaccine evaluation
- Advances in diagnostics for neglected infectious diseases

Weaknesses

ORGANISATION

- Relatively small player, in terms of funds available per pathogen, compared with some funders in global health research
- General lack of visibility/awareness
- Fewer funding partners than initially envisaged, especially with pharmaceutical companies
- Lack of flexibility in funding approach can be an obstacle to joint initiatives with other funders
- Challenges leveraging additional cash funding from PSs
- Lack of incentives to join EDCTP Association
- Challenges aligning funding strategies of EU PSs
- Lack of support to enable researchers from Frenchand Portuguese-speaking countries with weaker research systems to submit high-quality applications.

PORTFOLIO

- Disappointing results in early microbicide and HIV vaccine trials
- Large range of pathogens covered resulted in limited funding per disease category in EDCTP2 thus far, particularly for the newly incorporated diseases

Opportunities

ORGANISATION

- Enhanced global networking and engaged new partners
- Additional engagement with newer EU 'EU13' Member States
- Alignment with other global health agendas (e.g. outbreak preparedness, antimicrobial resistance, universal health coverage and design of peoplecentred health systems)
- Alignment with other EU initiatives (e.g. other Horizon Europe initiatives, Joint Programming Initiative on Antimicrobial Resistance, Innovative Medicines Initiative).
- Increased synergies and better coordination of the PSs' own contributions to research activities within EDCTP's scope (PSIAs).
- Additional joint funding initiatives and co-funding schemes
- Increased proportion of projects led by African and

Threats

ORGANISATION

- Insufficient funds to support all highly ranked projects
- Expanded scope to include non-communicable diseases or other bigger thematic areas could spread resources too thinly
- Ineffective global collaboration could lead to both duplication of efforts and missed opportunities
- Inappropriate use of funds by recipients could damage confidence and cause reputational harm to EDCTP
- Insufficient funding to support activities of the growing EDCTP Alumni Network and its integration with the EDCTP Regional Networks

PORTFOLIO

 Major disease outbreaks could overwhelm country response capacity and undermine research efforts on priority diseases

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- female researchers
- Increased collaboration among emerging research leaders funded by EDCTP

PORTFOLIO

- Improved pipelines offer more scope for later-phase studies and head-to-head comparisons
- Scope for additional implementation studies and synergy with health system strengthening in pursuit of universal health coverage
- Co-infections and co-morbidities associated with longer survival
- Maternal vaccination
- · Drug repurposing
- · Multiplex diagnostic platforms
- New digital and other technologies, to enhance diagnosis, delivery of interventions and design of people-centred care
- Opportunities for greater multi-disciplinary input, e.g. from social and behavioural sciences, anthropology
- Repurposing of platforms/infrastructure to address new threats, including emerging infectious disease threats and antimicrobial resistance
- Innovative trial designs for faster and more flexible clinical evaluation

- Rising antimicrobial resistance could compromise use of therapeutics
- Civil unrest and conflict could compromise countries' ability to conduct clinical research
- Public rejection of research or experimental interventions could threaten research and implementation
- Major adverse reactions to a new intervention could trigger negative public attitudes to clinical research
- Significant global funding gaps could compromise achievement of challenging global targets
- Insufficient local investment could threater sustainability of newly developed research capacity

2.5. Progress towards EDCTP2's objectives (2014-2019)

Medical interventions



New or improved medical interventions against poverty-related infectious diseases.

217

is the total number of clinical studies supported by EDCTP2 since 2014. Of these, 59% (130) are interventional (clinical trials) and 41% (87) are non-interventional studies.

57% (71)

of interventional studies are phase II and III trials of drugs and vaccines which aim to deliver key evidence on safety and efficacy. The phase III trials also aim to provide data to support product registration.

15% (18)

of the interventional studies involve post-license (phase IV) studies with a view to influencing health policies and practice and optimising the delivery of medical interventions for the wide-range of sub-Saharan health systems and diverse populations.

10% (21)

of all studies target pregnant women and their children. Other key populations are also involved in the studies, such newborns and infants (35;1796), children (64; 31%) and adolescents (60; 2996).

12

sub-Saharan Africa countries host recruitment sites of EDCTP-funded collaborative clinical studies.

Collaboration and capacity development



Increase cooperation with sub-Saharan Africa through capacity building for conducting clinical trials according to ethical principles and regulatory standards.

€51,07 M

is the total grant investment to support 57 projects to strengthen the enabling environment for clinical trials and research in sub-Saharan Africa.

27

sub-Saharan African countries have received EDCTP support for the establishment of functional regulatory systems and capacities for ethical review of clinical research.

€23,43 M

has been invested to support preparedness of 6 sub-Saharan African countries in the fight against Ebola outbreaks.

130

fellowships that focus on the career development of researchers.

42

sub-Saharan African institutions in 28 countries participate in the EDCTPsupported Networks of Excellence: CANTAM (Central Africa), WANETAM (Western Africa), TESA (Southern Africa) and EACCR (Eastern Africa).

7468

people have participated in EDCTP project-related trainings and workshops on topics such as study protocol, specimen collection, research and administration, Good Clinical Practice and epidemics preparedness.

European coordination



Improve coordination, alignment and integration of European National Programmes.

30

researchers from sub-Saharan Africa received funding from the 'Joint WHO AFRO/TDR/EDCTP Small Grants Scheme for implementation research on infectious diseases of poverty launched in 2017, The call was supported through a partnership between Germany, Sweden and the UK.

€158.8 M

the total cash received from the European Participating States to the EDCTP programme.

External partnerships



Increase international cooperation with public and private partners.

16

sub-Saharan African
countries are full members
of the EDCTP Association.
These members have
contributed to a total of
€1.21 million by end of 2018
through the Participating
States' Initiated Activities
(PSIAs) — research activities
within the scope of the
EDCTP programme that are
funded and implemented by
onig or more member
countries.

65

countries participate in EDCTP funded activities: 37 sub Saharan African countries and 20 European countries.

371

institutions are involved in EDCTP projects: 198 sub-Saharan African institutions and 137 European institutions.

57%

of the total EDCTP grant value is allocated to sub-Saharan African institutions (€302 million).

EU cooperation



Increase interaction with other EU initiatives, including those linked to development assistance.

162

private sector entities are involved in EDCTP projects. By end of 2018, these organisations have received 689.26 M in grant value.

1

grant consortia were established through an EDCTP call to support health systems/service optimisation research capacities in cooperation with development assistance. Two of these consortia received funding from international development cooperation partners (SIDA and USAID).

17

EDCTP African member countries participated in a survey to inform the development of a strategic policy plan for strengthening health research system capacities of countries in sub-Saharan Africa. This project is a joint initiative between EDCTP and WHO AFRO.

2.6. Success stories of the EU funding through FPs and EDCTPs programmes

The EU funding has contributed to:

• The generation of new knowledge through development research publications, best practices and guidelines:

As a result of the NeutNET (FP6) project, seven novel and reproducible types of neutralisation assays were developed, thus contributing to the advancement of scientific and medical knowledge and aiding future vaccine research; STOPPAM (FP7) provided valuable information with respect to a revision of the current administration regimen of Intermittent Preventive Therapy in pregnancy, to date the most effective and most widely adopted strategy for combatting pregnancy malaria; IDAMS (FP7) led to advancements in clinical knowledge about variables affecting dengue presence, and developed tools, strategies and treatments in order prevent the spread of dengue. New insights generated by the project led the WHO to revise their estimates of dengue prevalence and guidelines for outbreak protocol

• Development of new drugs, devices, diagnostics, vaccines and vector control methods:

NIDIAG (FP7) successfully developed a new Rapid Diagnostic Test for human African trypanosomiasis, which is now commercially available. CHAPAS (EDCTP) provided evidence in support of the current WHO guidelines for first-line paediatric antiretroviral therapy; the results also led to licensed combinations for treatment of children. GeneXpert (EDTCP) developed diagnostics technology that could potentially improve health care providers' ability to diagnose tuberculosis and could thereby lead to improved health systems. PanACEA (EDCTP) developed better treatments for tuberculosis. Anti-malarials for pregnant women PREGVAC (EDCTP) and for children 4ABC (EDCTP); MCD (FP7) developed the eave tubes a low-cost device and frugal innovation to control malaria mosquitoes in tropical settings with significant impact on disease prevention.

• Capacity building, primarily in relation to research and education system strengthening, but some evidence of health system strengthening:

EUROPRISE (FP6) brought together a new network of HIV/AIDS researchers from 32 institutions across the fields of vaccines and microbicides. The project developed the FluoroSpot essay that is now commercially available and could, in future, be an efficient tool for vaccine trials in low and middle income countries; COSMIC (FP7) brought health services closer to the people and used village health workers to provide an antimalarial prevention to women. Through training community health workers involved in the case management of malaria, it increased the capacity to test and treat women in Burkina Faso. SILVER (FP7), where leading international virologists, medicinal chemists and bio-informaticians across Europe, Russia, China and Africa joined forces to design small molecule inhibitors against emerging and neglected RNA viruses, including dengue. ELAN2LIFE (FP6) facilitated knowledge exchange and capacity

development through North-South and South-South research cooperation, with more than a thousand South American participating scientists; EACCR (EDCTP) achieved success in terms of capacity building and staff training, as well as in terms of research outputs, playing a pivotal role in supporting South-South cooperation in Africa.

• Generating evidence of later stage development and commercialisation:

EARNEST trial (EDCTP) provided strong support for the current WHO guidelines to switch antiretroviral therapy in a limited-resource setting for people with HIV; Kesho Bora study (EDCTP) identified ways to prevent mother-to-child transmission of HIV and findings of the study strongly influenced the WHO's 2010 Guidelines; 4ABC trials (EDCTP) contributed to key evidence on safety and efficacy of an antimalarial combination therapy that now is registered with the European Medicines Agency and recommended by the WHO for uncomplicated malaria.

• Improved access, affordability, equity and equality, or informing the revision of the World Health Organisation (WHO) guidelines:

WANETAM (EDTCP) developed a molecular line probe assay technology for rapid detection of multi-drug resistant tuberculosis in Ghana, which is now a unique asset to identify second-line anti-TB drugs. The new approach, promoted by the WHO, has contributed to changing policies regarding treatment of patients who had failed a first, standard therapy. The TB CHILD (EDCTP) was a proof of concept study to identify children with active tuberculosis, which could help to better diagnose TB in children in future.

2.7. Specific African countries consultation on GHP-EDCTP3

As the EU-Africa Global Health Partnership is addressing the clinical research of infectious diseases affecting sub-Saharan Africa in partnership with the sub-Saharan countries, an additional consultation was launched addressed to the African countries.

1. Executive Summary

On May 5, 2020, member states of the African Union and relevant stakeholders, including grantees and scientific advisors outside Africa, were invited to participate in an online survey about the future orientation of the European & Developing Countries Clinical Trials Partnership (EDCTP).

A short, user-friendly instrument of 25 items, was developed and disseminated by the government of South Africa.

A total of 161 people accepted to participate in the survey, but only 150 completed the online survey form. Responses were received from 26 countries in Africa, 12 countries in Europe and one in America.

Among the 130 participants who responded to the question about expertise in global health research, 59 indicated expertise in Epidemiology, 59 in Clinical trials, 58 in Public health, and 49 in Biomedical research.

Political will and awareness through education were perceived as the most important drivers for advancing Universal Health Coverage (UHC) in Africa.

Among the 115 participants that responded to the question about the benefit of EDCTP association membership, 89 (77.4%) considered membership to be beneficial to their countries.

'Mentorship programme for science writing' was ranked as most important by 42 (35.6%) of 118 responders addressing additional activities that could further facilitate the implementation of the current EDCTP2 programme. It was followed closely by 'simplification of the processing of calls' which was given the highest rank by 38 responders (32.2%). Most of the responders (74.8%) thought specific calls for female scientists was the most important driver for gender equity in health research in sub-Saharan Africa.

Increasing the number of new or improved medical interventions for HIV/AIDS, tuberculosis, malaria and other poverty-related diseases, including neglected ones; and strengthening cooperation with sub-Saharan African countries, in particular on building their capacity for conducting and interpreting clinical trials, were identified as the two most important objectives of EDCTP2.

When asked about how EDCTP3/GHP can bring onboard countries that are not currently members of the EDCTP Association, 38.7% of 119 responders considered 'Demonstrate benefit for African countries with limited capacities for health research' as the most important action, followed by 'Enhance South-South collaboration' (29.4%) and 'Enhance EU-Africa collaborations to achieve UHC in all countries' (25.2%).

The same responders identified the critical role of regional entities like Africa Centres of Disease Control (Africa CDC) and World Health Organisation – Regional Office for Africa (WHO-AFRO), as the most important lesson learnt so far from COVID-19 pandemic. Examples cited of important regional entities, networks and consortia that have been important during the COVID-19 pandemic include all EDCTP Regional Networks of Excellence (WANETAM, EACCR, CANTAM, TESA), EDCTP-supported epidemic consortia (PANDORA-ID-NET and ALERRT), and all regional economic communities in the African region.

For EDCTP participating states to be fully committed to the future EDCTP3/GHP programme, 'contributing to the regional and global health research agenda' was considered the most important factor.

An overwhelming majority (81.7%) of 115 responders indicated that EDCTP3/GHP can benefit from extending membership to the private sector, including industry and foundations. However, most of the responders thought it was a highly risky venture. The main risk identified is that relating to conflicts of interest and loss of control.

Conducting the survey during the COVID-19 pandemic was timely as it allowed input on the relevance of working for the global good and the importance of south-south networking, coordinated by EDCTP Regional Networks of Excellence, regional economic communities and key institutions like Africa CDC and WHO-AFRO. However, the COVID-19 outbreak also posed some limitations to the outcome of the survey. With most people working from home during lockdowns, there was limited access to the internet. Administering the survey form in English, targeting responders in all AU member states, met some language barriers, especially in Central Africa, where most of the AU members have French as the official language.

2. Background

This Report on the Global Health Partnership online consultation forms part of the deliberations regarding the successor to the second European & Developing Countries Clinical Trials Partnership programme (EDCTP2).

During the last EU-AU High Level Policy Dialogue on Science, Technology and Innovation (HLPD), held in Addis Ababa, Ethiopia in November 2019, senior officials called 'on all European and African Union Member States to consider the questions for reflection on the future orientation of the European & Developing Countries Clinical Trials Partnership (EDCTP), and proposed the convening of a consultation event'. The South African Department of Science and Innovation (DSI) offered to host the consultation. DSI and the EDCTP Secretariat duly set out to co-host a high-level consultative dialogue on EDCTP3/GHP, as part of the ongoing discussions and public consultation about the framework concerning the EDCTP2 successor programme.

The current EDCTP2 programme started in November 2014 and is expected to end in 2024. The proposed third EDCTP programme (EDCTP3/GHP) under Horizon Europe, the EU Framework Programme of Research and Innovation, is envisaged as a partnership between the European Union (EU), European countries and sub-Saharan Africa countries as well as other potential partners like private industry and foundations and other third countries. EDCTP3/GHP seeks to contribute to the United Nations global agenda for sustainable development, the sustainable development goals (SDG), by contributing to better health for all (SDG 3) and poverty reduction (SDG 1).

On 9 March 2020, the European Commission (EC) and the High Representative for Foreign Affairs and Security proposed the basis for a new strategy with Africa. In her address, the European Commission President, Ursula von der Leyen, said: "Today's Strategy with Africa is the roadmap to move forward and bring our partnership to the next level. Africa is the European Union's natural partner and neighbour. Together we can build a more prosperous, more peaceful and more sustainable future for all."

The renewed cooperation on the EU-Africa Global Health partnership (EDCTP3/GHP) proposed will build on the EDCTP2 programme, the public consultation launched in 2019 and the ongoing consultations with African partners, including the partners in global health security. The proposed EU-Africa Global Health Partnership (EDCTP3/GHP) will promote development of diagnostics, medical devices, medicines, and vaccines to combat infectious diseases including those of epidemic potential, and to improve national and global health security. This goal could not have been timelier given the COVID-19 pandemic that has clearly unveiled the research, human resources, infrastructure and coordination gaps on the Africa continent and globally.

It is noted that the first evaluation of EDCTP2 conducted in 2017 'positively assessed the EDCTP programme and acknowledged it as highly relevant as the challenges addressed by the EDCTP persist.'

3. Method

The consultative dialogue was to take the form of a workshop on 16 March 2020 at the Protea Breakwater Lodge, Cape Town, South Africa.

DSI, the EDCTP Africa Office and the Directorate General Research and Innovation (DG RTD) of the EC proceeded to organise the event to share views, and ideas, and to pave a way forward for the next programme.

Unfortunately, the COVID-19 pandemic led to the postponement of the event. Therefore, the consultative dialogue accordingly took the form of an online survey that was coordinated by the DSI in collaboration with the EDCTP Africa Office and the DG RTD of the EC. DSI, through a Project coordinator based at South African Medical Research Council (SAMRC), disseminated the instrument which was developed with assistance from the EDCTP secretariat. On 5 May 2020, invitations to participate in the survey were sent to member states in the African Union and strategic partners relevant to the EDCTP3/GHP programme.

The main objective of the online consultation is to explore the views of sub-Saharan Africa States, the African Union, and other key stakeholders on how practically to galvanise Africa-EU cooperation in global health research and innovation. The consultation informs the scope and possible modalities of the EU-Africa GHP/EDCTP3.

A questionnaire with 25 survey items (SI) was developed and hosted on the survey monkeyTM platform (see Appendix). The EDCTP Secretariat disseminated the instrument with the undertaking of confidentiality. Although the South African Protection of Personal Information Act was not mentioned, the associated legislation applies to the retention of personal information.

Aside from standard biodata (SI 1-5), fourteen items were completed by means of pre-assigned options of drop-down menus. SI 17, SI 20, SI 24 and SI 25 elicited free text responses.

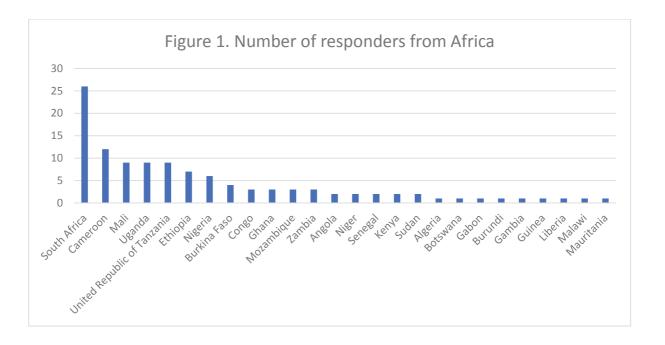
The free text responses were examined, interpreted, coded, and then clustered thematically.

All interpretation was anonymised. The author had no access to the individual questionnaire returns.

6. Results

General response

A total of 161 people accepted to participate in the survey but only 150 people completed the online survey form. Responses were received from 26 countries in Africa, 12 countries in Europe and the United States of America. All African member countries of EDCTP Association, including Angola (an aspirant member), participated in the survey. Out of the total 150 who participated in the survey, 113 (75.3%) were from Africa, 34 (22.7%) from Europe and 3 (2%) from USA. The number of responders per country in Africa is shown in Figure 1.



26 African countries participated in the survey, including 10 from West Africa, 5 from East Africa, 6 from southern Africa, 4 from Central Africa and 2 from North Africa, including Sudan. The highest number of responses (36) came from southern Africa, including 26 from South Africa. The total number of responses from Central, East, North and West Africa were 16, 29, 2 and 30 respectively.

Respondents from all 16 EDCTP African member states, and the aspirant member state (Angola) participated in the survey. Two or more people participated from each of the 16 EDCTP participating states except for Gabon and Gambia which returned one response each. There were two responders from Angola.

Responders from African countries outside the EDCTP Association came from Algeria, Burundi, Botswana, Guinea, Liberia, Malawi, Mauritania and Sudan.

All responses associated with African countries were from African participants because SI 1 specifically asked for country of origin. More than 73% of the African responders were from public institutions. The number of participants from EDCTP African participating states (102) accounted for 68% of all responders (150). While it was not possible to associate responses with countries of origin in most cases, it is clear from the 115 people who provided written text in their responses to SI 24 and SI 25 that the participants were overwhelmingly from Africa or promoters of the African interest.

The participants included 102 (68%) males, 46 (31%) females and two with unspecified gender.

Profiles of responders

Figure 2 shows responses for SI 7 about primary area of research expertise. Among the 130 participants who responded to SI 7 about expertise in global health research, 59 indicated expertise in Epidemiology, 59 in Clinical trials, 58 in Public health, and 49 in biomedical research. Expertise in Ethics was indicated by 25 people, followed by Policy (18), Data (12), Social Science (11) and Advocacy (7). The 'other responses' included research translation, product development and management. There was one response for Entomology.

Figure 2. Profiles of responders to SI7: What is your primary area of research expertise? (More than one can be selected)

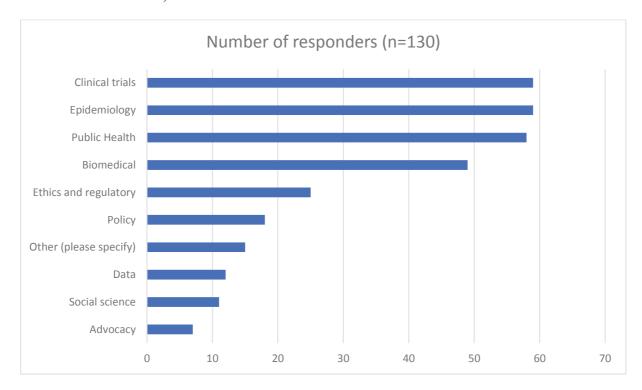
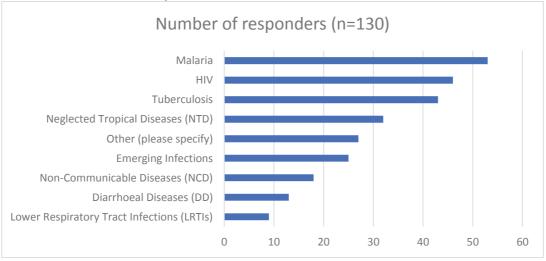


Figure 3 shows the number of responses indicating expertise in specific disease areas as asked in SI 8. Most responders to SI 8 indicated expertise in the malaria space (53), followed by HIV (46), tuberculosis (43), NTDs (32), Other (27), emerging infections (25), Non-Communicable Diseases (18), Diarrhoeal Diseases (13) and Lower Respiratory Tract Infections (9). The 'Other' category with 27 responders included management, public health and care, and research.

Figure 3. Profile of responders to SI 8: What is your primary area of health expertise? (You can select more than one choice)



Responders involvement in EDCTP2 Programme

The question about involvement in the EDCTP2 programme (SI 3) received the highest response rate. Over 99% (149) of the 150 participants responded to this survey item and 94 (63.1 %)

indicated an association with the current programme in various capacities as shown in Table 1 below. Only 38 of the 94 responders indicated that they were nationals of EDCTP participating states even though 102 had indicated an African EDCTP member country as country of origin.

Current or previous EDCTP grantees accounted for 42% (63) of the 149 participants that responded to SI 3.

Strategic partners in Africa, including the Africa Union Commission for Social Affairs, Africa CDC, AUDA-NEPAD and WHO-AFRO participated in the survey.

Table 1: Number of responders (94) who answered yes to involvement with the EDCTP2 programme in various capacities. Some were involved in more than one capacity

Are you associated with EDCTP in these capacities?	Yes
National of an EDCTP2 participating state	38
Current resident of an EDCTP2 participating state	20
Member of the EDCTP General Assembly	17
EDCTP High Representative	2
Member of the EDCTP Scientific Advisory Committee	4
Member of the AU Secretariat (Commissions)	1
Member of other organs of the AU	3
Member of WHO	1
Reviewer of EDCTP grants	11
Current EDCTP grantee	47
Independent researcher	7
Previous EDCTP Grantee	16
Have applied for EDCTP grants	25
Private sector (Industry, NGO)	6
Funder (Contributed to joint calls)	3

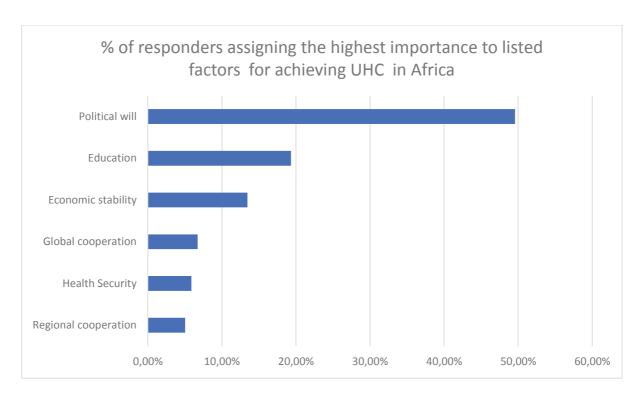
Among the 115 participants that responded to the question about the benefit of EDCTP Association membership (SI 21), 89 (77.4%) considered the membership to be beneficial to their countries, two responders (oen from Africa) thought it was not beneficial, and 24 (20.9%) responders had no comments.

Achieving Universal Health Coverage and SDG3 in Africa

SI 10 asked responders about the most important contextual factors for achieving Universal Health Coverage (UHC) in Africa, and what could be the role of EDCTP3/GHP in the transformation process in Africa.

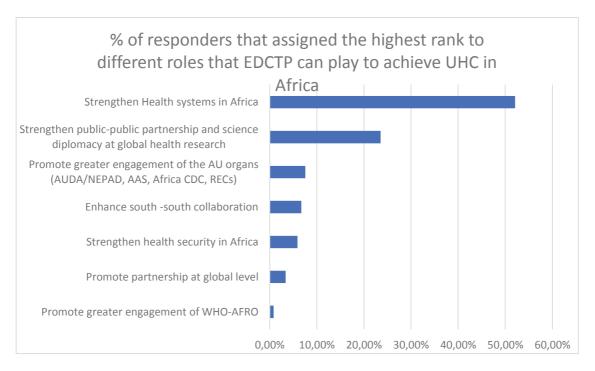
Given the choice to rank six factors indicated in Figure 4, in order of importance, for achieving UHC, almost half (49.9%) of the 119 responders considered 'Political will' to be the most important factor. 'Education' was ranked highest by 20% of responders. Only 13.5% considered 'Economic stability' as the most important factor. More responders (6.7%) ranked 'Global cooperation' as the leading factor than 'Regional cooperation' (5.0%). Strengthening 'Health Security' was considered the most important factor for achieving UHC by 5.9% of responders.

Figure 4. Percentage (%) of responders assigning the highest importance to listed factors affecting UHC in Africa (n=119).



More than half of the 119 responders (52.1%) to SI 11 considered 'Strengthening health (research) systems' as the most important role EDCTP can play to achieve UHC in Africa (Figure 5). This was followed by 'Strengthen public-public partnership and science diplomacy in global health research' which 23.5% of responders gave the highest ranking. The proportion of responders that ranked the other options as most important varied from 0.8% for 'Promoting greater engagement with WHO-AFRO' to 6.7% for 'Enhancing South-South collaboration'.

Figure 5. Percentage (%) of responders assigning the highest importance to listed roles that EDCTP can play to achieve UHC in Africa (n=119)



Achieving SDG3 (Good health and well-being)

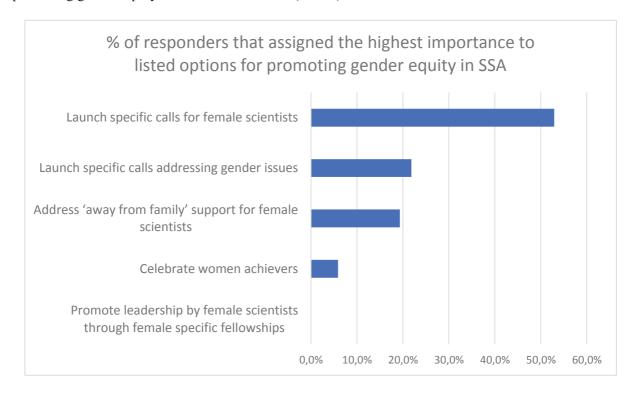
In response to SI 12, a large majority (83.2%) of the 119 responders agreed that achieving the following objectives will, to a large extent, facilitate meeting the SDG 3 (Good health and well-being):

- Reduction of the social and economic burden of infectious diseases in sub-Saharan Africa and by extension in Europe.
- Development and uptake of new or improved interventions against infectious diseases.
- Enhancement of health security in sub-Saharan Africa, and by extension in Europe and worldwide, in the context of environmental and climate change, by reducing the risk of outbreaks, pandemics or antimicrobial resistance.

Promotion of gender equity in global health research in sub-Saharan Africa (SSA)

Figure 6 shows the results for the level of importance 119 responders assigned to a list of options for promoting gender equity in global health research in Africa (SI 13). Most of the responders (74.8%) thought specific calls for female scientists was the most important driver for gender equity in health research in SSA. More than half of the responders (52.9%) considered launching specific calls for female scientists as the most important driver. This was followed by specific calls addressing gender issues (21.0%). Addressing 'away from family' support for female scientists was assigned the highest rank by 19.3% of the responders.

Figure 6. Percentage (%) of responders assigning the highest importance to listed options for promoting gender equity in sub-Saharan Africa (n=119).



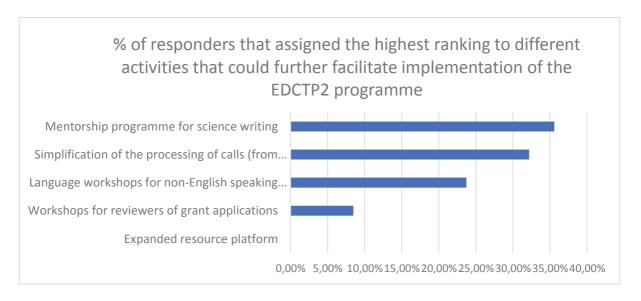
Additional activities to facilitate implementation of EDCTP2

A total of 118 participants responded to SI 18 about the additional activities that could further facilitate implementation of the current EDCTP2 (Figure 7).

'Mentorship programme for science writing' was ranked as most important by 42 (35.6%) responders, followed by 'simplification of the processing of calls' which was ranked highest by 38 responders (32.2%). Not far behind was 'Language workshops for non-English speaking applicants' which got 28 votes (23.7%) for the most important activity that accelerate the

implementation process for the EDCTP2 programme. Only 10 (8.5%) responders assigned the highest ranking to conducting 'Workshops for reviewers of grant applications'. 'Expanding the resource platform' was considered the least important of the five options provided for SI 18.

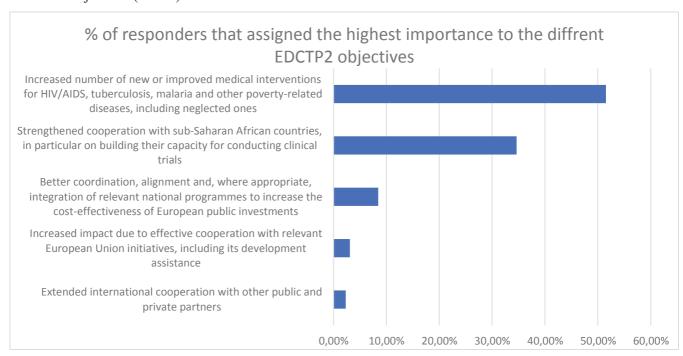
Figure 7. Ranking of additional activities that that could further facilitate implementation of the current EDCTP2 (n=118)



Objectives of the current EDCTP2

SI 9 requested participants to rank the EDCTP2 objectives in Figure 8 below in order of importance. Most of the 130 responders (51.5%) considered "Increased number of new or improved medical interventions for HIV/AIDS, tuberculosis, malaria and other poverty-related diseases, including neglected ones' as the most important objective. 'Strengthened cooperation with sub-Saharan African countries, in particular on building their capacity for conducting and interpreting clinical trials' was ranked the highest by 34.6% of the responders. Each of the other objectives were ranked as most important by less than 10% of the responders. 'Extended international cooperation with other public and private partners' received the least number of votes as the most important. It was ranked top by only 2.3% of responders.

Figure 8: Percentage (%) of responders assigning the highest importance to the different EDCTP2 objectives (n=130)



How to increase countries participation in the EDCTP3/GHP Programme.

To address SI 14, 119 participants responded to the question 'How could the EDCTP3/GHP bring onboard countries that are not currently members of the EDCTP Association?

Among the options listed for ranking, 38.7% gave the highest rank to 'Demonstrate benefit for African countries with limited capacities for health research', followed by 'Enhance South-South collaboration' (29.4%) and 'Enhance EU-Africa collaborations to achieve UHC in all countries' (25,2%). Only 6.7% of the responders considered 'Demonstrate benefit for EU countries' as the most important factor in bringing onboard countries that are not members of the EDCTP Association.

Additional areas to be tackled by EDCTP3/GHP

In response to the question 'Do you think that EDCTP3/GHP should tackle additional areas than the ones currently tackled by the EDCTP2 programme? (SI 15), 86.6 % (107) of the 119 responders answered in the affirmative. Among those that answered 'yes', 'Clinical epidemiology' was considered the most important area by 28.6% of the 119 responders. This was closely followed by 27% for 'Vector control' and 24.0% for 'Social science'. 'Climate change' was considered the most important additional area by only 20% of responders.

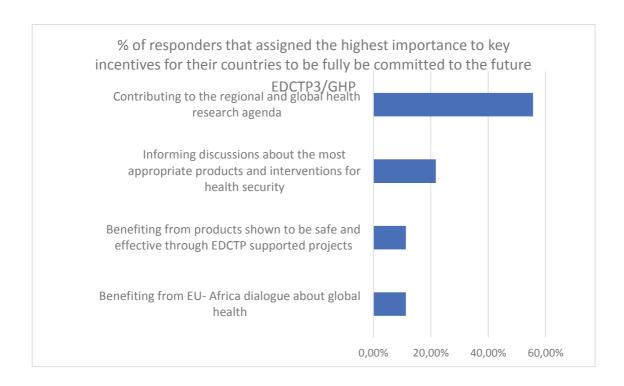
Lessons learned from COVID-19 pandemic

In response to SI 19, the most important lesson learnt from COVID-19 pandemic that could inform the EDCTP3/GHP funding scope, 'regional entities like Africa CDC and WHO-AFRO are critical for managing public health emergencies' was ranked number 1 by 43.2 % of responders. However, this was just marginally higher than the number of responders who thought that the roles of EDCTP Regional Networks of Excellence should be expanded with increased funding to accommodate regional entities (36.4%). One in five responders (20.3%) considered EDCTP3/GHP support for regional platforms (e.g. AVAREF and WAHO) to implement ethics and regulatory activities was the most important lesson learnt. The examples indicated of regional entities, networks and consortia that have been important during the COVID-19 pandemic include all EDCTP Regional Networks of Excellence (WANETAM, EACCR, CANTAM, TESA), EDCTP supported epidemic consortia (PANDORA-ID-NET and ALERRT), and all regional economic communities (RECs) in the African region. Also mention were H3Africa, COHRED, REACTing and Red Cross.

Incentives to commit to EDCTP3/GHP

Among the key incentives listed in Figure 9 for EDCTP participating states to be fully committed to the future EDCTP3/GHP programme, 'contributing to the regional and global health research agenda' was assigned the highest ranking by 64 (55.7%) out of 115 responders. 'Informing discussions about the most appropriate products and interventions for health security' was considered the most important by 25 (21.7%) responders. The other two options were each given high importance by 13 (11.3%) responders.

Figure 9. Importance of incentives for country commitment to EDCTP3/GHP (n=115)



Private sector involvement (industry and foundations)

In response to SI 23, 94 (81.7%) of the 115 responders indicated that EDCTP3/GHP can benefit from extending membership to the private sector including industry and foundations. The others did not think so. However, the majority of the responders thought it was a highly risky venture. The main risk identified is that relating to conflicts of interest and loss of control. The various narratives about the risk of engaging private partners are best exemplified by these three:

- 1. "For most Africa, the private sector is poorly regulated rendering highly risky for investment in terms of grants. However fostering Private-Public sector partnerships might be beneficial"
- 2. "In my opinion, membership in the private sector will rather contribute to strengthening the association by mobilizing financial resources. But as a risk I fear that c sector will want to change the orientations of the association for purposes other than those it has set for itself'.
- 3. "Increased risk for competing priorities of the private sector may not be UHC but as an expansion of their profit margins by the health hazards. If the private sector is to be involved, the regulations and ethical acumen should be updated to ensure the Public Health good is the priory and not otherwise"

5. Discussion

The primary goal of the online consultation was to explore the views of African institutions, including public and private initiatives, and member states of the African Union, about how EU-Africa cooperation in global health research and innovation might be enhanced through the envisaged EDCTP3/GHP initiative. To this end, a short, user friendly online instrument was developed, disseminated, collated and analysed.

African involvement

The majority of the 150 responders were from Africa. Respondents from all 16 current African member states of the EDCTP Association, and the aspirant member state (Angola) participated in the online consultation. Fewer responses were received from non-English speaking countries. particularly Francophone countries in central Africa. The low response rate from these countries may be because the questionnaire was available only in English. A similar low response rate, from Lusophone and Francophone, was reported by WHO-AFRO for a recent online survey, conducted English, about ethics and regulatory capacities (https://www.edctp.org/news/avaref-survey-highlights-edctps-role-supporting-ethical-regulatoryoversight-africa/). Most of the African participants were from public institutions, including government departments/ministries, national research institutions, the AU Commission for Social Affairs, the African CDC, the African Union Development Agency (AUDA-NEPAD) and the Regional Economic Communities (RECs). Responders were mainly epidemiologists and clinical trialists, but some had expertise in ethics and regulatory activities, social science, health policy, data, knowledge translation and advocacy. One was an entomologist.

Achieving Universal Health Coverage (UHC) in Africa

Political will and awareness through education were perceived as the most important drivers for advancing UHC in Africa. Most responders thought EDCTP can accelerate this process by strengthening health (research) systems and promoting public-public partnership and science diplomacy in global health research. There was an overwhelming agreement among participants that the sustainable development goal for health and well-being (SDG3) will be met largely through a reduction of the social and economic burden of infectious diseases in sub-Saharan Africa. Meeting the SDG3 targets can be accelerated by the development and uptake of new or improved interventions against infectious diseases in Africa and globally to reduce the risk of outbreaks, pandemics or antimicrobial resistance. To achieve UHC leaving no one behind, there were suggestions for closing the gender gap. Most of the responders advocated for specific calls for female scientists to enhance equity in health research in sub-Saharan African and 'away from family' support for female scientists.

The EDCTP2 Programme

All 150 participants, except one, responded to the question about involvement in the EDCTP2 programme. Most of the responders, mainly grantees, were associated with the EDCTP2 programme in various roles, but many of them were from countries that are not members of the EDCTP Association, indicating that responders outside the EDCTP participating states considered membership of the association to be beneficial to their countries. However, there was little enthusiasm for extending international cooperation with other public and private partners outside the EU-Africa network.

Increasing the number of new or improved medical interventions for HIV/AIDS, tuberculosis, malaria and other poverty-related diseases, including neglected ones; and strengthening cooperation with sub-Saharan African countries, in particular on building their capacity for conducting and interpreting clinical trials, were identified the two most important objectives of EDCTP2.

To further enhance the EDCTP2 programme, the participants thought that a mentorship programme for science writing should be implemented and the processing of calls should be simplified and presented in different languages.

Two responders did not think that the EDCTP2 programme was beneficial to their countries, but no reason was given except from one whose the country of origin was not in Africa which could be established through the free text narrative.

EDCTP3/GHP programme

There was a general consensus that for the EDCTP participating states to be fully committed to the future EDCTP3/GHP programme, it should be seen firstly as 'adding value to the regional and global health research agenda' and by 'providing current information about the most appropriate products and interventions for health security'. An overwhelming majority of responders (86.6%) wanted EDCTP3/GHP to embrace additional areas not addressed in the EDCTP2 programme. As the survey was conducted during the COVID-19 outbreak, Clinical epidemiology was the favourite new topic; followed closely, and in order of importance, by Vector control, Social science and Climate change. Vector control has become popular since the Zika outbreak, and more recently with the use of medicines for vector control to tackle vector-borne diseases like malaria and filariasis.

The coordinating role played by regional entities like Africa CDC and WHO-AFRO in managing public health emergencies was considered the most important lesson learnt so far from the COVID-19 pandemic that could inform the EDCTP3/GHP funding scope. But equally important are the emerging critical networking activities of the EDCTP Regional Networks of Excellence (NoE). The responders thought the support for EDCTP Networks of Excellence should be expanded with increased funding to accommodate more regional entities. The list, they provided, of regional entities, networks and consortia that have been important during the COVID-19 pandemic included all EDCTP Regional Networks of Excellence (WANETAM, EACCR, CANTAM, TESA), EDCTP supported epidemic consortia (PANDORA-ID-NET and ALERRT), and all regional economic communities (RECs) in the African region. Also listed were AVAREF, H3Africa, COHRED, REACTing and Red Cross.

Extending EDCTP3/GHP membership to the private sector, including industry and foundations was considered beneficial by most responders. However, many thought it was a highly risky venture because of conflicts of interest and loss of control. The following text about the risk of engaging private partners can best illustrate most of the views expressed

"For most Africa, the private sector is poorly regulated rendering highly risky for investment in terms of grants. However, fostering Private -public sector partnerships might be beneficial"

Conclusion

The views expressed in the online consultation process came from a wide range of strategic entities from across Africa. Key influencers in Africa, including the African Union Commission, Africa CDC, Africa Union Development Agency, and the WHO-AFRO shared their views on the way forward for EDCTP3/GHP. There was a consensus about demonstrating value addition to the regional and global health research agenda through support for the most appropriate products and interventions for health security. Conducting the survey during the COVID-19 pandemic was timely as it allowed input on the relevance of working for the global good and the importance of south-south networking, coordinated by EDCTP regional networks of excellence, regional economic communities and key institutions like Africa CDC and WHO-AFRO. Extending EDCTP3/GHP membership to the private sector, including funders and foundations was considered beneficial but should be managed carefully to avoid conflicts of interest and mitigate risks related to profits from products. EDCTP might also explore the best ways to determine country capabilities for health research and through resources like the WHO Joint External Evaluations, and the WHO-AFRO national health research systems barometer that is partly supported by EDCTP. Such analysis might assist in shaping the EDCTP3/GHP yet further in light of the COVID-19 pandemic.

Limitations

The online consultation survey had some limitations. Administering the survey form in English, targeting responders in all AU member states, met some language barriers, especially in Central Africa, where most of the AU members have French as the official language. Moreover, the online survey was performed during a public health emergency, with people observing lockdown restriction and working from home with limited access to the internet. The number of invitations sent out were also were limited by access to contact details due to privacy and data protection policies.

The visibility of EDCTP in Africa has been perceived as suboptimal, and it is not clear from the online survey what the leadership of strategic partners in health in Africa think about EDCTP as a valued partner going forward with the proposed EDCTP3/GHP programme. High-level engagements with leaders in the African Union, EU, Africa CDC and WHO-AFRO, after the survey, provided some indicators about the role of EDCTP in supporting health research in Africa. Their thoughts have been summarised in Appendix 2 in this report.

Questionnaire

- 1. Accept/reject conditions
- 2. Country of origin (Please add your country of origin, or that of your organisation when responding on behalf of one)
- 3. Gender
- 4. Current employer
- Government
- Public institution
- Private institution
- Multilateral institution
- Other (please specify)
- 5. Have you been involved in the on-going European and Developing Countries Clinical Trials Partnership (EDCTP2) programme? [Yes/No]
- 6. If yes, please identify in which capacity (You can select more than one choice)
- From an EDCTP 2 participating State
- Current resident of an EDCTP2 participating state
- Member of the EDCTP General Assembly
- EDCTP High Representative
- Member of the EDCTP Scientific Advisory Committee
- Member of the AU Secretariat (Commissions)
- Member of other organs of the AU (e.g. AUDA/NEPAD, AAS, Africa CDC, RECs).
- Member of WHO
- Reviewer of EDCTP grants
- Current EDCTP grantee
- Independent researcher
- Previous EDCTP Grantee
- Have applied for EDCTP grants
- Private sector (Industry, NGO)
- Funder (Contributed to joint calls)
- 7. What is your primary area of research expertise? (You can select more than one)
- Epidemiology

- Public health
- Clinical trials
- Biomedical
- Policy
- Data
- Advocacy
- Social science
- Ethics and regulatory
- Other (please specify)
- 8. What is your primary area of health expertise? (You can select more than one choice)
- Malaria
- TB
- HIV
- NTD
- LRTI
- Diarrhoeal diseases
- NCD
- Emerging infections
- Other (please specify)
- 9. Please rank, in order of importance, the specific objectives of the current EDCTP2 programme:
- a. Increased impact due to effective cooperation with relevant Union initiatives, including its development assistance
- b. Increased number of new or improved medical interventions for HIV/AIDS, tuberculosis, malaria and other poverty-related diseases, including neglected ones
- c. Better coordination, alignment and, where appropriate, integration of relevant national programmes to increase the cost-effectiveness of European public investments
- d. Strengthened cooperation with sub-Saharan African countries, in particular on building their capacity for conducting and interpreting clinical trials
- e. Increased impact due to effective cooperation with relevant European Union initiatives, including its development assistance
- f. Extended international cooperation with other public and private partners
- 10. What are the most important contextual factors in your opinion for achieving Universal Health Coverage (UHC) in Africa? Rank the choices below:
- a. Political will
- b. Economic stability
- c. Education
- d. Health Security
- e. Regional cooperation
- f. Global cooperation
- 11. What role can the EDCTP3/GHP programme play to achieve the UHC in Africa. Rank the choice below
- a. Strengthen public-public partnership and science diplomacy at global health research
- b. Strengthen Health (research) systems in Africa
- c. Strengthen health security in Africa
- d. Promote partnership at global level
- e. Enhance south -south collaboration
- f. Promote greater engagement of the AU organs (AUDA/AUDA-NEPAD, AAS, Africa CDC, RECs).
- g. Promote greater engagement of WHO-AFRO.
- 12. To what extent will achieving these objectives facilitate meeting the SDG 3 (Good health and well-being). The proposed EDCTP3/GHP general objectives are:

- Reduction of the social and economic burden of infectious diseases in sub-Saharan Africa and by extension in Europe
- Development and uptake of new or improved interventions against infectious diseases;
- Enhancement of health security in sub-Saharan Africa, and by extension in Europe and worldwide, in particular in the context of environmental and climate change, by reducing the risk of outbreaks, pandemics or antimicrobial resistance.
- Large extent
- Limited extent
- None
- 13. In your opinion, how could EDCTP3/GHP promote gender equity in sub-Saharan Africa? Rank choices below
- a. Launch specific calls for female scientists
- b. Promote leadership by female scientists through female specific fellowships
- c. Address 'away from family' support for female scientists
- d. Launch specific calls addressing gender issues
- e. Celebrate women achievers
- 14. How could the EDCTP3/GHP bring onboard countries that are not currently members of the EDCTP Association? Rank the choices below
- a. Enhance EU-Africa collaborations to achieve UHC in all countries
- b. Enhance South-South collaboration
- c. Demonstrate benefit for African countries with limited capacities for health research.
- d. Demonstrate benefit for EU countries
- 15. Do you think that EDCTP3/GHP should tackle additional areas than the ones currently tackled by the EDCTP2 programme? Yes/No
- 16. If yes, rank the choices below for other areas in order of importance.
- a. Climate change
- b. Vector control
- c. Clinical Epidemiology
- d. Social Science
- 17. If no, give reasons
- 18. In your opinion, what additional activities could further facilitate implementation of the current EDCTP2? Please rank the choices below in order of importance:
- a. Expanded resource platform
- b. Language workshops for non-English speaking applicants
- c. Mentorship programme for science writing
- d. Workshops for reviewers of grant applications
- e. Simplification of the processing of calls (from launch, review to outcome)
- 19. What lessons do you think we have learnt from the recent and ongoing Global Health Emergencies that should inform the EDCTP3/GHP future funding approach? Rank the choices below
- a. Regional entities like Africa CDC and WHO-AFRO are critical for managing public health emergencies
- b. The roles of EDCTP Regional Networks of Excellence should be expanded with increased funding to accommodate regional entities.
- c. EDCTP3/GHP should support regional platforms (e.g. AVAREF and WAHO) for ethics and regulatory activities
- 20. If appropriate, please give examples of regional entities, networks and or consortia that have been active during PHE (Max 50 words)

- 21. If your country is currently a member of the EDCTP Association, do you think that being part of the EDCTP Association is beneficial for your country?
- Yes
- No
- No comments
- 22. What are the key incentives for your country to be fully be committed to the future EDCTP3/GHP? Rank choices below.
- a. Contribution to the regional and global health research agenda
- b. Benefiting from EU- Africa dialogue about global health
- c. Informing discussions about the most appropriate products and interventions for health security
- d. Benefiting from products shown to be safe and effective through EDCTP supported projects
- 23. In your opinion, can EDCTP3/GHP benefit from extending membership to the private sector including funders and foundations?
- Yes
- No
- 24.In your view/opinion, what are the risks of extending membership to the private sector? (Max 50 words)
- 25. Please add any other comments, views or information you deem important, and that have not been tackled in this online consultation, which should be considered when developing the future EDCTP3/GHP (Max 200 words)

Post-survey engagements with AU, EU, Africa CDC and WHO-AFRO

High-level engagements with the African Union, EU, Africa CDC and WHO-AFRO after the survey provided some indicators about role of EDCTP in supporting health research in Africa. Members of the EDCTP secretariat contributed to important high-level discussions about EDCTP's role and value addition to the public health space in Africa. EDCTP was mentioned in speeches by African Ministers of Health, the AU commissioner for Social Affairs, the Regional Director for the WHO Africa Region and the Director of Africa CDC.

24 & 25 June 2020: Africa's Leadership in COVID-19 vaccine development and access

The role of EDCTP in research in vaccine development in Africa was highlighted during the virtual meeting of Africa's Leadership in COVID-19 vaccine development and access held on 24 and 25 June 2020 (https://africacdc.org/download/africas-leadership-in-covid-19-vaccine-development-and-access-highlights-day-1-2/).

The meeting, which was opened by H.E. President Cyril Ramaphosa, Chairperson of the African Union and President of the Republic of South Africa brought together African leaders, public health professionals, policymakers, the media, civil society, community leaders, private sector representatives, pharmaceutical industry experts, and partners to discuss a roadmap for the development of safe, efficacious, affordable, equitable and accessible COVID-19 vaccine in Africa, with the involvement of Africans.

During the closing session there were presentations by the Executive Director of UNAIDS, H.E. Amira Elfadil Mohammed, Commissioner for Social Affairs, African Union Commission and Dr Leonardo Simao, EDCTP High representative for Africa.

Dr Leonardo Simao, said that the conference was timely because it will ensure that Africa is not left behind in COVID-19 vaccine development. He highlighted some of the activities of EDCTP

in Africa since 2003. He reminded the participants EDCTP is engaged in high level dialogue in Africa, Europe and globally to find solutions to the vaccine challenge and they will continue working with partners as we move into the next phase of the programme.

16 July 2020: European Union (EU) - African Union (AU) Research & Innovation Ministerial meeting

The first ever EU - AU Research & Innovation Ministers' Meeting took place on 16 July 2020, under the framework of the EU-AU High-Level Policy Dialogue (HLPD) on Science, Technology and Innovation (https://ec.europa.eu/info/news/european-union-and-african-union-research-and-innovation-ministers-meet-first-time-2020-jul-16 en)

The policy discussions on public health focused on the human health impacts and the more far reaching socioeconomic effects of COVID-19. The two main discussion points for public health were i) the emergency call for expressions of interest launched by the EDCTP to support COVID-19 research activities and ii) the impact of COVID-19 on ongoing EDCTP Projects.

The ministers advocated for international cooperation (north-south and south-south), and better support for EDCTP and the successor, the planned Global Health Partnership (GHP). Some AU Ministers called for increasing the EDCTP membership by African countries currently not represented, giving the Partnership a whole of Africa approach. The Ministers (or their representatives) of non-EDCTP participating states, including Hungary, Egypt, Romania that advocated for additional financial resources for the EDCTP/GHP.

EDCTP was represented in the meeting by Dr Michael Makanga, EDCTP Executive Director; Dr Leonardo Simao, EDCTP High Representative Africa, and Professor Marcel Tanner, EDCTP High Representative Europe.

11-12 August 2020: 34th session of the African Advisory Committee for Health Research and Development (AACHRD) Meeting.

EDCTP participated in the 34th session of the WHO-AFRO African Advisory Committee for Health Research and Development (AACHRD) on 11-12 August 2020. The theme of the meeting was 'Health Research in the context of COVID-19' but the regional health research agenda for Africa was presented and discussed with inputs from EDCTP and strategic partners. The key partners included NEPAD, TDR, Africa CDC and the Regional economic Communities. More than 50 people participated in the meeting, including many that were invited to the proposed Cape Town meeting on EDCTP/GHP. The main goal of AACHRD is to provide advice to the Regional Director on the WHO core function of shaping the research agenda and stimulating the generation, translation and dissemination of valuable knowledge in Africa.

The WHO-AFRO Regional Director, Dr Matshidiso Moeti, in her opening remarks acknowledged the presence of EDCTP and highlighted the valuable recent outputs from joint activities that informed the MOU between WHO-AFRO and EDCTP signed in June 2020.

Professor Moses Bockarie gave an overview of the emergency call launched by EDCTP in April 2020 to support COVID-19 research activities, and the impact of COVID-19 on ongoing EDCTP Projects. Professor Bockarie also presented the roadmap for strengthening National Health Research Systems in Africa that was developed during the EDCTP-WHO joint meeting held in Brazzaville on in October 2019 (https://publications.edctp.org/nhrs-consultative-meeting-report/cover).

Recommendations and action points

The participants resolved to develop and implement a work plan around the following recommendations of the 34th AARCHD:

1. Leadership, governance and innovation in health research

- 3. Develop a collaboration framework to guide engagement with stakeholders.
- 4. Promote indigenous innovations from the region.
- 5. Develop guidance document on access options should a vaccine be available.
- 6. Finalise the strategy for strengthening the use of evidence information and research for policy making in the WHO/AFRO region for presentation at the 2021 regional committee meeting.
- 7. In the context of COVID 19, the AACHRD, resolved to go beyond the advisory capacity, to assist WHO-AFRO through collaborating with other partners in terms of shaping the research agenda and ensure the quality of ongoing research around COVID 19.
- 8. Encourage participation of African countries (and communities) in vaccine trials.
- 9. Put in place mechanism of accessing vaccines once available and in collaboration with partners (e.g. Africa CDC).
- 10. Encourage regulatory bodies and governments to be engaged actively in trials.
- 11. Orient research beyond the biomedical and public health areas spheres and address research questions in multiple sectors including social economic status, social sciences/ground realities and advise government based on the evidence.

2. Strengthening national health research systems

- 12. Develop COVID-19 research agenda for Africa.
- 13. Conduct deliberative dialogues that will identify topics for policy briefs.
- 14. Support and strengthen work on policy briefs.
- 15. Set up standing subcommittee to review policy briefs.
- 16. Endorse and strengthen work of AVAREF
- 17. Develop a regional health research directory.
- 18. Develop guideline for rapid ethics review.
- 19. Promote multisectoral, transdisciplinary, social science, health (research) systems, implementation and operational research.
- 20. Develop reports on COVID-19 best practice and research agenda from member states.

1. 3. Harmonisation and co-ordination of research

- 21. An expansive list was generated; further discussion on prioritising for WHO-Afro while also allowing country specific priorities
- 22. Consider interventions for prevention that are beyond the health care system.
- 23. Use of the Health systems building blocks to organise the priorities, as this is widely used as a conceptual framework and is well known.
- 24. Consider emerging and re-emerging infections.
- 25. Include social science among research priorities.



Brussels, 23.2.2021 SWD(2021) 37 final

PART 3/19

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT REPORT Accompanying the document

Proposal for a COUNCIL REGULATION establishing the Joint Undertakings under Horizon Europe

European Partnership for Innovative Health

{COM(2021) 87 final} - {SEC(2021) 100 final} - {SWD(2021) 38 final}

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Glossary

Term or acronym	Meaning or definition
AI	Artificial intelligence
AMR	Anti-microbial resistance
ATMP	Advanced therapy medicinal product
СРР	Co-Programmed Partnership
EFPIA	European Federation of Pharmaceutical Industries and Associations
EIT	European Institute of Innovation and Technology
ERA	European Research Area
H2020	Horizon 2020
НТА	Health technology assessment
ICT	Information and communication technologies
ІНІ	Innovative Health Initiative
IMI	Innovative Medicines Initiative
IP	Institutionalised partnership
JU	Joint undertaking
medtech	medical technologies (sector)
MS	EU Member States
NGO	Non-governmental organisations
R&D	Research and development
R&I	Research and innovation
SME	Small- and medium-sized enterprises
SRA	Strategic Research Agenda

1. BACKGROUND AND CONTEXT TO EUROPEAN PARTNERSHIPS IN HORIZON EUROPE AND FOCUS OF THE IMPACT ASSESSMENT—WHAT IS DECIDED

1.1. Focus and objectives of the impact assessment

This impact assessment accompanies the Commission proposal for Institutionalised European Partnerships to be funded under Horizon Europe, the 2021-2027 Framework Programme for EU Research and Innovation (R&I). It sets out to help decide in a coordinated manner the right form of implementation for specific candidate initiatives based on a common approach and methodology to individual assessments². It also provides an horizontal perspective on the portfolio of candidate European Partnerships to identify further efficiency and coherence gains for more impact.

European Partnerships are initiatives where the Union, together with private and/or public partners (such as industry, public bodies or foundations) commit to support jointly the development and implementation of an integrated programme of R&I activities. The rationale for establishing such initiatives is to achieve the objectives of Horizon Europe more effectively than what can be attained by other activities of the programme.³

Based on the Horizon Europe Regulation, European Partnerships may be set up using **three different forms**: "Co-funded", "Co-programmed" and "Institutionalised". The setting-up of **Institutionalised Partnerships** involves new EU legislation and the establishment of dedicated implementing structures based on Article 185 or 187 of the Treaty on the Functioning of the EU (TFEU). This requires an impact assessment to be performed.

The Horizon Europe Regulation defines **eight priority areas**, scoping the domains in which Institutionalised Partnerships could be proposed⁴. Across these priority areas, **13 initiatives** have been identified **as suitable candidate initiatives** for Institutionalised Partnerships because of their objectives and scope. This impact assessment aims to identify whether 12 of these initiatives⁵ need to be implemented through this form of implementation and would not deliver equally well with traditional calls of Horizon Europe or other lighter forms of European Partnerships under Horizon Europe. This means assessing whether each of these initiatives meets the necessity test set in the **selection criteria** for European Partnerships in the Horizon Europe Regulation, Annex III.

This assessment is done **without any budgetary consideration**, as the overall budget of the Multiannual Financial Framework of the EU – and hence of Horizon Europe – for the next financing period is not known at this stage.⁶

¹ Horizon Europe Regulation (common understanding), https://data.consilium.europa.eu/doc/document/ST-7942-2019-INIT/en/pdf
² Based on the European Commission B. (1) B. (1) C. (2) C. (2) C. (3) C. (4) C. (4)

² Based on the European Commission Better Regulation framework (SWD (2017) 350) and supported by an external study coordinated by Technopolis Group (to be published in 2020).

³ For further details on these points, see below Section 1.2.2.

⁴ Set out in the Annex Va of the Horizon Europe Regulation (common understanding). https://data.consilium.europa.eu/doc/document/ST-7942-2019-INIT/en/pdf

⁵ Only 12 are subject to this impact assessment, as one initiative on High Performance Computing has already been subject to an impact assessment in 2017 (SEC(2018) 47).

⁶ EU budget commitments to the European Partnership candidates can only be discussed and decided following the political agreement on the overall Multiannual Financial Framework and Horizon Europe

1.2. The political and legal context

1.2.1. Shift in EU priorities and Horizon Europe framework

European priorities have evolved in the last decades, and reflect the social, economic, and environmental challenges for the EU in the face of global developments. In her Political Guidelines for the new European Commission $2019 - 2024^7$, the new Commission President put forward six overarching priorities, which reach well beyond 2024 in scope⁸. Together with the Sustainable Development Goals (SDGs), these priorities will shape future EU policy responses to the challenges Europe faces, and thus also give direction to EU research and innovation.

As part of the Multi-annual Financial Framework (MFF) 2021-27 the new EU Framework Programme for Research and Innovation Horizon Europe will play a pivotal role for Europe to lead the social, economic, and environmental transitions needed to achieve these European policy priorities. It will be more impact driven with a strong focus on delivering European added value, but also be more effective and efficient in its implementation. Horizon Europe finds its rationale in the daunting challenges that the EU is facing, which call for "a radical new approach to developing and deploying new technologies and innovative solutions for citizens and the planet on a scale and at a speed never achieved before, and to adapting our policy and economic framework to turn global threats into new opportunities for our society and economy, citizens and businesses." While Horizon Europe continues the efforts of strengthening the scientific and technological bases of the Union and foster competitiveness, a more strategic and impact-based approach to EU R&I investment is taken. Consequently, the objectives of Horizon Europe highlight the need to deliver on the Union strategic priorities and contribute to the realisation of EU objectives and policies, contribute to tackling global challenges, including the Sustainable Development Goals by following the principles of the Agenda 2030 and the Paris Agreement. 10

In this context, at least 35 % of the expenditure from actions under the Horizon Europe Programme will have to contribute to climate action. Furthermore, a Strategic Plan is co-designed with stakeholders to identify key strategic orientations for R&I support for 2021-2024 in line with the EU priorities. In the Orientations towards the first Strategic Plan for Horizon Europe, the need to strategically prioritise and "direct a substantial part of the funds towards the areas where we believe they will matter the most" is emphasised. The Orientations specify, that actions under Pillar II of Horizon Europe "Global Challenges and European Industrial Competitiveness" will target only selected themes of especially high impact that significantly contribute to delivering on the political priorities of the Union. Most of the candidate European Partnerships fall under this Pillar.

budgetary envelopes. The level of EU contribution for individual partnerships should be determined once there are agreed objectives, and clear commitments from partners. Importantly, there is a ceiling to the partnership budgets in Pillar II of Horizon Europe (the legal proposal specifies that the majority of the budget in pillar II shall be allocated to actions outside of European Partnerships).

⁷ https://ec.europa.eu/info/strategy/priorities-2019-2024_en

⁸ 1.A European Green Deal; An economy that works for people; A Europe fit for the Digital Age; Promoting our European way of life; A Stronger Europe in the World; and 6.A New push for European Democracy

⁹ EC (2018) A Modern Budget for a Union that Protects, Empowers and Defends. The Multiannual Financial Framework for 2021-2027. Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, COM(2018) 321 final

¹⁰ Article 3, Common understanding regarding the proposal for Horizon Europe Framework Programme.

1.2.2. Key evolutions in the approach to partnerships in Horizon Europe

Since their start in 1984 the successive set of Framework Programmes uses a variety of instruments and approaches to support R&I activities, address global challenges and industrial competitiveness. Collaborative, competition-based and excellence-driven R&I projects funded through Work Programmes are the most traditional and long-standing approach for implementation. Since 2002, available tools also include **partnerships**, whereby the Union together with private and/or public partners commit to jointly support the development and implementation of a R&I programme. These were introduced as part of creating the European Research Area (ERA) to align national strategies and overcome fragmentation of research effort towards an increased scientific, managerial and financial integration of European research and innovation. Interoperable and integrated national research systems would allow for better flows of knowledge, technology and people. Since then, the core activities of the partnerships consist of building critical mass mainly through collaborative projects, jointly developing visions, and setting strategic agendas.

As analysed in the **interim evaluation of Horizon 2020**¹¹, a considerable repertoire of partnership initiatives have been introduced over time, with 8 forms of implementation¹² and close to 120 partnership initiatives running under Horizon 2020 - without clear exit strategies and concerns about their degree of coherence, openness and transparency. Even if it is recognised that these initiatives allow setting long-term agendas, structuring R&I cooperation between otherwise dispersed actors, and leveraging additional investments, the evaluation points to the complexity generated by the proliferation of instruments and initiatives, and their insufficient contribution to policies at EU and national level.

Box 1 Key lessons from the interim evaluation of Horizon 2020 and R&I partnerships

- The **Horizon 2020 Interim Evaluation** concludes that the overall partnership landscape has become overly complex and fragmented. It identifies the need for rationalisation, improve their openness and transparency, and link them with future EU R&I missions and strategic priorities.
- The **Article 185 evaluation** finds that these public-public partnerships have scientific quality, global visibility and networking/structuring effects, but should in the future focus more on the achievement of policy impacts. From a systemic point of view, it found that the EU public-to-public cooperation (P2P) landscape has become crowded, with insufficient coherence.
- The **Article 187 evaluation** points out that Public-Private Partnership (PPP) activities need to be brought more in line with EU, national and regional policies, and calls for a revision of the Key Performance Indicators. As regards the **contractual PPPs (cPPPs)** their reviews identified challenges of coherence among cPPPs and the need to develop collaborations and synergies with other relevant initiatives and programmes at EU, national and regional level.

Over 80% of respondents to the Open Public Consultation (OPC) indicated that a significant contribution by future European Partnerships is 'fully needed' to achieve climate-related goals, to develop and effectively deploy technology, and for EU global competitiveness in specific sectors/domains. Views converged across all categories of respondents, including citizens, industry and academia.

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¹¹ Interim evaluation of Horizon 2020, Commission Staff Working Document, SWD(2017)221 and 222 Interim evaluation of the Joint Undertakings operating under Horizon 2020 (Commission Staff Working Document, SWD(2017) 339); Evaluation of the Participation of the EU in research and development programmes undertaken by several Member States based on Article 185 of the TFEU, Commission Staff Working Document, SWD (2017)340)

¹² E.g. initiatives based on Article 187 (Joint Technology Initiatives), Article 185 TFEU, Contractual Public-Private Partnerships (cPPPs), Knowledge & Innovation Communities of the European Institute of Innovation & Technology (EIT-KICs), ERA-NETs, European Joint Programmes, Joint Programming Initiatives.

The impact assessment of Horizon Europe identifies therefore the need to rationalise the EU R&I funding landscape, in particular with respect to partnerships, as well as to reorient partnerships towards more impact and delivery on EU priorities. To address these concerns and to realise the higher ambition for European investments, Horizon Europe puts forward a major simplification and reform for the Commission's policy on R&I partnerships¹³. Reflecting its pronounced systemic nature aimed at contributing to EU-wide 'transformations' towards the sustainability objectives, Horizon Europe indeed intends to make a more effective use of these partnerships with a more strategic, coherent and impact-driven approach. Key related changes that apply to all forms of European Partnerships encapsulated in Horizon Regulation are summarised in the Box below.

Box 2 Key features of the revised policy approach to R&I partnerships under Horizon Europe based on its impact assessment

- ✓ **Simpler architecture & toolbox** by streamlining 8 partnership instruments into 3 implementation forms (Co-Funded, Co-Programmed, Institutionalised), under the umbrella 'European Partnerships'
- ✓ More systematic and transparent approach to selecting, implementing, monitoring, evaluating and phasing out all forms of partnerships (criteria for European Partnerships):
 - The selection of Partnerships is embedded in the strategic planning of Horizon Europe, thereby ensuring coherence with the EU priorities. The selection criteria require that partnerships are established with stronger ex-ante commitment and higher ambition.
 - The implementation criteria stipulate that initiatives adopt a systemic approach in achieving impacts, including broad engagement of stakeholders in agenda-setting and synergies with other relevant initiatives to promote the take-up of R&I results.
 - A harmonised monitoring & evaluation system will be implemented, and ensures that progress is analysed in the wider context of achieving Horizon Europe objectives and EU priorities.
 - All partnerships need to develop an exit strategy from Framework Programme funding. This new approach is underpinned by principles of openness, coherence and EU added value.

✓ Reinforced impact orientation:

- Partnerships are established only if there is evidence they support achieving EU policy objectives
 more effectively than other Horizon Europe actions, by demonstrating a clear vision and targets
 (directionality) and corresponding long-term commitments from partners (additionality).
- European Partnerships are expected to provide mechanisms based on a concrete roadmap to join
 up R&I efforts between a broad range of actors towards the development and uptake of innovative
 solutions in line with EU priorities, serving the economy and society, as well as scientific progress.
- They are expected to develop close synergies with national and regional initiatives, acting as dynamic change agents, strengthening linkages within their respective ecosystems and along the value chains, as well as pooling resources and efforts towards the common EU objectives.

Under Horizon Europe, a 'European Partnership' is defined as "an initiative where the Union, prepared with early involvement of Member States and/or Associated Countries, together with private and/or public partners (such as industry, universities, research organisations, bodies with a public service mission at local, regional, national or international level or civil society organisations including foundations and NGOs), commit to jointly support the development and implementation of a programme of research and innovation activities, including those related to market, regulatory or policy uptake."

The Regulation further specifies that European Partnerships shall adhere to the "principles of Union added value, transparency, openness, impact within and for Europe, strong leverage effect on sufficient scale, long-term commitments of all the involved parties, flexibility in implementation, coherence, coordination and complementarity with Union, local, regional, national and, where relevant, international initiatives or other partnerships and missions."

14 Article 8 and Annex III of the Horizon Europe Regulation (common understanding))

¹³ Impact assessment of Horizon Europe, Commission Staff Working Document, SWD(2018)307.

1.3. Why should the EU act

1.3.1. Legal basis

Proposals for Institutionalised European Partnerships are based on:

- 1) Article 185 TFEU which allows the Union to make provision, in agreement with the Member States concerned, for participation in research and development programmes undertaken by several Member States, including participation in the structures created for the execution of those programmes; or
- 2) Article 187 TFEU according to which the Union may set up joint undertakings or any other structure necessary for the efficient execution of Union research, technological development and demonstration programmes.¹⁵

1.3.2. Subsidiarity

The EU should act only in areas where there is demonstrable advantage that the action at EU level is more effective than action taken at national, regional or local level. Research is a shared competence between the EU and its Member States according to the TFEU. Article 4 (3) specifies that in the areas of research, technological development and space, the EU can carry out specific activities, including defining and implementing programmes, without prejudice to the Member States' freedom to act in the same areas. The candidate initiatives focus on areas where there is a demonstrable value added in acting at the EU level due to the scale, speed and scope of the efforts needed for the EU to meet its long-term Treaty objectives and deliver on its strategic policy priorities and commitments. In addition, the proposed initiatives should be seen as complementary and reinforcing national and subnational activities in the same area. Overall European Partnerships find their **rationale in addressing a set of systemic failures**¹⁶:

- Their primary function is to create a platform for a strengthened **collaboration** and knowledge exchange between various actors in the European R&I system and an enhanced **coordination** of strategic research agendas and/or R&I funding programmes. They aim to address **transformational failures** to better align agendas and policies of public and private funders, pool available resources, create critical mass, avoid unnecessary duplication of efforts, and leverage sufficiently large investments where needed but hardly achievable by single countries.
- The concentration of efforts and pooling of knowledge on common priorities to solve multi-faceted societal and economic challenges is at the core of these initiatives. Specifically, enhanced cross-disciplinary and cross-sectoral collaboration and an improved integration of value chains and ecosystems are among the key objectives of these instruments. In the light of Horizon Europe, the aim is to drive system transitions and transformations towards EU priorities.
- Especially in fast-growing technologies and sectors such as ICT, there is a need to **react to emerging opportunities** and address systemic failures such as shortage in skills or critical mass or cross-sectoral cooperation along the value chains that would hamper attainment of future European leadership and/or strategic autonomy.
- They also aim to address **market failures** predominantly to enhancing industry investments thanks to the sharing of risks.

¹⁵ Both Articles are under Title XIX of the TFEU - Research and Technological Development and Space.

¹⁶ The Interim Evaluation of Horizon 2020 and the impact assessment of Horizon Europe provide qualitative and quantitative evidence on these points. Sections 1 and 2 of each impact assessment on candidate European Partnerships include more detail on the necessity to act at EU level in specific thematic areas.

2. THE CANDIDATE EUROPEAN PARTNERSHIPS – WHAT NEEDS TO BE DECIDED

2.1. Portfolio of candidates for Institutionalised European Partnerships

The new approach for more objective-driven and impactful European Partnerships is reflected in the way candidate Partnerships have been identified. It involved a co-design exercise aiming to better align these initiatives with societal needs and policy priorities, while broadening the range of actors involved. Taking into account the 8 areas for Institutionalised European Partnerships set out in the Horizon Europe Regulation¹⁷, a codesign exercise as part of the Strategic Planning process of Horizon Europe lead to the identification of 49 candidates for Co-Funded, Co-Programmed or Institutionalised European Partnerships¹⁸. Out of these, 13 were identified as suitable candidate Institutionalised Partnerships because of their objectives and scope¹⁹. Whilst the Co-Funded and Co-Programmed Partnerships are linked to the comitology procedure (including the adoption of the Strategic Plan and the Horizon Europe Work Programmes), Institutionalised Partnerships require the adoption of legislation and are subject to an impact assessment. The figure below gives an overview of all candidate European Partnerships according to their primary relevance to Commission priorities for 2019-2024.

Figure 1 - Overview of the candidates for Co-Funded, Co-Programmed and Institutionalised European Partnerships according to Horizon Europe structure

Cluster 1: Health	Cluster 4: Digital, Industry & Space	Cluster. 5: Climate, Energy & Mobility	Cluster 6: Food, Bioeconomy, Agriculture,	
Innovative	Key digital technologies	Clean Hydrogen	Circular Bio-based Europe	
Health Initiative	Smart networks & services	Safe & automated road transport	Safe & sustainable food	
EU-Africa Global Health	High-Performance Computing	Transforming EU's rail system	system	
Large-scale	European Metrology	Clean Aviation	Climate-neutral, sustainable & productive blue bio-	
innovation & transformation of	AI-Data-Robotics	Integrated Air Traffic Management	economy	
health systems	Photonics	European industrial battery value	Animal Health	
Personalised	Made in Europe	chain	Water4All	
Medicine	Clean steel – low-carbon	Zero-emission waterborne	Accelerating farming systems transitions	
ERA for Health	steelmaking	transport		
Rare diseases	Carbon neutral & circular industry	Zero-emission road transport Built environment & construction	Environmental observations	
One-Health Anti	Global competitive space	Clean energy transition	for sustainable agriculture	
Microbial Resistance	systems	-	Rescuing biodiversity	
Chemicals risk	Geological Service for Europe	Sustainable, smart & inclusive cities & communities	EIT Food	
assessment	EIT Digital	EIT Climate	Cluster 2: Culture, Creativity & Inclusive Society	
EIT Health	EIT Manufacturing	EIT InnoEnergy		
	EIT Raw Materials	EIT Urban Mobility	EIT Cultural and Creative Industries	
Horizon Europe Innovative Europ	Cross_Villa	rs		
Innovative SMEs European Open Science Cloud				

Source: Technpolis group (2020)

¹⁷ Horizon Europe Regulation (common understanding), Annex Va.

¹⁸ Shadow configuration of Strategic Programme Committee for Horizon Europe. The list of candidate European Partnerships is described in "Orientations towards the Strategic Plan of Horizon Europe" - Annex 7 ¹⁹ Only 12 are subject to this impact assessment, as one initiative on High Performance Computing has already been subject to an impact assessment in 2017 (SEC(2018) 47)

There are only three partnerships for which implementation as an Institutionalised Partnership under Article 185 is an option, i.e. European Metrology, the EU-Africa Global Health partnership, and Innovative SMEs. Ten partnerships are candidates for Institutionalised Partnerships under Article 187. Overall the initiatives can be categorised into 'horizontal' partnerships and 'vertical' partnerships.

The 'horizontal' partnerships have a central position in the overall portfolio, as they are expected to develop methodologies and technologies for application in the other priority areas, ultimately supporting European strategic autonomy in these areas as well as technological sovereignty. These 'horizontal' partnerships are typically proposed as Institutionalised or Co-programmed Partnerships, in addition to a number of EIT KICs, they cover mainly the digital field in addition to space, creative industries and manufacturing, but also the initiative related to Innovative SMEs. 'Vertical' partnerships are focused on the needs and development of specific application areas, and are primarily expected to support enhanced environmental sustainability thereby addressing Green Deal related objectives. They also deliver on policies for more people centred economy, through improved wellbeing of EU citizen and the economy, like health related candidate European Partnerships.

2.2. Assessing the necessity of a European Partnership and possible options for implementation

Horizon Europe Regulation Article 8 stipulates that Institutionalised European Partnerships based on Article 185 and 187 TFEU shall be implemented only where other parts of the Horizon Europe programme, including other forms of European Partnerships would not achieve the objectives or would not generate the necessary expected impacts, and if justified by a long-term perspective and high degree of integration. At the core of this impact assessment is therefore the need to demonstrate that the impacts generated through a Partnership approach go beyond what could be achieved with traditional calls under the Framework Programme – the Baseline Option. Secondly, it needs to assess if using the Institutionalised form of a Partnership is justified for addressing the priority.

For all candidate Institutionalised European Partnerships the options considered in this impact assessment are the same, i.e.:

- Option 0 Baseline option Traditional calls under the Framework Programme
- Option 1 Co-programmed European Partnership
- Option 2 Co-funded European Partnership
- Option 3 Institutionalised Partnership
 - o Sub-option 3a Institutionalised Partnerships based on Art 185 TFEU
 - Sub-option 3b Institutionalised Partnerships based on Art 187 TFEU

2.2.1. *Option 0 - Baseline option – Traditional calls*

Under this option, strategic programming for R&I in the priority area will be done through the mainstream channels of Horizon Europe. The related priorities will be implemented through **traditional calls** of Horizon Europe covering a range of actions, mainly R&I and/or innovation actions but also coordination and support actions, prizes or procurement. Most actions involve consortia of public and/or private actors in ad hoc combinations, while some actions are single actor (mono-beneficiary). There will be no dedicated implementation structure and no support other than what is foreseen in the related Horizon Europe Work Programme. This means that discontinuation costs/benefits of predecessor initiatives should be factored in for capturing the baseline situation when relevant.

Under this option, strategic planning mechanisms in the Framework Programme will allow for a high level of flexibility in the ability of traditional calls to respond to particular needs over time, building upon additional input in co-creation from stakeholders and programme committees involving Member States. The Union contribution to addressing the priority covers the full duration of the initiative, during the lifetime of Horizon Europe. Without a formal EU partnership mechanism, it is less likely that the stakeholders will develop a joint Strategic Research Agenda and commit to its implementation or agree on mutual commitments and contributions outside their participation in funded projects.

2.2.2. European Partnerships

Under this set of options, three different forms of implementation are assessed: Co-funded, Co-Programmed, Institutionalised European Partnerships. These have **commonalities that cannot serve as a distinguishing factor in the impact assessment process**. They are all based on agreed objectives and expected impacts and underpinned by Strategic Research and Innovation Agendas / roadmaps that are shared and committed to by all partners in the partnership. They all have to follow the same set of criteria along their lifecycle, as defined in the Horizon Europe Regulation (Annex III), including ex ante commitment from partners to mobilise and contribute resources and investments. The Union contribution is defined for the full duration of the initiative for all European Partnerships. The Horizon Europe legal act introduces few additional requirements for Institutionalised Partnerships, e.g. the need for long-term perspective, strong integration of R&I agendas, and financial contributions.

Figure 2 - Key differences in preparation and implementation of European Partnerships

Type	Legal form	Implementation		
G. D.				
Co-Programmed	Contractual arrangement / MoU	Division of labour , whereby Union contribution is implemented through Framework programme and partners' contributions under their responsibility.		
Co-Funded	Grant Agreement	Union provides co-funding for an integrated programme with distributed implementation by entities managing and/or funding national research and innovation programmes		
Institutionalised	Basic act (Council regulation,	Integrated programme with centralised		
based on Article	Decision by European	implementation		
185/187 TFEU	Parliament and Council)			

The main differences between the different forms of European Partnerships are in their preparation and in the way they function, as well as in the overall impact they can trigger. The Co-Programmed form is assessed as the simplest, and the Institutionalised the most complex to prepare and implement. The functionalities of the different form of Partnerships – compared to the baseline option – are presented in Figure 3. They relate to the types of actors Partnerships can involve and their degree of openness, the types of activities they can perform and their degree of flexibility, the degree of commitment of partners and the priority setting system, and their ability to work with their external environment (coherence), etc. These key distinguishing factors will be at the basis of the comparison of each option to determine their overall capacity to deliver what is needed at a minimised cost.

Figure 3 Overview of the functionalities provided by each form of European Partnerships, compared to the traditional calls of Horizon Europe (baseline)

Baseline: Horizon Europe calls	Option 1: Co- Programmed	Option 2: Co-Funded	Option 3a: Institutio- nalised Art 185	Option 3b: Institutionalised Art 187
^	of actors (including openn		mansea Alt 103	Institutionalista Alt 10/
Partners: N.A., no common set of actors that engage in planning and implementation	Partners: Suitable for all types: private and/or public partners, foundations	Partners: core of national funding bodies or govern-mental research organisations Priority setting: Driven	governmental research organisation	Partners: Suitable for all types: private and/or public partners, foundations Priority setting: Driven
Priority setting: open to all, part of Horizon Europe Strategic planning Participation in R&I activities: fully open in line with Horizon Europe rules	Priority setting: Driven by partners, open stakeholder consultation, MS in comitology Participation in R&I activities: fully open in line with Horizon Europe rules	by partners, open stakeholder consultation Participation in R&I activities: limited, according to national rules of partner countries	Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: fully open in line with Horizon Europe rules, but possible derogations	by partners, open stakeholder consultation Participation in R&I activities: fully open in line with Horizon Europe rules, but possible derogations
Type and range of acti	vities (including additiona	lity and level of integrat	ion)	
Activities: Horizon Europe standards that allow broad range of individual actions Additionality: no additional activities and investments outside the	Activities: Horizon Europe standard actions that allow broad range of individual actions, support to market, regulatory or policy/ societal uptake	Activities: Broad, according to rules/programmes of participating States, State-aid rules, support to regulatory or policy/ societal uptake	Activities: Horizon Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to	Activities: Horizon Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to systemic
funded projects <u>Limitations:</u> No systemic approach beyond individual actions	Additionality: Activities/investments of partners, National funding Limitations: Limited systemic approach beyond individual actions	Additionality: National funding Limitations: Scale & scope depend on participating programmes, often smaller in scale	systemic approach <u>Additionality:</u> National funding	approach (portfolios of projects, scaling up of results, synergies with other funds. Additionality: Activities/investments of partners/ national funding
Priority-setting process	s and directionality			
Priority setting: Strategic Plan and annual work programmes, covering max. 4 years. Limitations: Fully taking into account existing or to be developed SRIA/roadmap	Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Input to FP annual work programme drafted by partners, finalised by EC (comitology) Objectives & commitments set in contractual arrangement	Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Annual work programme drafted by partners, approved by EC Objectives & commitments set in Grant Agreement	Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Annual work programme drafted by partners, approved by EC Objectives & commitments set in legal act	Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Annual work programme drafted by partners, approved by EC (vetoright in governance) Objectives & commitments set in legal act
Coherence: internal (H	lorizon Europe) & externa	nl (other Union program	mes, national program	mes, industrial strategies)
Internal: Coherence between different parts of the FP Annual Work programme can be ensured by EC External: Limited for other Union programmes, no synergies with national/regional programmes & activities	Internal: Coherence among partnerships & with parts of the FP Annual Work programme can be ensured by partners & EC External: Limited synergies with other Union programmes & industrial strategies. If MS participate, with national/regional programmes & activities	Internal: Coherence among partnerships & with parts of the FP Annual Work programme can be ensured by partners & EC External: Synergies with national/ regional programmes & activities	Internal: Coherence among partnerships & with parts of the FP Annual Work programme can be ensured by partners & EC External: Synergies with national/regional programmes & activities	Internal: Coherence among partnerships & with parts of the FP Annual Work programme can be ensured by partners & EC External: Synergies with other Union programmes and industrial strategies If MS participate, with national/ regional programmes & activities

2.2.2.1. Option 1 - Co-programmed European Partnership

This form of European Partnership is **based upon a Memorandum of Understanding or a Contractual Arrangement** signed by the Commission and the private and/or public partners. Private partners are represented by industry associations, which also support the daily management of the partnership. This type of partnership would allow for a large degree of flexibility for the activities, partners and priorities to continuously evolve. The commitments of partners are political efforts described in the contractual arrangement and the contributions from partners are provided in kind more than financially. The priorities for the calls, proposed by the Partnership's members for integration in the Horizon Europe's Work Programmes, are subject to further input from Member States (comitology) and Commission services. The Union contribution is implemented within the executive agency managing Horizon Europe calls for research and innovation projects proposals. The full array of Horizon Europe instruments can be used, ranging from research and innovation (RIA) types of actions to coordination and support actions (CSA) and including grants, prizes, and procurement.

2.2.2.2. Option 2 – Co-funded European Partnership

The Co-funded European Partnership is **based on a Grant Agreement** between the Commission and a consortium of partners, resulting from a specific call in the Horizon Europe Work Programme. This form of implementation only allows to address public partners at its core. Typically these provide co-funding to a common programme of activities established and/or implemented by entities managing and/or funding national R&I programmes. The recipients of the EU co-funding implement the initiative under their responsibility, with national funding/resources pooled to implement the programme with co-funding from the Union. The expectation is that these entities would cover most if not all EU Member States. Calls and evaluations would be organised centrally, beneficiaries in selected projects would be funded at national level, following national funding rules.

2.2.2.3. Option 3 – Institutionalised European Partnership

This type of Partnership is the most complex and high-effort arrangement, and requires meeting additional requirements. Institutionalised European Partnership are based on a Council Regulation (Article 187 TFEU or a Decision by the European Parliament and Council (Article 185 TFEU) and are implemented by dedicated structures created for that purpose. These regulatory needs limit the flexibility for a change in the core objectives, partners, and/or commitments as these would require amending legislation. The basic rationale for this type of partnership is the need for a strong integration of R&I agendas in the private and/or public sectors in the EU in order to address a strategic challenge. It is therefore necessary to demonstrate that other forms of implementation would not achieve the objectives or would not generate the necessary expected impacts, and that a long-term perspective and high degree of integration is needed. For both Article 187 and 185 initiatives, contributions from partners can be in the form of financial and in-kind contributions. Eligibility for participation and funding follows by default the rules of Horizon Europe, unless a derogation is introduced in the basic act.

Option 3a - Institutionalised Partnerships based on Article 185 TFEU

Article 185 of the TFEU allows the Union to participate in programmes jointly undertaken by Member States and limits therefore the scope to **public partners** which are Member States and Associated Third Countries. This type of Institutionalised Partnership aims

therefore at reaching the greatest possible impact through the integration of national and EU funding, aligning national strategies in order to optimise the use of public resources and overcome fragmentation of the public research effort. It brings together R&I governance bodies of most if not all EU Member States (legal requirement: at least 40% of Member States) as well as Associated Third Countries that designate a legal entity (Dedicated Implementation Structure) of their choice for the implementation. By default, participation of non-associated Third Countries is not foreseen. Such participation is possible only if it is foreseen in the basic act and subject to conclusion of an international agreement.

Option 3b - Institutionalised Partnerships based on Article 187 TFEU

Article 187 of the TFEU allows the Union to set up joint undertakings or any other structure necessary for the efficient execution of EU research, technological development and demonstration programmes. This type of Institutionalised Partnership brings together a stable set of public and private partners with a strong commitment to taking a more integrated approach and requires the set-up of a dedicated legal entity (Union body, Joint Undertaking (JU)) that carries full responsibility for the management of the Partnership and implementation of the calls. Different configurations are possible:

- Partnerships focused on creating strategic industrial partnerships where, most often, the partner organisations are represented by one or more industry associations, or in some cases individual private partners;
- Partnerships coordinating national ministries, public funding agencies, and governmental research organisations in the Member States and Associated Countries:
- Or a combination of the two: the so-called tripartite model.

Participation of non-associated Third Countries is only possible if foreseen in the basic act and subject to conclusion of an international agreement.

2.3. Overview of the methodology adopted for the impact assessment

The methodology for each impact assessment is based on the Commission Better Regulation Guidelines²⁰ to evaluate and compare options with regards to their efficiency, effectiveness and coherence. This also integrates key selection criteria for European Partnerships.

Box 2 Summary of European Partnerships selection criteria²¹

- *Effectiveness* in achieving the related objectives and impacts of the Programme;
- *Coherence* and synergies of the European Partnership within the EU R&I landscape;
- Transparency & openness as regards the identification of priorities and objectives and the involvement of partners & stakeholders from the entire value chain, backgrounds & disciplines;
- Ex-ante demonstration of *additionality* and *directionality*;
- Ex-ante demonstration of the partners' *long term commitment*.

2.3.1. Overview of the methodologies employed

In terms of **methods and evidence used**, the impact assessments draw on an external study covering all candidate Institutionalised European Partnerships in parallel to ensure a high

²¹ For a comprehensive overview of the selection criteria for European Partnerships, see Annex 6.

²⁰ European Commission (2017), Better Regulation Guidelines (SWD (2017) 350)

level of coherence and comparability of analysis, in addition to an horizontal analysis. 22 For all initiatives, the understanding of the overall context of the candidate institutionalised European Partnerships relied on desk research, including among others the lessons learned from previous partnerships. This was complemented by the analysis of a range of quantitative and qualitative evidence, including evaluations of past and ongoing initiatives; foresight studies; statistical analyses of Framework Programmes application and participation data, and Community Innovation Survey data; analyses of science, technology and innovation indicators; reviews of academic literature; sectoral competitiveness studies and expert hearings. The analyses included a portfolio analysis, a stakeholder and social network analysis in order to profile the actors involved as well as their co-operation patterns, and an assessment of the partnerships' outputs (bibliometrics and patent analysis). A cost modelling exercise was performed in order to feed into the efficiency assessments of the partnership options, as described below. Public consultations (both open and targeted) supported the comparative assessment of the policy options. For each initiative, up to 50 relevant stakeholders were interviewed by the external contractor (policymakers, business including SMEs and business associations, research institutes and universities, and civil organisations, among others). In addition, the analysis was informed by the results of the Open Public Consultation run between September and November 2019, the consultation of Member States through the Strategic Programme Committee and the online feedback received on the Inception Impact Assessments of the set of initiatives.

A more detailed description of the methodology and evidence base that were mobilised, completed by thematic specific methodologies, is provided in Annexes 4 and 6.

2.3.2. *Method for identifying the preferred option*

The first step of the assessments consisted in scoping the problems that the initiatives are expected to solve given the overall economic, technological, scientific and social context, including the lessons to be learned from past and ongoing partnerships on what worked well and less well. This supported the identification of the objectives of the initiative in the medium and long term with the underlying intervention logic – showing how to get there.

Given the focus of the impact assessment on comparing different forms of implementation, the Better Regulation framework has then been adapted to introduce "key functionalities **needed**" - making the transition between the definition of the objectives and what would be crucial to achieve them in terms of implementation. The identification of "key functionalities needed" for each initiative as an additional step in the impact assessment is based on the distinguishing factors between the different options (see Section 2.2.1). In practical terms, each option is assessed on the basis of the degree to which it would allow for the key needed functionalities to be covered, as regards e.g. the type and composition of actors that can be involved ('openness'), the range of activities that can be performed (including additionality and level of integration), the level of directionality and integration of R&I strategies; the possibilities offered for coherence and synergies with other components of Horizon Europe, including other Partnerships (internal coherence), and the coherence with the wider policy environments, including with the relevant regulatory and standardisation framework (external coherence). This approach guides the identification of discarded options while allowing at the same time a structured comparison of the options not only as regards their effectiveness, efficiency and coherence, but also against a set of

Technopolis Group (2020), Impact Assessment Study for Institutionalised European Partnerships under Horizon Europe, Final Report, Study for the European Commission, DG Research & Innovation

other key selection criteria for European Partnerships (openness, transparency, directionality)²³.

In line with the Better Regulation Framework, the assessment of the effectiveness, efficiency and coherence of each option is made compared to the baseline. Therefore, for each of these aspects the performance of using traditional calls under Horizon Europe is first estimated and scored 0 to serve as a reference point. This includes the discontinuation costs/benefits of existing implementation structures when relevant. The policy options are then scored compared to the baseline with a + and - system with a two-point scale, to show a slightly or highly additional/lower performance compared to the baseline. A scoring of 0 of a policy option means that it would deliver as much as the baseline option.

On the basis of the evidence collected, the intervention logic of each initiative and the key functionalities needed, the impact assessments first evaluate the **effectiveness** of the various policy options to deliver on their objectives. To be in line with the Horizon Europe impact framework, the fulfilment of the specific objectives of the initiative is translated into 'expected impacts' - how success would look like -, differentiating between scientific, economic/ technological, and societal (including environmental) impacts. Each impact assessment considers to which extent the different policy options provides the 'key functionalities needed' to achieve the intended objectives. The effectiveness assessment does not use a compound score but shows how the options would deliver on the different types of expected impacts. This is done to increase transparency and accuracy in the assessment of options²⁴.

A similar approach is followed to evaluate the coherence of options with the overarching objectives of the EU's R&I policy, and distinguishes between **internal** and **external coherence**. Specifically, internal coherence covers the consistency of the activities that could be implemented with the rest of Horizon Europe, including European Partnerships (any type). External coherence refers to the potential for synergies and/or complementarities (including risks of overlaps/gaps) of the initiative with its external environment, including with other programmes under the MFF 2021-27, but also the framework conditions at European, national or regional level (incl. regulatory aspects, standardisation).

To compare the expected costs and benefits of each option (efficiency), the thematic impact assessments broadly follow a cost-effectiveness approach²⁵ to establish to which extent the intended objectives can be achieved for a given cost. A preliminary step in this process is to obtain a measure of the expected costs of the policy options, to be used in the thematic assessments. As the options correspond to different implementation modes, relevant cost categories generally include the costs of setting-up and running an initiative. For instance, set-up costs includes items such as the preparation of a European Partnership proposal and the preparation of an implementation structure. The running costs include the annual work programme preparation costs. Where a Partnership already exists, discontinuation costs and cost-savings are also taken into account²⁶. The table below provides an overview of the cost

²³ The criterion on the ex-ante demonstration of partners' long term commitment depends on a series of factors that are unknown at this stage, and thus fall outside the scope of the analysis.

²⁴ In the thematic impact assessments, scores are justified in a detailed manner to avoid arbitrariness and spurious accuracy. A qualitative or even quantitative explanation is provided of why certain scores were given to specific impacts, and why one option scores better or worse than others.

²⁵ For further details, see Better Regulation Toolbox # 57.

²⁶ Discontinuation costs will bear winding down and social discontinuation costs and vary depending on e.g. the number of full-time-equivalent (FTEs) staff concerned, the type of contract (staff category and duration) and applicable rules on termination (e.g. contracts under Belgian law or other). If buildings are being rented, the cost of rental termination also apply. As rental contracts are normally tied to the expected duration of the

categories used in the impact assessment and a qualitative scoring of their intensity when compared to the baseline option (traditional calls). Providing a monetised value for these average static costs would have been misleading, because of the different features and needs of each candidate initiative.²⁷ The table shows the overall administrative, operational and coordination costs of the various options. These costs are then put into context in the impact assessments to reflect the expected co-financing rates and the total budget available for each of the policy options, assuming a common Union contribution (cost-efficiency):

- The costs related to the baseline scenario (traditional calls under Horizon Europe) are pre-dominantly the costs of implementing the respective Union contribution via calls and project, managed by the executive agencies (around 4%, efficiency of 96% for the overall investment).
- For a Co-Programmed partnership the costs of preparation and implementation increase only marginally compared to the baseline (<1%), but lead to an additional R&I investment of at least the same amount than the Union contribution²⁸ (efficiency of 98% for the overall investment).
- For a Co-Funded partnership the additional R&I investment by Member States accounts for 2,3 times the Union contribution²⁹. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the national programmes, can be estimated at 6% of the Union contribution (efficiency of 98% related to the overall investment).
- For an Article 185 initiative the additional R&I investment by Member States is equal to the Union contribution³⁰. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the dedicated implementation structure, can be estimated at 7% of the Union contribution (efficiency of 96% related to the overall investment).
- For an Article 187 initiative the additional R&I investment by partners is equal to the Union contribution³¹. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the dedicated implementation structure, can be estimated at 9% of the Union contribution (efficiency of 94% related to the overall investment).

current initiatives, these termination costs are likely to be very limited. In parallel, there would also be financial cost-savings related to the closing of the structure, related to operations, staff and coordination costs in particular. This is developed further in the individual efficiency assessments.

in particular. This is developed further in the individual efficiency assessments.

27 A complete presentation of the methodology developed to assess costs as well as the sources used is described in the external study supporting this impact assessment (Technopolis Group, 2020).

²⁸ Minimum contributions from partners equal to the Union contribution

²⁹ Based on the default funding rate for programme co-fund actions of 30%, partners contribute with 70% of the total investment.

³⁰ Based on the minimum requirement in the legal basis that partners contribute at least 50% of the budget.

³¹ Based on the minimum requirement in the legal basis that partners contribute at least 50% of the budget.

Figure 4 - Intensity of additional costs compared with Horizon Europe Calls (for Partners, *stakeholders*, *public and EU*)

Cost items	Baseline: traditional calls	Option 1: Coprogrammed	Option 2 Co-funded	Option 3a - Art. 185	Option 3b -Art. 187		
Preparation and set-up costs							
Preparation of a partnership proposal (partners and EC)	0		$\uparrow \uparrow$				
Set-up of a dedicated implementation structure		0		Existing: ↑ New: ↑↑	Existing: ↑↑ New: ↑↑↑		
Preparation of the SRIA / roadmap	0		$\uparrow \uparrow$				
Ex-ante Impact Assessment for partnership		0		↑ ↑	↑		
Preparation of EC proposal and negotiation		0		↑ ↑	↑		
Running costs (Annual cycle of implementation)							
Annual Work Programme preparation	0	↑					
Call and project implementation	0	0 In case of MS contributions: ↑	↑	\uparrow	1		
Cost to applicants Comparable, unless there are strong arguments of major differences in oversubscription					fferences in		
Partners costs not covered by the above	0	\uparrow	0	↑	↑		
Additional EC costs (e.g. supervision)	0	\uparrow	↑	↑	$\uparrow \uparrow$		
Winding down costs							
EC		0			$\uparrow \uparrow \uparrow$		
Partners	0	↑	0	\uparrow	↑		

Notes: 0: no additional costs, as compared with the baseline; \(\gamma\): minor additional costs, as compared with the baseline; $\uparrow \uparrow$: medium additional costs, as compared with the baseline; $\uparrow \uparrow \uparrow$: higher costs, as compared with the baseline.

The cost categories estimated for the common model are then used to develop a scorecard analysis and further refine the assessment of options for each of the 12 candidate Institutionalised Partnerships. Specifically, the scores related to the set-up and implementation costs are used in the thematic impact assessments to consider the scale of the expected benefits and thereby allow a simple "value for money" analysis (costeffectiveness)³². In carrying out the scoring of options, the results of fieldwork, desk research and stakeholder consultation undertaken and taken into account.

For the **identification of the preferred option**, the scorecard analysis builds a hierarchy of the options by individual criterion and overall in order to identify a single preferred policy option or in case of an inconclusive comparison of options, a number of 'retained' options or hybrid. This exercise supports the systematic appraisal of alternative options across multiple types of monetary, non-monetary and qualitative dimensions. It also allows for easy visualisation of the pros and cons of each option. Each option is attributed a score of the adjudged performance against each criterion with the three broad appraisal dimensions of effectiveness, efficiency and coherence.

As a last step, the alignment of the preferred option with key criteria for the selection of European Partnerships is described, reflecting the outcomes of the 'necessity test'. 33 The

³² More details on the methodology can be found in Annex 4.

³³Certain aspects of the selection criteria will be further addressed/ developed at later stages, notably in the context of preparing basic acts (e.g. Openness and Transparency; Coherence and Synergies), in the Strategic Research and Innovation Agendas (e.g. Directionality and Additionality), and by collecting formal commitments (Ex-ante demonstration of partners' long-term commitment).

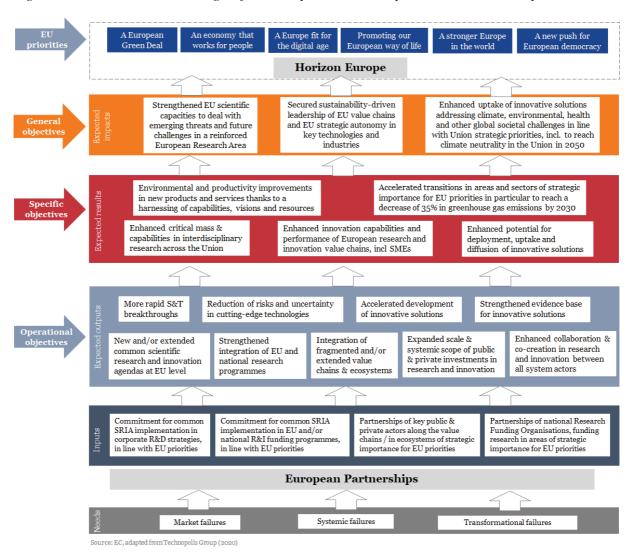
monitoring and evaluation arrangements are concluding the assessment, with an identification of the key indicators to track progress towards the objectives over time.

2.4. Horizontal perspective on candidate Institutionalised European Partnerships

2.4.1. Overall impact orientation, coherence and efficiency needs

The consolidated **intervention logic** for the set of candidate Institutionalised European Partnerships in the Figure below builds upon the objectives as reported in the individual impact assessments.

Figure 5 – Overall intervention logic of the European Partnerships under Horizon Europe



When analysed as a package the 12 candidate Institutionalised European Partnerships are expected to support the achievement of the European policy priorities targeted by Horizon Europe by pursuing the following joint general objectives:

a) Strengthening EU scientific capacities to deal with emerging threats and future challenges in a reinforced European Research Area;

- b) Securing sustainability-driven leadership of EU value chains and EU strategic autonomy in key technologies and industries; and
- c) Enhancing the uptake of innovative solutions addressing climate, environmental, health and other global societal challenges in line with Union strategic priorities, including to reach climate neutrality in the Union in 2050.

In terms of specific objectives, they jointly aim to:

- a) Enhance the critical mass and scientific capabilities in interdisciplinary research and innovation across the Union;
- b) Accelerate the transitions in areas and sectors of strategic importance for EU priorities, in particular to reach a decrease of 35% in greenhouse gas emissions by 2030, and deliver on the digital transition;
- c) Enhance the innovation capabilities and performance of European research and innovation value chains, incl. SMEs;
- d) Enhance the potential for deployment, uptake and diffusion of innovative solutions;
- e) Deliver environmental and productivity improvements in new products and services thanks to a harnessing of EU capabilities and resources.

In terms of their operations, taking a horizontal perspective on all initiatives allows for the identification of further possible collective efficiency and coherence gains for more impact:

- Coherence for impact: The extent and speed by which the expected results and impacts will be reached, will depend on the scale of the R&I efforts triggered, the profile of the partners involved, the strength of their commitments, and the scope of the R&I activities funded. To be fully effective it comes out clearly that future partnerships need to operate over their whole life cycle in full coherence with their environment, including potential end users, regulators and standardisation bodies. This relates also to the alignment with relevant EU, national or regional policies and synergies with R&I programmes. This needs to be factored in as of the design stage to ensure a wide take-up and/or deployment of the solutions developed, including their interoperability.
- Collaboration for impact: Effectiveness could also be improved collectively through enhanced cross-disciplinary and cross-sectoral collaboration and an improved integration of value chains and ecosystems. An adequate governance structure appears in particular necessary to ensure cross-fertilisation between all European Partnerships. This applies not only to initiatives where similar R&I topics are covered and/or the same stakeholders involved or targeted, but also to the interconnections needed between the 'thematic' and the 'vertical' Partnerships, as these are expected to develop methodologies and technologies for application in EU priority areas. Already at very early stages of preparing new initiatives, Strategic Research and Innovation Agendas and roadmaps need to be aligned, particularly for partnerships that develop enabling technologies that are needed in other Partnerships. The goal should be to achieve greater impacts jointly in light of common challenges.
- Efficiency for impact: Potential efficiency gains could also be achieved by joining up the operational functions of Joint Undertakings that do not have a strong context dependency and providing them through a common back-office³⁴. A number of operational activities of the Joint Undertakings are of a technical or administrative

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³⁴ See Annex 6 for an overview of key functions/roles that could be provided by a common back office.

nature (e.g. financial management of contracts), or procured from external service providers (e.g. IT, communication activities, recruitment services, auditing) by each Joint Undertaking separately. If better streamlined this could create a win-win situation for all partners leading to better harmonization, economies of scales, and less complexity in supervision and support by the Commission services.

2.4.2. Analysis of coherence of the overall portfolio of candidate initiatives at the thematic level

Looking at the coherence of the set of initiatives at the thematic level, the "digital centric" initiatives have a strong focus on supporting the digital competitiveness of the EU ecosystem. Their activities are expected to improve alignment and coordination with Member States and industry for the development of world-competitive EU strategic digital technology value chains and associated expertise. Addressing the Key Digital Technologies, the 5G and 6G connectivity needs as part of a Smart Networks and Services initiative and the underlying supercomputing capacities through a European High Performance Computing initiative present potential for synergies that can be addressed through cooperative actions (e.g. joint calls, coordinated support activities, etc.). They may as well profit from and contribute to Partnerships envisaged for Photonics, AI, data, robotics, Global competitive space system and Made in Europe, together with the EIT Digital. Synergies between these initiatives and several programmes (Digital Europe and Connecting Europe as well as cohesion programmes) are needed in areas where EU industry has to develop leadership and competitiveness in the global digital economy. They are expected to impact critical value chains including on sectors where digital is a strong enabler of transformation (health, industrial manufacturing, mobility/transport, etc.).

The transport sector face systemic changes linked to decarbonisation and digitalisation. Large scale R&I actions are needed to prepare the transition of these complex sectors to provide clean, safer, digital and economically viable services for citizens and businesses. Past decades have shown that developing and implementing change is difficult in transport due to its systemic nature, many stakeholders involved, long planning cycles and large investments needed. A systemic change of the air traffic network through an Integrated Air Traffic Management initiative should ensure safety and sustainability of aviation, while a Clean Aviation initiative should focus on the competitiveness of tomorrow's clean aircrafts made in Europe. The initiative for Transforming Europe's rail system would comprehensively address the rail sector to make it a cornerstone in tomorrow's clean and efficient door-to-door transport services, affordable for every citizen as well as the most climate-friendly mode of transport for freight. Connected and Automated Mobility is the future of road transport, but Europe is threatened to fall behind other global regions with strong players and large harmonised markets. The initiative Safe and Automated Road Transport would bring stakeholders together, creating joint momentum in digitalising road transport and developing new user-based services. Stronger links and joint actions will be established between initiatives to enable common progress wherever possible. The Clean Hydrogen initiative would be fundamental to that regard. Synergies would also be sought with partnerships driving the digital technological developments.

To deliver a deep decarbonisation of highly emitting industrial sectors such as the steel, transport and chemical industries would require the production, distribution and storage of **hydrogen** at scale. The candidate hydrogen initiative would have a central positioning in terms of providing solutions to the challenges for sustainable mobility and energy, but also is expected to operate in synergies with other industry related initiatives. The initiative would interact in particular with initiatives on the zero emission road and water transport, transforming Europe's railway system, clean aviation, batteries, circular industry, clean steel

and built environment partnerships. There are many opportunities for collaboration for the delivery and end-use of hydrogen. However, the Clean Hydrogen initiative would be the only partnership focused on addressing hydrogen production technologies.

Metrology, the science of measurement, is an enabler across all domains of R&I. It supports the monitoring of the Emissions Trading System, smart grids and pollution, but also contributes to meeting demands for measurement techniques from emerging digital technologies and applications. More generally, emerging technologies across a wide range of fields from biotechnologies, new materials, health diagnostics or low carbon technologies are giving rise to demands requiring a world-leading EU metrology system.

The initiative for a Circular Bio-based Europe is intended to solve a shortage of industry investments in the development of bio-based products whose markets do not have yet certain long-term prospects. The Innovative Health Initiative and EU-Africa Global Health address the lack of investments in the development of solutions to specific health challenges. The initiative on Innovative SMEs supports innovation-driven SMEs in participating in international, collaborative R&I projects with other innovative firms and research-intensive partners. As a horizontal initiative it is expected to help innovative SMEs to grow and to be successfully embedded in global value chains by developing methodologies and technologies for potential application in the other partnership areas or further development by the instruments of the European Innovation Council.

The description of the interconnections between all initiatives for each Horizon Europe cluster is provided in the policy context of each impact assessment and further assessed in the coherence assessment for each option.

PART 2 - THE CANDIDATE EUROPEAN PARTNERSHIP ON INNOVATIVE HEALTH

1. Introduction: Political and legal context

According to the EU Charter on Fundamental Rights, 'Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities' 35.

In the EU, Member States hold primary responsibility for organising and delivering health services and medical care. The EU health policy serves to complement national policies, and to ensure health protection in all EU policies. In particular, EU action shall promote research into the causes, transmission and prevention of major health scourges, in line with Article 168 TFEU ³⁶. As regards strengthening the EU scientific and technological bases and for addressing competitiveness, the legal ground is provided by Article 179 TFEU³⁷.

Good health is a major determinant of quality of life, wellbeing and social participation. Along with a vibrant and dynamic health industry, it contributes to shaping a sustainable economy. A status of good health in a society depends on a multitude of actors, including private companies that develop health technologies (such as medicines and vaccines, implantable medical devices or in vitro diagnostics). Since health technologies are applied directly to individuals (for examples, medicines are distributed in the human body, whereas implantable devices are introduced at a specific body site), they are subject to very stringent regulatory mechanisms³⁸. Hence, in order to develop a new health technology³⁹ and make it available to patients, health research and innovation (R&I) follows a long and costly pathway of pre-clinical testing and then clinical investigations on human subjects. This development pathway, which differs for medicines and medical devices, is usually conducted and financed by private companies. After obtaining necessary approvals, these companies can market such a novel development and bring it to the end-users (i.e. health

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Article 35, Health-Care, Official Journal of the European Union C 303/17 (2007) https://fra.europa.eu/en/eu-charter/article/35-health-care

³⁶ Article 168 TFEU, paragraph 1: 'Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health. The Union shall complement the Member States' action in reducing drugs-related health damage, including information and prevention'.

Article 179 TFEU, paragraph 1: 'The Union shall have the objective of strengthening its scientific and technological bases by achieving a European research area in which researchers, scientific knowledge and technology circulate freely, and encouraging it to become more competitive, including in its industry, while promoting all the research activities deemed necessary by virtue of other Chapters of the Treaties'.

Directive 2001/83/EC on the Community code relating to medicinal products for human use, Regulation

Directive 2001/83/EC on the Community code relating to medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use, Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use, Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices.

Health technology refers to a pharmaceutical, a medical technology or medical and surgical/radiation procedures as well as measures for disease prevention, diagnosis or treatment used in health care (Directive 2011/24/EU).

care providers and patients). Decisions on reimbursement⁴⁰ and pricing⁴¹ lie within the competence of Member States⁴². Such decisions are in most cases based on the evaluation of the added value⁴³ brought by the new technology to patients and society.

This document focuses on assessing the most effective, efficient and coherent way of implementing an initiative which would focus on joint European research and innovation activities in health care under Horizon Europe.

1.1. Emerging challenges in the field

Health in the EU faces current and emerging challenges in domains ranging from the social to the economic. These challenges could be addressed, to some extent at least, through research and innovation (R&I).

Europe's health faces major challenges due to an ageing of society and the related health conditions it brings, as well as to the increasing burden of chronic diseases such as cancer, dementia, diabetes, arthritis, and to the threat of infectious diseases with resulting potential pandemics and growing antimicrobial resistance (AMR), as explained in detail in Annex 6 Section 2.1. Health R&I can help to address these demands by working towards better, safe, more effective and cost-effective solutions to promote health, to prevent, early detect, diagnose, treat and manage health conditions and to deliver health care. These opportunities are amplified by new advances in digital technologies, big data, artificial intelligence, the knowledge of human genes and advanced therapies that create opportunities to design solutions tailored to patients' specific health care needs.

However, there are still considerable knowledge and evidence gaps when it comes to understanding the underlying mechanisms of diseases and the determinants of health⁴⁴. In addition, novel therapies, technologies and approaches face specific barriers and hurdles in R&I, implementation and scale-up before they can be useful to patients and health care systems. These barriers stem from a lack of sufficient investment, scientific knowledge and relevant R&I expertise, from the absence of appropriate standards and of frameworks for intellectual property management, as well as from high market prices of the end products.

How to redesign pricing, reimbursement and procurement? http://www.euro.who.int/en/about_us/partners/observatory/publications/policy-briefs-and-summaries/ensuring-access-to-medicines-how-to-stimulate-innovation-to-meet-patients-needs

⁴⁰ Reimbursement refers to covering the cost of health care services, including medicines, by a third-party payer (e.g. a public payer such as a social health insurance fund or national health service). European Observatory of Health Systems (a partnership hosted by WHO) (2018), Ensuring access to medicines: How to redesign pricing, reimbursement and procurement? http://www.euro.who.int/en/about-payership.

⁴¹ Pricing is the act or process of determining a price, be it by a responsible authority, the manufacturer or market forces. Idem.

⁴² Article 168 TFEU, paragraph 7: 'Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them.' and Directive 89/105/EEC relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems.

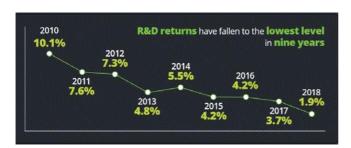
⁴³ Value in health care is a multidimensional concept as highlighted by the Expert Panel on effective ways in investing in Health (EXPH). Most common elements of existing value frameworks to assess health interventions include: therapeutic benefit, safety, costs, innovation level, health problem (severity of the disease and medical need), organisational aspects, ethical aspects, societal and legal aspects. Those various elements need to be evidence-based informed and combined using an appropriate approach (e.g. cost-effectiveness analysis, multi-criteria decision analysis) so that to inform decision-making on the reimbursement, pricing, adoption, and implementation of health interventions.

⁴⁴ European Commission (2019), Orientations towards the first Strategic Plan implementing the research and innovation framework programme Horizon Europe. Annex: Horizon Europe Cluster 1 Health.

Regulatory, legal and ethical aspects are also crucial elements to consider for a successful development and implementation of technological innovations⁴⁵. For example, unlocking the potential of data and digitalisation for health-related use depends on the capacity to access, collect, distribute, combine and analyse vast amounts of data. This requires longterm investments in existing or future data infrastructure, dealing with ethical and data security concerns, and putting in place frameworks for information sharing 46. Similarly, appropriate regulatory pathways, as well as new health technology assessment (HTA⁴⁷) methods and tools, are required for the assessment of emerging and converging technologies. Such technologies include e.g. drug-device combination products⁴⁸, nanotechnology-enabled products and medical devices that use digital communication tools or rely on artificial intelligence (AI) or software and are often referred to as "smart" medical devices.

According to a Deloitte report⁴⁹, research and development (R&D) productivity (expected returns on R&D investments) in the biopharmaceutical sector has steadily decreased over the last decade (Figure 1), while the cost of bringing of an asset to market has significantly increased⁵⁰. If this trend persists, the industry will see less and less incentives to invest in the risky and costly search for health innovations, which will endanger their future provision to tackle current and emerging health needs and result in fewer new treatment options being available to patients.

Figure 1. Return on R&D investment in biopharmaceutical sector over time



Health-care expenditure is enormous. It accounts for EUR 1.5 trillion in the EU annually and USD 3.6 trillion in the US or 10.0% and 17.2% of the GDP respectively⁵¹. It also means a vast market for health industry as one fifth of the expenditure is on medical goods⁵². Beyond the EU and US, there is a rapidly growing global market and it is essential that the

⁴⁵ European Commission Directorate General for Research and Innovation (2019), Analysis of responses to the Innovative Health Initiative, Public Consultation on the Roadmap - inception impact assessment. Consultation period 30 July – 27 August 2019.

46 EC (2019), Strengthening strategic value chains for a future-ready EU industry.

⁴⁷ Health technology assessment (HTA) is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value. HTA is primarily used to inform decision-making in Member States by providing a scientific evidence base for decisions on the pricing and reimbursement of health technologies.

⁴⁸ European Medicines Agency (2018), EMA Regulatory Science to 2025. Strategic reflection.

⁴⁹ Deloitte (2018), Unlocking R&D productivity, Measuring the return from pharmaceutical innovation 2018, Available at: www2.deloitte.com/content/dam/Deloitte/global/Documents/Life-Sciences-Health Care/deloitte-uk-measuring-return-on-pharma-innovation-report-2018.pdf.

Wouters OJ et al, (2020), Estimated R&D investment needed to bring a new medicine to market, 2009-2018. JAMA. 323(9) 844-853.

⁵¹ OECD (2018), Health at a glance.

⁵² Impact Assesment report of European Partnership for Innovative Health (2020), Annex 5.

EU maintains a world-leading health industry that innovates and contributes to economic growth. The health industry is a key driver for growth through creation of high-value jobs and a positive trade balance, trading not only within Europe but also worldwide. It has the potential to attract foreign direct investment and create global companies that bring revenue to the EU. In addition, developing new solutions to improve prevention of diseases would be key to alleviate the burdens on the health care systems.

1.2. EU relative positioning in the field

The EU has significant monetary resources and is competitive across many industry sectors globally, allowing the EU and its Member States (MS) to make substantial investments in R&I. The EU accounts for one-fifth of the world's R&D spend and 23% of global public R&D⁵³. The EU has more than 1.8 million researchers overall, compared to 1.6 million in China and 1.3 million in the United States. Building on the strengths of its community of researchers and innovators, the EU is in a position to take the lead in developing and deploying scientific breakthrough solutions to improve health and wellbeing, not only within the EU but also globally.

However, the EU has not been able to capitalize fully on its strengths. This is due to lower investment in R&D-intensive businesses and in education and skills development (e.g. ICT and economics skills), coupled with relatively weaker knowledge flows between stakeholders compared to other leading countries⁵⁴. Furthermore, the EU health industry and market are fragmented. The different health industry sectors, e.g. pharmaceuticals, diagnostics, imaging, medical devices, etc. have diverging business models and development timelines, making collaboration difficult. This situation is exacerbated by the EU's own nature of individual Member States with varying regulatory and market access procedures and approaches applicable to health care. The EU health care systems represent a complex network and introduction of new solutions is difficult especially for SMEs that struggle to access new markets and ecosystems. One of the reasons could be a lack of knowledge and experience related to these new markets, and (perceived or real) lack of budget and time to overcome the costs associated with entering into new partnerships and markets 55. This factor - being beyond the scope of any funding initiative under EU framework programmes – directly affects the willingness of EU companies to invest in costand time-intensive R&I in the EU. Hence, other world economies with more uniform health technology approval pathways become a more attractive place for health R&I and subsequent introduction of innovations to the market.

In terms of overall R&D investments, China is quickly overtaking both the EU and the US. This may be one reason why the EU is lagging behind China (and the US) in areas such as e.g. artificial intelligence (AI)⁵⁶, which has the potential to significantly increase productivity in health care. The global health data market is predicted to increase from around USD 14 billion in 2019 to about USD 70 billion in 2025⁵⁷. The EU needs to react

⁵³ European Commission (2018), Science, Research and Innovation Performance of the EU (SRIP) report.

⁵⁴ European Commission (2018), Science, Research and Innovation Performance of the EU (SRIP) report.

⁵⁵ European Commission (2018) Commission staff working document 'Enabling the digital transformation of health and care in the Digital Single Market'

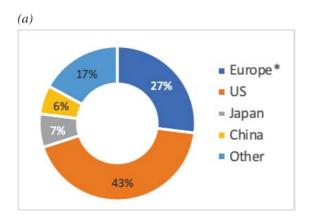
European Commission (2018), USA-China-EU plans for AI: where do we stand?,https://ec.europa.eu/growth/tools-databases/dem/monitor/content/usa-china-eu-plans-ai-where-do-we-stand.

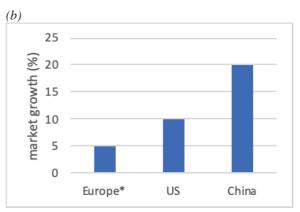
⁵⁷ Statista 2019, Global healthcare big data market size in 2016 and a forecast for 2025, https://www.statista.com/statistics/909654/global-big-data-in-healthcare-market-size/.

strategically to ensure its current health data market (valued at EUR 2 billion⁵⁸) retains sovereignty and at the same time, captures its fair share of this growth to providing European citizens with health solutions designed and produced in Europe.

The medical technology (medtech) and pharmaceutical sectors are two of the main healthrelated industry sectors in Europe, they are also the crucially affected by the problems described in Section 1.1. Medtech covers many disease areas and includes in vitro diagnostics and imaging. There are about 27,000 medtech companies in Europe (mostly SMEs based in Germany, UK, Italy, Switzerland, Spain and France) directly employing over 675,000 people⁵⁹. By comparison, the US medtech industry employs about 400,000⁶⁰. The medtech industry is an important source of health innovation and in 2017 there were more patent applications (13,000) filed with the European Patent Office in the area of medtech than in the areas of pharmaceuticals (6,300) and biotechnology (6,300) combined. The European medtech market was estimated to be roughly EUR 115 billion in 2017 and is currently estimated to make up 27% of the world market, making it the second largest medtech market after the US (43%) (Figure 2a). Europe has a positive medtech (excluding in vitro diagnostics) trade balance of EUR 19.7 billion (2017) with the US, China and Japan being the major trade partners. In comparison, the US medical devices trade surplus is at EUR 2 billion. However, without sufficient investment in R&D, Europe's leadership position in the area of medtech may change in the future. The predicted annual growth of the industry in Europe is 5% compared to at least 20% in China and 10% in the US (Figure

Figure 2. (a) Global market share of medtech industry and (b) anticipated annual industry growth. Source: (a) medtech Europe Facts Figures 2019. (b) Technopolis analysis of data reported in Hospodková, P, 2019⁶¹. *Europe includes EU28 + Norway and Switzerland.





The biotech and pharma sector are a cornerstone of Europe's knowledge based economy. The pharmaceutical industry directly employs approximately 750,000 people, and the sector is Europe's second largest R&D investor with an annual EUR 40 billion spending on

⁵⁸ International Data Corporation, 2018. European Data Market Monitoring Tool.

The European Medical Technology Industry in figures 2019, Medtech Europe, https://www.medtecheurope.org/wp-content/uploads/2019/04/The-European-Medical-Technology-Industry-infigures-2019-1.pdf.

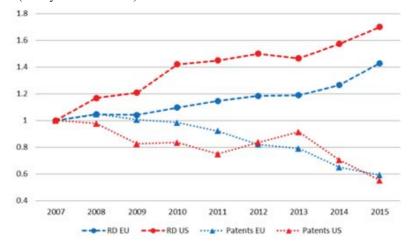
⁶⁰ Hospodková, P., et al., 2019. Global centers of medical device technology: United States, Europe and China. Lékař a technika-Clinician and Technology, 48(4), pp.136-144.

⁶¹ Hospodková, P., et al., 2019. Global centers of medical device technology: United States, Europe and China. Lékař a technika-Clinician and Technology, 48(4), pp.136-144.

R&D⁶². The innovativeness of the sector translates into high volumes of exports, generating a EUR 91 billion trade surplus⁶³ in 2018 for the EU.

However, this leading position is already being challenged by global competitors, notably by the US and China. Figure 3 shows that while R&D investment in the EU has continuously increased in the last decade, the pace of growth was higher in the US, which also started from a higher base.

Figure 3. Evolution of the R&D investment and number of patents in the pharma and biotech sectors for EU and US companies (base year 2007 = 1.0).



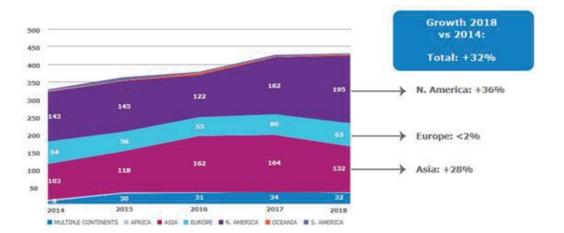
The changing pharmaceutical landscape is also evident in the development of advanced therapy medicinal products (ATMPs). ATMPs represent the new frontier of innovative health solutions; they are based on genes (gene therapy), cells (cell therapy) and tissues (tissue engineering). Cell and gene therapies offer treatments, even cures for patients affected by life-threatening diseases. They not only extend life and improve the quality of life of patients, but at the same time have the potential to reduce medium and long-term the economic burden of care. While it was the EU that pioneered research in ATMPs, other regions in the world, notably the US and China, have gained momentum in the last couple of years and are initiating increasingly more clinical trials involving ATMPs⁶⁴. The number of new clinical trials increased by 32% globally, 36% in North America, 28% in Asia, and less than 2% in Europe (Figure 4).

Figure 4. Clinical trials with ATMPs initiated Jan 2014 – June 2019, by continent and year.

⁶² The 2019 EU industrial R&D investment scoreboard, https://ec.europa.eu/info/news/2019-eu-industrial-rd-investment-scoreboard-report-2019-dec-18-en.

⁶³ Eurostat, International trade in medicinal and pharmaceutical products (2020), https://ec.europa.eu

[/]eurostat/statistics-explained/index.php/International_trade_in_medicinal_and_pharmaceutical_products 64 Alliance for Regenerative Medicine: Clinical Trials in Europe: Recent Trends in ATMP Development, - https://alliancerm.org/wp-content/uploads/2019/10/Trends-in-Clinical-Trials-2019-Final Digital.pdf.



Moreover, private investors have little economic incentives to allocate R&I resources to areas where market prospects are poor or expected return on investment is low. While some areas might indeed provide attractive market prospects, innovation is particularly challenging given the significant gaps in scientific knowledge⁶⁵.

As regards entity size, smaller companies tend to have greater R&I productivities than big companies as the former tend to focus more on new product pipelines, have less costly infrastructure and less organisational complexity (e.g. no mass-scale production facilities). On the other hand, bigger companies have more resources to take forward the costly late-phase development of promising assets, such as candidate new drugs or medical devices.

Box 1 Support for the field in the previous Framework Programmes – key strengths & weaknesses identified

What was/is being done with EU research and innovation funding until now

Under Horizon 2020, the overall budget for the 'Health, demographic change and wellbeing' Societal Challenge was EUR 7.5 billion, including Joint Undertakings (JUs).

The Innovative Medicine Initiative (IMI) was one such joint undertaking that supported R&I in the field of pharmaceutical development. For the 2014-2024 period it is named IMI2 JU to distinguish it from its predecessor IMI JU operating under the Seventh Framework Programme (FP7). IMI2 JU's total budget of up to EUR 3.276 billion makes it the world's largest public-private partnership in life sciences, with world-wide recognition. The EU's financial contribution to IMI2 JU was set at up to €1.638 billion to match the contribution of EFPIA (at least €1.425 billion) and other members or associated partners (industrial partners other than pharmaceutical industries e.g. technology providers, diagnostics companies, charities or data handlers). IMI2 JU has managed to attract significant investment from associated partners and from non-EU entities, demonstrating the attractiveness of this programme globally.

IMI contributes to improving citizens' health by speeding up the development of innovative medicines, particularly in areas where there is an unmet need. In IMI projects, a number of big industry partners (members of the European Federation of Pharmaceutical Industries and Associations, EFPIA) collaborate with public sector partners (such as

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⁶⁵ OECD (2018), Pharmaceutical Innovation and Access to Medicines, OECD Health Policy Studies, OECD Publishing, Paris. https://doi.org/10.1787/9789264307391-en;

academia) and smaller companies, including SMEs.

These latter partners are funded by the EU, while EFPIA members use their own resources and do not receive EU funding. For more details about IMI, the participation patterns and achievements, please see Annex 6, Sections 2.3-2.4.

What has or is being achieved so far by IMI

Thanks to IMI, positive contributions on the drug development process have been realised.

Quoting IMI2 JU interim evaluation⁶⁶: 'the main achievement of IMI2 JU on which there was general consensus, was that since the JU started, collaborations between different competing global companies, SME's and academia became possible'. Together with the available budget and long-term strategy, these collaborations were considered an important asset for European pharmaceutical research'. These collaborations created trust and triggered a mind shift as partners came to understand each other's needs. The quality of the research emerging from IMI projects is beyond average⁶⁷. The initiative has international visibility and an established positive 'brand'⁶⁸.

IMI was given as an example of 'radical collaboration' where multinational companies work together and share data instead of keeping it secret, which is helping to change the model of the pharmaceutical industry and solve problems more quickly, by Carlos Moedas, the former EU commissioner for research, science and innovation ⁶⁹.

IMI created important resources for drug development, used by researchers and helping patients. For example: A vaccine against Ebola Virus Disease was developed, with support by IMI's Ebola+ programme⁷⁰. The impact of chronic obstructive pulmonary disease (COPD) on how patients experience physical activity was measured, achieving a qualification of European Medicines Agency (EMA) for novel methodologies, which opens the way for the development of more effective treatments⁷¹. A compact, easy-to-use diagnostic device was developed for Ebola infection that delivers results in a little over an hour⁷². Several pan-European clinical platforms were established to build clinical trial readiness, foster clinical R&I in Europe and develop innovative treatments for the European citizens, in challenging areas such as paediatrics⁷³, prevention of Alzheimer's disease dementia⁷⁴ and autism⁷⁵.

⁶⁶ European Commission (2017) <u>The Interim Evaluation of the Innovative Medicines Initiative 2 Joint Undertaking (2014-2016) operating under Horizon 2020</u>. Experts Group Report. Luxembourg: Publications Office of the European Union.

⁶⁷ The citation impact of IMI research is higher than EU and world averages. The field-normalised citation impact for all IMI papers is 1.98, compared to 0.97 for the EU and the baseline of 1 for the world. IMI2 JU Annual Activity Report 2018. https://www.imi.europa.eu/sites/default/files/uploads/documents/reference-documents/AAR2018 final.pdf

documents/AAR2018 final.pdf
68 In 2018 only, IMI was mentioned in 4048 articles worldwide, including in the title or opening lines of some 7% of these articles. The tonality of the media coverage was predominantly neutral (90%), with the remaining 10% of articles registering a positive tone. Idem.

⁶⁹ https://horizon-magazine.eu/article/radical-collaboration-shaking-pharmaceutical-industry-carlos-moedas.html

⁷⁰ https://ec.europa.eu/commission/presscorner/detail/en/ip 20 1248

⁷¹ https://www.imi.europa.eu/projects-results/project-factsheets/pro-active

https://www.imi.europa.eu/projects-results/project-factsheets/mofina

⁷³ https://www.imi.europa.eu/projects-results/project-factsheets/c4c

⁷⁴ https://www.imi.europa.eu/projects-results/project-factsheets/epad

⁷⁵ https://www.imi.europa.eu/projects-results/project-factsheets/aims-2-trials

What are the key areas for improvement and unmet challenges

The evaluations and experience so far highlighted several 'areas for improvement' for a potential future partnership:

- active engagement of other health industry sectors with the pharmaceutical industry should be enabled;
- the public interest, including accessibility of the eventually resulting products to patients, should be better taken into account,
- the transparency of the strategic research agenda and call topics development should be increased;
- the timelines from identifying R&I needs and topics to the start of resulting projects should be shortened;

More detailed information, including recommendations on the design of the present initiative and how they were addressed, can be found in Annex 6, section 2.3.1.

1.3. EU policy context beyond 2021

The von der Leyen Commission's political priorities for 2019-2024⁷⁶, notably 'An economy that works for people' and 'A Europe fit for the digital age', are both of high relevance to the Innovative Health Initiative (the 'European Green Deal' is also relevant albeit to a lower degree). The specific political guidance for the proposed initiative is provided in the mission letters for Commissioners Gabriel (Innovation, Research, Culture, Education and Youth) and Kyriakides (Health and Food Safety). The mission letter of Mariya Gabriel emphasises that research, policy and economic priorities have to go hand in hand, using missions and industrial strategy as a vehicle⁷⁷. The mission letter of Stella Kyriakides highlights medical devices addressing emerging challenges and the use of e-health to provide high-quality health care, along with Europe's Beating Cancer Plan and a call for ensuring the supply of affordable medicines to meet Europe's needs whilst supporting an innovative and world-leading European pharmaceutical industry⁷⁸.

In Horizon Europe, the Innovative Health Initiative (IHI) would be part of R&I activities funded under Pillar II Cluster 1 Health, which is one of the six Horizon Europe clusters addressing global challenges and industrial competitiveness. Cluster Health is supporting the Sustainable Development Goals, notably SDG 3 'Ensure healthy lives and promote well-being for all at all ages'.

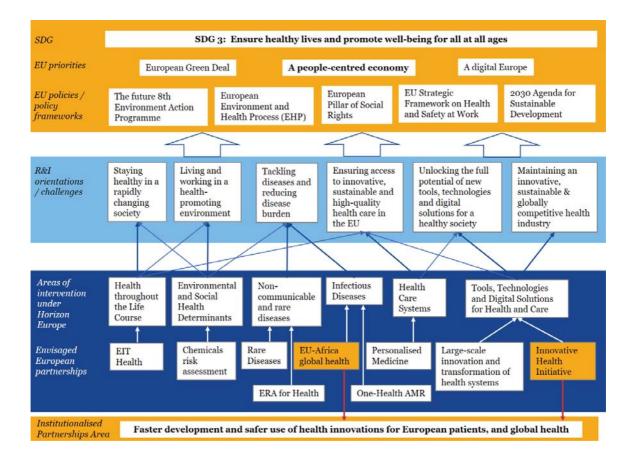
Figure 5. Innovative Health Initiative in the EU policy context. Source: Technopolis Group

77 https://ec.europa.eu/commission/commissioners/sites/comm-

cwt2019/files/commissioner mission letters/mission-letter-mariya-gabriel-2019 en.pdf.

⁷⁶ https://ec.europa.eu/info/priorities_en

⁷⁸ https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-stella-kyriakides en.pdf.



In addition to IHI, other initiatives are put forward as possible partnerships under Horizon Europe. Within Cluster Health, the most relevant would be the Partnership on Transforming Health and Care Systems, facilitating the uptake of innovative health solutions so as to improve the quality of delivered health services and to support the sustainability of health care systems. IHI could contribute to developing innovative health products, services and tools, while the candidate public-public partnership (with Member States) on Transforming Health and Care Systems could develop methods to facilitate the rapid implementation of those solutions into health care systems ⁷⁹. Conversely, the Partnership on Transforming Health and Care Systems could formulate the needs of the health care systems so as to inform the R&I activities pursued by IHI. Another relevant candidate partnership is on EU-Africa Global Health, aiming to increase health security in sub-Saharan Africa, and globally, by reducing the risk of outbreaks, pandemics or antimicrobial resistance. Some solutions developed in IHI, for example those related to novel diagnostics or to feasibility of new clinical trials methods, could be relevant for, and potentially deployed at larger scale under the EU-Africa Global Health partnership.

Beyond Cluster Health, the proposed partnership on Key Digital Technologies (successor of ECSEL JU⁸⁰), could provide access to the latest digital technologies and data-driven tools, applicable to several fields. Some of them could prove essential for IHI due to the key role of health data for innovative, integrated health technologies.

⁷⁹ It is important to emphasise that IHI would work towards developing goods or services (e.g. medicines, diagnostics, medical devices incl. digital tools etc) rather than organisational solutions. Organisational processes will be in the remit of health care authorities/organisations to consider whether and how these could be deployed in the best way.

⁸⁰ https://www.ecsel.eu/

Other relevant initiatives include: the Connecting Europe Facility (addressing the deployment of cross-border exchange of patients' health data in the EU and enabling Cross Border eHealth Information Services as a leading reference to set up international standards) and the Digital Europe Programme (offering opportunities to deploy, implement and upscale the digital health solutions, including those possibly initiated by the proposed initiative at the level of pre-competitive collaborations, for example in the area of modernising the public health services or advancing digital skills for health and care professionals). The potential inter-connections between partnership initiatives in the Health cluster of Horizon Europe are presented in Figure 6.

Horizon Europe has introduced the novelty of missions, with cancer being one of the five mission areas, that will use the full spectrum of European R&I instruments and policies to reach their targets. The Innovative Health Initiative could play an important role in supporting the development of innovations to prevent, faster diagnose and treat cancer and thus significantly contribute to the Europe's Beating Cancer Plan⁸¹

Furthermore, the proposed initiative may foster the concept of 'Smart Health', an area that has been identified as one of the 'strategic value chains' by a forum of industrial experts 3, with potential to drive EU's industrial competitiveness and promote technological sovereignty. Value chains are defined as a set of interdependent economic activities that add value around a product, process or service, involving a group of interlinked economic actors that operate across sectors and borders. The proposed initiative unites these features and has all elements to be considered as "strategic", i.e. revealing systemic importance and making a clear contribution to growth, jobs and competitiveness 4. The value of IHI to serve as a precursor in this context has been further strengthened by the recently published new Industrial Strategy for Europe 5. It may demonstrate its full potential when delivering innovative health technologies that integrate digital components, thereby preparing the ground for a potential Important Project of Common European Interest (IPCEI) on Smart Health.

Figure 6. Potential inter-connections between partnership initiatives in the Health cluster of Horizon Europe. Source: Technopolis Group

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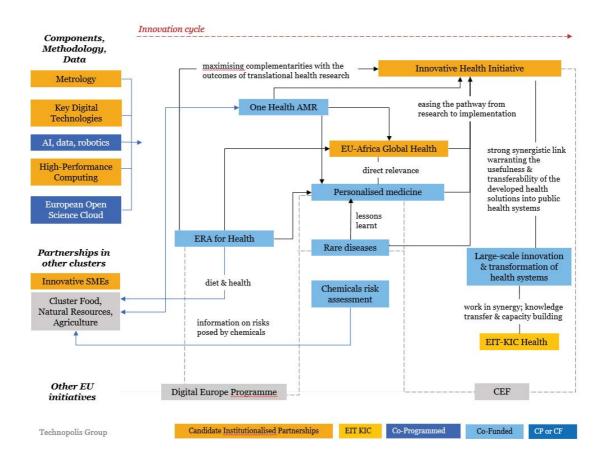
⁸¹ https://ec.europa.eu/health/non_communicable_diseases/cancer_en

⁸² European Commission (2019), Strengthening strategic value chains for a future-ready EU industry. Report and annex available at: https://ec.europa.eu/docsroom/documents/37824; factsheet available at: https://ec.europa.eu/docsroom/documents/37825

Strategic Forum for Important Projects of Common European Interest: https://webgate.ec.europa.eu/fpfis/wikis/pages/viewpage.action?spaceKey=StrategicForum&title=Strategic+Forum+for+IPCEI

⁸⁴ In the European political context, strategic value chains are characterised by: i) technological innovativeness; ii) economic and market potential; iii) societal and political importance for Europe; supporting Strategic Value Chains is a political priority at the interface of a number of other EU policies – R&I, industrial and the Green Deal.

⁸⁵ COM(2020) 102 final.



2. PROBLEM DEFINITION

Given the current and anticipated challenges in the health research field and the overarching policy context, a set of problems have been identified where EU R&I in this field would have a specific role to play (Figure 7).

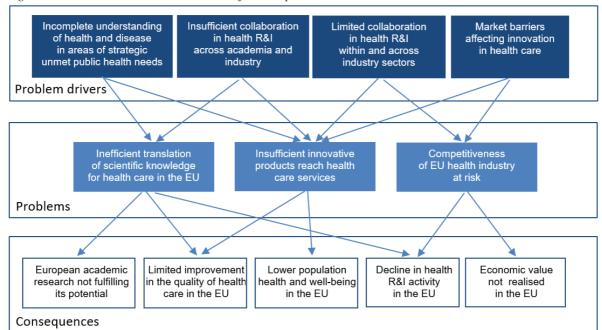


Figure 7. Problem tree behind an initiative for European R&I on Innovative Health

2.1. What are the problems?

The predecessor initiative, IMI2 JU, was set up to address the challenges of increasing cost, lack of incentives and decreasing productivity in drug and vaccine development. Based on the success of IMI in bringing together pharmaceutical companies and the lessons learned explained in Section 1.2, the problem definition reflects the progress in converging of health technology areas (e.g. drug development and diagnostics) and a much more prominent role of digital technologies and data analytics in health research than it was the case when IMI2 JU was established.

2.1.1. Inefficient translation of scientific knowledge for health care in the EU

Despite Europe being a leading region in health research, a gap remains in its ability to translate this excellent health research into products and services that will make a difference to patients and reduce the burdens on health care systems ⁸⁶.

The high failure rate is mostly a scientific problem due to, among others: (1) the lack of adequate translational expertise (i.e. the skills and knowledge required to turn research results into products and services under high regulatory scrutiny), (2) insufficient reproducibility of academic research⁸⁷, (3) insufficient understanding of the mechanisms of disease, (4) weak academia-industry and industry-industry collaboration, within and across different industry sectors, (5) market failures (low investment in some health areas, e.g.

⁸⁶ EC (2018) Science, Research and Innovation Performance of the EU (SRIP) report.

⁸⁷ Friedman L.P., et al, (2015). The Economics of Reproducibility in Preclinical Research, PLoS Biol, available at https://doi.org/10.1371/journal.pbio.1002165.

infectious diseases, brain disorders and anti-microbial resistance⁸⁸, or marke fragmentation).

2.1.2. Insufficient innovative products reach health care services

Even when innovation does happen, insufficient early consideration of societal or user needs and preferences acts as barrier to acceptance and uptake of the resulting products or services⁸⁹, which denotes a societal problem. Therefore, better innovation requires better involving patients, users and citizens from project design and specifications to implementation. In addition, access to products (e.g. drugs) and services (e.g. diagnostic procedures or e-health services) by patients and health care professionals may be delayed for reasons such as lack of evidence on relative effectiveness and cost-effectiveness to demonstrate their added value, high prices raising affordability issues⁹⁰, or lack of readiness of health care systems to embed new technologies. The latter aspect depends, among others, on organisational, structural, financial, regulatory and cultural factors⁹¹

For example, tapping the potential of big data, real world data and digitalisation depends on the capacity to access data, to ensure data quality, to collect, combine and analyse vast amounts of heterogeneous data; on the availability of appropriate regulatory frameworks and data infrastructures; on the fulfilment of all ethical and legal requirements⁹² and on workforce skills.

2.1.3. Competitiveness of EU health industry at risk

The EU has a large health industry. However, it is struggling to maintain a leadership position in health R&D versus the US and China in many sectors, including the

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⁸⁸ European Commission (2017). The Interim Evaluation of the Innovative Medicines Initiative 2 Joint Undertaking (2014-2016) operating under Horizon 2020. Experts Group Report. Luxembourg: Publications Office of the European Union.

⁸⁹ It should be noted that health products and services behave differently than it is the case in most areas of the free-market economy because: (1) the health area is subject to strict regulation at national and/or European level, depending on the actual type of products or services, (2) the pricing of these products or services does not follow the free-trade rules but is subject to reimbursement and pricing decisions which are a national competence, (3) the cost of most health products is partly or fully reimbursed by government or compulsory insurance schemes. Therefore, the aspects of 'product availability' and 'product uptake' have meanings specific to this particular area. In addition, reimbursement decisions can also include provisions on the conditions of use of the product, e.g. in certain diseases.

Providing universal access to innovative medicines and other medical technologies creates tremendous social value. However, the rising prices of innovative technologies and, in particular, the proliferation of very expensive medicines in recent years have increased pressures on public health spending. Equitable access to essential, high-quality innovative health technologies depends on affordable and fair pricing and effective financing schemes. According to WHO definition, an "affordable and fair" price is one that can reasonably be funded by patients and health budgets and simultaneously sustains research and development, production and distribution within a country (World Health Organization (2017). Essential medicines and health products. https://www.who.int/medicines/areas/access/en/.) Even though reimbursement and pricing are a national competence of EU Member States, research could be done at European level on the development or refinement of pricing and reimbursement instruments. This research could in turn support Member States developing and implementing their national policies. Besides pursuing affordable and fair prices, promoting cost-effective interventions is also seen as central to the achievement of universal health coverage. IHI can play a role here in developing methods and tools to assess the added-value of innovative technologies, and that can be taken-up by health care authorities/organisations if deemed relevant to inform their decisions.

While solutions to these problems are beyond reach of IHI, they would fall in scope of the candidate Partnership on Transforming Health and Care Systems involving Member States who are in charge of organising their health care systems.

⁹² European Commission (2019). Orientations towards the first Strategic Plan implementing the research and innovation framework programme Horizon Europe. Annex: Horizon Europe Cluster 1 Health.

pharmaceutical and medtech (see Section 1.2.1), which is considered an economic/technological problem.

R&I creates new opportunities, supporting sustainable economic growth and the competitiveness of businesses and industries⁹³. However, slow translation of scientific discoveries into tangible innovations and limited technology convergence lead to dwindling innovation pipelines. This puts Europe at risk of becoming dependent on other countries for technological developments and new health care solutions, not only endangering European competitiveness but also putting into question the future sovereignty and preparedness to face issues like e.g. shortage of essential medicines⁹⁴ or emerging pandemics.

In the **open public consultation**, 73% of respondents (77 out of 105) saw the innovation gap in translating the results of health research into the development of innovative health products and services as a very relevant problem. Insufficient consideration of societal or user needs was identified as a relevant barrier to uptake particularly by most respondents from the 15 NGOs, 5 public authorities and 6 small company/business organisations (<250 employees). Academic/research institutes and public authorities reported that ethical issues were also a barrier. Nevertheless, on average, structural and resource problems were reported as more relevant than problems in the uptake of health innovations (assessed as 'very relevant' by 56% vs 34% of all stakeholders, respectively). The need for the partnerships to contribute to EU global competitiveness was supported by most respondents (59%, 63 of 106) in the **open public consultation**, including most of the 6 respondents from business associations, the 20 respondents from industry and the 35 respondents from academic/research organisations. Only among public authorities and 'other', the majority did not cite the contribution to EU competitiveness as a need.

During **interviews**, industry representatives referred to a lack of trust between the public and industry. A positive working relationship between public and private partners could increase public trust, and therefore uptake, of new products developed by industry.

2.2. What are the problem drivers?

2.2.1. Incomplete understanding of health and disease in areas of strategic unmet public health need

Many of the diseases that are increasingly affecting the health of EU citizens, are not completely understood in terms of what causes them, how environmental and genetic factors affect the occurrence and course of the diseases, what affects treatment success, etc. Consequently, it is difficult to develop adequate prevention strategies, accurate diagnostics and targeted therapeutic interventions⁹⁵. Further research is urgently needed to understand the causes and factors affecting development of these complex diseases⁹⁶. Understanding of diseases should also link better to health promotion, disease prevention, prediction and staying in good health longer while aging.

⁹³ European Commission (2019). Orientations towards the first Strategic Plan implementing the research and innovation framework programme Horizon Europe.

⁹⁴ WHO list of essential medicines and health products, available at: https://www.who.int/topics/essential medicines/en/

⁹⁵ The top ten leading causes of death in Europe in 2016 included dementia, in particular Alzheimer's disease, and diabetes mellitus. See Annex 6 Section 2.1 for more details.

⁹⁶ WHO data on Disease burden and mortality estimates, https://www.who.int/healthinfo/global burden disease/estimates/en/index1.html.

The predecessor initiative, IMI, has greatly contributed to better understanding of certain diseases (e.g. by elucidating the five subtypes of diabetes rather than only two as known currently, which paves the way for proposing the adequate treatment for patients with individual disease subtypes⁹⁷). Nevertheless, the knowledge gaps remain, due to the inherent complexity of biological processes in the human body. Such knowledge gaps are a roadblock for efficient translation into products or services and one of the root causes why no treatments are available in some therapeutic areas. These knowledge gaps must indeed be addressed by research but as regards human health, unlike in some engineering or IT areas, research can be unsuccessful, despite years of effort. For example, in the case of dementia, there is still a vast market demand as a growing proportion of the ageing population of rich countries are affected, with no available treatment. Despite this, the biggest drug companies pulled out of this area, following a string of repeated failures: between 1998 and 2017, 146 candidate medicines in clinical development for Alzheimer's were halted and did not receive regulatory approval. 18% of the failures occurred in late-stage clinical trials⁹⁸, which by then had consumed 5-10 years of R&D and USD hundreds of million, sometime over a billion in costs each. Science needs to advance and provide new therapeutic targets to industry, and industry needs to be stimulated to continue investing in this field.

Another example is the emergence of infectious diseases, demonstrated by the 2019/2020 SARS-CoV-2 (coronavirus) pandemic of unprecedented scale. Despite existing knowledge about other coronaviruses that caused earlier epidemics⁹⁹, the global spreading of COVID-19 could not be avoided.

The reason for identification of this aspect as a problem for the proposed initiative is that it is a prerequisite for being able to translate research into products. A more efficient use of various research tools or paradigms offered by new industry sectors (e.g. using innovative imaging methods or artificial intelligence) may bring a new stimulus to understanding areas not fully understood today. This persisting problem calls for continued investment into R&I on unmet health needs, intensified collaboration of academia with the main health industry sectors and the use of digital technologies in order to give a new angle to addressing these gaps.

The lack of understanding/knowledge about disease was cited as a very relevant problem by the majority within each group of respondents in the **open public consultation** with the exception of small company/business organisations. In the **feedback to the inception impact assessment**, stakeholders from business, academia, NGOs and 'others' referred specifically to antimicrobial resistance (AMR), brain disorders and neglected diseases.

2.2.2. Insufficient collaboration in health R&I across academia and industry

Collaboration between academia and industry is widely considered a key requirement for translating research into innovations but it can be inhibited by a range of factors. These include the compartmentalisation of departments within universities and hospitals; a cultural divide between academic, industry and clinical researchers; and lack of training or experience in multidisciplinary teams working among academics. In combination with these

docs.phrma.org/files/dmfile/AlzheimersSetbacksSteppingStones FINAL digital.pdf.

⁹⁷ IMI's BEAT-DKD and RHAPSODY projects: https://imi-rhapsody.eu/.

⁹⁸ Researching Alzheimer's medicines (2018), http://phrma-

⁹⁹ SARS-CoV outbreak started in 2002 and MERS-CoV outbreaks started in 2012

factors is also a university system that rewards individual achievement rather than joint working practices ¹⁰⁰.

Unfortunately, in the health area, the majority of European academics do not collaborate with business¹⁰¹. This is exemplified by the fact that less than 8% of participations in Societal Challenge 1 (Health, demographic change and wellbeing) Horizon 2020 collaborative projects from 2014 to 2019 were from non-SME industry partners (Table 1). The joint participation of several industry partners in one project was even less frequent.

Table 1: Proportion of non-SME private sector participation (labelled as Industry participation) in regular Horizon 2020 collaborative health R&I projects (please note that the figures exclude IMI2 JU)

Call year	Total EU funding	EU funding for industry	Total participation	Industry participation	% of industry funding	% of industry participation
2014	EUR 595,619,918	EUR 41,542,476	1609	109	6.97%	6.77%
2015	EUR 584,270,458	EUR 31,235,638	1308	98	5.35%	7.49%
2016	EUR 440,330,074	EUR 20,460,519	1111	83	4.65%	7.47%
2017	EUR 367,686,472	EUR 21,747,256	886	59	5.91%	6.66%
2018	EUR 691,315,336	EUR 51,995,267	1588	156	7.52%	9.82%
2019	EUR 796,496,156	EUR 56,131,198	1459	115	7.05%	7.88%
Total	EUR 3,475,718,414	EUR 223,112,354	7961	620	6.42%	7.79%

Source: European Commission

Differing concerns in industry and academia contribute to this frequent lack of collaboration ¹⁰². Industry has concerns about the poor reproducibility of research, high valuation of early intellectual property, and maintaining confidentiality. Academia has concerns about the freedom to publish and about strategic changes at the industrial partner (such as change of the disease area interest, or mergers and acquisitions) which can lead to discontinuation of research projects. Furthermore, academics have less resources to comply with increasingly complex regulatory requirements compared to industry ¹⁰³. For instance, analysis of data from the EU's Clinical Trial Register shows that clinical trial results of 90% of clinical trials led by academics in Europe are not reported within a year of ending, while

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¹⁰⁰ Fudge, N. et al. (2016) Optimising translational research opportunities: A systematic review and narrative synthesis of basic and clinician scientists' perspectives of factors which enable or hinder translational research. PLoS ONE, 11(8), pp. 1–23.

Davey, T. et al. (2018). The state of university-business cooperation in Europe, https://www.ub-cooperation.eu/pdf/final report2017.pdf.

¹⁰² Freedman, S. and Mullane, K. (2017) The academic–industrial complex: navigating the translational and cultural divide. Drug Discovery Today, 22(7), pp. 976–993.

¹⁰³ Vesper I. (2018). Europe's academics fail to report results for 90% of clinical trials, Nature, Available at: https://www.nature.com/articles/d41586-018-06676-8.

70% of industry-sponsored clinical trials have published outcomes within 12 months of completion.

The situation described was significantly alleviated by the activities of IMI, as explained in Section 1.2 and in Annex 6. However, this successful outcome of IMI benefitted the collaboration mostly between academia and the pharmaceutical sector, not covering other sectors of health R&I.

Interviews with industry stakeholders indicate that while there are a few examples of large pharmaceutical companies participating in collaborative projects in Horizon 2020, this remains the exception due to low perceived success rates, small project sizes (by their standards) and time-consuming administrative requirements. In fact they prefer not to receive any funding from the EU, which is seen as a reputational risk, and rather turn to the alternative avenue offered by IMI2 JU, which allows large-scale, strategically oriented collaboration without receiving any monetary funding, while contributing own resources instead.

2.2.3. Limited collaboration in health R&I within and across industry sectors

An overarching organisational problem driver holding back the full potential of European creativity is the limited collaboration between various health-related industry sectors including pharmaceuticals, diagnostics, medical devices, imaging, biotech and digital industries¹⁰⁴. Reasons for this are competition and varying definitions of pre-competitive space, different problem solving approaches, diverging business models and varied development timelines across sectors¹⁰⁵, further compounded by varying regulatory requirements across types of products (e.g. drugs vs. medical devices).

In the cross-sectoral digital health sector, which was less prominent at the onset of IMI2 than it is the case today, R&I is also held back by missing data standards, interoperability and accessibility; inadequate or non-existing analytical methods and tools; and issues around ethics, privacy and security¹⁰⁶. All this diminishes the EU's ability to tap the immense potential presented by digitalisation, artificial intelligence (AI) and big data. The capacity to access, collect, combine and analyse large, complex data sets also varies across industry sectors and stakeholder groups resulting in a lack of collaboration¹⁰⁷.

In the **open public consultation**, limited collaboration and pooling of resources between industry sectors was seen as a very relevant problem across stakeholder groups (52%, 55 of 106 respondents) and in particular by business associations. Comparatively, it was more strongly agreed that limited collaborations and pooling of resources across public, private and charity sectors was a problem, with the majority of respondents (59%, 61 of 104) selecting this aspect as very relevant. During the **interviews**, stakeholders from academic/research organisations remarked on this barrier, highlighting, in particular, that the lack of data sharing between the health sector and industry was a major barrier to innovation.

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¹⁰⁴ This problem driver for IHI is defined much more broadly than it was the case for IMI that focussed on the pharmaceutical sector only. In preparation for IHI, associations representing several health industry sectors expressed interest to enter into joint pre-competitive collaboration.

¹⁰⁵ The Interim Evaluation of the Innovative Medicines Initiative 2 Joint Undertaking (2014-2016) operating under Horizon 2020 (2017), Experts Group Report. Luxembourg: Publications Office of the European Union.

European Commission (2019), Strengthening strategic value chains for a future-ready EU industry.
 European Commission (2018), Science, Research and Innovation Performance of the EU (SRIP) report.

2.2.4. Market barriers affecting innovation in health care

Market barriers discourage companies from investing in R&D, particularly where a high return on investment is unlikely. This is a significant problem in some areas of high unmet public health need such as infectious diseases and anti-microbial resistance. In the latter area, the problem persists despite the significant and recognised achievements ¹⁰⁸ of IMI that, however, without additional pull mechanisms, are not able to improve the attractiveness of the overall market ¹⁰⁹.

The issues around market barriers are exacerbated by the fact that complex innovations combining different types of technologies do not easily fit into existing regulatory schemes. In addition, demonstrating their added value for patients and society poses new methodological challenges, partly because technologies converge in ways that alter the delivery of health care in ways not anticipated before and that could not be effectively addressed by predecessor initiatives. For example, mobile health offers potential for more effective and efficient provision of care, which should ultimately translate into better outcomes for patients. Such complex and cross-sectoral innovations require the development of adapted approaches, methods and tools not only to assess their safety and efficacy but also to fully capture the value they create for society and to enable efficient integration into health care systems. These novel methods would be essential for Member States to take the best informed decisions – including as regards the reimbursement and pricing policies – and put them in a stronger position to negotiate affordable prices that would in turn facilitate patient access to high-value innovations.

Health industries, in particular SMEs, may encounter difficulties in accessing the necessary investments from various sources. While IHI could serve as a source of funding to bridge possible gaps in funding between basic research grants and other financial instruments (e.g. loans) this is an issue that could also be addressed by several initiatives at EU level (e.g. by the European Innovation Council¹¹⁰ or by the European Investment Bank¹¹¹), at national level or by venture capital. However, industries may also find it difficult to enter new markets and value chains, or to create partnerships and alliances and this is precisely where IHI would have a unique role to play. Health innovation requires a broader variety of stakeholders to be involved from supply, demand and regulatory side than it would be the case for many other market sectors¹¹².

In the **open public consultation**, there was some disagreement between small and large (>250 employees) company/business organisations about the relevance of market failure,

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According to the European Court of Auditors: '...despite the general withdrawal of pharmaceutical industries from antimicrobial research, JU IMI together with its partners was overall able to maintain the expected level of public-private collaboration in the ND4BB programme. While this is encouraging, there are concerns about the insufficient commercial incentives for pharmaceutical companies to invest in this field'. European Court of Auditors (2019), Addressing antimicrobial resistance: progress in the animal sector, but this health threat remains a challenge for the EU – special report no 21, findings 60-61. https://www.eca.europa.eu/Lists/ECADocuments/SR19_21/SR_Antimicrobial_resistance_EN.pdf.

¹¹⁰ Under Horizon Europe's innovation pillar, the proposed European Innovation Council (EIC) will offer grants and blended financing (grants and equity) opportunities mainly for small, highly innovative companies from early stage to development and scale-up. https://ec.europa.eu/research/eic/index.cfm.

For example, InnovFin Infectious Diseases Finance Facility (IDFF) from the European Investment Bank (EIB) can provide standard debt to equity-type financing for amounts typically between EUR 7.5 million and EUR 75 million

¹¹² European Commission (2019), Orientations towards the first Strategic Plan implementing the research and innovation framework programme Horizon Europe. Annex: Horizon Europe Cluster 1 Health.

the adequacy of business models, and ethical concerns over digital tools. Small companies (9 respondents) found these problems less relevant as barriers to uptake of innovations, whereas most of the 12 stakeholders from larger companies reported these as very relevant.

The problems at stake remain valid for both the predecessor initiative, IMI2 JU, and the proposed. However, under IMI2 JU, the problems were more closely related to the process of pharmaceutical development (covering medicines and vaccines). It was also reflected by the constituency of the partnership, with the European Federation of Pharmaceutical Industries and Associations (EFPIA) as the only member industry association. IMI2 was able to indeed progress significantly on addressing the underlying problems and successfully deliver on several of its objectives. However, the problems at stake constantly evolve and therefore, they are going to be addressed by the proposed initiative in a broader than it was the case for IMI: the Innovative Health Initiative (IHI) aims to cover several technology areas of health R&I (medtech, biotech, vaccines, digital), rather than the pharmaceutical sector only. Thanks to this broadening, the Innovative Health Initiative could address the problems at stake from a different angle, capitalising on broadened experience of the new set of industry actors.

2.3. How will the problem(s) evolve?

The problems of Europe's ageing society and prevalence of diseases are unlikely to dissipate over time. As people age, the prevalence of chronic diseases is likely to increase, thus also leading to co-morbidities¹¹³. In addition, in an increasingly global world, as more people continue to travel, the spread of new emerging infections and the possibility of pandemics cannot be ruled out, as clearly demonstrated by the 2019/2020 COVID-19 outbreak. All this would exert pressure on carers and health care systems.

In the baseline scenario of regular Horizon Europe calls and absence of a follow-up partnership to IMI2 JU (which exists until 2024 but launches its last calls in 2020), the problem of insufficient provision and deployment of innovations in health care, which includes both the lack of innovations itself and existing innovations not reaching users quickly enough, will persist or even worsen without intervention. However, if addressed, effective, cost-effective and easy to use innovations responding to the needs of end-users should help reduce the pressure on health care systems.

Without intervention, many of the innovative health technologies will potentially be disruptive for health care systems. They will rely on cross-sectoral collaborations and will therefore necessitate early dialogue between all relevant health care actors (including patients, developers, regulators¹¹⁴, health technology assessment bodies, health authorities

¹¹³ EC Reflection Paper (2019), Towards a sustainable Europe by 2030.

¹¹⁴ In this document, the term 'regulators' refers to the different bodies involved in the processes regulating medical products (e.g., scientific assessment, production of scientific guidelines, scientific advice to manufacturers, granting/refusal/suspension of marketing authorisations, post-market surveillance, withdrawing/recalling of devices put on the market, authorisation and oversight of clinical trials). It includes the European Commission, National Competent Authorities (NCA), the Medical Device Coordination Group (MDCG), and the European Medicines Agency (EMA). Notified Bodies (NB), while designated to perform a regulatory function (verification of medical device/in-vitro diagnostics conformity), cannot be considered as regulators in the strict sense of this definition. However, the potential input and expertise of Notified Bodies may still be relevant for the design and implementation of the activities of the proposed initiative

involved in pricing and reimbursement) to become accessible ¹¹⁵ to patients, at fair conditions. In addition, the increasing EU public's expectations about health care – i.e. that health care is high quality, effective, cost-effective, and accessible – is also likely to influence the burden on health care systems and how health care is delivered ¹¹⁶.

Overall, if left unaddressed, the problems described will result in:

- not capturing the full potential of European research, with the knowledge created by European academics not translated more efficiently into tangible innovations;
- limited improvement in the quality of health care and unsustainable health care systems that will remain reactive, addressing diseases on incident basis, rather than moving towards preventive, integrated health care that would put the person in the centre, during her/his lifetime;
- negative impact on health and wellbeing in the society (incl. increasing access barriers to novel health solutions), entailing limited preparedness to emerging health threats (such as e.g. the COVID-19 outbreak) where new diagnostics, preventive vaccines or therapeutics need to be developed quickly;
- decline in health-related R&I activity in Europe with jobs and revenue going outside the EU and economic value not being realised in Europe, leading to gradual loss of technological sovereignty and readiness to quickly respond to emerging health threats.

During **interviews**, stakeholders (including those from industry, partnerships and research infrastructures), referred to digitalisation as one of the major needs this initiative could address. This was confirmed during the **open public consultation** where respondents generally agreed (50%, 53 of 105) that insufficient digitalisation was a very relevant problem, particularly according to NGOs, business associations and EU citizens. Feedback to the **inception impact assessment** emphasised the need for integrated solutions, especially with regard to personalised health care.

3. WHY SHOULD THE EU ACT?

3.1. Subsidiarity: Necessity of EU action

The problems described in this document are of a nature and magnitude that EU-level concerted action will be more appropriate than individual Member States developing their own initiatives. This will enable more coherent and coordinated effort, and avoid duplication. To elaborate, EU action is required for the following reasons¹¹⁷:

Current health challenges and threats are global, respecting no borders. They call for a
quick and coordinated response, while health research capabilities and data are dispersed
over Europe. No Member State alone could mobilise and engage the diverse range of

Access to health care is the result of interactions between different factors, including health system coverage (i.e. who is entitled to health care), depth of coverage (i.e. what citizens are entitled to), availability of health care services and economical accessibility (affordability), based on Commission Communication on

effective, accessible and resilient health systems (2014). Access also includes non-discrimination, physical accessibility, and information accessibility, in line with General Comment on the Right to Health, UN Committee on Economic, Social and Cultural Rights (2000). In addition to financial and organisational aspects, health care access may also be affected by social or cultural barriers that limit the utilisation of services

Weale A. et al. (2011), High Quality, Comprehensive and Without Barriers to Access? The Future of Healthcare in Europe. In: The Future of Healthcare in Europe (eds. Chaytor, S. and Staiger, U.), UCL: London. ¹¹⁷ DG RTD (2019), Inception impact assessment of the candidate European Partnership on Innovative Health.

- stakeholders and companies individually and reach the required critical mass of expertise and data that are necessary to tackle these challenges.
- Actions at Member State level would be limited in terms of industrial and academic experience available in a given country. An EU-level action is much better positioned to coordinate multiple stakeholders effectively and meet the planned objectives, at the same time avoiding duplication in research.
- Most health-related companies operating in Member States have an EU-wide presence. Their activities and products are governed by EU-wide legal frameworks, e.g. on medicinal products, medical devices and cross-border health care. Therefore, it is logical to have an initiative focused on innovation in health at the EU level. Moreover, the EU is best placed to develop and implement common standards and frameworks related to health innovations applicable for the entire EU internal market.
- Member States alone would not have the legal and financial framework to enable multisectoral collaboration with the scope and/or at the scale envisaged.

3.2. Subsidiarity: Added value of EU action

An EU initiative can help bring together a broad spectrum of stakeholders, both private and public in the health field. Industry participation would help to drive academic research efforts towards applicable health innovations, while the EU represented by the European Commission would guarantee that projects address important unmet health needs and deliver innovations that can be taken up by health care systems. An EU-level initiative has the potential to provide the necessary scale and scope of investment to attract additional, or shift existing, investment into R&I into strategic unmet public health needs where industry would not act on its own or where sufficient national funding is not available 118. Moreover, an initiative under the aegis of the EU would create a trustful and neutral environment for sharing expertise, resources and knowledge¹¹⁹. In summary, it can provide added value in the following areas 120:

- creation of critical mass to address global challenges;
- stability in long-term commitment and work towards common goals (directionality);
- increased industry investment into areas of unmet public health needs,
- increased coordination across public and private actors and across Member States;
- increasing the EU's competitive advantage vis-a-vis major competitors;
- creation of new market opportunities;
- leveraging more public and private investment in health-related R&I (additionality).

The proposed initiative does not go beyond what is necessary to achieve its objectives.

¹¹⁸ According to its interim evaluation, "IMI2 JU... leveraged additional funding for medicines research and development at a time when research funding was reduced in most of the European countries". European Commission (2017) The Interim Evaluation of the Innovative Medicines Initiative 2 Joint Undertaking (2014-2016) operating under Horizon 2020. Experts Group Report. Luxembourg: Publications Office of the European Union.

For example, IMI2 JU AIMS-2-TRIALS project (<a href="https://www.imi.europa.eu/projects-results/projects-res factsheets/aims-2-trials) working on autism created a clinical trials network that covers 118 sites across 37 with access to over 20 000 new patients per year. The c4c project (https://www.imi.europa.eu/projects-results/project-factsheets/c4c) is setting up a paediatric clinical trial network with 19 paediatric national hub trials and national coordinators of trial sites to oversee site activity related to trials. Reaching beyond national borders facilitates the conduct of large clinical trials that would not be possible at national level.

¹²⁰ DG RTD (2018), Horizon Europe Impact Assessment. A New Horizon for Europe.

The legal basis for EU action, the same for every option discussed, is provided by Articles 168 and 179 TFEU (in addition, the legal ground for Option 3 – Institutionalised Partnership – lies in Art 187 TFEU). At the same time, Member States hold the primary responsibility for organising health services and medical care as well as for reimbursement and pricing decisions ¹²¹. Therefore, the potential products, solutions or methodologies that might result from IHI would become subject to further independent decisions of relevant authorities and bodies, in line with relevant legislation in place.

The added value of EU action was underlined in the **open public consultation**, especially in terms of responding to: (1) the need to increase the EU's global competitiveness (selected as very relevant by 59% (63 of 106) of respondents) and the problem of limited collaboration between industry sectors (selected as very relevant by 52% (55 of 105) of respondents). Industry **interviewees** commented that investment at EU level was essential to maintain/improve the R&I competitiveness of the European health industry.

4. OBJECTIVES: WHAT IS TO BE ACHIEVED?

4.1. General objectives

Based on the identified problems, the general objectives of an EU action for research and innovation in health care would be to:

- 1. contribute towards the creation of an EU-wide health R&I ecosystem that facilitates translation of scientific knowledge into innovations, notably by launching at least 30 large-scale, cross-sectoral projects, focusing on health innovations;
- 2. foster the development of safe, effective, people-centred¹²² and cost-effective innovations that respond to strategic unmet public health needs, by exhibiting, in at least 5 examples, the feasibility of integrating health care products or services, with demonstrated suitability for uptake by health care systems. The related projects should address the prevention, diagnosis, treatment and/or management of diseases affecting the EU population, including contribution to Europe's Beating Cancer Plan;
- 3. drive cross-sectoral health innovation for a globally competitive European health industry, and contribute to reaching the objectives of the new Industrial Strategy for Europe and the Pharmaceutical Strategy for Europe.

General objective 1 is mainly aimed at addressing current inefficiencies in translating scientific knowledge generated in Europe into health and care innovations, such as new prevention strategies, diagnostics or drugs. General objective 2 addresses the insufficient innovative products reaching health care services for unmet public health needs. Fostering the development of innovations that are not only safe and effective, but also people-centred and cost-effective will increase the likelihood of innovations being adopted by people and health care systems, and thus providing benefit to EU citizens and also strengthening the

¹²¹ Elaborated in Section 1.

¹²² People-centred care refers to an approach to care that consciously adopts individuals', carers', families' and communities' perspectives and sees them as participants as well as beneficiaries of health care systems that are organised around their needs and preferences rather than individual diseases.. This approach requires that people have the education and support to enable them to make decisions and participate in their own health and care, while also supporting carers. Based on: World Health Organization 2016, Framework on integrated, people-centred health services.

economy, if health care systems become more efficient. Finally, **general objective 3** is mainly aimed at addressing the risk to the global competitiveness of the EU health industry.

The general objectives align with Horizon Europe objectives, and in particular with its objective to 'strengthen the scientific and technological bases of the Union' and 'to foster competitiveness¹²³. They also align with strategic EU priorities to promote health and wellbeing for all including access to innovative, sustainable and high-quality health care, and with the Sustainable Development Goal 3 of 'Ensuring healthy lives and promote wellbeing for all at all ages'¹²⁴. In particular, thanks to these general objectives, the initiative will contribute to 'Europe's Beating Cancer Plan'¹²⁵ and the 'European One Health Action Plan against Antimicrobial Resistance'¹²⁶, as well as the new Industrial Strategy for Europe¹²⁷, the Pharmaceutical Strategy for Europe¹²⁸ and the SME strategy for a sustainable and digital Europe¹²⁹.

4.2. Specific objectives

The proposed partnership is conceived as being agnostic with regard to specific disease areas, while focussing on unmet public health needs¹³⁰. It intends to cover various stages at which it intends to intervene in the health care pathways, including prevention, diagnostics, treatment and disease management¹³¹. This broadened technological and thematic scope compared to IMI2 JU explains the proposed new name, the Innovative Health Initiative (IHI).

With the rapid scientific and technical progress and the digital evolution, new types of products integrate the different components (such as medicines, diagnostics, treatment monitoring) in ways that has never been done before. For example, a new treatment may be accompanied by a sensor and a mobile health solution that monitors the adherence to the prescribed regime, and it may also collect data for monitoring the safety of treatment. The new possibilities for health interventions can benefit patients while offering new market opportunities to companies. At the same time, while the scientific and technical evolution is rapid and provide many new opportunities, merging of technologies must be fostered in an environment that ensures the quality and the safety of the new innovations, respecting the ethical principles. Therefore, in order to achieve the general objectives, five specific objectives are defined, that respond to the problem drivers discussed in Section 2.2.

¹²³ DG RTD (2018), Horizon Europe Impact Assessment. A New Horizon for Europe.

European Commission (2019), Orientations towards the first Strategic Plan implementing the research and innovation framework programme Horizon Europe. Annex: Horizon Europe Cluster 1 Health.

https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12154-Europe-s-Beating-Cancer-Plan

 $^{^{126} \}quad https://ec.europa.eu/health/sites/health/files/antimicrobial_resistance/docs/amr_2017_action-plan.pdf$

¹²⁷ COM(2020) 102 final

¹²⁸ COM(2020) 761 final

¹²⁹ COM(2020) 103 final

¹³⁰ Unmet public health needs are needs currently not addressed by the health care systems for various reasons, for example if no medicines are known to treat a disease. Areas of public health importance are those where the burden of disease if high for patients and society due to the severity of the disease (in terms of mortality, physical and functional impairment, comorbidities, loss of quality of life, ...) and/or the number of people affected by it. For example, Alzheimer's disease.

¹³¹ The actual thematic areas of activities will be further defined in the SRA and the resulting annual work programmes.

4.2.1. Contribute towards a better understanding of the determinants of health and priority disease areas

By focusing on elucidation of the mechanisms of diseases and factors contributing to health, an initiative on innovative health can provide better targets and approaches to develop new health innovations for prevention, diagnosis and therapy. In this way, this specific objective can lead to more translation of basic research into practical application, covering the priority disease areas, i.e. those of high burden to the society. This objective should result in:

- novel targets for disease prevention, diagnosis and therapy, through improved understanding of disease mechanisms in various disease areas ¹³²;
- novel solutions for continued monitoring of health status;
- novel solutions for disease management and for efficient follow-up of treatment.

4.2.2. Integrate fragmented health R&I efforts bringing together health industry sectors and other stakeholders, focussing on unmet public health needs, to enable the development of tools, data, platforms, technologies and processes for improved prediction, prevention, interception, diagnosis, treatment and management of diseases, meeting the needs of end users

This specific objective is related to breaking down barriers to cross-sectoral collaboration. This applies not only between academia and industry, and between different health industry sectors of different sizes, but also across all health care actors. The expected integration of actors would thus extend to patients and civil society, health care professionals, health care providers, regulators, health technology assessment bodies and health care payers. This objective should lead to:

- demonstrated feasibility of developing combination products (e.g. diagnostics + treatment), in various disease areas, focussing on unmet public health needs;
- harmonised approaches for clinical evidence generation of products combining different technologies.

To give an example, on average 10,000 substances are tested to develop one safe and efficacious medicine that can be used in health care, taking about 10-15 years using traditional approaches¹³³. It is expected that the drug development process can be accelerated by using novel approaches, afforded e.g. by bespoke medical devices and machine learning algorithms¹³⁴.

4.2.3. Demonstrate the feasibility of people-centred, integrated health care solutions

Innovative health care solutions¹³⁵ integrating various technologies, coupled with complementary tools and services promise breakthrough solutions to tackle health issues

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¹³² Examples of disease areas: cardiovascular, neurological, respiratory etc.

¹³³ Chakravarthy R et al (2016), Public- and private-sector contributions to the research and development of the most transformational drugs in the past 25 years. Therapeutic Innovation and Regulatory Science, 50(6) 759-768. http://dx.doi.org/10.1177/2168479016648730.

134 For example, it was recently shown that pre-clinical development of candidate medicinal products can be

for example, it was recently shown that pre-clinical development of candidate medicinal products can be dramatically accelerated using AI techniques: Zhavoronkov A., Ivanenkov YA., Aliper A. et al. (2019) Deep learning enables rapid identification of potent DDR1 kinase inhibitors. Nat. Biotechnol. 37, 1038–1040,doi:10.1038/s41587-019-0224-x.

Health care solution refers here to a medical product, ancillary service or tool used either alone or in combination in order to address a specific health care need, be it a medical need or an organisational need.

that cannot be effectively tackled today. Those products and services should be centred around people needs and preferences across the health care pathway, so that can be taken up by individuals and health care systems, thereby addressing the problem of insufficient knowledge translation. This objective should result in:

- demonstrated feasibility of developing people-centred, integrated health care solutions along the health care pathway, in various disease areas;
- health care solutions ready to be implemented by health care authorities or organisations.

For example, this could cover the integration of the following interventions in the case of chronic diseases, such as asthma or diabetes: (1) prevention programmes supported by apps to help people manage their health and to identify those at high risk for certain chronic diseases, (2) diagnostic tools to early detect those diseases, (3) personalised treatment for people with the disease, (4) solutions to help improve patient's adherence to treatment, (5) tools, e.g. wearables to monitor patients' health status, (6) solutions to detect and/or report adverse events, and (7) products and services supporting efficient workflows along the health care pathway, e.g. digital health solutions to facilitate communication between health care providers.

4.2.4. Exploit the full potential of digitalisation and data exchange in health care

Harnessing the full potential of big data¹³⁶ and real-world data¹³⁷ requires the digitalisation of health services, finding new ways to observe health and disease states, collecting the relevant digital biomarkers using health technologies, and developing advanced analytics/artificial intelligence approaches and software to convert data into valuable knowledge. These aspects are at the heart of data-focused approaches and could help innovators to develop more effective tools and products, including innovative, integrated solutions for preventing, diagnosing, treating and managing health conditions (e.g. tools to support real-time shared decision-making between patients and their health care providers using big data analytics platform). This objective should lead to:

• successful application of digital and data-driven solutions for health care, integrating various public and private data sources.

Health care solutions to be developed within this partnership do not include organisational innovation (also known as management innovation or administrative innovation). Organisational innovation encompasses a wide range of processes, from changing professional practices and roles, to changing organisational structures and governance arrangements. While industry can propose solutions (mostly concrete goods) on organisational processes, these remain in the remit of health care authorities/organisations to consider whether and how they could be deployed in the best way.

¹³⁶ Big Data refers to extremely large datasets which may be complex, multi-dimensional, unstructured and heterogeneous, which are accumulating rapidly and which may be analysed computationally to reveal patterns, trends, and associations. In general, big data sets require advanced or specialised methods to provide an answer within reliable constraints.

¹³⁷ Real world data are data regarding the effects of health interventions that are not collected in the context of conventional randomised controlled trials but prospectively and retrospectively from observations in routine clinical practice from many sources including patient registries, electronic medical records, and observational studies.

4.2.5. Enable the development of new and improved methodologies and models for a comprehensive assessment of the added value of innovative and integrated health care solutions

There is a need for new approaches to assess the added value of novel health care solutions, thereby strengthening the overall conditions for R&I to target strategic unmet public health needs in areas where industry has traditionally been less active, due to perceived high risk and/or low return on investment.

The advent of complex and integrated solutions necessitates the development of adapted methodological approaches and tools to assess the value that these products will bring to the patient, the health care system and the society as a whole (see footnote 39 for the explanation on "value" in this context). This specific objective envisages the development of methods and tools by working transparently and collaboratively across academia, industry, regulatory and health technology assessment (HTA) bodies, health care professionals and providers, patients, informal carers and citizens. As a result of reaching this objective, health care authorities and organisations should avail of:

- methodological toolbox for the comprehensive assessment of the added value of combined products;
- methodological toolbox for assessing the added value of novel, integrated health care solutions;

The actual deployment of products or solutions in health care settings are in the remit of individual health care organisations and in the national competence of Member States according to Art. 168 TFEU. Moreover, while outputs of certain actions are supposed to serve as input to regulators, health technology assessment bodies or health care organisations to optimise their internal processes, implementation of these inputs will remain at full discretion of the bodies concerned as they need to remain independent, objective and free of conflicts of interest. The IHI objectives are focussed on precompetitive space, therefore not infringing EU competition- and state-aid rules.

There is risk that the proposed objective would be seen as a 'push' from industry and therefore public authorities and health technology assessment bodies would be hesitant to engage. However, such approaches – if ultimately implemented in real life settings – would result in a win-win for the public and private sectors, and would lead to a shift into new areas of health innovation and eventually deployment of innovative solutions.

Interviewees were overall supportive of the initially defined specific objectives, in particular respondents coming from industry and research infrastructures. Patient associations expressed the most concern, feeling the objectives were not sufficiently patient-centric. These views were taken into account when formulating the specific objectives presented above. There were some comments across stakeholder groups that the objectives were too broad, but it was understood by stakeholders, primarily in industry and research infrastructures, that it was not possible to define specific disease areas at this stage.

In the **feedback to the inception impact assessment**, non-private actors (NGOs, academics/research institutions, and public authorities) were calling for broader stakeholder involvement. This point was stressed in particular by NGOs including patient organisations and public authorities. This was also repeated by **interviewees** who emphasised the need to include additional stakeholders beyond industry and academia.

Fulfilling the specific objectives will indeed help to address the underlying problems, improving the industry competitiveness, health status of the citizens and preparedness for future health threats. This would be achieved by focusing on pre-competitive collaboration in areas that are of strategic interest for the EU, based on the public health needs but also based on the positioning of the EU industry in the global health value chains.

IMI has delivered innovations in the pharmaceutical domain, therefore they were mainly focussed on therapy, while IHI could address health challenges in a much broader manner, with more focus on prevention strategies, preparedness and diagnostics. Compared to the scope of IMI: SO1 which was partly addressed by the predecessor initiatives from the point of view of the action of drugs but less so from the point of view of prevention; SO2 is far broader as it covers improved prediction, prevention and diagnosis; SO3 will work explicitly towards integration of various health technologies (for example, medicines and diagnostics); SO4 expects to harness new digital solutions to improve health and health care, not available to a significant extent at the time of establishing IMI2 JU; SO5 reflects the regulatory and uptake needs stemming from the emergence of combination products (e.g. medicines and mobile apps) that do not easily fit into current regulatory schemes.

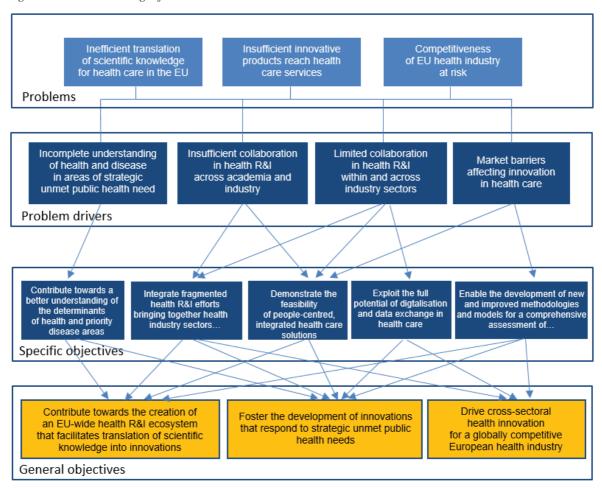
The COVID-19 crisis, as earlier the Ebola and Zika crises, have confirmed the need to address health challenges at multiple entry points, but in an agile and coordinated manner, encompassing data collection and analysis, diagnostics, prevention including by mobile health approaches, development of therapeutics and long-term prevention by vaccination – taking into account the specificities of the EU health research systems and industrial value chains.

By targeting these objectives, IHI would (a) address clear public health needs, (b) contribute to alleviate market barriers, such as those related to insufficient regulatory convergence, (b) increase the uptake of innovations by better reflecting the needs of the end-users and (d) fulfil industries' expectations in terms of return on investment in the early phases of research. The principal value of the proposed partnership for its stakeholder would be access to novel multisector collaborations at pre-competitive stage. This goes together with sharing new skills and data necessary to tackle new objectives and ultimately increasing the future competitive edge of participating companies. This opportunity is not offered at this scale by any other EU funding instrument.tar

4.3. Intervention logic of the initiative

The relationship between the general and specific objectives of the potential Innovative Health Initiative is shown in Figure 8.

Figure 8: Intervention logic for the initiative on Innovative Health



The translation of health R&I into products is a complex phenomenon that — beyond understanding the molecular basis of certain diseases — also depends on successful demonstration of safety and efficacy during the clinical phases of development, followed by regulatory steps and pricing & reimbursement decisions before innovations can reach the market and end-users, such as patients and health care professionals. In that respect, health R&I differs from a purely engineering or technological development where one outcome (e.g. a working prototype that can be up-scaled for market uptake) could directly result from one underlying intervention (e.g. a certain number of clearly defined technological improvements). For this initiative, specific objectives can be interlinked and address jointly one or more problem drivers.

For example, integrating health R&I efforts across actors and technology sectors (specific objective 2) and exploiting data and digital tools (specific objective 4), will facilitate understanding the causes of disease (specific objective 1), e.g. by more efficient use of data in clinical trials. It can also contribute to accelerated development of integrated health solutions (specific objective 3), for example by introducing mobile health solution to monitor the efficacy of treatment. Providing regulators with adequate data and methodological toolboxes to speed up regulatory uptake (specific objective 5), will also support the accelerated development of relevant health innovations (specific objective 3) by shortening the time to market and thus increasing the return on initial investment.

In particular, specific objective 4 relating to the use of data and digitalisation in health care was presented separately because it is key for linking all health industry sectors and it can

give a new angle to the process of developing new prevention or treatment strategies. Various companies indeed need and want to avail of and share consistent and interoperable data to successfully perform translational R&I but this cannot be done efficiently without inter-operable data standards, reliable data analytics tools or addressing privacy concerns. This is the reason why this initiative intends to enable a more effective, safer and ethical use digital technologies and data analytics in health research (for example, by the definition of common data exchange standards for electronic health records such that can be efficiently combined with data obtained during clinical trials of new medicines). In this way, this specific objective will help address the problems of lower R&I productivity and inefficient translation of research results into clinical practice.

The development of integrated people-centred solutions (specific objective 3) would be based on the integration of products and services developed by different industry sectors (specific objective 2), which would trigger collaboration between those sectors, thus responding to problem driver 2 "insufficient collaboration within and across industry sectors" but also problem driver 4 "market barriers affecting innovation in health care". It would indeed require addressing existing barriers to collaboration such as, for example, developing common definition of precompetitive space, looking for convergence of business models, alignment of regulatory requirements (in particular for clinical evidence generation) and developing new methodologies to assess the value of those complex and cross-sectoral health solutions.

People-centred solutions are those developed around the needs and preferences of patients, their carers (formal and informal) and citizen at large rather than individual diseases (see footnote 122 for a full definition). This approach aims at limiting siloed approaches across health care services but also across industry sectors. In this respect, specific objective 3 would also respond to problem driver 2. In addition, development of people-centred approaches implies taking into account, from the start, the needs and preferences of the patients and health care professionals. This would in turn increase the probability of better responding to the needs people and health care systems, thus lowering market barriers to innovation (problem driver 4).

Specific objective 5, related to delivering new methodologies for assessing the added value of health innovations, is indeed linked to market barriers affecting innovation in health care (identified as problem driver 4) that are partly due to the lack of methods to assess the added value for patients and society of novel, cross-sectoral health solutions. Such methods are used by the industry to demonstrate the benefit brought by an innovative solution and by health care authorities/institutions to inform their decision on reimbursement and pricing. A lack of such methods has consequences on both availability and accessibility of health innovations. It negatively impacts R&I investment decisions due to increased uncertainty around the future reimbursement by health systems. It also has an impact on implementation of innovations in health care systems because such methods are essential for the public health actors to assess the added value for patients and society, decide on coverage decisions, negotiate prices with industry and determine the conditions under which to implement those innovations in order to maximise health benefit for society.

Unmet public health needs result from a lack of availability or accessibility to health care in areas of public health importance. Specific objective 5 would imply developing solutions able to tackle either availability of health care technologies (e.g., by stimulating their development and providing the necessary conditions for it) or their accessibility (e.g., by providing the support to efficiently implement those technologies in health care systems so that they are available to people). Developing methods to assess the added value of

integrated, cross-sectoral innovations would indeed help to tackle both availability and accessibility issues, thus reducing barriers to market for those innovations (problem driver 4).

How would success look like?

Should the initiative deliver on its specific objectives, it is expected that it would translate in practice into the following expected impacts:

Scientific impacts

If successful, the initiative is expected to demonstrate various types of scientific impacts:

- Strengthened EU skills and capacity in academic and industrial health R&I;
- A thriving EU-wide cross-sectoral health R&I ecosystem created;
- New scientific paradigms established in areas of unmet public health needs.

Overall the initiative would strengthen the scientific base for the development of new prevention strategies, diagnostics and treatments. Additionally, integrating the main biomedical industry sectors is expected to lead to improved mutual understanding of particular knowledge needs of the different industry sectors and improved cost-effectiveness of R&I investment by reducing inefficiencies due to boundaries between disciplines. In the long run, this would result not only in an increased cross-sectoral collaboration at research level, but could also stimulate changes of paradigms for the actual translation of scientific findings into concrete health and care approaches. Moreover, knowledge creation and skills development through collaborative projects, especially across public and private actors, is set to strengthen Europe's human capital in health R&I.

Economic/technological impacts

If successful, the initiative is expected to demonstrate a set of economic/technological impacts:

- More productive and globally competitive EU health industries that create jobs and growth and are able to quickly respond to health threats;
- Better, safe, effective and cost-effective health technologies, tools and digital solutions;
- Increased level of public and private investments into strategic unmet public health needs, providing the foundation for innovative technologies to address these areas.

If successful, the initiative would further lead to reduced investment risk in R&I, due to collaborations and the involvement of several industrial sectors; increased access to industrial data for academic researchers; increased efficiency of R&I investments through targeted use of biomedical research resources, both public and private. In doing so, the initiative could contribute to strengthening the competitiveness of Europe's health industry, a cornerstone of Europe's knowledge-based economy, to an increased economic activity in the production, distribution and sales of health technologies, and thus serve as a tool for increasing technological sovereignty. It could directly and indirectly create highly skilled jobs, both in academia and industry.

Societal and environmental impacts

If successful, the initiative is expected to demonstrate a set of societal impacts:

- Improved health and wellbeing of EU citizens;
- Reduced health inequalities and improved access to high-quality health care in priority disease areas, thereby addressing unmet public health needs;
- Strengthening circular economy and mitigating the negative health impacts of climate change.

Overall, if successful, the initiative is likely to contribute to improved health outcomes for European citizens, expressed as more life-years in good health thanks to more effective prevention, a lower burden of disease, improved patient experience of care, better diagnoses and more efficient therapies. It is expected to constitute an incentive for industry to invest in unmet public health needs, such as brain disorders. More effective, affordable and easily implementable solutions for health care, would allow more patients to be treated more effectively and potentially with fewer resources thus further reducing operational and financial burden on health systems in the longer term.

The scope of the proposed initiative would also cover innovation in manufacturing, including green manufacturing, a circular economy approach to the product lifecycle and the overall environmental footprint, thus leading to a positive effect on the climate and the ecosystem in general. Moreover, a more wide-spread use of digital solutions in medicine should lead to better health or disease monitoring in real life and to reduced need for travel to health care centres.

However, whether these impacts will actually be achieved and to what extent, will depend on the types of projects funded through the initiative. Digital health technologies that can be used remotely are likely to result from the initiative, leading to lowering greenhouse emissions in the long term. At the same time, the increased use of energy related to more wide-spread use of data-intensive approaches and digital tools (e.g. using energy to store, process, analyse and exchange data), may counterbalance this benefit, depending on the proportion of energy from renewable sources used to power health care.

4.4. What is needed to achieve the objectives – key functionalities needed

Given the focus of the impact assessment on comparing different forms of implementation, the identification of "key functionalities needed" allows making the transition between the definition of the objectives and what would be crucial to achieve them *in terms of implementation*. These functionalities relate to the type and composition of actors that have to be involved, the type of range of activities that should be performed, the degree of directionality needed and the linkages needed with the external environment.

4.4.1. Type and composition of actors to be involved

The initiative needs to involve all type of actors along the health value chain in priority setting and in funded projects:

- Key actors: researchers from academia and various industry sectors, to ensure the best opportunity for generating new scientific ideas and successful R&I activities (and thus for reaching specific objectives 1, 2 and 3 that lead to expected scientific and economic/technological impacts);
- Users: patients and citizens, health care professionals and health care providers to provide input into the strategic design and activities of the initiative, ensuring that it addresses the needs of end-users (necessary to reach specific objectives 2 and 3, and consequently the scientific/technological and societal impacts);

• EU-wide and national regulatory authorities, HTA bodies and health care payers to provide early input to the activities of IHI. Given that health products and services are subject to evaluation of safety, effectiveness and in many cases, cost-effectiveness before being placed on the market, this early input would help avoid wasted research and would increase likelihood that the results of IHI actions will meet regulatory requirements necessary for uptake (via reaching specific objectives 3 and 5, ultimately leading to societal impacts.

Based on the interim evaluation of IMI2 JU (see Annex 6 for details), a lesson to be learned is the need to 'enable the active engagement of other industry sectors with the pharmaceutical industry to capitalise on their expertise in the development of new health care interventions'. Therefore, the industry sectors need to cover the biopharmaceutical, biotechnology and medical technology sectors, including companies active in the digital area. These actors are necessary (to a varying degree, though) to achieve each of the specific objectives. As an overarching requirement, better early engagement with regulatory bodies would likely limit wasteful or inefficient research and speed up deployment, at the same time addressing a weakness identified in IMI2 JU interim evaluation (explained in Annex 6) and a recommendation from IMI2 JU Scientific Committee 138.

Member States overall (except one) did not express the wish for a tripartite partnership involving the industry, Member States and the EU¹³⁹.

Openness and flexibility to integrate players from emerging and/or adjacent technologies is vital, notably to reach specific objectives 2 and 3 to demonstrate feasibility of people centred, integrated health care solutions, as well as objective 4 aiming at harnessing the full potential of data and digitalisation for health innovations that rely on data use and on the rapidly changing field of digital technologies. Therefore, new entities should be able to join the initiative as members if emerging health challenges would so require, in this way also responding to input from targeted stakeholder consultation. This openness and flexibility should also be reflected in the participation into IHI-funded actions, notably to ensure the agility and ability to quickly mobilise all actors in the health value chain, in order to respond to newly emerging health threats, including pandemics¹⁴⁰.

Furthermore, it is essential to facilitate the participation of innovative SMEs in projects (thus addressing another weakness identified for IMI2 JU) to ensure reaching specific objective 2 aimed at integration of fragmented R&I across technology sectors and other stakeholder, and to help achieve the scientific and economic/technological impacts.

There are areas of health technology, data analytics and expertise in certain health conditions that are more advanced in non-EU countries (or where a higher number of people

¹³⁸ Early dialogue with regulators was identified by IMI2 JU Scientific Committee as desirable for a successful public-private collaboration. IMI2 JU Scientific Committee recommendations regarding public private partnership funding – what makes a topic ultimately suitable for this kind of funding model, https://www.imi.europa.eu/sites/default/files/uploads/documents/About-

<u>IMI/Governance/sc/SCrecommendations PPPfunding.pdf</u>; IMI2 JU Scientific Committee recommendations regarding involvement of regulators and regulatory science, https://www.imi.europa.eu/sites/default/files/SC%20Recommendation_Involvement%20of%20regulators%20 and%20regulatory%20science_FINAL.docx.pdf.

¹³⁹ Specific reasons were not provided in the structured consultation of the Member States.

¹⁴⁰ In the case of COVID-19 pandemic, IMI2 JU was able to – within a few weeks only – mobilise the investment of EUR 72 million of EU contribution accompanied by EUR 45 million in-kind investment from pharmaceutical companies, aimed at development of treatments and rapid diagnostic tests useful in the fight against the current and/or future outbreak. https://www.imi.europa.eu/apply-funding/open-calls/imi2-call-21.

are affected by a certain disease that also threatens EU population). Therefore, a certain openness of the initiative and participation by these international academic, industrial and regulatory actors is also desirable, in order to be able to benefit from this expertise, to respond to emerging health threats and thus realise the necessary societal impact, notably of improved health outcomes for EU citizens.

Type and range of activities needed

The fundamental building blocks of an initiative on innovative health would need to be collaborative R&I actions that foster academia-industry, industry-industry and cross-sectoral collaborations, particularly important for specific objectives 1, 2 and 3 (related to better understanding the determinants of health and disease, integration of R&I efforts and fostering the development of integrated health solutions). Some actions may also advance assets¹⁴¹ to technology validation and the building of technology prototypes, thus benefitting from more focussed pilots, validation and demonstration activities, notably to demonstrate the feasibility of integrated health care solutions, exploit the potential of digitalisation and deliver methodologies and models for the assessment of added value of health innovations (covered by specific objectives 3, 4 and 5). The involvement of a broader set of actors, including users, is necessary, to ensure that the initiative accelerates the development of people-centred products as defined in specific objective 3. Coordination and support actions can provide useful means to conduct policy dialogues around ethics, standardisation and regulation, in line with specific objective 5.

The activities would need to focus on pre-competitive R&I, thus creating a safe space for collaboration between potential market competitors, such as pharmaceutical companies active in the same therapeutic area, e.g. cardiology or oncology, or diagnostic companies developing related technologies, e.g. for improved imaging or for rapid viral infection testing. This range of activities is important for better understanding the determinants of health and disease, integration of R&I efforts over technology areas and for making it possible to develop integrated health solutions (in line with specific objectives 1, 2 and 3), as well as for reaching the impacts of strengthened health R&I capacity in a cross-sectoral, EU-wide ecosystem. This proposed range of activities builds on the positive experience from IMI2 JU¹⁴² that should now be expanded to cover more health industry sectors.

Priority setting system and level of directionality required

Reaching all the objectives requires a long-term strategic vision and committed partners working in collaborative R&I projects, aiming to achieve more than would be possible to achieve if working in isolation, in order to make a step change in accelerating the development of innovations in specific health and disease areas, for the benefit of patients, health care providers and systems. A jointly agreed strategic research agenda is therefore needed so that the shared vision aligns with the individual goals of the members of the initiative, and so that all actors have a clear understanding of how the various elements of the initiative will fit together in a coherent manner, building commitment and trust and contributing to reaching the jointly agreed objective and thus impacts. The strategic vision

¹⁴² According to IMI2 JU interim (2014-2016) evaluation: 'the main achievement of IM2 JU on which there was general consensus, was that since the JU started, collaborations between different competing global companies, SME's and academia became possible. These collaborations created trust and new links [and] were

considered an important asset for European pharmaceutical research.'

^{141 &}quot;Assets" may be e.g. new drug or diagnostic candidates, drug targets, biomarkers, health research tools, clinical trial methodologies, industrial processes, services etc.

should be shared and implemented as much as possible by the key stakeholders along the whole value chain.

The EU contribution is expected to mobilise an additional (at least 100%) private sector contribution (in-kind or financial) that the industry would not have otherwise spent in strategic unmet public health areas, in particular in cross-sectoral collaboration. This type of commitment to pool resources only happens beyond the scope of individual projects and requires long-term predictability and commitment to the jointly accepted strategic research agenda. Thanks to these additional resources, the initiative would ensure the necessary leverage to be able to successfully tackle its objectives and deliver on its impacts.

4.4.4. Coherence needed with the external environment

The initiative would need to seek synergies with other Horizon Europe initiatives and partnerships in the health domain, in particular with the planned Partnership on Transforming Health and Care Systems (potential interdependencies were explained in Section 1.3). Beyond health, the 'Key Digital Technologies' initiative would likely offer complementary approaches to promote the digital transformation of the health sector, at the same time ensuring the protection of privacy and sensitive human data (relevant in particular for specific objective 4 and 5).

The EU policies on clinical trials, market authorisation of pharmaceuticals, ATMPs and medical devices would need to frame the activities from the regulatory side. The new Industrial Strategy for Europe¹⁴⁴, the EU Pharmaceutical Strategy for Europe¹⁴⁵ and the SME strategy for a sustainable and digital Europe¹⁴⁶ will provide an additional policy guidance for the initiative.

On digitalisation (linked in particular to specific objective 4 on exploiting the potential offered by digitalisation in health innovations), the initiative should be linked with the Digital Europe programme as regards the necessary test and experimentation infrastructures and advanced digital skills for the validation and initial deployment and uptake of digital health innovations. The initiative should be linked with the Connecting European Facility, with its eHealth Digital Service Infrastructures (eHDSI), as regards the capacities to scale up these digital health services across EU Member States via cross-border (interoperable) health data exchange and related international standards.

Effort to ensuring internal and external coherence would reflect a lesson learned from one the weaknesses identified in IMI2 JU, i.e. insufficient coherence and alignment with regional and national policies and strategies (see Annex 6).

5. WHAT ARE THE AVAILABLE POLICY OPTIONS?

This section describes the specific functionalities that could be provided under the baseline scenario of traditional calls and the different options of different types of European partnerships.

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¹⁴³ The leverage of IMI2 JU reached 99% in 2018, according to IMI2 JU Annual Activity Report 2018 (private commitment vs EU funding).

¹⁴⁴ COM(2020) 102 final

¹⁴⁵ COM(2020) 761 final

¹⁴⁶ COM(2020) 103 final

5.1. Option 0: Horizon Europe calls (baseline)

The baseline scenario used in this impact assessment is a situation without a partnership and only traditional calls of Horizon Europe. Given that there is a predecessor partnership (IMI2 JU) as well as other funding sources in the area, these will continue generating effects even if there is no new partnership. These already existing initiatives are expected to create longer-term effects on health innovations. This is taken into account in the effectiveness assessment.

IMI2 JU was established by on a Council regulation and is time-bound, without a mechanism for automatic renewal of the initiative. With no action, 2020 is the last year of launching calls and IMI2 JU will cease to exist in 2024. This justifies the choice of regular Horizon Europe calls as the baseline. Therefore, in the baseline situation, the current implementation structure of the Article 187 would be closed, which bears winding down and social discontinuation costs. There would also be financial cost-savings related to the closing of the structure, related to operations, staff and coordination costs in particular (analysed in more detail in Section 6.2). This is also taken into account in the efficiency assessment.

Table 2: Key characteristics of the baseline situation - Horizon Europe calls

	What is feasible under this option - Functionalities of option
Enabling appropriate profile of participation	 Given the broad range of activities and actors envisaged, the Commission would need to consult extensively with a wide range of stakeholders to translate the strategic R&I agenda for health into annual work programmes. However, under this option, the setting of scientific priorities and definition of call topics would follow the usual Commission comitology procedure that does not involve formal consultation of the industry and hence tends to be more academically oriented. The feasibility of engaging key actors: researchers from academia and various industry sectors users (patients, health care professionals, health care providers) and regulatory authorities would be low since traditional calls do not offer a structured mechanism for such engagement. Regarding specifically the necessary industry sectors (pharmaceuticals, medtech, biotech, imaging, vaccines), the likelihood of engaging the various industry participants jointly would be very low 147
Supporting implementation of R&I agenda	 All types of funding instruments could be used. Implementing the strategic research agenda would require the mobilisation, expertise and support of the health care industry. The calls are very open and flexible, though, enabling participation of actors along the health value chain in ad-hoc combinations, on a project basis. Calls for proposals would be published in the work programmes of Horizon Europe. Implementation would thus rely on standard infrastructure underpinning the open calls, drawing on resources of the Commission or relevant executive agency and Commission IT systems. Additional administrative costs for the European Commission would be low. Dissemination of knowledge and sharing of practice would happen predominantly among partners within the project consortia.
Ensuring alignment with	- Annual work programmes developed through the comitology process are expected to cover a broad range of health issues, with fundamental discovery research prioritised.

¹⁴⁷ See details in Section 2.2.2.

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R&I agenda

- Receiving the necessary input from representatives of all relevant stakeholders (including industry and end-users) is unlikely, in absence of a dedicated mechanism for that.
- Projects delivered within and across calls may not synergise and critical mass for addressing priorities may be limited.
- Annual work programmes could respond to emerging R&I needs and new technological developments in health over time but the process is less agile to adapt to unforeseen changes in a coordinated manner.
- Commission input into specification and oversight of calls would help to ensure alignment with overarching policy objectives, even if full integration with other programmes would require additional coordination. In the absence of a dedicated implementing structure, traditional calls would offer less effective alignment with other key initiatives and organisations in the global health R&I arena.

Securing effective leveraging of resources

- EU grant funding would be the dominant financial contribution to projects, attracting mainly academic and SME researchers and other public sector organisations.
- Traditional calls are not capable of attracting additional funds from industry; rather, the calls provide funding for industry partners.
- Participation of big pharmaceutical companies would be unlikely or limited, due among others to those companies' aversion to accepting such public funding.

Key differences compared to the current situation

- Discontinuation of IMI2 JU without a successor, entailing the winding down costs and losing a large amount of intangible assets, such as the brand, networks and partly also the know-how built up since 2008, when IMI started to operate.
- Potential applicants and the general public would lose the targeted communication activities and various forms of support offered by the Programme Office after it has closed operations.
- The pharmaceutical sector would lose a 'neutral platform' of collaboration in precompetitive space.

5.2. Option 1: Co-Programmed European Partnership

Table 3: Key characteristics of Option 1 – Co-Programmed European Partnership

What is feasible under this option - Functionalities of option **Enabling** - The initiative would be based on a memorandum of understanding or a contractual appropriate arrangement between the European Commission and the private partners. profile of - The partnership would need to consult with industry representatives and a wide range participation of stakeholders, including end-users, to ensure that the strategic research agenda (and ultimately the annual work programmes) is aligned with industry needs, is feasible and that it addresses strategic unmet public health needs. - It would enable participation in projects by all key public and/or private stakeholders along the entire health and care innovation pathway, across communities and technology sectors and/or value chains and where the actors have widely differing capacities and capabilities. - The composition of partners can change over time, allowing for flexibility and adaptation to emerging needs in the health R&I arena. - All types of funding instruments could be used. Supporting

implementation Calls for proposals would be published in the work programmes of Horizon Europe. of R&I agenda Implementation would thus rely on standard infrastructure underpinning the open calls, drawing on resources of the Commission or relevant executive agency and Commission IT systems. - Progress in the delivery of the R&I programme would depend on the willingness of stakeholders to support individual projects, rather than on longer term, firm commitments. Other stakeholders would have limited control over the precise definition of the calls, limiting the extent to which calls can be adapted to the specific needs of certain endusers. **Ensuring** - Under the co-programmed option, a strategic roadmap is agreed between the EC and alignment with the partners involved. The work programmes are developed through a comitology R&I agenda process. - R&I activity would be likely to focus on the medium-term needs of partners. - This option allows for the creation of a dedicated small office to manage the initiative, financed via a Coordination and Support Action. However, this option would not allow for creation of a dedicated implementation structure and a broader coordination of programmes. - This option could mobilise additional private sector resources, with the likely low level Securing effective of 'additionality'. Lower level industry contribution would probably be reflected in smaller overall EU commitment. leveraging of resources - Aspirations for partners' contributions would need to be clearly defined at the outset, in line with the level of predictability of open call topics. - Projects under this option are funded under the same rules as in option 0, and thus are not attractive for certain big companies, including from the pharmaceutical sector. These firms play a key role in the targeted industry-academia and industry-industry collaborations and are the most capable of providing additional resources (in-kind or in-cash). **Key differences** - Discontinuation of IMI2 JU without a successor, entailing the winding down costs and compared to the losing a large amount of intangible assets, such as the brand, networks and partly also the know-how built up since 2008, when IMI started to operate. current situation - Potential applicants and the general public would lose the targeted communication

5.3. Option 3: Institutionalised European Partnership under Article 187 TFEU

collaboration in pre-competitive space.

closed operations.

Table 4: Key characteristics of Option 3 – Institutionalised European Partnership (Article 187 TFEU)

activities and various forms of support offered by the Programme Office after it has

- The pharmaceutical sector would, to a large extent, lose a 'neutral platform' of

	What is feasible under this option - Functionalities of option				
Enabling appropriate	 A membership structure clearly defined from the outset allows for a binding engagement of the necessary industry partners. 				
profile of participation	- Participation would be less flexible than under other options, but it might nevertheless be possible to change the composition of founding partners over time, to support new				

areas of activity in response to emerging challenges and evolving priorities.

- It would provide a platform for consulting stakeholders on R&I priorities and the work programmes, ensuring that they are aligned with industry, research and end-user needs and with the agenda of other partnerships.
- The integration of the needs of all relevant industry sectors and public actors would be reflected in the specification and expected delivery of the strategic research agenda.
- Eligibility for participation and funding would follow Horizon Europe rules by default, the basic act may include, e.g. certain adaptations of intellectual property rules and broader participation, e.g. of international actors from non-EU countries. This has particular relevance in health R&I, since many world-leading industrial players, particularly from the UK, US and Japan, have extensive R&I activities in the EU.

Supporting implementation of R&I agenda

- Legally binding funding arrangements and dedicated administrative resources would ensure implementation of the strategic research agenda for the whole duration of Horizon Europe.
- A dedicated legal entity would be created with responsibility to coordinate the implementation of the jointly agreed strategic research agenda, manage implementation of calls, monitor key indicators and report on the results.
- Dissemination of knowledge and share of practices would happen among the stakeholders of the community, with potential diffusion activities managed by the Programme Office. A dedicated administrative structure would be established to coordinate the specification of R&I activity, manage implementation and report on the results (with administrative expenditure limited to a percentage of the budget).

Ensuring alignment with R&I agenda

- The partnership would be responsible for specifying work programmes in line with strategic research agenda.
- The work programme would reflect the medium- and long-term needs of industry, the EU policy needs as well as the needs of end-users represented in the governance structures.
- Commission participation in the partnership governance arrangements and approval of the work programme would help to ensure alignment with overarching policy objectives and enable integration with other programmes and initiatives.

Securing effective leveraging of resources

- Legally binding funding requirements would be clearly defined at the outset.
- High possibility for leveraging funding from industry partners as their contributions can be matched by the EU.
- Risk sharing, new collaborations and EU co-financing would likely stimulate additional industry investment, not mobilised otherwise.

Key differences compared to the current situation

- Building on the current partnership albeit with a significantly broadened scope, enlarged partner composition and revised objectives to better harness cross-sectoral collaborations and the new opportunities they may offer.
- Extensive explanation of similarities and differences is provided in a tabular format in Section 6.4.

This partnership type could build on the lessons learnt and achievements of the IMI's almost 15-years long history. Associations of medtech, biotech, imaging and vaccine industry sectors have indicated a strong preliminary interest in becoming members of such an Institutionalised Partnership, along with EFPIA's continued interest. The new associations have a large number of SME partners, across various geographies, which could help address

three issues of the current IMI2 JU¹⁴⁸: (1) low participation of industry sectors other than pharma such as imaging, diagnostics, medical technology and ICT; (2) limited SME participation; (3) geographic disparities in participation patterns.

For big companies, this option could allow participation while refraining from receiving EU-funding, which would increase their willingness to engage. An Article 187 partnership offers strong, long-term strategic steer (directionality) and the highest additional private sector resources to reach the objectives (additionality). A pre-requisite for such a significant additional investment is that industry partners have a role in co-developing and executing the strategic research agenda (SRA), in programme supervision (via membership in the governing board with voting rights) and in communications. All these conditions are fulfilled if the initiative is implemented as an Institutionalised Partnership.

5.4. Options discarded at an early stage

A Co-Funded Partnership and an Institutionalised Partnership created under Article 185 TFEU are not considered relevant for this candidate partnership. As the initiative's objectives include facilitating innovation and boosting competitiveness of European industry, this naturally requires participation from industry at its core. The discarded options focused on public-to-public cooperation and thus would be not be appropriate for this initiative.

6. How do the different policy options compare to achieve the expected impacts?

Based on the objectives pursued by the initiative and the key functionalities identified to be able to achieve them, each option for implementation is assessed in terms of effectiveness, efficiency and coherence compared to the baseline scenario of traditional calls. The analysis is primarily based on the degree to which the different options would cater for the key needed functionalities. All options are compared to the baseline situation of traditional calls, which is thus consistently scored at 0 to serve as reference point.

6.1. Effectiveness

To be in line with the Horizon Europe impact framework, the fulfilment of the specific objectives of the initiative is translated into 'expected impacts' – how success would look like – differentiating between scientific, economic/ technological, and societal (including environmental) impacts. This section considers to which extent the different policy options would allow delivering these expected impacts – confronting what is needed (functionalities) with what each form of implementation can provide in practice. The assessments in this section set the basis for the comprehensive comparative assessment of all retained options against all dimensions in Section 6.4, based on a scoring system 149.

Scientific impacts

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The baseline option is expected to result in many discovery science projects, leading to the elucidation of mechanisms of various health and disease conditions, and likely to major fundamental discoveries. However, by themselves, these calls would likely not be focused on clinical development nor would deliver implementable complex health solutions. For that

¹⁴⁸ European Commission (2017), The Interim Evaluation of the Innovative Medicines Initiative 2 Joint Undertaking (2014-2016) operating under Horizon 2020. Experts Group Report. Luxembourg: Publications Office of the European Union.

¹⁴⁹ A more in depth and detailed analysis of each policy option is provided in Technopolis Group (2020)

to happen, a more strategic approach is needed, with a broader 'portfolio-level' thinking, strategic steer (directionality) towards common objectives, alignment of individual projects and the joint participation of industrial partners.

Multi-company and multi-sector collaborations are infrequent in research projects funded through regular calls so far¹⁵⁰ and the same is likely in the future. Horizon Europe calls would therefore miss out on the opportunity to link up SMEs, academia or public research organisations having innovative concepts with large companies that have the resources to develop these concepts further and ultimately bring solutions to market.

Moreover, under the baseline option, neither the Commission nor the partners make an upfront budgetary commitment. This also implies less political commitment and reduced visibility to the field compared to an initiative under a partnership approach. Therefore, the impact on increasing the scientific leadership in the EU, readiness to respond to new health threats and technological sovereignty would be significantly lower than in a partnership.

Stakeholder opinion

Interviews indicated that regular calls would be effective at achieving scientific impacts but would have a more limited scope due to budget and timeline constraints. Many smaller projects under regular calls could potentially result in duplication of efforts and limited internal coherence, and would be unlikely to enable the establishment of large research platforms. No respondent from the consultation on the inception impact assessment mentioned Horizon Europe regular calls as a preferred option to implement IHI.

Option 1 (Co-Programmed Partnership, CPP) would be able to attract broader communities and a diverse set of actors with differing capacities and capabilities. It is conducive to working across the public/private divide and to engagement with health professionals, health authorities, patient organisations and standards bodies to work towards common objectives (directionality). SMEs, some larger companies and other strategic partners could be engaged to some extent due to the medium-term strategic research direction. However, industry stakeholders would have more limited contribution to the detailed definition of the calls, hence restricting their interest to participate at full scale and commit financially to the initiative (especially the larger companies). The absence of an established mechanism to value private entities' contributions, such for in-kind on additional activities (established only at the level of Council regulation for Art. 187 initiatives) that increase the leverage and bring valuable resources to projects, would leave large industries' involvement and investment in projects at a very moderate level. This option therefore provides a similar potential as the baseline to lead to strengthened EU skills and capacity in academic and industrial health R&I, without reaching the full potential of this impact dimension. A CPP would likely focus on creating new cross-sectoral networks and opportunities for sharing expertise, resources and new knowledge. Therefore it has a similar potential as the baseline to create a thriving EU-wide cross-sectoral health R&I ecosystem.

The CPP would likely succeed in exploring some major scientific questions, including those that advance regulatory science to a great extent. Therefore, this option would offer similar potential as the baseline to *establish new scientific paradigms in areas of unmet public health needs*, therefore scored as 0.

63

¹⁵⁰ The main beneficiaries of the 7th Framework Programme (FP7) and Horizon 2020 health areas were academia and public research organisations. The private sector made up about one fifth of all participants, mainly SMEs plus some large companies, albeit sporadically. Further analysis of this situation can be found in the impact assessment study report Section 6.1.1.

Stakeholder opinion

Interviews indicated that a Co-Programmed Partnership was preferred to Horizon Europe regular calls in particular due to the longer term focus. However, it was felt that the commitment under the CPP option would not deliver the security needed to invest in truly innovative and risky ideas and may therefore not be attractive to some partners. Establishing common research agendas was seen as valuable but insufficient to overcome the barriers of different sectors working in isolation from one another, and the CPP would therefore not benefit from the full set of outcomes stemming from the cross-pollination of skills and knowledge under a partnership

Option 3 would have its long-term priorities enshrined in the SRA developed after broad stakeholder consultation, with the possibility to amend it when needed following a transparent process. The Institutionalised Partnership would have full responsibility for developing and implementing the annual work programmes without using the formal comitology process (the Member States' input would be secured via representation in IHI governance structures).

This option ensures the highest level of integration of stakeholders and the highest level of focus on strategic R&I questions to meet the desired specific objectives. With a high level of directionality, the strategic and potentially 'portfolio-level' approach would increase the chances of (1) integrating the currently disparate technologies of the various industry sectors and (2) creating a multi-stakeholder initiative that shares expertise, resources and knowledge for disruptive ideas of health innovation, necessary for addressing specific objectives, notably 1 and 2. In addition, option 3 offers stability with regard to funding members and financial commitments which will in turn support long-term scientific commitments. This option would thus offer a unique opportunity to bring academia, public research bodies and other actors (SMEs, but also regulators and health technology assessment bodies as well as end-users) closer to industrial partners. This would translate into good potential compared to the baseline for both strengthened EU skills and capacity in academic and industrial health R&I and contribute to the creation of a thriving EU-wide cross-sectoral health R&I ecosystem and facilitate uptake by health care systems. These two aspects would therefore be scored as +, compared to the baseline of 0 (of note, creating an R&I ecosystem is considered an endeavour of a very long time horizon, dependent on external factors such as the tax incentives or economic situation in general, preventing this option from receiving an even higher score).

This should, in principle, result in an increase in the relevance, quality and coherence of the portfolio of projects. There is, however, also a certain risk that the partnership calls for proposals will be 'over-specified' and, as a result, they will not attract the broadest array of applicants or any 'unorthodox' scientific proposals. On the other hand, this potential risk would be mitigated by the involvement of the EU in the decision-making process and ensuring sufficient openness of the call topics, and also compensated by the access of academic consortia to additional scientific expertise and valuable dataset held by the industrial partners. This would lead to equal impact potential *in establishing new scientific paradigms in areas of unmet public health needs* as the baseline 151. Its score would therefore

¹⁵¹ The citation impact of IMI research is higher than EU and world averages. The field-normalised citation impact for all IMI papers is 1.99, compared to 1.10 for the EU and the baseline of 1 for the world. IMI is also compares favourably with similar organisations such as the Wellcome Trust, the Medical Research

also be 0. At the same time, the resulting developments would likely be of higher direct relevance for the end-users, including EU citizens, health care practitioners and health care systems.

Stakeholder opinion

The proposed use of Article 187, and the establishment of a Joint Undertaking, was supported by 73% of Member States.

In the **inception impact assessment** consultation, 17 of the 18 respondents who spontaneously expressed their views on the mode of implementation were in favour of an Institutionalised Partnership, without any difference of views between the categories of respondents. Reasons cited for preferring this option were that it would enable long-term commitment of key stakeholders and ensure continuity of research ideas.

The majority of **stakeholders interviewed** felt that and Institutionalised Partnership would be the most effective means of delivering scientific impact. Stakeholders from industry saw this option as attractive because it would offer industry opportunity to co-develop research agendas. Similarly, stakeholders from other groups felt that having a diverse range of players would enable the development of research agendas that are more balanced across the needs of all actors, leading to more realistic and holistic research goals. The legally binding arrangement was seen as an advantage by providing a level of confidence to the stakeholders involved, hence facilitating the sharing of data required to achieve impact.

As for the **public consultation** on the 12 candidate Institutionalised Partnerships, respondents viewed long term commitment and long-term funding as major advantages for IHI. 55% of respondents indicated that IP was the best fit (with no difference between the views of citizens and other respondents), while only 9% supported a Co-Programmed Partnership (the remainder preferred either regular calls or a Co-Funded Partnership, a discarded option).

Economic/technological impacts

The baseline option would entail limited private sector involvement, as explained in Table 2 and in Section 6.1. Industry participation (by small, medium and large enterprises) is, however, essential to the process of advancing innovative assets (e.g. new candidate drugs or diagnostics) closer to deployment in the health care sector and international markets. The primary goal of IHI, namely to integrate the currently disjointed components of drugs, devices and software into real integrated health solutions (and thereby the specific objective 3) would not be achieved.

Under **Option 1**, the SRA could have industry contribution and therefore the Horizon Europe work programmes would be expected to have some technology focus mobilising interests from across the value chain, including the private sector.

Still, Option 1 would not offer dedicated support for managing the programme at a required scale, which is needed to ensure the proper budgetary control over industry contributions, ensuring consistency with other funding programmes, safeguard the establishment and

Council (MRC) and the Foundation for the National Institutes of Health (FNIH). IMI2 JU Annual Activity Report 2019. https://www.imi.europa.eu/sites/default/files/events/IMI%20AAR%202019 FINAL.pdf

implementation of potential intellectual property arrangements that may stem from public-private collaborations, and to offer targeted communication activities (incl. to support SMEs participation). Therefore, the longer term prize of *more productive and globally competitive EU health industries that create growth and jobs and are able to quickly respond to health threats* would be beyond reach due to low integration of stakeholders (especially across industry sectors) and hence the likely impact for these aspects remains similar to the baseline, also receiving the score of 0.

The CPP's reliance on Horizon Europe calls would place some limitation on its directionality, as discussions on its strategic direction would be conducted through the comitology process. From this perspective, the impact on developing *better*, *safe*, *effective* and cost-effective health technologies is likely be good compared to the baseline but still missing greater directionality facilitated by a dedicated implementation structure. Its score would therefore be + compared to the baseline of 0.

At the same time, openness under this option would likely favour collaborative working between the private sector and various public authorities, HTA bodies and end-users, thus contributing to improved conditions for health R&I, new adapted tools and models for value assessment and de-risking in strategic areas (notably, addressing specific objective 5). These would offer a good potential (scored as +) compared to the baseline (scored as 0) to translate into an *increased level of public and private investments into strategic unmet public health needs, providing the foundation for innovative technologies to address these needs*.

Option 3 would result in the closest alignment of research agendas, pooling of resources (including those from non-EU countries where the additional funds mobilised might be to a certain extent matched with the EU funding) and strong oversight of its project portfolio. Through a dedicated implementation structure, participants (including SMEs) would be able to benefit from adapted project support from set-up to post-R&I project activities. This should increase the likelihood of all actions delivering to their full potential.

The EU funding, combined with the high degree of directionality, would most likely attract commitment and financial leverage from the private sector supporting long-term challenges and priorities. The balance of private and public interest should be ensured through extensive stakeholder consultations prior to launching the initiative. During the partnership's lifetime, this balance would be supported by the governance structures with 50% voting rights for the EC and consultation processes to gather input from others public authorities, health care professionals and patients.

Industry could gain the long-term horizon and certainty needed to tackle risky projects in a safe environment. An Institutionalised Partnership therefore has high potential (++) compared to the baseline to develop better, safe, effective and cost-effective health technologies, tools and digital solutions through significant technology convergence, via fulfilling the specific objectives 2 and 3. A key element for the linking of the industry sectors is the necessity to avail of and share consistent and interoperable data, involving a wider use of innovative digital tools, leading to more productive and globally competitive EU health industries that create jobs and growth and are able to quickly respond to health threats and justifying the high potential (++) of option 3 to contribute to this impact, compared to the baseline. This assessment is supported by prior experience with public-private partnerships through the Innovative Medicines Initiative (IMI JU and IMI2 JU) and ECSEL where public and private stakeholders could innovate in a safe environment. IMI and IMI2 demonstrated the capacity to mobilise resources quickly to respond to emerging

challenges, such as the Ebola outbreak¹⁵² or COVID-19 outbreak¹⁵³. In the biomedical research field, IMI has international visibility and 'brand' that opens doors to new collaborations; an Institutionalised Partnership on Innovative Health could achieve the same or even more, given its envisaged broader composition.

There is also a question as to whether, in the longer term, the initiative would result in an increased level of public and private investments into strategic unmet public health needs, providing the foundation for innovative technologies to address these needs. On one hand, under option 3, the industrial partners would provide an up-front, legally binding commitment to the jointly agreed strategic research agenda. Thanks to risk sharing with other partners, new collaborations and EU co-financing of the resulting projects, this would likely stimulate additional industry investment, not mobilised otherwise. On the other hand, the initiative would be co-financed from the part of EU research budget devoted to health, therefore attributing a 'good' potential in this impact area (scored as +), compared to the baseline of 0.

Stakeholder opinion

Interviewees indicated that investors would have more confidence contributing to a partnership with a higher degree of integration as seen in the Institutionalised Partnership. This was particularly discussed in relation to industry, whose participation would precipitate essential market knowledge needed to achieve economic impacts. It was reported that this option would enable more detailed discussion around intellectual property upfront, further increasing confidence in the partnership from the outset. The majority of feedback to the inception impact assessment from business associations stated that Institutionalised Partnership would be the most effective option to guarantee commitment from the different partners, in particular SMEs for which a legal framework respecting intellectual property ownership requirements was seen critical for their involvement. This point was also highlighted by public authorities.

Out of the listed economic impacts in the **public consultation**, the largest number of respondents (81%) across all stakeholder groups indicated that the Institutionalised Partnership was very relevant to 'better, safe, effective and cost-effective health technologies, tools and digital solutions for health'. This was also the case for 'highly skilled jobs' (54%), with the exception of 'other' stakeholders who generally felt this was less relevant. There was some disagreement between stakeholders from industry (business associations, company/business organisation) and non-private actors with regard to the partnership's relevance to the economic impact of 'more innovative, sustainable and globally competitive health industries', with higher rates of industry stakeholders finding this 'very relevant' compared to non-private actors whose responses were more varied.

Societal impacts

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¹⁵²https://www.imi.europa.eu/projects-results/project-factsheets/ebola;

https://ec.europa.eu/commission/presscorner/detail/en/ip 20 1248

IMI2 JU was able to – within a few weeks only – mobilise the investment of EUR 72 million of EU contribution together with EUR 45 million commitment from industry, aimed at development of treatments and rapid diagnostic tests useful in the fight against the current and/or future outbreak of COVID-19. 8 project were selected from funding out of 144 proposals submitted. https://www.imi.europa.eu/apply-funding/open-calls/imi2-call-21.

Under the **baseline option**, the scale and size of these individual projects would not allow for the 'pull through' and valorisation of breakthrough discoveries in a timely manner. As discussed before, scientific breakthroughs in themselves do not create technological, economic and societal impacts. Individual projects under regular calls are unlikely to lead to significant change without strong consistency (external coherence) and the involvement of key actors, including from industry, over a more extended period of time. In the absence of strategic steer and outside contributions (directionality and additionality), the baseline option would translate to low potential for achieving societal impacts even in the longer term. In the absence of a dedicated implementation structure, traditional calls would not allow creating a common platform for large-scale collaboration between industry sectors (inherent to specific objective 2), which in turn would not allow the society to benefit from potential faster availability of new drugs or diagnostics (as targeted by specific objectives 2 and 3). This is because the 'intermediary' health technologies are not well-placed on their own to improve health promotion and disease prevention. Consequently, this option would not lead to improved health and wellbeing of EU citizens, reduced health inequalities and improved access to high-quality health care in priority disease areas or strengthening circular economy and mitigating the negative health impacts of climate change, all these impacts being scored at 0, like the baseline.

Option 1, as discussed above, offers openness and potential for engaging the entire health value chain likely favours dialogue between private sector and various public authorities and HTA bodies. As a result, option 1 offers a higher potential (scored as +) than baseline to contribute to *improved health and wellbeing of EU citizens* that would gain prominence through working more closely with public sector organisations. However, those health innovation aspects that require a longer term horizon and stronger integration of partners would not progress sufficiently towards reaching some of the more challenging types of impact sought, including *reduced health inequalities and improved access to high-quality health care in priority disease areas* and *strengthening circular economy and mitigating the negative health impacts of climate change*. This justifies only a good potential compared to the baseline in these two impact areas, hence scored at +.

Under **option 3**, the significant scale and size of Institutionalised Partnership projects have the potential to enable faster 'pull through' of breakthrough discoveries, their valorisation and translation into societal impacts. An Institutionalised Partnership offers greater strategic steer (directionality) and greater potential for outside contribution (additionality). Through the development of better health technologies and the combination of health technologies, this option offers high potential (in the long-term, compared to the baseline) to impact on improved health and wellbeing of EU citizens, receiving the score of ++. This is likely to happen thanks to the co-designed (public and private, including end-users) development of better health technologies and combination of health technologies, the focus of specific objective 3. This could also lead to scaling-up of health technologies that are currently of limited availability to patients and, thanks to higher efficiency of these improved health technologies, to liberating medical personnel in clinics for priority activities, e.g. in intensive care units. In addition, exploiting health data, using digital tools and rolling out the resulting digital health innovations (under specific objective 4) in areas of unmet public health needs would offer good potential for reduced health inequalities and improved access to high-quality health care in priority disease areas, thereby addressing unmet public health needs, thus scored as + compared to the baseline scored 0. Another beneficial impact of digital health solutions includes a reduced need to travel (e.g. to hospital) and the possibility to receive care remotely. This latter point was acutely demonstrated during the 2019/2020 COVID-19 pandemic when many non-coronavirus patients were delaying seeking medical advice or even emergency care (in fear of contracting the SARS-CoV-2

coronavirus when contacting other, potentially infected persons), while health care authorities were also suggesting to postpone certain visits or interventions. All this lead to worsening of their health condition as a collateral effect of the pandemic. Wider availability and use of remote care, such as remote diagnostics, would also lead to reduced burden on health care systems (and last but not least, less emissions). At the same time, decreasing the environmental footprint of health industries and promoting circular economy could contribute to the greeninig of health care. All that would lead to good potential for *strengthening circular economy and mitigating the negative health impacts of climate change*. This effect might be even stronger if the targeted R&I collaborations incentivise industries to increase their production capacities in the EU, which then in turn would improve Europe's technological sovereignty. Its score would therefore be + versus the baseline of 0.

Expected impact on fundamental rights

R&I activities leading to creation of new technologies and solutions for health care can be expected to contribute to the right to health and right to health care, the right of equitable access to preventive and treatment-related health care for all, including marginalised groups. Advances in data-based products and tools including those based on electronic health records and real-world health data could have implications on the privacy rights of citizens. The use of digital technologies in health care could make diagnosis and treatment more accessible, less invasive and accessible to all individuals, including those living in remote areas, or across borders. Digital technologies could thus contribute to access rights to preventive health care and to benefit from medical treatment as well as to a high level of human health protection 154.

Stakeholder opinion

Interviewees indicated that achieving societal impact required the involvement of a broad range of stakeholders and that an Institutionalised Partnership would be the most effective platform to create and sustain such a collaboration. In all consultation activities, there was a general call from respondents from the public sector for the partnership to involve of a broad scope of stakeholders beyond industry and academics, including in the partnership's governance. Examples of broader stakeholders include patients' organisations, health care payers, regulators, HTA bodies, health and social care professionals, health care providers, national health care system actors and public authorities, research and technology organisations. To a lesser extent, NGOs, civil society organisations and citizens' groups were also mentioned. Respondents explicitly asked for a balance between relevant stakeholders in strategic decision-making so that research priorities would be set according to public health needs while ensuring commitment from industry. This was considered one of the key requirements to delivering impact in relation to unmet health needs.

Out of the listed societal impacts in the **public consultation**, the largest number of respondents across all stakeholder groups indicated that the Institutionalised Partnership was very relevant to 'improved access to innovative, sustainable and high-quality health care' and 'effective health services'. An 'improved patient experience' was found to be less relevant by stakeholders from academic/research institutes, small company/business organisations and 'other' respondents.

Summary

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¹⁵⁴ Charter of Fundamental Rights of the European Union (2012/C 326/02). Article 8 Protection of personal data, and Article 35 Health care.

Table 5 lists the scores for each of the policy options, based upon the assessments above, while also taking into account the support expressed by the different stakeholders.

Table 5: Overview of the options' effectiveness compared to the baseline

	Baseline: Horizon Europe calls	Option 1: Co- Programmed European Partnership	Option 3: Institutionalised European Partnership Art 187
Scientific impacts			
Strengthened EU skills and capacity in academic and industrial health R&I	0	0	+
A thriving EU-wide cross-sectoral health R&I ecosystem created	0	0	+
New scientific paradigms established in areas of unmet public health needs	0	0	0
Economic/technological impacts			
More productive and globally competitive EU health industries that create jobs and growth and are able to quickly respond to health threats	0	0	++
Better, safe, effective and cost-effective health technologies, tools and digital solutions	0	+	++
Increased level of public and private investments into strategic unmet public health needs, providing the foundation for innovative technologies to address these needs	0	+	+
Societal impacts			
Improved health and wellbeing of EU citizens	0	+	++
Reduced health inequalities and improved access to high-quality health care in priority disease areas, thereby addressing unmet public health needs	0	+	+
Strengthening circular economy and mitigating the negative health impacts of climate change	0	+	+

Notes: Score ++: Option presenting *high* potential compared to baseline; Score +: Option presenting *good* potential compared to baseline; Score 0: Potential of the baseline.

6.2. Efficiency

In order to compare the policy options consistently in terms of their efficiency, a standard cost model was developed for the external study supporting the impact assessment for the set of candidate Institutionalised Partnerships. The model and the underlying assumptions and analyses are set out in the Common Part of this impact assessment, Section 2.3.2 and in the Methodology Annex 4. A dedicated Annex 3 also provides more information on who is affected and how by this specific initiative in line with the Better Regulation framework. The scores related to the costs set out in this context allow for a "value for money" analysis (cost-effectiveness) in the final scorecard analysis in Section 6.4.

In addition, for this specific initiative under the baseline scenario or under option 1, there would be winding down and discontinuation costs for the existing IMI2 JU Programme

Office. While IMI2 JU is expected to launch its last calls in 2020¹⁵⁵, the Programme Office as the implementation structure would be in place until the end of 2024 as set out in the Council regulation. The yearly cost of functioning of IMI2 JU Programme Office amounts to approximately EUR 10 million per year¹⁵⁶, hence for the period of 2021-2024 the administrative cost would likely reach approximately EUR 40 million¹⁵⁷. This amount is divided equally between the EU and EFPIA, the private partner, therefore the administrative cost to the EU budget would be in the range of EUR 20 million in total until 2024. The cost savings related to the closing of the Programme Office would become visible only as of 2025¹⁵⁸.

On the other hand, setting up a dedicated implementation structure would require additional costs compared to the baseline option. If implemented under option 3, IHI would likely entail yearly administrative costs comparable to those of IMI2 JU (depending on several parameters, such as the operational budget of the initiative and the potential use of a common back office). The additional administrative cost would be moderate if the implementation structure is built on the existing IMI2 JU Programme Office that, with some adaptations to account for a broader industry composition or revisited governance structure, could serve IHI. Nevertheless, it is estimated that the savings on administrative costs from using option 0 instead of an existing IMI2 JU Programme Office would – in the long term – exceed the costs incurred for winding down. The score of the baseline scenario (traditional Horizon Europe calls) is therefore set to 0 as a reference point. Running costs and winding-down costs of the current JU under the future Option 1 would be similar to the baseline option. Under the future Option 3, the running costs would be the highest, hence receiving the score of (-)(-).

On this basis, the scores for the costs of the different options range from a value of 0, in case an option does not entail any additional costs compared to the baseline, to a score of (-) when an option introduces limited additional costs when compared to the baseline and a score of (-)(-) when substantial additional costs are expected in comparison with the baseline. In case the scores are lower than for the baseline scenario, (+) is used.

It is considered that while there is a clear gradation in the overall costs of the policy options, the cost differentials are less marked when one takes into account the expected co-financing rates and the total budget available for each of the policy options, assuming a common Union contribution. From this perspective, there are only one or two percentage points that split the most cost-efficient policy options – the baseline (traditional calls) and the Co-Programmed policy option – and the least cost-efficient – the Institutionalised Partnership

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¹⁵⁵ In duly justified cases, calls for proposals may also be launched in 2021.

¹⁵⁶ For years 2014-2019, the real administrative costs of IMI2 JU ranged between EUR 8.8 and 11.2 million per year, as reported in respective IMI2 JU Annual Activity Reports. https://www.imi.europa.eu/about-imi/reference-documents.

¹⁵⁷ This assumption does not take into account the situation in which some staff would be released because of lower workload due to no news calls being launched, which could bring certain savings. However, the workload related to new calls being launched is only one element among many others to consider, such as the tasks related to monitoring projects launched in previous years – there are 11 IMI JU and 79 IMI2 JU projects active at the moment of writing, with approx. 20 new projects expected to be launched in 2020. The IMI Programme Office needs to maintain all the staff functions necessary for its functioning (e.g. human resources, IT, legal, audit) and cover all related costs (IT equipment, renting of premises, communications etc) that are not directly linked to the actual number of new calls launched and need to be borne until the end of existence of the Programme Office.

¹⁵⁸ Certain residual costs would still have to be borne by the Commission or its executive agencies to manage the "legacy" projects after 2024, as some projects IMI2 JU are expected to run until 2026-2027.

option. Indeed, in terms of cost-efficiency, the Co-Programmed Partnership (Option 1) is 2 percentage points more efficient than the baseline; and an Article 187 Partnership is 2 percentage points less cost-efficient than the baseline. However, looking at the different options in terms of their ability to attract additional private sector resources and thus leverage the EU action's investment and impact, there are significant differences.

Option 0 does not warrant a significant (or even any) in-kind or financial contribution from industry; on the contrary, in these projects industry participation would be largely financed by EU grant funding.

Under **option 1**, in-kind industry contribution is expected but its exact level would only be set in the annual work programmes. Memoranda of understanding would probably give an indication of the total contribution upfront, but such agreements have weak legal power to enforce these commitments. Stakeholder interviews also revealed that several big pharmaceutical companies would stay away from this type of partnership as the calls might not automatically offer participation without receiving EU funding (which would be preferred e.g. by large pharma industry, so as to facilitate reporting obligations and not to complicate potential pricing considerations on innovations that could ultimately result from the partnership; it is already the case in IMI where EFPIA members do not receive funding). Due to these factors, additionality in option 1 would be far smaller than in option 3.

Option 3 offers a legally binding funding arrangement laid down at the outset, with the EU providing 50% of resources to R&I activities through a financial contribution and private sector partners providing (at least) 50% of the resources, mainly through in-kind contribution but potentially also financial resources. In practice, 1 Euro of EU commitment to the initiative would bring in (at least) an additional 1 Euro from private sector partners¹⁵⁹. This offsets the higher overall operating costs by orders of magnitude and thus offers the most cost-efficient option¹⁶⁰. The set-up under Option 3 would also allow for leveraging the additional investment of entities other than member industries, such as charities, similarly to the 'associated partner' status already successfully implemented by IMI2 JU. While Option 3 could potentially create complexities for accessing funding, notably by start-ups and SMEs, they could be mitigated by the activities of the future JU Programme Office offering support to applicants and project beneficiaries.

Of note, Option 1 and even more so Option 0 would imply the discontinuation of IMI2 JU without a successor. Apart from the winding down cost, these options would entail losing a large amount of intangible assets, such as the brand, networks and partly also the know-how built up since 2008, when IMI started to operate. These factors were also taken into account when assessing the effectiveness of the options above.

Table 6: Matrix on 'overall costs' and 'adjusted cost scoring'

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¹⁵⁹ The leverage of IMI2 JU reached 99% in 2018, according to IMI2 JU Annual Activity Report 2018 (private commitment vs EU funding).

¹⁶⁰ Note that the planned EU investment for this initiative is unknown at the moment of writing the impact assessment, and depends on several factors (e.g. the Horizon Europe budget, final decisions on strategic R&I priorities and the related industry commitment). For the sake of comparison, the same EU investment was used throughout the different policy options and this is correct when comparing to the baseline. However, for a Co-Programmed Partnership (option 1) it is probable that less EU funds would be dedicated to the partnership than in the case of an Institutionalised Partnership (option 3), likely creating less prominent impacts, and the remaining funds would be deployed through traditional calls.

	Option 0: Horizon Europe calls	Option 1: Co- Programmed	Option 3: Institutionalised
Administrative, operational and coordination costs	0	0	(-)(-)
Administrative, operational and coordination costs adjusted per expected co-funding (i.e. cost-efficiency)	0	+	(-)

Notes: Score 0 = same costs as for the baseline; score (-) = limited additional costs compared to the baseline; score (-)(-) = substantial additional costs compared to the baseline; score +: Option presenting *good* cost-efficiency compared to baseline.

The analysis above remains equally valid independent of the development of COVID-19 pandemic. The reason is that IHI was designed from the start as a collaboration of several health industry sectors, including diagnostics, pharmaceutical and vaccine areas. Providing an R&I response to emerging health threats would fall naturally in its scope.

6.3. Coherence

6.3.1. Internal coherence

In this section we assess the extent to which the policy options show the potential of ensuring and maximising coherence with other actions, programmes and initiatives under Horizon Europe, in particular European Partnerships.

For the initiative to deliver on its ambitious specific objectives, it needs to show a high degree of internal coherence, from developing a research agenda and coordination of stakeholders to developing linkages to other initiatives within Horizon Europe.

Under the **baseline option**, it would be challenging for individual Research and Innovation Actions to identify linkages, opportunities for coordination and communication, or to make steady progress on enabling the uptake of health innovation from the actions' limited budget. In addition, Horizon Europe would not provide dedicated support to these individual health R&I projects to put their outputs on the pathway to impact. This limitation is significant if the initiative's emphasis is on achieving shorter term impacts. Coordination and Support Actions could, to some extent, create a dedicated R&I collaborative platform that is necessary to create a 'learning' health care ecosystem but these would need to be closely linked to the collaborative research actions so that the fledging network can test innovative ideas and experiment in a safe environment. The latter is, however, hard to achieve across a multiplicity of uncoordinated calls.

Under **option 1**, a Co-Programmed Partnership would draw up its strategy in consultation with key stakeholders across the public and private sectors to ensure a high degree of internal coherence within the strategic research agenda and through linkages to other initiatives within Horizon Europe. In addition, implementation through regular calls means that it may align with and link to important parallel activities within other parts of the Horizon Europe programme. It is likely that Coordination and Support Actions could create a dedicated R&I collaborative platform that is necessary to create a 'learning' health care ecosystem and link to the (more strategic) collaborative research actions. This could also help cross-project activities to further exploit synergies and enhance potential for impacts.

Hence, this option offers good potential (score of +) to achieve internal coherence compared to the baseline (score of 0).

Under **option 3**, the Institutionalised Partnership's structure enables a high degree of internal coherence: from developing a research agenda and coordination of stakeholders to creating and/or strengthening linkages to other initiatives within Horizon Europe. This would minimise duplication and wasted research. There are a number of other candidate partnerships in the Health cluster that are closely related to innovative health but with a more thematic or geographical focus: personalised medicine, rare diseases, One Health AMR and EU-Africa Global Health partnerships. Results emerging from an Institutionalised Partnership on innovative health could be implemented and scaled up in a complex European health environment where other health initiatives (candidate Partnership on Transforming Health and Care or EIT Health) may prove complementary. Finally, the environment also seems conducive to helping the partnership achieve its goals with candidate partnerships on (1) Key Digital Technologies; (2) Artificial Intelligence, Data and Robotics; and (3) High Performance Computing. The IHI Programme Office would lead all coordination activities to ensure internal coherence, translating into high potential of option 3 (scored as ++) on this aspect versus the baseline (score of 0).

Stakeholder opinion

During the **public consultation**, the majority of respondents from all stakeholder groups reported that it would be possible to rationalise the candidate Innovative Health Initiative and its activities, and/or to better link it with other comparable initiatives. This response was less uniform among EU citizens, where a large proportion selected that they did not feel it would be possible. Of respondents who provided details for selecting 'no', a common response was that it could increase the complexity of the partnership.

Nevertheless, the overall opinion of respondents was positive: in the feedback on the **inception impact assessment**, business associations encouraged the generation of synergies between the different partnership initiatives. Similarly, there was general consensus among **interviewees** on the need for links between the partnerships including development of similar data management methodologies and establishing a flexible set of rules to facilitate collaboration.

6.3.2. External coherence

In this section we assess the extent to which the policy options show the potential of ensuring and maximising coherence with their external environment, including EU-level programmes and initiatives beyond the Framework Programme and/or national and international programmes and initiatives, but as well as with overarching framework conditions, such as regulation, standardisation, etc.

Under **the baseline option**, Horizon Europe's work programmes are developed through a comitology process that involves several iterations of consultation with various key stakeholders, within other Commission Directorates-General and EU Member States. Health calls can also be framed to maximise their complementarity with initiatives in the wider landscape. For IHI, they would include other programmes under the 2021-2027 multiannual financial framework (e.g. Digital Europe Programme, Connecting Europe Facility) other key EU stakeholders (e.g. EUnetHTA, Heads of Medicines Agencies, Competent Authorities for Medical Devices) and research infrastructures (e.g. Elixir, BMBRI, EATRIS, ECRIN). However, it is unlikely those external programmes and networks could effectively

interact with a health initiative under Horizon Europe regular calls without the presence of a long-term dedicated strategy and central programme office.

Under **option 1**, Horizon Europe's work programmes are developed through a comitology process. A major difference compared to the baseline option is that the CPP can interact with external programmes and networks via a central administrative infrastructure (financed via a Coordination and Support Action) to bolster its long-term strategy. In addition, individual partners at a national level may have the ability to improve coherence between activities supported within the partnership and those outside of it. However, alignment with globally operating initiatives would be difficult in the absence of a dedicated implementing structure. Hence, under this option there is good potential to achieve internal coherence (scored as +), compared to the baseline option (score of 0).

Under **option 3**, the interaction with actors listed under the baseline option would be greatly enhanced by the creation of a programme management office to act as a single point of contact for all external programmes and networks. Indeed, for the partnership to meet its objectives (especially specific objective 4 'Strengthen the conditions for R&I for strategic unmet public health needs' that should lead to novel methods to assess the value of combined products and integrated health care solutions) it needs to interact with other European and international actors in the health arena, including from the regulatory side. Hence, this option offers high potential (scored as ++) to achieve external coherence compared to the baseline (score of 0).

We have also analysed the extent to which various options would lead to higher participation and larger contribution from companies active in health research, as a necessary ingredient of a successful public-private partnership.

Under the baseline option (regular calls of Horizon Europe), the setting of scientific priorities and definition of call topics would be done by the Commission services followed by the usual comitology procedure. This does not involve any formal step of consultation of the industry and hence tends to be more academically oriented. The limited interest of large private industries in regular calls is reflected in the limited participation in collaborative projects of large industrial entities under Horizon 2020 Societal Challenge 1 (Health, demographic change and wellbeing), with only few projects where several large companies would collaborate. Horizon Europe calls also use standard intellectual property rules that in some situations do not fully cater for all possible setups of collaborations between academia and industry, including SME.

Under **Option 1**, the implementation of programmes would follow a similar procedure as under the baseline option, differing in the industry partners would provide input on call topics to the relevant sections of the work programmes. Option 1 would not offer a dedicated staff for managing the programme at a required scale, which is needed to ensure the proper budgetary control over industry contributions, ensuring consistency with other funding programmes, safeguard the establishment and implementation of the intellectual property arrangements that may stem from public-private collaborations, and to offer targeted communication activities (incl. to support SMEs participation). Because of the limited contribution of private stakeholders to the definition of the calls, they would have only a limited interest to commit financially to the initiative. The absence of an established mechanism to value private entities' contributions, such as for in-kind on additional activities (established only at the level of Council regulation for Art. 187 initiatives) that increase the leverage and bring valuable resources to projects, would leave the investment and involvement of large industries in projects at a moderate level.

In contrast, under **Option 3**, scientific priorities would be identified by the health industries jointly with the Commission services and other stakeholders involved in health care, including end-users. The support of the Programme Office and the system of voting rights in the Governing Board would help maintain the balance of interests. Structured involvement of Member States via the States Representatives Group would help ensure consistency with national priorities and initiatives. The final decisions on the scientific priorities would be in the hands of the Governing Board, with equal representation of private (industry) and public (EU) interest. These elements, together with matching of private commitment with EU funding, would cater for the firm commitment of private industries and hence be the base for strong additionality. For example, the leverage (private commitment vs EU funding) under IMI2 JU reached 99% in 2018.

Under option 3, the industry would have a safer environment for exchanging knowledge and translating it to future products, also in case of possible adaptations of intellectual property rules, not available under option 0 and 1. The set-up under Option 3 would also allow for leveraging the additional investment of entities other than pharmaceutical industries such as charities, via the mechanism of associated partners to a future Joint Undertaking.

Stakeholder opinion

The majority of respondents from all stakeholder groups during the public consultation reported that the candidate Innovative Health Initiative would be able to link its activities with other comparable initiatives. It was discussed in both the interviews and public consultation that having a more aligned research agenda would reduce duplication and would further advancements in specific areas of research, e.g. priority disease areas. Interviewees also noted how cooperation between initiatives could enhance learning and outputs, e.g. the ECSEL Joint Undertaking (predecessor of the candidate partnership on Key Digital Technologies) could provide digital support to ensure uniform data standards and methods. It was also stated that establishing a flexible set of rules for the different initiatives could reduce bureaucratic barriers. During the consultation on the inception impact assessment, representatives of research infrastructures stressed the importance of leveraging the power and network of research infrastructures such as BBMRI, EATRIS and ECRIN. This was repeated during the interviews with stakeholders from research infrastructures.

Summary

Table 7 lists the scores for each of the policy options, based on the assessments above, while also taking into account the support expressed by the different stakeholders.

Table 7: Overview of the options' potential for ensuring and maximising coherence

	Option 0: Horizon Europe calls	Option 1: Co- Programmed	Option 3: Institutionalised Art 187
Internal coherence	0	+	++
External coherence	0	+	++

Notes: Score ++: Option presenting *high* potential compared to the baseline; Score +: Option presenting *good* potential compared to the baseline; Score 0: Potential of the baseline.

6.4. Tabular comparison of the options and identification of the preferred option

Building upon the outcomes of the previous sections, this section compares the options' 'performance' against the three dimensions of effectiveness, efficiency and coherence (Table 8). It should be noted that the process of the preparation of the partnership has not yet been finalised (see also Section 7.1) and some quantitative data are not available, some criteria of this assessment represent a qualitative judgement rather than a full quantitative assessment.

Table 8: Scorecard of the policy options

	Criteria		Option 1: Co- Programmed European Partnership	Option 3: Institutionalised European Partnership Article 187
	Scientific impacts			
	Strengthened EU skills and capacity in academic and industrial health R&I	0	0	+
	A thriving EU-wide cross-sectoral health R&I ecosystem created	0	0	+
	New scientific paradigms established in areas of unmet public health needs	0	0	0
	Economic/technological impacts			
Effectiveness	More productive and globally competitive EU health industries that create jobs and growth and are able to quickly respond to health threats	0	0	++
	Better, safe, effective and cost- effective health technologies, tools and digital solutions	0	+	++
	Increased level of public and private investments into strategic unmet public health needs, providing the foundation for innovative technologies to address these needs	0	+	+
	Societal impacts			
	Improved health and wellbeing of EU citizens	0	+	++
	Reduced health inequalities and improved access to high-quality health care in priority disease areas, thereby addressing unmet public health needs	0	+	+
	Strengthening circular economy and mitigating the negative health impacts of climate change	0	+	+
	Administrative, operational and coordination costs	0	0	(-)(-)
Efficiency	Administrative, operational and coordination costs adjusted per expected co-funding (i.e. costefficiency)	0	+	-

		Baseline: Horizon Europe calls	Option 1: Co- Programmed European Partnership	Option 3: Institutionalised European Partnership Article 187
Coherence	Internal coherence	0	+	++
	External coherence	0	+	++

Notes: Score 0 = same costs as for the baseline; score (-) = limited additional costs compared to the baseline; score (-)(-) = substantial additional costs compared to the baseline. Score ++ : Option presenting *high* cost-efficiency compared to baseline; Score +: Option presenting *good* cost-efficiency compared to baseline; Score 0: Potential of the baseline.

The scorecard shows that the baseline performs less well against all dimensions and criteria compared to Co-Programmed and Institutionalised Partnership options, except for the net administrative cost. Even though it has a higher score in the efficiency criteria, this does not weigh up against its lower performance in the effectiveness and coherence criteria.

The scorecard also shows that benefits are clearly maximised under the Institutionalised Partnership Art 187 option. In particular, compared with the other options, option 3b would:

- Provide greater effectiveness by maximising leverage effects, allowing for greater strategic alignment among partners, and supporting a broader range of activities in research and innovation.
- Improve coherence by enhancing collaboration and alignment with the other key stakeholders.

As regards **effectiveness** in terms of the scientific impact that can be achieved, Option 3 performs better overall than Option 1 due its ability to better integrate industry sectors and as a result strengthen EU skills and innovation capacity. It also has the highest potential to contribute towards the creation of a health innovation and learning ecosystem. The baseline option, while performing well on purely addressing scientific paradigms, cannot provide a platform for cross-sectoral stakeholder collaboration effectively due to its low directionality and weak industry engagement.

As regards effectiveness in terms of the economic impact that can be achieved, Option 3 performs significantly better than either of the alternative options. This is due to an Institutionalised Partnership's ability to provide strong strategic steer (directionality) and to garner substantial outside contributions (additionality), and thanks to its dedicated implementation mechanism through which industry expertise, resources and knowledge can be best leveraged. As a result, the likelihood is highest for achieving increased productivity and growth in the EU health industry by speeding up development of health innovations in health and priority disease areas. In contrast, Option 3 has only limited benefit in terms of its contribution to a sustainable and efficient health care system.

As regards effectiveness in terms of the societal impact that can be achieved, Option 3 is most likely to deliver on the needs of the public system provided the stakeholder consultation, prioritisation exercises and call implementation mechanism are optimally set up. This is because an Institutionalised Partnership is able to make assets progress much faster and eventually help to integrate them into health products and services that can benefit patients and consumers.

On **coherence**, Option 3 is most likely to develop a coherent project portfolio to address the initiative's specific objectives. Option 3 would also be most likely to ensure the external

coherence with other initiatives, programmes and networks through its dedicated implementation structure and EU partnership.

As for **efficiency**, Option 0 (regular calls under Horizon Europe) requires the lowest administrative cost. This is due to the existence of a large-scale, highly refined overall administrative, IT and professionalised management system delivered by specialised agencies (e.g. the Research Executive Agency). Option 3 would have the highest cost, due to the need to set up a dedicated implementation structure to support the thematic area. Nevertheless, much learning can be transferred from the current IMI2 JU experience. In terms of cost-efficiency however, the higher administrative costs are offset by the additional operational funds that industry would bring to the partnership. These additional funds would leverage EU funds, offering approximately twice as much budget and impact for the same EU investment.

Option 3 would be the only one to allow setting up fully fledged Programme Office that would offer dedicated programme management as well as legal and communication expertise under one roof. The Office functions as a "neutral broker" bringing together the different industries that usually compete, to cooperate around jointly agreed objectives. It would be of particular usefulness to project participants, notably SMEs, as regards e.g. explanation of call rules or handling of intellectual property issues that can prove complex in a multi-stakeholder health research setting. The Programme Office would also offer the necessary support function to the Innovation Panel and as such, help to increase the transparency of call topics definition and to ensure that they genuinely reflect the public health needs.

In function of the **risks** of the options to deliver on the expected impacts, the **baseline option** would offer only a low certainty of delivering on the various expected impacts. A co-programmed partnership (option 1) would qualify as second in this category, while option 3 is preferred thanks to its functionalities. The ultimate success of the initiative would depend on whether the significant commitment of the industrial partners materialises and on whether the initiative is successful in attracting a high number of SMEs and academics, necessary to provide sufficient scientific expertise and innovative ideas, to multi-sector collaborations. Another risk to achieving the expected impact would be linked to the relative novelty of this type of multi-stakeholder collaboration in health and to the need of combining varying R&I development timelines that can be very long in the pharmaceutical sector but much shorter in medtech or even more so, in the digital sector.

An external risk is related to the potential post-COVID-19 slowdown of the economy. If a strong recession scenario materialises, companies' investments into R&I usually suffers the most. This factor may potentially limit the overall up-front investment of the industry members or it may affect their ability to live up to the initially declared commitment. The impact of this potential risk on the EU funding is mitigated by the fact that EU funds are committed globally on yearly basis and disbursed for individual projects only on the basis of the industry commitment. The agility of adapting the work programmes would also allow reflecting such a situation in the revised scientific priorities for future call topics. Proportionality of the preferred option is demonstrated by the fact that options 0 (baseline) or 1 would not ensure a sufficient level of directionality and additionality, while option 3 is – among the available options – the one that would best allow fulfilling these needs.

In conclusion, the scorecard analysis shows that the benefits are clearly maximised under Option 3, an Article 187 Institutionalised Partnership, and thus it is the single preferred option to deliver on the effectiveness (impacts) and coherence measures.

Comparison between the preferred option and the current partnership (IMI2 JU) taking into account lessons from past evaluations¹⁶¹

What would continue	What would be different
 A European public-private partnership based on Article 187 TFEU. Programme implementation supported by the dedicated Programme Office. The EU holds 50% of the voting rights and contributes up to 50% of the administrative and operational costs. Member States (MS) and Associated Countries do not contribute financially. Member States do not have voting rights in the Governing Board but are represented in the States Representative Group. A jointly agreed strategic research agenda based on consultation with all stakeholders. Draft calls for proposals are published by the Programme Office, ensuring maximum transparency to all relevant stakeholders. The partnership strives to attract investment from outside of the EU. Part of these contributions could be matched by EU funding. Project results are subject to the same transparency provisions as under regular Horizon Europe calls. 	 A cross-sectoral partnership between EU and five health care industry sectors (pharmaceutical, medtech, biotech, imaging, vaccines), rather than only pharmaceutical as in IMI2 JU. Thematic focus broadened from pharmaceutical to also other areas of health R&I, including digital technologies. More focus on disease prevention. Governance structure adapted to better incorporate views of various stakeholders involved in health care. All types of actors along the health value chain better involved in priority setting and in funded projects. A new governance body ('Innovation Panel') brings together representatives of EU and member industry associations as well as various other stakeholders involved in health care, to identify and review potential call topics, ensuring that they adequately address public health interest and needs of end users Industry eligible for funding up to a certain ceiling (including large companies and mid-caps), with individual industry sectors or companies entitled to opt-out from receiving funding at own discretion.

The direct continuation of IMI2 JU as it is today, i.e. a partnership between the EU and pharma sector, was not prioritised because (1) it would not capitalise on the resources, expertise and data of other health industry sectors, now ready to enter into such a collaboration; (2) it would not allow addressing more ambitious objectives of harnessing cross-sectoral collaborations to address the problem of insufficient innovative health solutions (new medicines, devices, diagnostics...) being made available to patients, (3) it would disregard the explicit recommendation of the IMI2 JU interim evaluation for a potential follow-up initiative, i.e. to ensure active engagement of other health industry sectors with the pharmaceutical industry. What was also learned from the past is that for the

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¹⁶¹ Working ideas that need further discussion between future partners and validation in the legislative act or any other documents laying down the functioning of the partnership (e.g. statutes, rules of procedure of individual governance bodies etc). A detailed analysis of how lessons learned were reflected in the design of the new partnership can be found in Annex 6.

underlying problems to be addressed more efficiently, the end-users need to be involved in the initiative to a greater extent than in the past.

7. THE PREFERRED OPTION – HOW WILL ACTUAL IMPACTS BE MONITORED AND EVALUATED?

7.1. Description of the preferred option

An Institutionalised Partnership (under Article 187 TFEU) is the preferred option due to its effectiveness in delivering on the initiative's specific objectives, coherence and efficiency, and thus to achieve highest impacts. It aims to build on and learn from the current IMI2 JU's management processes and extend its know-how, international visibility and established positive brand. However, the new initiative will also bring about a step change in: (1) facilitating the integration of disparate technologies from several health industry sectors currently not collaborating to a significant extent; and (2) accelerating the development of better, safe, effective and cost-effective health products and solutions for European citizens, as part of Partnership Area 1 of Horizon Europe.

Table 9 depicts how the preferred option aligns with the selection criteria for European partnerships defined in Annex III to the Horizon Europe Regulation. The design process of the candidate Institutionalised Partnerships is not yet concluded and several of the related topics are still under discussion at the time of writing. These include, among others (1) the budget, depending notably on the multiannual financial framework 2021-2027 negotiations, (2) strategic research agenda, planned to be adopted at the first meeting of the future governing board, (3) certain details of the governance structure and the process for call topic generation, (4) inclusion of partners from non-EU countries and the threshold for matching their contributions with EU funding, (5) intellectual property rules and questions related to the access and affordability of the resulting health innovations. Therefore, the criteria of additionality/directionality and long-term commitment are covered in terms of expectations rather than ex-ante demonstration.

Table 9: Alignment with the selection criteria for European partnerships

Criterion	Alignment of the preferred option
Higher level of effectiveness	An Article 187 Institutionalised Partnership provides the closest integration of key stakeholder groups across the value chain to ensure that the initiative can respond to ambitious objectives corresponding to scientific, technological/economic and societal impacts. The mode of implementation ensures that there is sufficient scale, commitment, leverage and long-term vision for the accelerated development and deployment of health innovations. The partnership has a comprehensive set of objectives that tackle the main challenges identified and which contribute towards the creation of a health R&I ecosystem. An Article 187 Institutionalised Partnership would score significantly higher overall than the baseline option (traditional calls under Horizon Europe) and Option 1 (Co-Programmed Partnership) in terms of effectiveness.
Coherence and synergies	An Article 187 Institutionalised Partnership presents the most coherent choice to maximise synergies internally within the initiative (portfolio approach), within the EU R&I landscape and beyond. The future Programme Office, similar to the Programme Office in the current IMI2 JU, would have thematic competence in programme management and dedicated administrative support for partners and project participants to exploit such synergies and further align roadmaps between initiatives, programmes and networks.
Transparency and	An Article 187 Institutionalised Partnership aims to significantly expand the range of partners involved from health-related industries, covering the full spectrum of pharmaceutical, vaccines,

Criterion	Alignment of the preferred option
openness	biotech and medtech sectors (including diagnostics, medical devices, imaging and digital industries). In this way, relevant but currently disparate technologies (drugs, devices and software) can be usefully integrated into innovative health solutions. The partnership will maximise its impacts by being open and transparent, involving all relevant public actors (including the academic research community, patients, health care regulators, health care payers, health care providers and health care professionals) and private actors along the value chain, and by ensuring a robust governance structure. Other stakeholders may also be philanthropic organisations, charities, research infrastructures and other partnerships. Flexibility is needed in the operational processes to create trust and equity among stakeholders. Using standard Horizon Europe instruments and abiding by all the related processes (including e.g. budgetary controls, access to documents etc) will ensure that the partnership is transparent. Since a seven-year horizon is a relatively long time in a fast-moving technological R&I space, it will be important for the partnership to keep an open mind and allow entry for new actors, including those from outside the EU to allow learning across the best in class. The partnership recognises the need for broad stakeholder consultation to develop the long-term strategic directions and annual priorities. The implementation structures will provide an optimal governance, monitoring and management system.
Additionality and directionality	The legal and financial commitments made by partners at the outset of the partnership are binding and will commit partners to drive the partnership forward over the entire partnership timeframe, which is particularly important in health research with its long development timelines. The approved SRA ensures close alignment of research agendas to achieve a high-level of focus and directionality to meet the strategic unmet public health needs. No other public or private initiative is able to coordinate a similar partnership at the European level above and beyond national interests. In addition, the partnership will provide the ability to leverage other resources for the benefit of the EU.
Long-term commitment	The expectation is that in an Institutionalised Partnership on Innovative Health under Art 187, the EU and partners will be committed to pooling resources for the entire partnership period and that financial and/or in-kind contributions from partners other than the EU will represent at least 50% of the aggregated European partnership budgetary commitment.

7.2. Objectives and corresponding monitoring indicators

7.2.1. Operational objectives

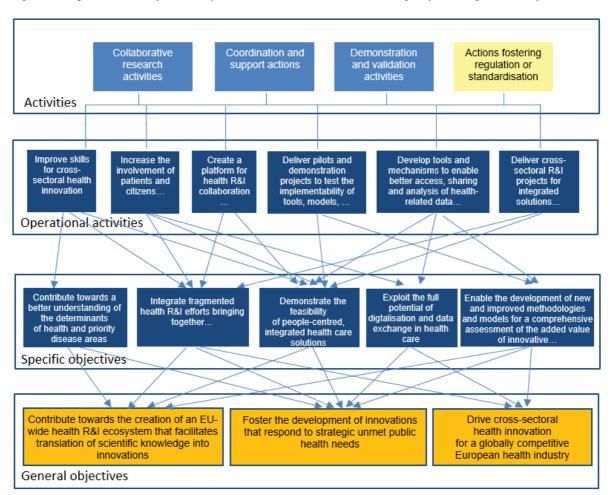
Several operational objectives were identified that would enable the partnership to achieve its specific objectives:

- 1. improve skills for cross-sectoral health innovation;
- 2. increase the involvement of patients and citizens in the generation and implementation of health innovations in Europe;
- 3. create a platform for health R&I collaboration as a safe, pre-competitive space for brokering knowledge exchange, sharing ideas and resources across the various actors in the health care pathway (e.g. academics, health industry sectors, regulators, health technology assessment bodies, health care professionals and providers, payers, patients, informal carers, and citizens);

- 4. deliver pilots and demonstration projects to test the implementability of tools, models, methodologies and innovations generated by the initiative;
- 5. develop tools and mechanisms to enable better access, sharing and analysis of health-related data, e.g., ethical frameworks, common standards and protocols;
- 6. deliver cross-sectoral R&I projects for the development of integrated, people-centred solutions and progress the understanding of the determinants of health and disease.

Figure 9 lists a range of actions and activities, also going beyond the R&I activities that can be implemented under Horizon Europe (highlighted in yellow). This reflects the definition of European Partnerships in the Horizon Europe regulation as initiatives where the Union and its partners 'commit to jointly support the development and implementation of a programme of R&I activities, including those related to market, regulatory or policy uptake'.

Figure 9: Operational objectives of the initiative in relation to the specific and general objectives



To select focused areas for support by the partnership, two criteria will be considered: (1) the high burden of disease for patients and/or society due to the severity of the disease and/or the number of people affected by it, and (2) the high economic impact of the disease for patients and society.

The selection of detailed areas for support would be done through an inclusive process involving a broad range of stakeholders from the public sector. Drawing on the lessons from IMI2 JU and to increase openness of this process, an improved mechanism would be put in

place with the creation of a dedicated multi-stakeholder governance body ("Innovation Panel"). This body would include not only representatives of the EU and member industry associations but also regulators, national health technology assessment bodies, health care professionals, health care providers, payers and patients as well as representatives of other relevant initiatives. The Innovation Panel would be in charge of identifying and prioritising areas for support so as to reflect needs of end-users (including patients) and public health interest. It would also help avoid overlaps and foster synergies with other programmes or initiatives.

The flexibility of choosing from a range of priorities updated at regular intervals would offer agility to adapt to new situations and needs, including public health emergencies, via adjustment of the Annual Work Programmes in line with the SRA. Such a rapid mobilisation was demonstrated by the ability of IMI to launch a fast-track call for proposals to develop therapeutics and diagnostics for current and future coronavirus outbreaks ¹⁶². Thanks to the support of the Programme Office, the call could be designed quickly and coordinated with other global initiatives on COVID-19 to increase synergies while limiting overlaps. Of note, a similar mobilisation was possible to respond to the Ebola virus disease outbreak in western Africa in 2014. The resulting Ebola+ program led to the development of an Ebola vaccine regimen that received market authorisation in July 2020¹⁶³.

The call topics will be based on the SRA and reflect the scientific priorities/workplan as put forward by the Innovation Panel. Its opinions would validated by the Governing Board, the main decision-making body of the partnership composed of representatives of the Commission and member industry associations. The 50% of voting rights in the Governing Board attributed to the Commission would provide reassurance that the EU public interest would be adequately taken into account.

A majority of activities will be cross-sectoral, thus reflecting the integrative nature of the partnership. The cross-sectoral activities should enable overcoming barriers such as insufficient collaboration of companies active in diagnostics and therapeutics development, or the current scattered nature of large health data sets. At the same time, IHI activities will have to consider the different innovation cycles of pharmaceutical and medical technology industries. While the R&I processes towards novel medicines are very lengthy, the development of medical technologies and even more so, digital solutions, can be much faster. In order to create a safe space for collaboration of companies without affecting their commercial activities, the initiative will primarily address pre-competitive activities, including demonstration pilots.

Compared to the activities implemented by IMI2 JU under Horizon 2020:

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¹⁶² IMI2 JU Call 21 topic "Development of therapeutics and diagnostics combatting coronavirus infections" was launched on 3 March 2020 and closed on 31 March 2020. By 12 May 2020, 8 projects were provisionally selected for funding, with the total investment from the EU and from the industry partners reaching EUR 117 million. Of the eight projects, five focus on diagnostics and three on treatments. The diagnostics projects hope to develop devices that can be used anywhere, including a doctor's surgery or patient's home, and will deliver results fast (below 1 hour). The treatment projects focus primarily on the current COVID-19 outbreak but they also include efforts to prepare for future coronavirus outbreaks. The projects form part of the European Commission's wider response to the coronavirus outbreak.

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- The scope of IHI activities will be broader, including the areas of medical technologies, imaging, vaccines, Advanced Therapy Medicinal Products (ATMPs) and digital technologies;
- IHI activities will engage a broader set of participants in terms of company sizes as Member industry associations; their national member associations will bring in small-and medium enterprises, in addition to large companies;
- The composition of consortia will be different;
- The activities will more directly respond to the future needs of end-users, such as patients and health care professionals, thanks to increased openness of the initiative and thanks to better involvement of these stakeholders in the definition of scientific priorities and of topic texts.

7.2.2. Monitoring indicators

In addition to Key Impact Pathways indicators set centrally in the Regulation of Horizon Europe, additional monitoring indicators have been identified to enable the tracking of progress of the partnership towards meeting its objectives.

Table 10 below represents monitoring indicators proposed to track the initiative's progress towards achieving its specific objectives and targets as defined in Table 2. Health R&I is a complex and lengthy process that does not follow a 'linear' path of development and scale-up, and various intermediate steps are needed before the objectives and end targets can be reached. The proposed indicators reflect parameters that can effectively be measured for an initiative aiming to operate in a pre-competitive space of the health R&I area, during the initiative's lifetime¹⁶⁴. Similarly, the short-term indicators are more activity-driven since the actual outputs of health research projects are unlikely to be visible immediately after initiative's start¹⁶⁵.

These proposed indicators take into account the experience gathered during the definition of IMI2 JU Key Performance Indicators¹⁶⁶ and will be further refined before the start of the initiative to strike a balance between defining parameters that are representative of the initiative's progress, and minimising additional reporting obligations for project participants.

¹⁶⁶ IMI2 JU Key Performance Indicators. https://www.imi.europa.eu/sites/default/files/uploads/documents/About-IMI/mission-objectives/IMI2_KPIs_approved_14_DEC_2017.pdf.

¹⁶⁴ The medical sector is characterised by long development timelines, with uptake dependent on fulfilling stringent regulatory steps and on subsequent reimbursement and pricing decisions that remain the competence of EU Member States. Therefore, the attainment of some of the initiative's objectives would not be appreciated until after the projects have finished. The same is even more true for certain impacts that could be appreciated

only long after individual projects end. Additional information is provided in Annex 3, Section 2. ¹⁶⁵ The quantification of expectations for individual indicators, as well as their evolution from shorter to longer term, can be done reliably when the process of defining the strategic research agenda has been advanced further.

Table 10: Monitoring indicators in addition to the Horizon Europe key impact pathway indicators

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Specific objective	Short-term indicators (typically as of year 1+)	Medium-term indicators (typically as of year 3+)	Long-term indicators (typically as of year 5+)
1. Contribute towards a better understanding of the determinants of health and priority disease areas	Share of projects covering priority disease areas	Number of international co- authorships and cross-sector publications Number of times that journal articles generated by the partnership are cited in the global literature	Number of new taxonomies of diseases and new methods of stratification Number of new early biomarkers of disease identified and validated Number of validated new targets for preventive or therapeutic strategy
2.Integrate fragmented health R&I efforts bringing together	Share of projects bringing together representatives of two or more industry sectors Share of projects bringing together SMEs and large companies	Number of projects sharing data outside of consortia partners for further research Impact factor of international co-authorships and cross-sector and cross-institutions publications generated by IHI projects	Number of new tools shared outside of consortia partners for further research Number and types of innovations in industrial use
3. Demonstrate the feasibility of people-centred, integrated, health care solutions	Share of projects involving patient/citizen associations	Number of assets progressed through key milestones ¹⁶⁷ Number of new or improved guidelines, methodologies, tools, technologies or solutions submitted for acceptance to regulatory authorities for use in the context of R&D, relevant for integrated, people-centred solutions	New standards and common processes adopted in official (regulatory) guidelines and in use Number of integrated health care solutions developed
4.Exploit the full potential of digitalisation and data exchange in health care		Number of projects that integrate data from public and private sectors	Number and type of digital health innovations developed
5.Enable the development of new and improved methodologies and models for comprehensive assessment of the added value of innovative and integrated health care solutions.	Share of projects addressing strategic unmet public health care needs/priority health and disease areas Number of health care stakeholders (e.g. providers, professionals, regulators) involved in projects	Number of projects developing methodological frameworks to assess the cost-effectiveness of innovation. Number of projects developing patient-reported outcome measures and/or patient-reported experience measures	Number of new tools and models ready for implementation in health care

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 $^{^{167}}$ Examples of assets are drug or diagnostic candidates, targets, biomarkers or other tools that can be shown to have reached a significant milestone or pass a significant stage gate.

In addition to the above monitoring framework that will help track progress over the lifetime of the initiative, a set of targets were defined in relation to the specific objectives, against which the success or failure of the initiative could be measured. These targets are based on the experience of IMI2 JU¹⁶⁸ in terms of what could be achieved by an initiative of a similar financial scale and broadened scope. They will be further developed and refined during the preparation of the strategic research agenda before the start of the initiative. The necessary data would be gathered as part of the periodic project reporting as implemented for the whole of Horizon Europe, building upon what is currently done for IMI2 JU.

Table 11. Specific objectives and targets by the end of the initiative

Specific objective	Targets by the end of the initiative
SO1. Contribute towards a better understanding of the determinants of health and priority disease areas	 new tools relevant for studying new potential drug targets, e.g. new pharmacological tools, therapeutic modalities and patient-derived assays openly available to the scientific community (tools for 1,000 proteins); new diagnostically- and/or therapeutically-relevant hypotheses tested in pre-clinical models and/or clinically (100); new biomarkers of disease (relevant for diagnosis, efficacy, safety or prevention) identified and experimentally validated, new taxonomies of diseases or new stratifications to define patient subpopulations (at least 10 biomarkers).

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IMI2 JU Key Performance Indicators, including baselines and target values. https://www.imi.europa.eu/sites/default/files/uploads/documents/About-IMI/mission-objectives/IMI2 KPIs approved 14 DEC 2017.pdf.

SO2. Integrate fragmented health R&I efforts bringing together health industry sectors and other stakeholders, focussing on unmet public health needs	 demonstrated feasibility of developing combination of products and services, including methods for generation of clinical evidence (5 examples); new tools for prediction, prevention, surveillance, diagnosis, treatment options (incl. to prepare for major epidemic outbreaks) - development, validation and demonstrated deployment readiness of new tools (10 examples); publications between European researchers on IHI projects (at least 1000); share of projects involving civil society, patient organisations, health care professionals' associations or regulators: at least 80%; share of budget allocated to projects bringing together representatives of two or more technology sectors: 95%.
SO3. Demonstrate the feasibility of peoplecentred, integrated health care solutions	 validated new targets for preventive or therapeutic strategy, in different therapeutic areas (at least 3 biomarkers); demonstrated feasibility of developing people-centred, integrated health care solutions (5 examples); projects engaging regulatory acceptance processes to contribute to new or improved guidelines or methodologies (20 examples);
SO4. Exploit the full potential of digitalisation and data exchange in health care	 demonstrated integration of data, provided by the public and private sectors (20 examples); demonstration of feasibility of use of artificial intelligence in health care (3 examples).
SO5. Enable the development of new and improved methodologies and models for a comprehensive assessment of the added value of innovative and integrated health care solutions	 methodologies for a comprehensive assessment of the added value of combinations of products/services or combined products (including PROMs/PREMs and statistical methods or tools), submitted to health care authorities and organisations (5 examples).

7.2.3. Evaluation framework

The evaluation of the Partnership will be done in full accordance with the provisions laid out in Horizon Europe Regulation Article 47 and Annex III, with external interim and expost evaluations feeding into the overall Horizon Europe evaluations. As set in the criteria for European Partnerships, the evaluations will include an assessment of the most effective policy intervention mode for any future action; and the positioning of any possible renewal of the Partnership in the overall European Partnerships landscape and its policy priorities. In the absence of renewal, appropriate measures will be developed to ensure phasing-out of Framework Programme funding according to conditions and timeline agreed with the legally committed partners ex-ante.



Brussels, 23.2.2021 SWD(2021) 37 final

PART 4/19

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT REPORT Accompanying the document

Proposal for a COUNCIL REGULATION establishing the Joint Undertakings under Horizon Europe

European Partnership on Innovative Health

{COM(2021) 87 final} - {SEC(2021) 100 final} - {SWD(2021) 38 final}

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Annex 1 Procedural information

1. LEAD DG, DECIDE PLANNING REFERENCES

Lead DG: Directorate General Research and Innovation (RTD)

Decide number: PLAN/2019/5302

2. ORGANISATION AND TIMING

Institutionalised Partnerships are foreseen in Articles 185 and 187 of the Treaty on the Functioning of the European Union (TFEU). The preliminary agreement on Horizon Europe contained a list of possible areas for Institutionalised Partnerships based on Article 185 and 187. For each of these areas the Commission considered 12 potential Institutionalised Partnerships. Their set up involves new EU legislation and the establishment of dedicated implementing structures and therefore an impact assessment for each of these initiatives.

Following political validation in June 2019, the impact assessment process started with the publication of inception impact assessments for each initiative in August 2019.

An inter-service steering group (ISSG) on research and innovation partnerships under Horizon Europe was set up in May 2019 and held 4 meetings before submission of the Staff Working Document to the Regulatory Scrutiny Board (7 May 2019, 19 June 2019, 5 December 2019, 20 January 2020). The ISSG consisted of representatives of the Secretariat-General, Directorate-General for Budget, Directorate-General for Research and Innovation Directorate-General for Communications Networks, Content and Technology, Directorate-General for Mobility and Transport, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, Directorate-General for Energy, Directorate-General for Environment, Directorate-General for Climate Action, and the Legal Service.

An online public stakeholder consultation was launched between September and November 2019, gathering 1635 replies for all 12 initiatives.

3. CONSULTATION OF THE RSB

Two upstream meetings with the Regulatory Scrutiny Board of were held on 10 July 2019 and 30 September 2019.

In accordance with the feedback received from the Regulatory Scrutiny Board on 15 May 2020, the Staff Working Document has been revised as presented in Figure 1. These revisions were endorsed by the Inter Service Steering Group on 20 January 2020.

4. EVIDENCE, SOURCES AND QUALITY

To ensure a high level of coherence and comparability of analysis for all candidate initiatives, an external study was procured to feed into the impact assessments of the 12 candidate Institutionalised Partnerships¹ (Technopolis Group, 2020). It consisted of a horizontal analysis and individual thematic analyses for each of the initiatives under review.

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¹ Technopolis Group, 2020, forthcoming.

For all initiatives, the evidence used includes desk research partly covering the main impacts and lessons learned from previous partnerships. A range of quantitative and qualitative data sources complement the evidence base, including evaluations; foresight studies; statistical analyses of Framework Programmes application and participation data and Community Innovation Survey data; analyses of science, technology and innovation indicators; reviews of academic literature; sectoral competitiveness studies and expert hearings. The analyses included a portfolio analysis, a stakeholder and social network analysis in order to profile the actors involved as well as their co-operation patterns, and an assessment of the partnerships' outputs (bibliometrics and patent analysis). A cost modelling exercise was performed in order to feed into the efficiency assessments of the partnership options. Public consultations (open and targeted) supported the comparative assessment of the policy options. For each initiative up to 50 relevant stakeholders were interviewed by the external contractor (policymakers, business including SMEs and business associations, research institutes and universities, and civil organisations, among others). In addition the analysis was informed by the results of the Open Public Consultation (Sep - Nov 2019), the consultation of the Member States through the Strategic Programme Committee and the online feedback received on the Inception Impact Assessments of the set of candidate Institutionalised European Partnerships.

A more detailed description of the methodology and evidence base used, completed by thematic specific methodologies, is provided in Annexes 4 and 6.

Figure 1 Modifications to the draft Staff Working Document based on comments received from the Regulatory Scrutiny Board

1	mments from the Regulatory Scrutiny Board – in considerations	Actions taken for the Staff Working Document				
(1)	The report does not sufficiently explain how the problems and challenges addressed by the new partnership differ from those addressed by the present one.	More information on the problems and challenges was added in Sections 2.2.1 (page 36) and 2.2.4 (page 40), and the differences in scope and activities were further highlighted in Section 7.2.1 (pages 82-83).				
(2)	The report does not clearly explain to what extent the different partnership types are likely to attract health industry partners (small or big) and why.	More detail on the expected attractiveness of the various forms of partnerships to industry was provided in Sections 5 (page 56) and 6 (notably 6.3.2, pages 61 and 73-74).				
(3)	The report does not provide sufficient information about how the partnership would be implemented in practice.	Information was added in Section 7.2.1, notably on the selection of the actual areas for support (pages 81/82), practical functioning of the initiative and comparison of IHI activities with those of IMI2 JU (pages 82-83).				

Furthermore, the whole text was revised to provide more clarity on the aspects raised in the "Further considerations and adjustment requirements" section of RSB opinion. The main of these revisions are listed below:

- The presentation of stakeholder views in all sections were re-visited (throughout the whole text).
- The reasons for the change of scope from IMI2 JU further were explained (section 6.4, pages 82/83).
- The definitions of specific and general objectives were adjusted to better convey the intended content (Sections 4.1 and 4.2 in pages 43-46, and in related figures).
- The intervention logic was revisited to provide more clarity and to better explain the interdependencies between objectives, problems and their drivers (Sections 4.2 and 4.3, pages 48-50).
- The differences between the various partnership forms considered in the report were explained in more detail, notably for an Institutionalised Partnership (Sections 5 and 6, page 58, 59, 70, 73-74).
- Discrepancies in the scoring of options were removed and further explanation was added to justify certain conclusions and scores (throughout Section 6).
- The analysis of the options is better linked to the objectives (Sections 5 and 6).
- A clear justification for the choice of Horizon Europe calls as baseline, rather than a continuation of the current partnership, was provided in Section 5.1 (page 56).
- The advantages of a dedicated Programme Office were presented in Section 6.4 (page 77).
- The analysis of risks and uncertainties of the final choice was provided in Section 6.4 (page 77).
- Targets by the end of the initiative were presented together with the proposed monitoring indicators in Section 7.2 (pages 84-86).
- A statement was added to clarify that the comparison and choice of the options is a qualitative judgement rather than a quantitation (Section 6.4, page 75).
- Numerous revisions were made to increase readability and strengthen the argumentation, also using more examples, and taking into account various technical comments received from the RSB. The content of the text was also updated to reflect developments in the preparation of the partnership that took place since the RSB assessment (throughout the whole text), including making the general objectives (page 43), the operational objectives (pages 80-81), the indicators and targets (pages 84-86) more measurable and representative of the partnership.

Annex 2 Stakeholder Consultation

1. OVERVIEW FOR ALL CANDIDATE INSTITUTIONALISED EUROPEAN PARTNERSHIPS

1.1. Introduction

In line with the Better Regulation Guidelines,² the stakeholders were widely consulted as part of the impact assessment process of the 12 candidates for Institutionalised Partnerships, including national authorities, the EU research community, industry, EU institutions and bodies, and others. These inputs were collected through different channels:

- A feedback phase on the inception impact assessments of the candidate initiatives in August 2019, gathering 350 replies for all 12 initiatives on the "Have your say" web portal during a period of 3 weeks;
- A structured consultation of Member States performed by the EC services over 2019 through the Shadow Strategic Configuration of the Programme Committee of Horizon Europe (in line with the Article 4a of the Specific Programme of Horizon Europe). This resulted in 44 possible candidates for European Partnerships identified as part of the first draft Orientations Document towards the Strategic Plan for Horizon Europe (2021-2024), taking into account the areas for possible Institutionalised Partnerships defined in the Regulation.
- An online public stakeholder consultation administered by the EC, based on a structured questionnaire, open between September and November 2019, gathering 1635 replies for all 12 initiatives:
- A targeted consultation run by the external study contractors with a total of 608 interviews performed as part of the thematic studies by the different study teams between August 2019 and January 2020.

1.2. Horizontal results of the Open Public Consultation

The consultation was open to everyone via the EU Survey online system³. The survey contained two main parts to collect views on general issues related to European partnerships (in Part 1) and specific responses related to one or more of the 12 candidate initiatives (as selected by a participant). The survey was open from 11 September till 12 November 2019. The consultation was available in English, German and French and advertised widely through the European Commission's online channels as well as via various stakeholder organisations.

1.2.1. Profile of respondents

In total, 1635 respondents filled in the questionnaire of the open public consultation. Among them, 272 respondents (16.64%) were identified to have responded to the consultation as part of a campaign (coordinated responses). Based on the Better Regulation Guidelines, the groups of respondents where at least 10 respondents provided coordinated answers were labelled as 'campaigns', segregated and analysed separately and from other responses. In total 11 campaigns were identified, the largest of them includes 57 respondents⁴. In addition,

² https://ec.europa.eu/info/files/better-regulation-guidelines-stakeholder-consultation en

https://ec.europa.eu/eusurvey/runner/ConsultationPartnershipsHorizonEurope
The candidate Institutionalised Partnership Clean Hydrogen has the highest n

⁴ The candidate Institutionalised Partnership Clean Hydrogen has the highest number of campaigns, namely 5. A few initiatives, such as Innovative SMEs, Smart Networks and Systems, were not targeted by campaigns. Some campaign respondents decided to provide opinions about several partnerships.

162 respondents in the consultation also display similarities in responses but in groups smaller than 10 respondents. Hence, these respondents were not labelled as campaigns and therefore were not excluded from the general analysis.

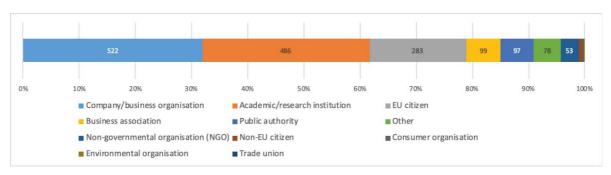
Table 1: Country of origin of respondents (N=1635)

Country	Number of respondents	Percentage of respondents
Germany	254	15.54%
Italy	221	13.52%
France	175	10.70%
Spain	173	10.58%
Belgium	140	8.56%
The Netherlands	86	5.26%
Austria; United Kingdom	61	3.73%
Finland	49	3.00%
Sweden	48	2.94%
Poland	45	2.75%
Portugal	32	1.96%
Switzerland	28	1.71%
Czechia	24	1.47%
Greece	23	1.41%
Norway; Romania	22	1.35%
Denmark	20	1.22%
Turkey	19	1.16%
Hungary	14	0.86%
Ireland	12	0.73%
United States	11	0.67%
Estonia; Slovakia; Slovenia	10	0.61%
Bulgaria; Latvia	9	0.55%
Bosnia and Herzegovina	7	0.43%
Lithuania	4	0.24%
Canada; Croatia; Israel	3	0.18%

China; Ghana; Iceland; Japan; Luxembourg; Morocco	2	0.12%
Bhutan; Botswana; Cyprus; Iran; Malta; Mexico; Moldova; Mongolia; Palestine; Russia; Serbia; South Africa; Tunisia; Ukraine; Uruguay	1	0.06%

As shown in Figure 2, the three biggest categories of respondents are representatives of companies and business organisations (522 respondents or 31.9%), academic and research institutions (486 respondents or 29.7%) and EU citizens (283 respondents or 17.3%). Among the group of respondents that are part of campaigns, most respondents are provided by the same groups of stakeholders, namely company and business organisations (121 respondents or 44.5%), academic and research institutions (54 respondents or 19.8%) and EU citizens (42 respondents or 15.4%).

Figure 2. Type of respondents (N=1635) - For all candidate initiatives



Among all consultation respondents, 1303 (79.69%) have been **involved in the on-going research and innovation framework programme** Horizon 2020 or the preceding Framework Programme 7, while 332 respondents (20.31%) were not. In the group of campaign respondents, the share of those who were involved in these programmes is higher (245 respondents out of 272 or 90.07%) than in the group of non-campaign respondents (1058 out of 1363 or 77.62%). When respondents that participated in the Horizon 2020 or in the preceding Framework Programme 7 were asked to indicate in which capacity they were involved in these programmes, the majority stated they were a beneficiary (1033 respondents) or applicant (852 respondents). The main stakeholder categories, e.g. companies/business organisation, academic/research institutions, etc., show a similar distribution across the capacities in which they 'have been involved in Horizon 2020 or in the Framework Programme 7' as the overall population of consultation respondents.

Among those who have been involved in Horizon 2020 or the preceding Framework Programme 7, 1035 respondents (79.43%) are/were involved in a partnership. The share of respondents from campaigns that are/were involved in a partnership is higher than for non-campaign respondents, 89.80% versus 77.03% respectively. The list of partnerships under Horizon 2020 or its predecessor Framework Programme 7 together with the numbers, percentages of participants is presented in Table 2, the table also show the key stakeholder categories for each partnership. Most consultation respondents participated in the following partnerships: Fuel Cells and Hydrogen 2 (FCH2) Joint Undertaking, Clean Sky 2 Joint Undertaking, European Metrology Programme for Innovation and Research (EMPIR) and in Bio-Based Industries Joint Undertaking. The comparison between the non-campaign and campaign groups of respondents shows that the overall distribution is quite similar. However, there are some differences. For the campaign group almost a half of respondents

is/was involved in the Fuel Cells and Hydrogen 2 (FCH2) Joint Undertaking, a higher share of campaign respondents is/was participating in Clean Sky 2 Joint Undertaking and in Single European Sky Air Traffic Management Research (SESAR) Joint Undertaking.

When respondents were asked in which **role**(s) **they participate(d) in a partnership**(s), over 40% indicated that they act(ed) as partner/member/beneficiary in a partnership. The second largest group of respondents stated that they applied for funding under a partnership. The roles selected by non-campaign and campaign respondents are similar.

Table 2: Partnerships in which consultation respondents participated (N=1035)

Name of the partnership	Number and % of respondents from both groups (n=1035)	Number and % of respondents from a non-campaign group (n=815)	Academic/research institutions	Business associations	Company/business organisations (<250)	Company/business organisations (250+)	EU citizens	NGOs	Public authority
Fuel Cells and Hydrogen 2 (FCH2) Joint Undertaking	354 (33.33%)	247 (30.31%)	97	9	37	43	41	8	5
Clean Sky 2 Joint Undertaking	195 (18.84%)	145 (17.79%)	57	2	10	27	37	1	7
European Metrology Programme for Innovation and Research (EMPIR)	150 (14.49%)	124 (15.21%)	64	0	13	9	14	2	19
Bio-Based Industries Joint Undertaking	142 (13.72%)	122 (14.97%)	39	8	20	27	14	1	6
Shift2Rail Joint Undertaking	124 (11.98%)	101 (12.40%)	31	7	5	31	14	3	7
Electronic Components and Systems for European Leadership (ECSEL) Joint Undertaking	111 (10.72%)	88 (10.80%)	42	2	7	20	12	0	5
Single European Sky Air Traffic Management Research (SESAR) Joint Undertaking	66 (6.38%)	46 (5.64%)	10	3	3	20	3	2	3
5G (5G PPP)	53 (5.12%)	47 (5.77%)	20	1	6	14	5	0	1
Eurostrars-2	44 (4.25%)	40 (4.91%)	17	0	6	1	7	0	6

Name of the partnership	Number and % of respondents from both groups (n=1035)	Number and % of respondents from a non-campaign group (n=815)	Academic/research institutions	Business associations	Company/business organisations (<250)	Company/business organisations (250+)	EU citizens	NGOs	Public authority
(supporting research-performing small and medium-sized enterprises)									
Innovative Medicines Initiative 2 (IMI2) Joint Undertaking	37 (3.57%)	35 (4.29%)	18	2	3	3	2	4	3
Partnership for Research and Innovation in the Mediterranean Area (PRIMA)	28 (2.71%)	26 (3.19%)	15	0	3	1	2	0	2
European and Developing Countries Clinical Trials Partnership	25 (2.42%)	24 (2.94%)	12	0	1	2	3	3	2
Ambient Assisted Living (AAL 2)	22 (2.13%)	21 (2.58%)	11	2	1	1	3	0	3
European High- Performance Computing Joint Undertaking (EuroHPC)	22 (2.13%)	18 (2.21%)	6	0	2	3	5	0	2

For the remaining of the consultation respondents could provide their views on each/several of the candidate initiatives. The majority of respondents (31.4%) provided their views on the Clean Hydrogen candidate partnership. More than 45% of respondents from the campaigns selected this partnership. Around 15% provided their views for European Metrology, Clean Aviation and Circular Bio-based Europe. The share of respondents in the campaign group that chose to provide views on the Clean Aviation candidate partnership is of 20%. The smallest number of respondents provided opinions on the candidate initiative 'EU-Africa research partnership on health security to tackle infectious diseases – Global Health'.

Table 3: Candidate Institutionalised Partnerships for which consultation respondents provide responses (N=1613)

Name of the candidate Institutionalised European partnership	Number and % of respondents from both groups	Number and % of respondents from a non-campaign
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	(n=1613)	group
		(n=1341)
Clean Hydrogen	506 (31.37%)	382 (28.49%)
European Metrology	265 (16.43%)	225 (16.78%)
Clean Aviation	246 (15.25%)	191 (14.24%)
Circular bio-based Europe	242 (15%)	215 (16.03%)
Transforming Europe's rail system	184 (11.41%)	151 (11.26%)
Key Digital Technologies	182 (11.28%)	162 (12.08%)
Innovative SMEs	111 (6.88%)	110 (8.20%)
Innovative Health Initiative	110 (6.82%)	108 (8.05%)
Smart Networks and Services	109 (6.76%)	107 (7.98%)
Safe and Automated Road Transport	108 (6.70%)	102 (7.61%)
Integrated Air Traffic Management	93 (5.77%)	66 (4.92%)
EU-Africa research partnership on health security to tackle infectious diseases – Global Health	49 (3.04%)	47 (3.50%)

1.2.2. Characteristics of future candidate European Partnerships

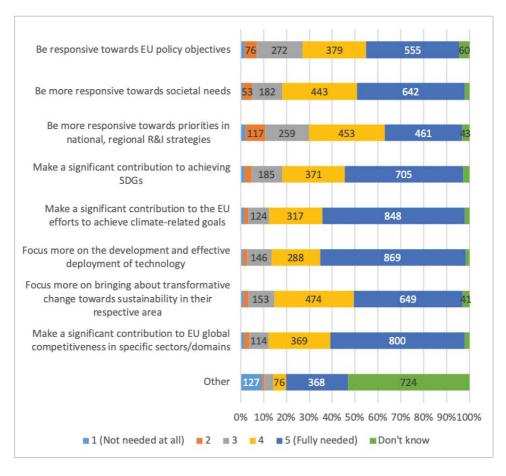
Respondents were asked to assess what areas, objectives, aspects need to be in the **focus of the future European Partnerships** under Horizon Europe and to what extent. According to Figure 6, a great number of respondents consider that a significant contribution by the future European Partnerships is 'fully needed' to achieve climate-related goals, to the development and effective deployment of technology and to EU global competitiveness in specific sectors/domains. Overall, respondents' views reflect that many aspects require attention of the Partnerships. The least attention should be paid to responding towards priorities of national, regional R&D strategies, including smart specialisation strategies, according to respondents.

Overall, only minor differences can be found between the main stakeholder categories. Academic/research institutions value the responsiveness towards EU policy objectives and focus on development and effective deployment of technology a little less than other respondents. Business associations, however, find that the future European Partnerships under Horizon Europe should focus a little bit more on the development and effective deployment of technology than other respondents. Furthermore, business associations, large companies as well as SMEs value the role of the future European Partnerships for significant contributions to EU global competitiveness in specific sectors domains a little higher than other respondents. Finally, both NGOs and Public authorities put a little more emphasis on the role of the future European Partnerships for significant contributions to achieving the UN SDGs. The views of citizens (249, or 18.3%) do not reflect significant differences with other types of respondents. However, respondents that are/were directly involved in a

partnership under Horizon 2020 or its predecessor Framework Programme 7 assign a higher importance of the future European Partnerships to be more responsive towards EU policy objectives and to make a significant contribution to achieving the UN's Sustainable Development Goals.

A qualitative analysis of the "other" answers highlights the importance of collaboration and integration of relevant stakeholders to tackle main societal challenges and to contribute to policy goals against which fragmentation of funding and research efforts across Europe should be avoided. Additionally, several respondents suggested that faster development and testing of technologies, acceleration of industrial innovation projects, science transfer and market uptake are needed. Next to that, many respondents provided answers related to the hydrogen and the energy transition, which corresponds to the high number of respondents that provided answers to the candidate initiative on this topic.

Figure 3: To what extent do you think that the future European Partnerships under Horizon Europe need to (N=1363) (non-campaign replies) For all candidate initiatives



1.2.3. Main advantages and disadvantages of Institutionalised European Partnerships

An open question asked to outline the main advantages and disadvantages of participation in an Institutionalised European Partnership (as a partner) under Horizon Europe (1551 respondents). The advantages mentioned focus on the development of technology, overall collaboration between industry and research institutions, and the long-term commitment.

Disadvantages mentioned are mainly administrative burdens. An overview is provided below.

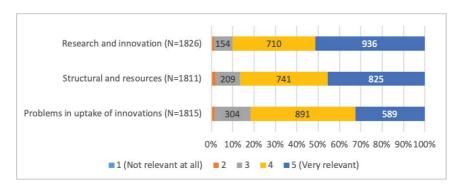
Advantages mentioned: Long term commitment, stability, and visibility in financial, legal, and strategic terms; Participation of wide range of relevant stakeholders in an ecosystem (large/small business, academics, researchers, experts, etc.); Complementarity with other (policy) initiatives at all levels EU, national, regional; Efficient and effective coordination and management; High leverage of (public) funds; Some innovative field require high levels of international coordination/standardisation (at EU/global level); Ability to scale up technology (in terms of TRL) through collaboration; Networking between members; Direct communication with EU and national authorities

Disadvantages mentioned: Slow processes; System complexity; Continuous openness to new players should be better supported as new participants often bring in new ideas/technologies that are important for innovation; Lower funding percentage compared to regular Horizon Europe projects; Cash contributions; Administrative burdens; Potential for IPR constraints.

1.2.4. Relevance of EU level to address problems in Partnerships' areas

Respondents were asked to rate the relevance of research and innovation efforts at EU level efforts to address specific problems in the area of partnerships. Research and innovation related problems were rated as most relevant across all candidate initiatives, followed by structural and resources problems and problems in the uptake of innovations. Overall, all three areas were deemed (very) relevant across the partnerships, as more than 80% of respondents found these challenges (very) relevant. Only minor differences were found between stakeholder categories. Research and innovation problems were found slightly more relevant by academic/research institutions, yet slight less relevant by large companies and SMEs. Structural and resource problems were indicated as slightly more relevant by NGOs, but slightly less by academic/research institutions. While both NGOs and public authorities find slightly more relevant to address problems in uptake of innovation than other respondents. The views of citizens are not differing significantly. Respondents that are/were directly involved in a current/preceding partnership find, however, the need to address problems related to the uptake of innovations slightly more relevant than other respondents.

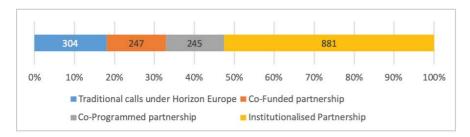
Figure 4: To what extent do you think this is relevant for research and innovation efforts at EU level to address the following problems in relation to the candidate partnership in question? (non-campaign replies) Aggregation of responses of all candidate initiatives



1.2.5. Horizon Europe mode of intervention to address problems

Respondents were asked to indicate how these challenges could be addressed through Horizon Europe intervention. Just over 50% of all respondents indicated that Institutionalised Partnerships were the best fitting intervention, with relatively strong differences between stakeholder categories. The use of Institutionalised Partnership was indicated more by business associations and large companies, but less by academic/research institutions and SMEs. While academic/research institutions valued traditional calls more often, this was not the case for business associations, large companies and public authorities. Public authorities indicated a co-programmed intervention more often than other respondents. Citizens indicated slightly less often that Institutionalised Partnerships were the best fitting intervention. Respondents that are/were directly involved in a current/preceding partnership, selected the Institutionalised Partnership intervention in far higher numbers (nearly 70%).

Figure 5: In your view, how should the specific challenges described above be addressed through Horizon Europe intervention? (non-campaign replies) For all candidate initiatives



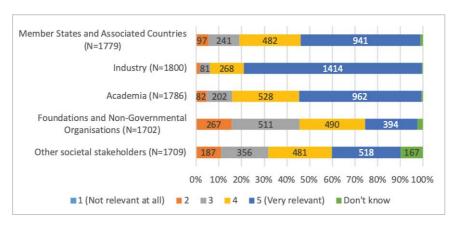
When asked to reflect on their answers, respondents that pointed to the need for using Institutionalised Partnership mentioned the long-term commitment of collaboration, a common and ambitious R&I strategy as well as the overall collaboration between industry and research institutions. Others shared positive experiences with other modes of interventions:

- Traditional calls, because of their flexibility and integration of a wide range of actors, as long as the evaluation panels do not deviate from the policy focus. This was mentioned by 94 participants, including companies (25), academics (26) and EU citizens (25).
- Co-funded partnership, as a mechanism to ensure that all participants take the effort seriously, while allowing business partnerships to develop. This approach was deemed suitable based on previous experiences with ERANETs. This was raised by 84 participants, 36 of them academic respondents, 18 companies and 16 EU citizens.
- Co-programmed partnerships, to tackle the need to promote and engage more intensively with the private sector. This was mentioned by 97 participants, most of them companies (34), followed by academics (22), business associations (15) and EU citizens (11).
 - 1.2.6. Relevance of a set of elements and activities to ensure that the proposed European Partnership would meet its objectives

Setting joint long-term agendas

Respondents were asked how relevant it is for the proposed European Partnerships to meet their objectives to have a strong involvement of specific stakeholder groups in setting joint long-term agenda. All respondents see stakeholders from industry as the most relevant, followed by academia and governments. The involvement of foundations and NGOs as well as other societal stakeholders were, however, still found to be (very) relevant by more than 50% of the respondents. Most respondents indicated the stakeholder group they belong to themselves or that represent them as relevant to involve.

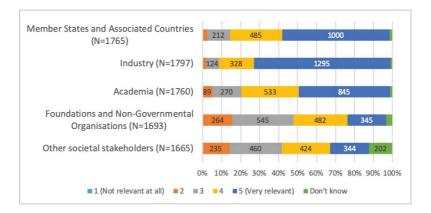
Figure 6: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives - Setting joint long-term agenda with strong involvement of: (non-campaign replies) For all candidate initiatives



<u>Pooling and leveraging resources through coordination, alignment and integration with stakeholders</u>

Respondents were asked how relevant it is for the proposed European Partnership to meet its objectives to pool and leverage resources (financial, infrastructure, in-kind expertise, etc.) through coordination, alignment and integration with specific groups of stakeholders. Respondents see stakeholders from industry as the most relevant, followed by academia and governments (Member States and Associated Countries). The involvement of foundations and NGOs as well as other societal stakeholders are also still found to be (very) relevant for more than 50% of the respondents. Similarly as described for the question on setting joint long-term agendas, most stakeholder categories valued their own involvement higher than other respondents – although also here differences between stakeholder categories were minor.

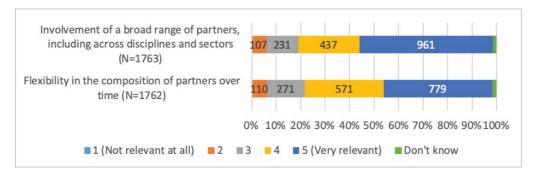
Figure 7: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives – Pooling and leveraging resources (financial, infrastructure, in-kind expertise, etc.) through coordination, alignment and integration with: (non-campaign replies) For all candidate initiatives



Composition of the partnerships

Regarding the composition of the partnership most respondents indicated that for the proposed European Partnership to meet its objectives the composition of partners needs to be flexible over time and that a broad range of partners, including across disciplines and sectors, should be involved (see Figure 6). When comparing stakeholder groups only minor differences were found. Academic/research institutions and public authorities found the involvement of a broad range of partners and flexibility in the composition of partners over time slightly more relevant than other respondents, while large companies found both less relevant. SMEs mainly found the flexibility in the composition of partners over time less relevant than other respondents, while no significant differences were found regarding the involvement of a broad range of partners. Citizens provided a similar response to noncitizens. Respondents that are/were directly involved in a current/preceding partnership, when compared to respondents not involved in a current/preceding partnership, indicated a slightly lower relevance of the involvement of a broad range of partners and flexibility in the composition of partners over time.

Figure 8: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives – Partnership composition (non-campaign replies) Aggregation of responses of all candidate initiatives

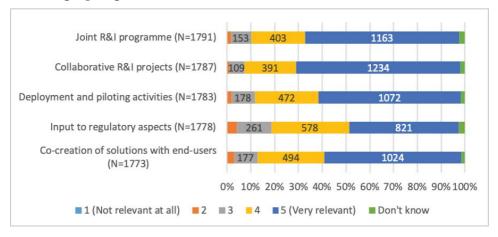


Implementation of activities

Most respondents indicated that implementing activities like a joint R&I programme, collaborative R&I projects, deployment and piloting activities, providing input to regulatory aspects and the co-creation of solutions with end-users are all (very) relevant for the partnerships to be able to meet its objectives. Minor differences were found between the main stakeholder categories, the differences found were in line with their profile. As such, academic/research institutions found joint R&I programme & collaborative R&I projects

slightly more relevant and deployment and piloting activities, input to regulatory aspects and co-creation with end-users slightly less relevant than other respondents. For SMEs an opposite pattern is shown. Large companies, however, also found collaborative R&I projects slightly more relevant than other respondents, as well as input to regulatory aspects. The views of citizens are similar to non-citizens. Respondents that are/were directly involved in a current/preceding partnership, when compared to respondents not involved in a current/preceding partnership, show a slightly higher relevance across all activities.

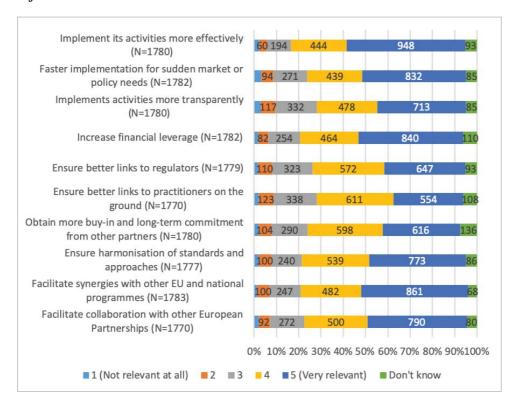
Figure 9: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives – Implementing the following activities (non-campaign replies) For all candidate initiatives



1.2.7. Relevance of setting up a legal structure (funding body) for the candidate European Partnerships to achieve improvements

Respondents were asked to reflect on the relevance of setting up a legal structure (funding body) for achieving a set of improvements, as shown in the Figure below. In general, 70%-80% of respondents find a legal structure (very) relevant for these activities. It was found most relevant for implementing activities in a more effective way and least relevant for ensuring a better link to practitioners on the ground, however differences are small.

Figure 10: In your view, how relevant is to set up a specific legal structure (funding body) for the candidate European Partnership to achieve the following? (non-campaign replies) Aggregation of responses of all candidate initiatives



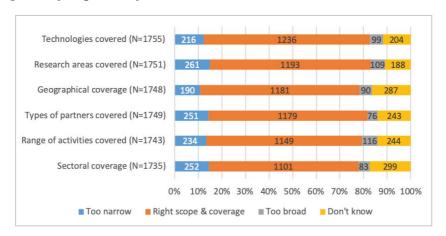
When comparing stakeholder categories there only minor differences. are Academic/research institutions indicated a slightly lower relevance for transparency, better links to regulators as well as obtaining the buy-in and long-term commitment of other partners. SMEs also indicated a lower relevance regarding obtaining the buy-in and longterm commitment of other partners. Large companies showed a slightly higher relevance for implementing activities effectively, ensure better links to regulators, obtaining the buy-in and long-term commitment of other partners, synergies with other EU/MS programmes and collaboration with other EU partnerships. NGOs find it slightly more relevant to implement activities faster for sudden market or policy needs. Public authorities, however, find it slightly less relevant to facilitate collaboration with other European Partnerships than other respondents. The views of citizens show a slightly lower relevance for a legal structure in relation to implementing activities in an effective way. Respondents that are/were directly involved in a current/preceding partnership indicated a higher relevance across all elements presented.

1.2.8. Scope and coverage of the candidate European Partnerships based on their inception impact assessments

Consulted on the scope and coverage for the partnerships, based on their inception impact assessments, the large majority feels like the scope and coverage initially proposed in the inception impact assessments is correct. However, about 11% to 15% of the respondents indicated the scope and coverage to be too narrow. About 11%-17% of respondents answered "Don't know". Overall, differences between the main stakeholder categories were found to be minor. Academic/research institutions indicated slightly more often that the

research area was "too narrow" then other respondents. SMEs on the other hand indicated slightly more often that the research area and the geographical coverage were "too broad". NGOs and public authorities, however, found the geographical coverage slightly more often "too narrow". Large companies found the range of activities slightly more often "too broad" and the sectoral focus slightly more often "too narrow" when compared to other respondents. The views of citizens are the same as for other respondents. Respondents that are/were directly involved in a current/preceding partnership more often indicated that the candidate Institutionalised European Partnership have the "right scope & coverage".

Figure 11: What is your view on the scope and coverage proposed for this candidate institutionalised European Partnership, based on its inception impact assessment? (non-campaign replies) Aggregation of responses of all candidate initiatives



1.2.9. Scope for rationalisation and alignment of candidate European Partnerships with other initiatives

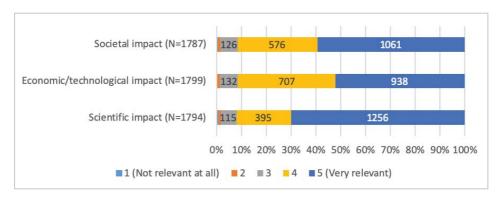
When asked whether it would be possible to rationalise a specific candidate European Institutionalised Partnership and its activities, and/or to better link with other comparable initiatives, nearly two thirds of respondents answered "Yes" (1000, or 62%), while over one third answered "No" (609, or 39%). Nearly no differences were found between stakeholder categories, only large companies and SMEs indicated slightly more often "Yes" in comparison to other respondents. The views of citizens are the same as for other respondents. Respondents that are/were directly involved in a current/preceding partnership, indicated "No" more often, the balance is about 50/50 between "Yes" and "No" for this group.

1.2.10. Relevance of European Partnerships to deliver targeted scientific, economic/technological and societal impacts

Finally, respondents were asked to rate the relevance of partnership specific impacts in three main areas: Societal; Economic/technological; and Scientific impacts. All three areas were deemed (very) relevant across the candidate partnerships. Scientific impact was indicated as the most relevant impact, more than 90% of respondents indicated that this as (very) relevant. Only minor difference between stakeholder groups were found. Academic/research institutions found scientific impacts slightly more relevant, while large companies found economic and technological impacts slightly more relevant than other respondents. NGOs found societal impact slightly more relevant, while SMEs found this slightly less important.

Citizens did not a significantly different view when compared to other respondents. Respondents that are/were directly involved in a current/preceding partnership find all impacts slightly more relevant than other respondents.

Figure 12: In your view, how relevant is it for the candidate European Institutionalised Partnership to deliver on the following impacts? (non-campaign replies) Aggregation of responses of all candidate initiatives



1.3. Stakeholder consultation results for the Innovative Health Initiative

An overview of the number and description of participants in each consultation activity targeting this specific initiative is available in Table 2. Participants were clustered into five categories: academic/research institutions, companies/business associations, Non-Governmental Organisations (NGOs), public authorities and European citizens. European patient organisations, health care professionals' organisations, organisations promoting the interest of specific groups of the population (e.g. people aged 60 and above), organisations of social health care payers were included among NGOs. Respondents from companies and business associations covered the various sectors potentially involved in IHI: pharmaceutical, biotech and vaccines, medical devices, imaging, in-vitro diagnostics and digital technologies. In addition to Member States, feedback has been received from the entire scope of all relevant stakeholders, in particular researchers, industry, health care professionals, patients, payers and public authorities.

Table 2. Participation in the various consultation activities

Consultation activity	Consultation period	Participation and profile of participants
Structured consultation of Member States	June 2019	26 Member States (all but Lithuania and Bulgaria), Iceland and Norway
Public consultation on IHI Inception Impact Assessment	July – August 2019	 43 respondents: 12 academic/research institutions (28%) 9 companies/business associations (21%) 14 NGOs (32%) 5 public authorities incl. the German government (12%) 3 EU citizens (7%)
Targeted consultation of stakeholders	September – December 2019	 48 interviewees: 8 academic/research institutions/research infrastructures (17%) 22 companies/business associations (46%) 4 NGOs: patient associations (8%) 5 public authorities incl. regulators, HTA bodies and payers (10%) 7 European Commission officials (15%) 2 members of the management team of the current public-private partnership (4%)
Open public consultation	September – November	108 respondents:

2019	- 35 academic/research institutions (32%)	
	- 19 companies/business organisations (19%)	
	- 17 EU citizens (16%)	

In terms of methods, public consultations were based on structured questionnaires also including open questions and offering the possibility to hand in position papers with additional information. If needed, depending on the number of replies, responses were first scanned using text-mining technique to facilitate further analysis.

1.3.1. Feedback to the inception impact assessment

Following the publication of the inception impact assessment, a feedback phase of 3 weeks allowed any citizen to provide input on the proposed initiatives on the "Have your say" web portal. In total 43 individual feedbacks were collected from NGOs (14; 32%), academic/research institutions (12; 28%), business associations (9; 21%), public authorities including the German government (5;12%) and EU citizens (3; 7%).

Relevance of the initiative and implementation mode

Three quarters of the respondents (32/43, 74%) explicitly expressed their support to the initiative (around 90% among business associations and academic/research institutions and 60% of public authorities and NGOs). No respondent gave a negative opinion on the proposed roadmap. Among the 18 respondents who explicitly expressed their preference regarding the implementation mode, all but one were in favour of an Institutionalised Partnership and one in favour of a co-programmed partnership.

Comments made from the respondents of the public and private sectors varied in terms of focus:

- public actors called for broader stakeholder involvement, transparency, open access to research results, public return on investment, and increased participation of SMEs;
- business associations called for flexibility in various aspects of the partnership: topic generation process, funding models, in-kind contributions from industry, legal framework for intellectual property management, and better involvement of SMEs.

This feedback is presented below according to the following categories: stakeholder involvement (in governance including priority setting, and in programme implementation), involvement of SMEs, transparency issues, participation from third countries, funding models, open access to research results, intellectual property right management, public return on investment, synergies with other initiatives, ethics and data privacy issues, sustainability of projects' results, and comments related to the R&I content of the potential partnership.

Stakeholder involvement

There was a general call from respondents of the public sector for the involvement of a broader variety of stakeholders in the partnership beyond industry and academics: patients' organisations, health care payers, regulators, health and social care professionals, health care providers, national health system actors and public authorities, Research and Technology

Organisations, and to a lesser extent, civil society organisations and citizens' groups were mentioned. A broader stakeholder involvement is expected at different levels: in the governance of the partnership, including in research priority setting, and in the implementation of the programme itself, including topic generation and participation in projects.

Regarding governance and priority setting, respondents from the public sector requested a model that would enable multi-stakeholder collaboration with a balance of relevant stakeholders in strategic decision-making and a stronger role of the Commission and national authorities. Respondents highlighted the need to put in place mechanisms ensuring that priorities will be set according to public health needs.

Regarding programme implementation including generation of call topics, there was a call for an inclusive process of topic generation involving patients, health care providers, health care professionals, and regulatory agencies. Respondents indicated the need for a balanced role of partners within the projects, in particular in projects addressing highly sensitive areas (e.g. projects on regulatory research).

Involvement of SMEs

Improved involvement of SMEs was strongly supported, in particular by business associations. The unique contribution of SMEs to the development of innovative health solutions was stressed by several respondents. To facilitate the participation of SMEs, the following measures were suggested: a legal framework respecting intellectual property ownership requirements for SMEs, a limitation of the administrative burden (and therefore a limitation of topics' scopes to limit consortia sizes), and process simplification (simple formats for proposals, fast feedback, simple reporting).

Transparency

Respondents form the public sector and in particular NGOs explicitly called for greater transparency with regard to decision-making processes (including in agenda-setting process) and in-kind contribution related to operational activities provided by the industry.

Participation of third countries

Business associations strongly advocated for eligibility of in-kind contributions without limitation for non-EU legal entities while the German government argued that the core of the activities and of the industry contributions needed to remain in Europe, even though international partners could provide valuable input to the initiative especially in the field of global health.

Industry contribution and funding models

Business associations asked for a funding model that encourages diverse in-kind contributions. Some companies were in favour of a flexible funding model where industry could be eligible for receiving funding, including large companies and mid-caps. Financial contribution from industry partners was suggested by some respondents form the public sector (NGO and public authority).

Open access to research results

Respondents from the public sector and in particular NGOs strongly called for open access to research results (mandatory and free) with derogations restricted to rare circumstances.

Intellectual property rights management

Some NGOs asked that ownership of publicly funded R&I results be driven by public interest and that various forms of intellectual property management and licensing be explored, including equitable licensing. Other respondents including business associations, and the German government, advocated for a revision of the rules for intellectual property rights to facilitate the involvement of the new industrial sectors with different business models and to offer better opportunities for SMEs to participate.

Public return on investment

Some NGOs called upon public return on investment by ensuring complete transparency regarding the costs of research, development and production and by safeguarding equitable access to publicly funded biomedical R&I: "Parties receiving EU biomedical R&I funding should agree on provisions to tackle the end product's affordability, accessibility, availability and efficiency along all the R&I stages".

Ethics and data privacy issues

Respondents highlighted the importance of addressing ethics and data privacy issues in the programme. One respondent called for ethical debates on the limits of digitalization, robotisation and the use of AI in the provision of health care so that to pave the way for a human-centred use of new technologies.

Synergies with other initiatives

Respondents highlighted the need for alignment, synergies and collaborations with i) national and regional initiatives and ii) other EU funded programmes, especially other candidate partnerships such as EU-Africa Global Health, Health and Care Systems Transformation, Personalised Medicine and Rare Diseases.

Sustainability of project results

The issue around sustainability of project results beyond the lifetime of individual projects was mentioned at several occasions. Solutions were asked in particular for sustainability of data infrastructures (e.g., through models of financing large equipment and data access handling).

Comments related to the R&I content of the partnership.

Specifically, respondents requested a better focus on and consideration of the following:

- health promotion and preventive interventions including personalised prevention, and early diagnostics in healthy population;
- sex and gender aspects (e.g. impact of digitalisation of services, implementation of artificial intelligence) as well as specific needs of subgroups of the population;
- improved cooperation between research and clinical practice;
- regulatory research;
- implementation research: methodologies to achieve large scale deployment of health care solutions and technologies;

- research in health economics;
- implementation of "green technology solutions" in the manufacturing of drugs and European Union Strategic Approach to Pharmaceuticals in the Environment.

In addition, comments were received on specific disease areas that should be considered as priorities (e.g. neglected diseases, paediatric cancer, asthma, brain disorders).

1.3.2. Structured consultation of the Member States

A structured consultation of Member States through the Shadow Strategic Configuration of the Programme Committee Horizon Europe in May/June 2019 provided early input into the preparatory work for the candidate initiatives (in line with the Article 4a of the Specific Programme of Horizon Europe). This resulted in 44 possible candidates for European Partnerships identified as part of the first draft Orientations Document towards the Strategic Plan for Horizon Europe (2021-2024), taking into account the areas for possible Institutionalised Partnerships defined in the Regulation.

The feedback provided by 30 countries (all Member States, Iceland and Norway) was analysed and summarised in a report, with critical issues discussed at the Shadow Strategic Programme Committee meetings.

During the structured consultation of Member States, there was overall a strong endorsement of the Innovative Health Initiative, including the proposed implementation via the Institutionalised Partnership with the participation of several industry sectors.

Relevance and positioning in a national context

Overall the results of the Member States consultation confirmed the relevance of the proposed Innovative Health Initiative, with 89% considering it very relevant and 7% somewhat relevant for national policies and priorities. Equally there was a very strong confirmation of the overall relevance for research organisations, including universities, as well as for industry (Figure 1).

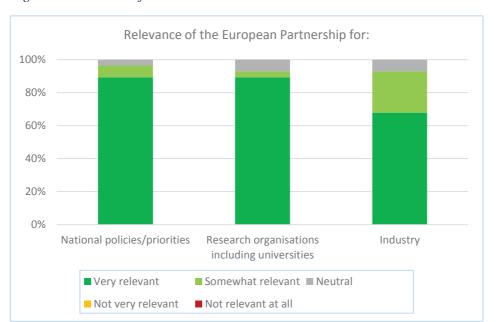


Figure 1. Relevance of the Innovative Health Initiative in the national context

On the question of existing national/regional R&I strategies, plans and/ or programmes in support of the proposed Innovative Health Initiative, 28 countries (93 %) reported to have relevant elements in place. National R&I strategies or plans were identified most frequently (89%), followed by national economic, sectoral strategy and/or plan with a strong emphasis on research and/or innovation (79%) and regional R&I and/or smart specialisation strategies (75%). Dedicated funding programmes exist in 57% of the countries.

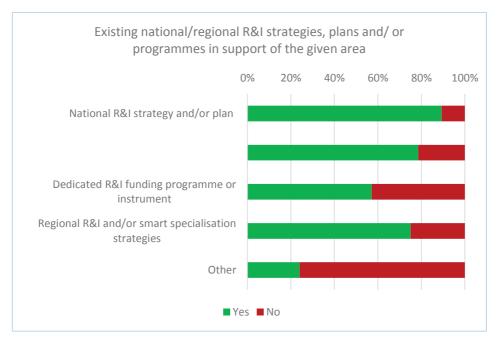
Delegations identified a number of aspects that could be reinforced in the proposal for this partnership that would increase its relevance for national priorities. There was a general call for better SME participation, including more favourable intellectual property rights for them. Other comments address e.g.:

- stronger role of national authorities in the governance to address the public health need and to allow for synergies with national programs;
- inclusion of health care providers;
- clear link to national health systems and an early dialogue with regulatory bodies;
- structured coordination with academia to support the translational process;
- reinforcement of the European digital industry with regard to global competitors;
- need to ensure that the agenda setting supports joint, converging industry collaboration;
- including research on vaccines, including method development for the quality control of vaccines, as well as the implementation of "green technology solutions" in the manufacturing of drugs;
- education and training of users, incentives for health care providers.

A majority of countries, 17, have expressed an interest to participate (it should be noted that the question did not allow to draw conclusion on the exact nature of participation – see also

below under 'Views on partners, contributions and implementation), and only 3 countries at this stage expressed no national interest to participate. Identified elements for their participation covered broadly existing or planned national R&I programmes, governmental research organisations, research infrastructures, as well as regional R&I and/or smart specialisation strategies (Figure). All countries expressed interest in having access to results produced in the context of the partnership.

Figure 2. Possible participation and contribution to the Innovative Health Initiative, from the 17 countries that have expressed an interest to participate.



Objectives and impacts

Overall there was a strong agreement (82%) on the use of a partnership approach for innovative health issues. There was broad agreement (89%) that the partnership was more effective in achieving the objectives and delivering clear impacts for the EU and its citizens, and there was agreement (53%) that it would contribute to improving the coherence and synergies within the EU R&I landscape. No country expressed any disagreement.

Countries indicated good agreement with the proposed objectives at short, medium and long term (96% agree or strongly agree) and the expected scientific, economic and societal impacts at European level (93% agree or strongly agree), with the rest remaining neutral. The vast majority of countries (85%) considered the impacts very relevant in the national context. There was agreement (56%) with the envisaged duration of the proposed partnership, but an important share (22%) considered the duration too long and requested clear exit strategies.

Additional comments supported a clearer articulation between the Innovative Health Initiative and other partnerships, and the need to clarify the role of IT aspects. A request was made to better focus on the sustainability of health care systems and on health promotion and preventive interventions.

Views on partners, contributions and implementation

The majority (66%) agrees on the type and composition of partners, and 15% disagreed. Many comments supported the shift towards other industrial sectors and would welcome better inclusion of health care providers. Most countries (65%) would need more information on contributions and level of commitments expected from partners, while 31% agreed with the proposal. Individual comments related to the following issues:

- the role of Member States in the agenda setting and governance should be strengthened;
- ensure realistic commitments from industry, including meaningful financial contributions, with regards to the scale and budget of the initiative;
- support industries in jointly addressing common and growing operational, regulatory and economic challenges;
- ensure sufficient representation of health ICT companies and research organisations;
- impact on promoting EU competitiveness should be at the forefront of the initiative, by limiting contributions from non-EU legal entities, or even limiting it to EU and Associated Countries;
- funding to industry in accepted projects should be possible, to allow for peer-to-peer collaborations between academia, RTOs and industry partners;
- important to strengthen the role of health care providers in the agenda setting.

The proposed use of Article 187, and the establishment of a Joint Undertaking, was supported by the majority (73%), while one country disagreed, with the rest expecting more details in order to be able to make an informed decision. One country would support a tripartite partnerships with industry, Member States and the Union, while another country explicitly excluded any national co-funding. Furthermore, the issue was raised of how to ensure sufficient Member State and stakeholder involvement in the agenda setting and set-up of the programme in order to achieve people-centred health care.

1.3.3. Targeted consultation of stakeholders

In addition to the consultation exercises coordinated by EC services, the external study thematic team performed a targeted consultation with key stakeholders on different aspects of the Innovative Health Initiative. The objective of the programme of interviews was to provide an insight into the views of these key stakeholders on the context, problem definition, objectives, policy options, impact analysis, coherence and monitoring of the new initiative. Semi-structured interviews were conducted using a tailored interview topic guide and were subsequently transcribed/summarised and analysed.

Forty-eight interviews were conducted with representatives from industry (22; 46%), the European Commission (7; 15%), academic and research institutes (5; 10%), research infrastructures (3; 6%), patient associations (4; 8%), members of the management team of existing partnerships (2; 4%), regulators, HTA bodies and payers (5; 10%).

Key results/messages from the targeted consultation are presented below.

Problems and problem drivers

Several interviewees shared their thoughts on what problems could be addressed with this investment. These included antimicrobial resistance, ageing populations and skills migration to other countries. It was felt that Europe was struggling to maintain its leadership position in health R&I compared to US and China.

It was discussed that the fragmentation of the health care systems including differences in capacities, standards of care and cultural expectations leads to challenges implementing health innovations uniformly across Europe and may act as a barrier to uptake. In particular, it was mentioned that uneven IT literacy across Europe and poor public perception of industry were hindering uptake.

Other points were the need to reference ethics along with digitalisation and data exchange as areas where barriers need to be overcome and the need to include "standardisation" of the methodologies and models to better assess market value.

Objectives

Interviewed stakeholders expressed an overall support for IHI general objectives. A large proportion of interviewees were satisfied with the specific objectives with positive feedback around the push for a people-centred approach. There was some discussion around the broad nature of the objectives and the potential difficulty of measuring the associated outcomes. Nevertheless, it was generally agreed as a strategic decision to encompass the needs of the variety of stakeholders likely to be involved.

Expected impacts

- In terms of **scientific impacts**, bringing together a broad range of expertise and actors from across the innovation value chain was seen as instrumental for the majority of interviewees. In their opinion, such a configuration would allow: i) to support the development of innovations that would meet patients and health systems needs while having a realistic transition to market, ii) to drive cross-pollination of ideas and creativity leading to innovative health solutions that would not be possible from a more siloed approach, and iii) to foster scientific advancements by overcoming barriers of data exchange.
- According to the majority of interviewees, **economic impacts** would result from more efficient development processes, thus reducing the cost of development that may in turn contribute to lower innovation cost to the end users. It was also discussed that the development of digital platforms and technologies coupled with effective data exchange would also have economic benefits to the health care system (e.g. eHealth platforms containing diagnostic data would reduce the need to duplicate diagnostic tests across multiple health care sites). Regarding the impact on job growth, some interviewees felt that any boost in the economy would lead to a general growth in jobs, while others referred to jobs that would be created as a direct result of carrying out IHI or from the products that would be created. This was particularly discussed in reference to start-ups and SMEs. Skill development, in particular data skills, was a key aspect of this growth and a number of interviewees suggested that education or training activities within the partnership project would enhance this impact. Many interviewees indicated that due to the synergies that would be developed as part of the partnership, the economic benefits of the investment would be felt by all stakeholders along the value chain. Nevertheless,

SMEs were identified as key beneficiaries and the business growth of SMEs was considered as a driver for innovation and global competitiveness in health R&I.

- In terms of **societal impacts**, the majority of interviewees agreed that IHI would lead to improved health and wellbeing. Many of the discussions were general in nature suggesting that the specific impacts would be determined by the nature of the actual IHI projects. Societal impact would also be achieved through increased uptake of innovations. This would be primarily driven by engaging end-users, ensuring the relevance of innovations to the target groups and sufficient training of end-users to benefit from the innovations. It was also discussed that inequality in health care access could be partially addressed in the partnership by developing innovations that account for variations in digital literacy, ageing and geographical diversity.
- Positive **environmental impacts** were discussed primarily with regard to reduced need for travel (via advancements in remote testing and monitoring) and less/better waste management (e.g. via enhanced data exchange replacing the need to duplicate tests). Some interviewees raised concern that there are also negative environmental impacts of digital technologies e.g. energy consumption of datacentres and extraction of raw materials, suggesting that the net environmental impact would be important to consider.

Stakeholder involvement

It was strongly felt that a broad range of stakeholders alongside academia and industry was required to make the partnership a success. In particular the involvement of regulators, patient representatives, and representatives of health care systems to strengthen the impact and uptake of innovations was encouraged.

Synergies with other EU initiatives

In general, there was strong support for working synergistically with other EU initiatives, in particular since health is complex and feeds into many aspects of other initiatives. Developing similar data management methodologies or use of similar platforms was discussed as a key way to ensure that findings can be shared between initiatives. It was also discussed that cooperation between initiatives could enhance learning. Establishing a flexible set of rules for the different initiatives would reduce bureaucratic barriers that have prevented past collaborations. An opportunity was noted for projects, partners or ideas to flow between different funding initiatives such as Horizon Europe regular calls and IHI in order to exploit the sequential needs of the project.

Transparency

Interviewees were in favour of increased transparency of the initiative in terms of decision-making, financing and activities, as a means to increase public confidence in the initiative.

Broadening the membership of the partnership

It was generally felt that a broader membership would be a positive change, but it was discussed that membership should be based on research/knowledge excellence rather than geographical representation. There was strong support for keeping membership open to potential future partners as a token of flexibility and to help address gaps in membership that may develop later in the partnership.

Dissemination of results and re-use by others across Europe

This notion was supported as it was felt that better dissemination would enable more efficient future research. At the same time, sharing of results should not compromise the development of intellectual property. There were also some concerns around GDPR and patient data.

Increased level of private partners' contributions

Some interviewees supported the increased level of private partners' contributions provided there was a strong agreement across industry. On the other hand, it was felt that it may make IHI less attractive to industry and that a true partnership should have a 50/50 contribution ratio. There were also some concerns about the public perception and the shift in balance to industry in determining the research agendas.

Increased level of private partners' financial contributions

Interviewees were asked whether they would support an increased level of private partners' contributions, ideally to a point where around 10% of all private members' contributions are financial rather than in-kind. This question led to a mix of responses. Some interviewees felt that in-kind was a more valuable contribution than cash as the knowledge and expertise of industry is where the true value of the partnership lies. Others felt that a financial contribution would lead to a stronger commitment from industry partners. Some others felt that a flexible, case-by-case approach would be most suitable suggesting that commitments may change over time once industry has the opportunity to assess the value of the partnership.

Implementation mode

The majority of interviewees felt that Institutionalised Partnership would be the most effective option of delivering scientific, economic and societal impacts. Commonly given reasons for this were the broader range of stakeholders engaged, stronger commitment from all parties, flexibility on setting research agendas and the longer-term outlook.

• Horizon Europe Regular Calls

It was generally felt that Horizon Europe has an important place in the funding landscape through regular calls and is effective in achieving impacts in smaller projects and enhancing academic excellence. However, is was discussed that the structure would not be able to enable large-scale collaboration between a broad range of stakeholders as required to achieve the abovementioned impacts. There were concerns that it would not be very attractive to industry due to a reduced role in setting research priorities and a potentially less binding agreement. Projects under Horizon Europe were viewed as having a smaller scope so would not be able to holistically evaluate digital platforms or comparable technologies. This would have to be accomplished by combining many smaller Horizon Europe projects, leading to fragmentation and inefficiencies. The timeframe of regular calls was also discussed as being insufficient to adequately achieve the objectives.

• <u>Co-Programmed Partnership</u>

Co-programmed partnerships were preferred to Horizon Europe Regular Calls in particular due to their longer-term focus. Co-programming was seen as suitable for a partnership structure where a more flexible arrangement was desirable such as involving pre-existing partnerships or for projects of a smaller scope. There were, however, concerns over co-

programming delivering an in-depth partnership of diverse stakeholders. It was felt that the commitment under this option would not deliver the security needed to invest in truly innovative and risky ideas and may therefore not be attractive to some partners. Furthermore, some interviewees felt that industry would have less input in developing research agendas under this option. Establishing common research agendas was seen as valuable but insufficient to overcome the barriers of different sectors working in silos and would therefore not benefit from the full set of outcomes stemming from the cross-pollination of skills and knowledge under a partnership. For these reasons, it was felt that a co-programmed partnership would not be as effective in delivering the impacts described above.

• Institutionalised Partnership

Institutionalised Partnerships were generally seen as more integrated partnership structures. The most frequently discussed advantage of Institutionalised Partnerships over the other policy options was that this structure would attract and enable a broader set of actors to engage. Diversity of stakeholders along the value chain was seen as an essential component to achieve impacts. Similar to a co-programmed partnership model, the longer-term outlook was also seen as a key advantage of this option.

It was discussed that this arrangement would be attractive to industry because there would be the opportunity to co-develop research agendas. Similarly, stakeholders from other groups felt that having a diverse range of players would enable the development of research agendas that are more balanced across the needs of all actors, leading to more realistic and holistic research goals.

The legally binding arrangement was seen as an advantage because it provided a level of confidence to the stakeholders involved and it was also viewed as an important conduit to facilitate the sharing of data required to achieve the impacts. It was discussed that this integrated approach would also enable a more detailed discussion around intellectual property upfront, further increasing confidence in the partnership from the outset. This in turn could lead to greater commitments from private partners since the risk of investment is shared, leading to more innovative and potentially more impactful outcomes.

It was discussed that Institutionalised Partnerships may suffer from a large administrative burden. However, it was also felt to be a necessary component of such a complex arrangement and that the administrative burden of Horizon Europe and co-programmed partnership was likely to be similar. Nevertheless, it was suggested that this could be a barrier to smaller companies, i.e. SMEs and start-ups, that may not have the capacity to meet the administrative needs.

Key Performance Indicators (KPIs)

In general, KPIs such as publications and patents were seen as easy to measure but limited in showcasing the partnership's impact. Instead, it was suggested to focus on indicators such as adoption into health care systems, uptake of citizens and ultimately a change in health outcomes or the burden of disease.

It was discussed that health and economic KPIs would be difficult to measure and would require a well-defined baseline at the start of the project, tailored to the specific project objectives.

Some proposed KPIs were:

- health and wellbeing: disease prevalence, Quality Adjusted Life Years (QALYs), probability of treating disease, life expectancy, time in hospital, cost of treatment;
- economic: job growth, number of new SMEs/start-ups, business performances, product development, follow-up on funding;
- scientific: publications (but acknowledged as insufficient alone).

There was also a discussion on monitoring the success of IHI overall. This could be measured by examining the number of stakeholder types involved, meeting timeline goals, and development of products.

A number of interviewees stressed it was important to focus on a small number of high quality KPIs. Some even suggested establishing a small project dedicated to defining the most effective KPIs for each project and IHI overall.

1.3.4. Open Public Consultation

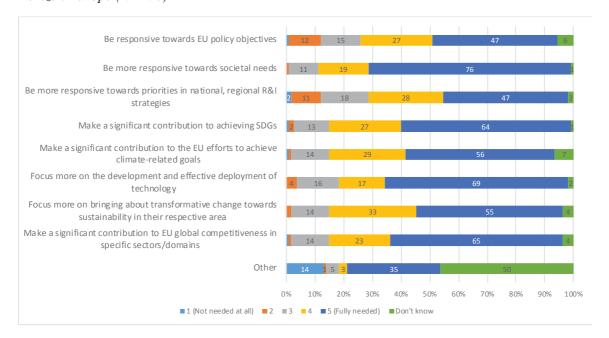
This section outlines the results of the Open Public Consultation for the candidate European Partnership on Innovative Health Initiative.

There were 108 respondents who provided views about the Innovative Health Initiative Partnership. Among them, 35 respondents (32%) are representatives of academic and research institutions, 19 respondents (19%) are company/business organisations, and 17 respondents (16%) are citizens. The majority of respondents, namely 77 (71%), have been involved in the on-going research and innovation framework programme, while 49 respondents (64%) were directly involved in a partnership under Horizon 2020 or its predecessor Framework Programme 7.

Relevance of efforts of the Innovative Health Initiative to address problems

At the beginning of the consultation, the respondents indicated their views regarding the needs of the future Innovative Health Initiative (Figure 3). Overall, respondents indicated that many of the options presented were relevant. The option where most respondents indicated this, was "be more responsive towards societal needs" (76; 70%). No statistical differences were found between the views of citizens and other respondents. Other needs indicated were those around investment in long term European partnership, extensive support and the value chain.

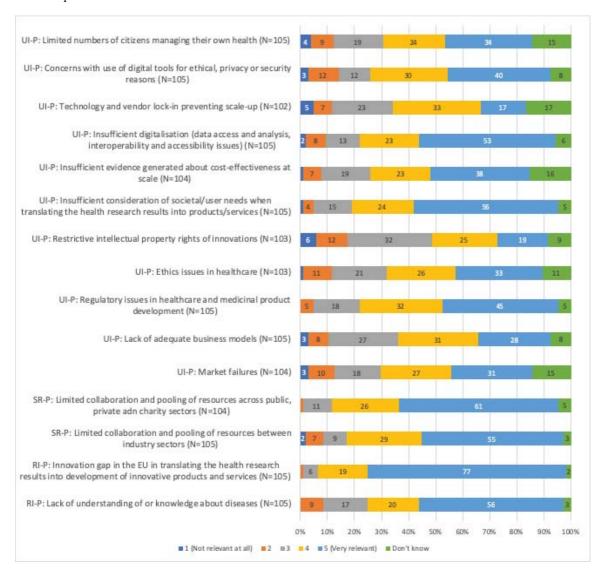
Figure 3. Views of the respondents in regard to the needs of future Innovative Health Initiative under Horizon Europe (N=108)



Relevance of R&I efforts at the EU level to address problems in relation to health and health care innovation

Respondents were asked to provide their view on the relevance of R&I efforts at EU level to address three types of problems: problems in uptake of health innovations (UI-P), structural and resource problems (SR-P) and research and innovations problems (RI-P). Responses are presented in Figure 4.

Figure 4. Views of respondents on relevance of research and innovation efforts at the EU level to address problems in relation to health and health care innovation



With regard to uptake of health innovations (UI-P), the issue for which EU-level R&I efforts were considered very relevant by the greatest amount of respondents (56; 53%) is "insufficient consideration of societal or user needs when translating the results of health research into better health products and services". This option was closely followed by "Insufficient digitalisation (data access and analysis, interoperability and accessibility issues)" (53; 50%).

With regard to structural and resource problems (SR-P), the answers to the two proposed options ("Limited collaboration and pooling of resources - across public, private and charity sectors or - between industry sectors") are fairly similar, with the majority of respondents considering those two problems as very relevant to be addressed at EU-level.

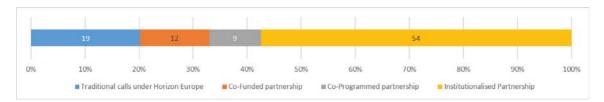
With regard to R&I problems (RI-P), "Innovation gap in the EU in translating the results of health research into the development of innovative health products and services" was considered by the greatest number of respondents (77; 73%) as a very relevant issue to be addressed at EU-level.

No statistical differences were found between the views of citizens and other respondents.

Horizon Europe interventions to address problems

As shown in Figure 5, 57% of respondents indicated that Institutionalised Partnerships were the best fitting intervention. No statistical differences were found between the views of citizens and other respondents.

Figure 5. Assessment of Horizon Europe intervention

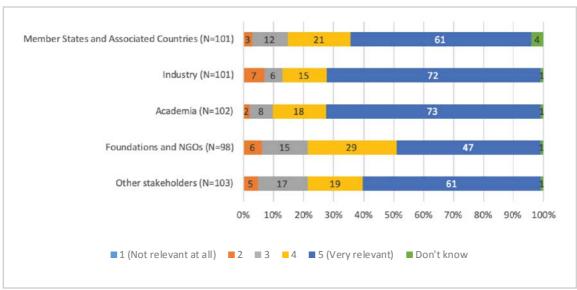


People who stated that an Institutionalised Partnership was the best fitting answer mentioned long term collaboration, global health issues and financial commitment. Respondents who did not select Institutionalised Partnership as their preferred intervention (N=47) mentioned traditional calls, industry partners and collaborative research as crucial for innovation.

Involvement of actors in setting joint long-term agenda

A higher number of respondents consider that the involvement of academia and industry is highly relevant for reaching the objectives of the Innovative Health Initiative Partnership. In contrast, the importance of involvement of foundations and NGOs in setting joint long-term agenda is considered lower, with 47 respondents (48%) viewing them as highly relevant actors for setting the agenda. Respondents that are/were involved in a current/preceding partnership (Horizon 2020 or Framework Programme 7) find industry a more important stakeholder to involve in joint long-term agenda setting than other respondents. No statistical differences were found between the views of citizens and other respondents.

Figure 6. Views of respondents on relevance of actors in setting joint long-term agenda



Relevance of actors in pooling and leveraging resources

The role of Member States and Associated Countries is perceived as relevant or very relevant by 86% of respondents. The importance of involvement of other actors, such as

industry and academia, is also considered high by 81% and 80% of respondents, respectively. The role of foundations and NGOs as well as other stakeholders in pooling and leveraging resources, is seen as less relevant (74% and 64%, respectively).

A slight statistical difference was found between the views of citizens and other respondents. Citizens show slightly less relevance for industry, for other categories the views show no statistical differences.

Figure 7. Views of respondents on relevance of actors for pooling and leveraging resources

Partnership composition

The involvement of a broad range of partners is considered more relevant to meet the objectives of the Partnership than the flexibility in composition of partners over time, as 73 respondents (72%) versus 52 (50%) respectively consider them very relevant.

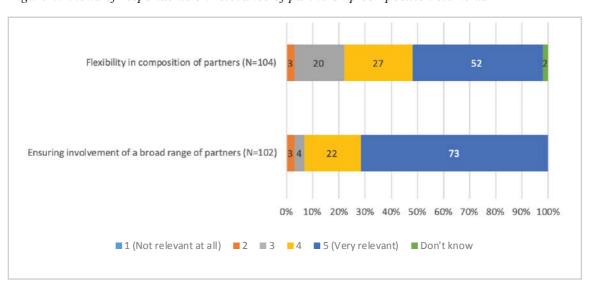


Figure 8. Views of respondents on relevance of partnership composition elements

Implementation of activities

Over 67% of respondents consider collaborative and joint R&I projects very relevant for reaching the objectives of the Partnership. The least number of respondents, namely 44 (42%), view the input to regulatory aspects as relevant for meeting the objectives. No statistical differences were found between the views of citizens and other respondents.

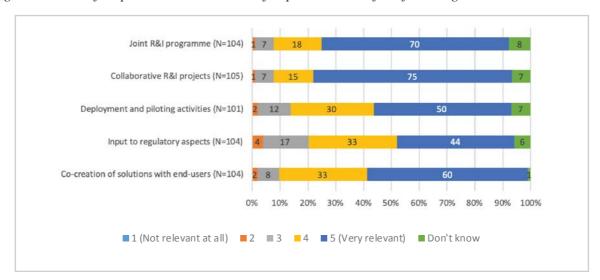


Figure 9. Views of respondents on relevance of implementation of the following activities

Relevance of a legal structure (funding body) to achieve specific objectives

Respondents were asked to assess the relevance of a specific legal structure (funding body) for the candidate European Partnership to achieve several objectives. The opinions of respondents reveal that the legal structure would be equally beneficial for most listed activities, as Figure 10 reflects a similar pattern of responses. However, the least number of respondents suggest that the legal structure would be very relevant for ensuring better links to practitioners on the ground and to regulators. No statistical differences were found between the views of citizens and other respondents.

Implement its activities more effectively (N=105) Implement activities faster to respond to sudden market or policy needs (N=105) Implement activities more transparently (N=103) Increase financial leverage (N=105) Ensure better links to regulators (N=105) Ensure better links to practictioners on the ground (N=105) Obtain more buy-in and long-term commitment from other partners (N=105) Ensure harmonisation of standards and approaches (N=105)Facilitate synergies with other EU and national programmes (N=104) Facilitate collaboration with other relevant European Partnerships (N=105) 0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

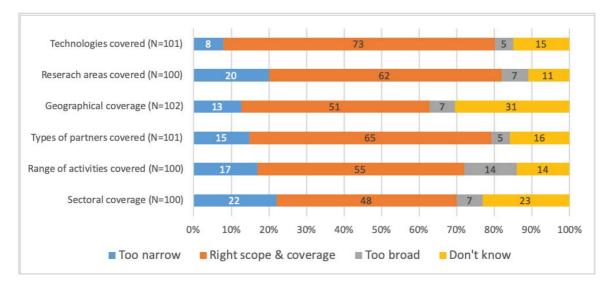
Figure 10. Views of respondents on relevance of a specific legal structure

Scope and coverage

Respondents were asked to assess the scope and coverage of the proposed Innovative Health Initiative, based on its inception impact assessment. As presented in Figure 11, 73 respondents (72%) consider that the coverage and scope of technologies is right, while the least number of respondents, namely 51 (50%), think that the proposed sectoral and geographical coverage and scope are right. Moreover, 20 respondents (20%) indicated that the research areas covered are too narrow. No statistical differences were found between the views of citizens and other respondents.

■ 1 (Not relevant at all) ■ 2 ■ 3 ■ 4 ■ 5 (Very Relevant) ■ Don't know

Figure 11. Views of respondents on the scope and coverage proposed for the Innovative Health Institutionalised Partnership



Aside from this multiple choice question, the respondents were also asked to provide comments on the proposed scope and coverage for this candidate Institutionalised Partnership. The keyword analysis showed the respondents used this open question to talk about infectious diseases, the scope of the partnership with regard to global health, the health systems and public health.

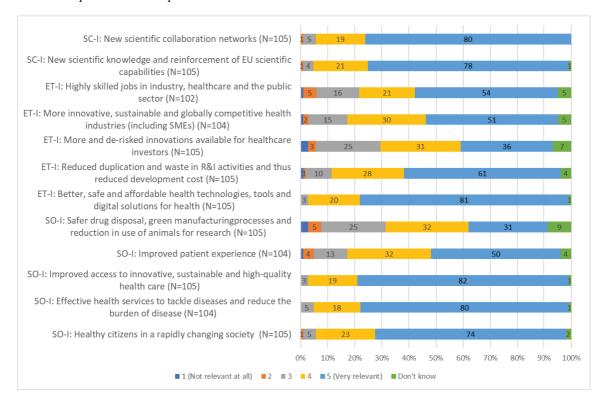
Alignment of the European Partnership with other initiatives

Out of 91 respondents, 78 (86%) think that it is possible to rationalise the candidate Innovative Health Initiative and its activities, and/or to better link it with other comparable initiatives. Respondents mentioned other programmes, complementary initiatives, health systems partnerships and digital technology.

Relevance of the Candidate European Partnership to deliver impacts

According to Figure 12, the candidate Partnership is expected to be 'very relevant' for "improved access to innovative, sustainable and high-quality health care", for ensuring "effective health services to tackle diseases and reduce the burden of disease", and for ensuring that there are "healthy citizens in a rapidly changing society". Among listed economic and technological impacts, a greater number of respondents (81; 77%) indicated that the candidate Partnership would make a significant contribution towards "better, safe and affordable health technologies, tools and digital solutions for health". The results for listed scientific impacts are very similar and positive, reflecting high expectations about potential impacts of the candidate Partnership. The economic and technological impact regarding "more and de-risked innovations available for healthcare investors" was found more relevant by respondents that are/were involved in a current/preceding partnership (Horizon 2020 or Framework Programme 7). No statistical differences were found between the views of citizens and other respondents for most of the discussed impacts.

Figure 12. Views of respondents on the relevance of the candidate European Institutionalised Partnership to various impacts



1.3.5. Integration of feedback received in the preparation of the partnership⁵

• Stakeholder involvement

To address the request for broader involvement of stakeholders in IHI governance, a separate body ('Innovation Panel') is envisaged. It would be composed of the representatives of EU and member industry associations, as well as of various other stakeholders such as representatives of patients, health care professionals, patients, health care providers, academia, research and technology organisations, research infrastructures, other partnerships and ad-hoc members as necessary. One of the major tasks of the Innovation Panel will be to identify and review potential areas and topics, ensuring they are suitable for the scope of IHI, they adequately address public health interest and needs of end users, and that they have a chance of securing sufficient in-kind commitment from the industry. The members of the Innovation Panel will be expected to be in close contact with their respective constituencies and to seek expert opinion in advance, thus maintaining openness of the initiative and at the same time, ensuring smooth operation.

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⁵ This chapter provides information on various measures and solutions that could be proposed to address the feedback received. It should be noted that these ideas need validation in the legislative act or any other legal documents laying down the functioning of the partnership (e.g. statutes or rules of procedure of individual governance bodies).

Member States and Associated Countries would be represented in the States Representatives Group. Its task will be to provide opinions on the activities of the partnership and information on related activities at national level. The proposed partnership will thus benefit both industrial and public partners and the governance system will ensure representation of the views of all key stakeholders.

Involvement of SMEs

To encourage SMEs involvement in the partnership, dedicated support and communication actions and could be offered by the Programme Office, benefitting from the implementation mode as an Institutionalised Partnership.

Transparency

Regarding the transparency of research priority setting and the topic generation process, the revised governance structure would better incorporate views of various stakeholders involved in health and care thanks to the Innovation Panel. As regards the transparency of in-kind contribution provided by the industry in relation to operational activities, detailed requirements for its valuation would be defined in documents laying down the functioning of the initiative. The project results are going to be subject to the same transparency provisions as under regular Horizon Europe calls. Access to the information about the initiative will be ensured through communication activities and publication of relevant documents on its website. Additionally, appropriate partnering/promotion events and communication campaigns may be organised.

Participation of industry from third countries

EU Member States expressed a strong wish to strengthen competitiveness of Europe's health technology industry. At the same time, health research goes beyond national borders and the necessary global dimension of the partnership should be ensured. The partnership will aim to attract investments also from outside Europe to increase its international footprint, capture resources of global companies and benefit from other previous international investments or address specific scope (such as e.g. disease prevalence in non-EU countries, with relevance for EU population). In order to balance these needs, in-kind contributions committed out of EU or Horizon Europe Associated Countries might be accounted for and eligible for matching with EU funds, albeit to a certain extent. If formalised in the relevant legal provisions, this approach would follow the practice established under IMI2 JU.

• Funding models

To address the need for financial flexibility requested by some industrial sectors, industry could be eligible for funding up to a certain ceiling (including large companies and midcaps), and could also be entitled to opt-out from receiving funding at their discretion. The detailed arrangements will be laid down in the relevant legal provisions.

• Open access to research results

As a principle, general Horizon Europe provisions will apply.

• Intellectual property rights management

As a principle, general Horizon Europe provisions will apply.

• Public return on investment

The proposed partnership is set to work in the pre-competitive R&I area of unmet health needs and as such will aim at fostering collaborations between public and private stakeholders in order to accelerate the future development of health innovations. As a principle, the partnership does not envisage engaging mechanisms to influence pricing and reimbursement as these are a national competence. Nevertheless, in case the partnership would conduct research at a significant scale in the competitive area, a mechanism could be foreseen so that products or services developed by the partnership are accessible at fair conditions.

• Synergies with other initiatives

The partnership will be operating in connection with several other relevant initiatives at various levels so that synergies can be strengthened and waste in research minimised. Duplication of efforts with other partnerships could be avoided by consultation and potential direct representation in the IHI governance structures (the Innovation Panel) of representatives of other relevant initiatives, such as e.g. the potential future public-public partnership on "Health and Care Systems Transformation". Draft topic texts will be consulted with the relevant services of the European Commission and approved by the Governing Board that will include EC members. To ensure coherence with national/regional initiatives, the States Representatives Group (composed of representatives of relevant national ministries) is foreseen to be represented in the Innovation Panel, will be consulted on future call topics and will provide advice on potential complementarities and overlaps with relevant national initiatives.

• R&I content of the partnership

The comments related to the content of the partnership were taken into account when designing the proposed objectives and are going to be further considered during the elaboration of the Strategic Research Agenda.

Annex 3 Who Is Affected And How?

1. PRACTICAL IMPLICATIONS OF THE INITIATIVE

The Institutionalised Partnership implementing the Innovative Health Initiative will be offering funding and collaboration opportunities to those interested in it, on a voluntary basis. As a result, it will not impose any obligations generally applicable to citizens, businesses including SMEs or administrations. Certain obligations will be imposed, though, on industry associations who will become formal Members of the initiative as enshrined in the legislative act, and on stakeholders directly involved in the funded actions because of obligations resulting from signed grant agreements.

The impact on national public administrations will be limited to the allocation of human and financial resources to attend the States Representatives Group meetings (approx. 3-4 per year, in Brussels) and ensuring the flow of information at national level between stakeholders, notably between the relevant ministries. These processes are similar to those required for attending various Horizon Europe programme committees but an additional effort will be needed for a separate channel of communication activities to national stakeholders. Such activities are usually organised by National Contact Points as the main structure existing at the Member States level to provide guidance, practical information and assistance on all aspects of participation in EU funding programmes. A similar impact can be expected on various stakeholder groups such as health care professionals, providers, patient associations or research and technology organisations, to ensure their potential input into the governance and priority setting process.

Industry associations who are formal members of the Partnership will be bound by the various obligations stemming from the Regulation establishing the initiative. Due to their representation in the partnership's Governing Board, these associations will need to organise their internal workflows for efficient decision making and allocate representatives to attend Board meetings, and to follow-up on the Governing Board's decisions taken by written procedures.

For all other enterprises active in health R&I, some limited additional costs may be linked to understanding the rules of the new funding programme and allocating staff to follow up calls as they are prepared and published, and to networking and finding collaboration opportunities. SMEs might find these costs to be proportionally higher (versus their overall staff effort) as such activities are not directly linked to the entity size. Overall, these costs and effort will be lower for those already familiar with other private-public partnerships, such as ECSEL or IMI Joint Undertakings.

As the major positive impact, all stakeholders interested to take part in the initiative and respond to calls for proposals will stand a chance of benefiting from funding opportunities and access to new scientific ideas, intellectual property and collaborators beyond their usual interlocutors. For industries – including SMEs – this will enhance business viability and speed up the path of designing products or services that better respond to the needs of endusers: patients, health care professionals and health care systems.

2. SUMMARY OF COSTS AND BENEFITS

It is not possible to quantify – with an acceptable level of confidence – how this initiative would lead to the reduction or increase of costs of developing health innovations, or to the health status of EU citizens.

The development cost and timelines in the field of health play a crucial role. In the pharmaceutical area, successful development of a new drug takes on average 10 to 15 years, far beyond the typical duration of projects seen e.g. in IMI2 JU (usually 4-6 years). The cost of development is, in most cases, shared between various funding sources, such as private investors and governments that complement various phases of product development pathway⁶. While the success of drug development process is variable between areas, such as oncology versus infectious disease vaccine development⁷, a common feature is that the cost of failures needs to be factored in the cost (and ultimately, market price) of products that will successfully enter the market.⁸.

Furthermore, the funding made available by this initiative can only make a partial contribution to the important development costs of medical interventions. A recent independent analysis demonstrates that (after accounting for the costs of failed trials) the median capitalized R&D investment to bring a new drug to market was estimated at approx. USD 985 million (mean investment approx. USD 1.3 billion). The figures vary greatly between therapeutic areas: median between USD 765.9 million for nervous system agents and USD 2.7 billion for antineoplastic and immunomodulating agents. Earlier estimates – based on different type of input data – suggested that out-of-pocket cost per approved new drug reached approx. USD 1.4 billion (2013), with fully capitalised costs reaching approx. USD 2.6 billion ¹⁰.

This analysis gets inevitably more complex in the case of a cross-sector partnership such as IHI that will bring together the several technology sectors: medical devices, pharmaceuticals, biotechnology, imaging and vaccines. Indeed, it is expected that the majority – if not all – projects funded under IHI will operate in the thematic areas of two or more sectors. Moreover, various sectors have varying development timelines and disparate definitions of pre-competitive space, where this partnership actually intends to intervene. The combination products (such as e.g. diagnostics + treatment) that could result from the partnership in the long term, would also reflect these underlying complexities.

The direct monetary benefit for citizens cannot be quantified, either, because the status of health is influenced by numerous factors, such as e.g. income and social status, education, environment, social support networks, genetic factors, the place where one lives, access to

⁶ Chakravarthy R et al (2016) Public- and private-sector contributions to the research and development of the most transformational drugs in the past 25 years. Therapeutic Innovation and Regulatory Science, 50(6) 759-768. http://dx.doi.org/10.1177/2168479016648730

⁷ Wong CH, Siah KW and Lo AW (2018) Estimation of clinical trial success rates and related parameters. Biostatistics (February) 1-14. http://dx.doi.org/10.1093/biostatistics/kxx069

⁸ OECD (2018), Pharmaceutical Innovation and Access to Medicines, OECD Health Policy Studies, OECD Publishing, Paris. https://doi.org/10.1787/9789264307391-en

⁹ Wouters OJ, McKee M, Luyten J (2020): Estimated R&D investment needed to bring a new medicine to market, 2009-2018. JAMA. 323(9) 844-853. doi:10.1001/jama.2020.1166 https://jamanetwork.com/journals/jama/fullarticle/2762311

¹⁰ DiMasi JA et al (2016): Innovation in the pharmaceutical industry: New estimates of R&D costs, Journal of Health Economics 47, pp. 20-23.

health care services and many others¹¹. Majority of these factors are beyond the control of any funding initiative, including this one.

For all these reasons, the ensuing analysis will provide a qualitative assessment and some estimates, while refraining from computing potential gains or loss values, as these would be based on too many assumptions to warrant credibility.

I. Overview of Benefits (total for all provisions) – Preferred Option						
Description	Estimation	Comments				
Direct benefits						
Strengthened EU skills and capacity in academic and industrial health research and innovation	New scientific paradigms, new high-impact publications ¹² .					
EU-wide cross-sectoral health research and innovation ecosystem created	Easier interactions between potential new collaborators: across stakeholder types (e.g industry with academia, SMEs with large industry) and across sectors (e.g. pharma with medtech). A neutral platform created for interactions between academia, industry, end-users and regulators.					
New scientific paradigms established providing the foundation for innovative health technologies	New health solutions (e.g. drugs, diagnostics, combination products) available to citizens. Potential new business opportunities for industry, incl. SMEs	Potential new solutions might be entering the market in the future, thus changing the competitive position of companies, incl. SMEs.				
Indirect benefits						
More productive and globally competitive EU health industries that create jobs and growth	Positive impacts on European economy, including access to new markets for companies.	Potential salary increase for highly-skilled jobs and/or increase of high-salary employment in health sectors.				
Better, safe, effective and cost-effective health technologies, tools and digital solutions for health	EU citizens will benefit.	Companies may need to adapt to changing landscape and new business models.				
Increased level of public and private investments into strategic unmet public health	EU citizens will benefit.	For companies, need to adapt to new business models and areas.				

¹¹ https://www.who.int/hia/evidence/doh/en/
The citation impact (which measures how many times a paper is cited in subsequent papers) for all IMI papers is 2.03 (compared to 1.14 for the EU and the baseline of 1 for the world). https://www.imi.europa.eu/sites/default/files/news/Brochure ResultsImpact.pdf

needs		
Improved health outcomes and wellbeing in priority disease areas (SDG3)	EU citizens will benefit.	Health care systems might need to shift focus from treatment to prevention.
Reduced health inequalities and improved access to high quality health care in priority disease areas (SDG 10)	EU citizens will benefit.	For companies, need to adapt to new business models and areas.
Reduced need for travel impacting on climate (SDG 13)	EU citizens will benefit.	Lowered revenues for certain enterprises active in the travel sector.

(1) Estimates are relative to the baseline for the preferred option as a whole (i.e. the impact of individual actions/obligations of the <u>preferred</u> option are aggregated together); (2) Please indicate which stakeholder group is the main recipient of the benefit in the comment section; (3) For reductions in regulatory costs, please describe details as to how the saving arises (e.g. reductions in compliance costs, administrative costs, regulatory charges, enforcement costs, etc.; see section 6 of the attached guidance).

II. Overview of costs – Preferred option							
		Citizens/Consumers		Businesses		Administrations	
		One- off	Recurrent	One-off	Recurrent	One-off	Recurrent
Management/ Administrative costs	Direct costs						EUR 4,7 million ¹³
	Indirect costs						
Personnel costs	Direct costs						EUR 6.3 million ¹⁴ to cover the cost of 56 staff
	Indirect						

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¹³ Figure for IMI2 JU in 2019, based on IMI2 JU Annual Activity Report 2019, Title 2 expenditure. Under IMI2 JU, this amount is covered jointly by the EU and by the private JU Member. This value is given as illustration only since the administrative/personnel costs of IHI will depend several factors, including the total budget of the initiative, organisation of the programme office and the number of staff.

¹⁴ Figure for IMI2 JU in 2019, based on IMI2 JU Annual Activity Report 2019, Title 1 expenditure. Under IMI2 JU, this amount is covered jointly by the EU and by the private JU Member. This value is given as illustration only since the administrative/personnel costs of IHI will depend several factors, including the total budget of the initiative, organisation of the programme office and the number of staff.

(1) Estimates to be provided with respect to the baseline; (2) costs are provided for each identifiable action/obligation of the <u>preferred</u> option otherwise for all retained options when no preferred option is specified; (3) If relevant and available, please present information on costs according to the standard typology of costs (compliance costs, regulatory charges, hassle costs, administrative costs, enforcement costs, indirect costs; see section 6 of the attached guidance).

All these individual costs and benefits are likely to contribute to, or even trigger, changes in the health care systems. For individual citizens, this could mean that the health care will shift from disease/incident-based treatments to more holistic care throughout the lifetime.

REFIT Cost savings table

Not applicable for the proposed Innovative Health partnership. The initiative will build on the existing implementation structure (the Programme Office) already in place for IMI2 JU. There are no additional regulatory costs associated, and no specific simplification measures apply in this case.

Annex 4 Analytical Methods

The methodology for each impact assessment is based on the Commission Better Regulation Guidelines¹⁵ to evaluate and compare options with regards to their **efficiency**, **effectiveness** and **coherence**. This is complemented by integrating the **conditions and selection criteria** for European Partnerships, as well as requirements for setting up Institutionalised Partnerships.¹⁶

1. OVERVIEW OF THE METHODOLOGIES EMPLOYED

In terms of **methods and evidence used**, the set of impact assessments for all candidate Institutionalised European Partnerships draw on an external study covering all initiatives in parallel to ensure a high level of coherence and comparability of analysis ¹⁷ (Technopolis Group, 2020).

All impact assessment mobilised a mix of qualitative and quantitative data collection and analysis methods. These methods range from desk research and interviews to the analysis of the responses to the Open Consultation, stakeholder analysis and composition/portfolio analysis, bibliometrics/patent analysis and social network analysis, and a cost-effectiveness analysis.

The first step in the impact assessment studies consisted in the definition of the context and the problems that the candidate partnerships are expected to solve in the medium term or long run. The main data source in this respect was desk research. This includes grey and academic literature to identify the main challenges in the scientific and technologic fields and in the economic sectors relevant for the candidate partnerships, as well as the review of official documentations on the policy context for each initiative.

In the assessment of the problems to address, the lessons to be learned from past and ongoing partnerships were taken into account, especially from relevant midterm or ex-post evaluations.

The description of the context of the candidate Institutionalised European Partnerships required a good understanding of the corresponding research and innovation systems and their outputs already measured. Data on past and ongoing Horizon 2020 projects, including the ones implemented through Partnerships, served as basis for descriptive statistic of the numbers of projects and their respective levels of funding, the type of organisations participating (e.g. universities, RTOs, large enterprises, SMEs, public administrations, NGOs, etc.) and how the funding was distributed across them. Special attention was given to analysing the participating countries (and groups of countries, such as EU, Associated Countries, EU13 or EU15) and industrial sectors, where relevant. The sectoral analysis required enriching the eCORDA data received from the European Commission services with sector information extracted from ORBIS, using the NACE codification up to level 2. These data enabled the identification of the main and, where possible, emerging actors in the

¹⁶ A pivotal element of the present analysis is the so-called two-step 'necessity test' for European Partnerships, used to establish: step 1) the need for a partnership approach in the first place, followed by step 2) a justification for the form of Institutionalised Partnership. The necessity test is described in Annex 6. This impact assessment focuses on the second step of the test.

¹⁵ European Commission (2017), Better Regulation Guidelines (SWD (2017) 350)

¹⁷ Technopolis Group (2020), Impact Assessment Study for Institutionalised European Partnerships under Horizon Europe

relevant systems, i.e. the organisations, countries and sectors that would need to be involved (further) in a new initiative.

A Social Network Analysis was performed by the contractors using the same data. It consisted in mapping the collaboration between the participants in the projects funded under the ongoing R&I partnerships. This analysis revealed which actors – broken down per type of stakeholders or per industrial sector – collaborate the most often together, and those that are therefore the most central to the relevant research and innovation systems.

The data provided finally served a bibliometric analysis run by the contractor aimed at measuring the outputs (patents and scientific publications) of the currently EU-funded research and innovation projects. A complementary analysis of the Scopus data enabled to determine the position and excellence of the European Union on the international scene, and identify who its main competitors are, and whether the European research and innovation is leading, following or lagging behind.

A cost modelling exercise was performed in order to feed into the efficiency assessments of the partnership options.

The conclusions drawn from the data analysis were confronted to the views of experts and stakeholders collected via three means:

- The comments to the inception impact assessments of the individual candidate institutionalised European Partnerships;
- The open public consultation organised by the European Commission from September to November 2019;
- The interviews (up to 50) conducted by each impact assessment study team conducted between August 2019 and January 2020 (policymakers, business including SMEs and business associations, research institutes and universities, and civil organisations, among others).

The views of stakeholders (and experts) were particularly important for determining the basic functionalities (see further below) that the future partnerships need to demonstrate to achieve their objectives as well as their most anticipated scientific, economic and technological, and societal impacts. The interviews allowed more flexibility to ask the respondents to reflect about the different types of European Partnerships. Furthermore, as a method for targeted consultation, it was used to get insights from the actors that both the Study Teams and the European Commission were deemed the most relevant. For the comparative assessment of impacts, the external contractors confronted the outcomes of the different stakeholder consultation exercises to each other with a view of increasing the validity of their conclusions, in line with the principles of triangulation.

Annex 2 includes also the main outcomes of the stakeholder consultation exercises.

2. METHOD FOR ASSESSING THE EFFECTIVENESS, EFFICIENCY AND COHERENCE OF EACH OPTION - THE USE OF FUNCTIONALITIES

Given the focus of the impact assessment on comparing different forms of implementation, the Better Regulation framework has been adapted to introduce "functionalities". These are

used to reflect what is needed in terms of implementation for each candidate initiative to be able to deliver on its objectives. The functionalities are the **distinguishing factors** between the different options and are directly linked to the European Partnerships' selection criteria of openness and transparency, additionality and directionality (see Annex 6). Based on the objectives identified and the targeted impact, functionalities describe what this requires in terms of implementation. Each form of implementation is then assessed to establish to which degree it would allow for these functionalities to be covered, e.g. the type and composition of actors that can be involved ('openness'), the range of activities that can be performed (including additionality and level of integration), the level of directionality and integration of stakeholders' R&I strategies¹⁸; the possibilities offered for coherence and synergies with other components of Horizon Europe, including other Partnerships (internal coherence), and the coherence with other EU, national or regional policy environments, including with the relevant regulatory and standardisation framework (external coherence). This approach guides the identification of discarded options and allows a structured comparison of the options against the selection criteria for European Partnerships.

Figure 1. Overview of key functionalities of each form of implementation of European Partnerships

Baseline: Horizon Europe calls	Option 1: Co- programmed	Option 2: Co- funded	Option 3.1: Institutionalised Article 185	Option 3.2: Institutionalised Article 187
Type and compositi	on of actors (including	openness and roles)		
Partners: N.A., no common set of actors that engage in planning and implementation Priority setting: open to all, part of Horizon Europe Strategic planning Participation in R&I activities: fully open in line with standard Horizon Europe rules	Partners: Suitable for all types: private and/or public partners, foundations Priority setting: Driven by partners, open stakeholder consultation, MS in comitology Participation in R&I activities: fully open in line with standard Horizon Europe rules	Partners: core of national funding bodies or governmental research organisations Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: limited, according to national rules of partner countries	Partners: National funding bodies or governmental research organisation Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: fully open in line with standard Horizon Europe rules, but possible derogations	Partners: Suitable for all types: private and/or public partners, foundations Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: fully open in line with standard Horizon Europe rules, but possible derogations
Type and range of a	nctivities (including add	itionality and level of	integration)	
Activities: Horizon Europe standards that allow broad range of individual actions Additionality: no additional activities and investments outside the funded	Activities: Horizon Europe standard actions that allow broad range of individual actions, support to market, regulatory or policy/ societal uptake Additionality: Activities/investment	Activities: Broad, according to rules/programmes of participating States, State-aid rules, support to regulatory or policy/ societal uptake Additionality:	Activities: Horizon Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to systemic approach	Activities: Horizon Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to systemic approach (portfolios of

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¹⁸ The criterion on the ex-ante demonstration of partners' long term commitment depends on a series of factors that are unknown at this stage, and thus fall outside the scope of the analysis.

Baseline: Horizon Europe calls	Option 1: Co- programmed	Option 2: Co- funded	Option 3.1: Institutionalised Article 185	Option 3.2: Institutionalised Article 187
projects <u>Limitations:</u> No systemic approach beyond individual actions	s of partners, National funding Limitations: Limited systemic approach beyond individual actions.	National funding <u>Limitations:</u> Scale and scope depend on the participating programmes, often smaller in scale	Additionality: National funding	projects, scaling up of results, synergies with other funds. Additionality: Activities/investments of partners/ national funding
Directionality				
Priority setting: Strategic Plan and annual work programmes, covering max. 4 years. Limitations: Fully taking into account existing or to be developed SRIA/ roadmap	Priority setting: Strategic R&I agenda/ roadmap agreed between partners and COM, covering usually 7 years, including allocation of Union contribution Input to FP annual work programme drafted by partners, finalised by COM (comitology) Objectives and commitments are set in the contractual arrangement.	Priority setting: Strategic R&I agenda/ roadmap agreed between partners and COM, covering usually 7 years, including allocation of Union contribution Annual work programme drafted by partners, approved by COM Objectives and commitments are set in the Grant Agreement.	Priority setting: Strategic R&I agenda/ roadmap agreed between partners and COM, covering usually 7 years, including allocation of Union contribution Annual work programme drafted by partners, approved by COM Objectives and commitments are set in the legal base.	Priority setting: Strategic R&I agenda/ roadmap agreed between partners and COM, covering usually 7 years, including allocation of Union contribution Annual work programme drafted by partners, approved by COM (veto-right in governance) Objectives and commitments are set in the legal base.
Coherence: internal industrial strategies	l (Horizon Europe) and ()	external (other Union	programmes, national	programmes,
Internal: Between different parts of the Annual Work programme can be ensured by COM External: Limited for other Union programmes, no synergies with national/regional programmes and activities	Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Limited synergies with other Union programmes and industrial strategies If MS participate, with national/regional programmes and activities	Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Synergies with national/regional programmes and activities	Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Synergies with national/regional programmes and activities	Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Synergies with other Union programmes and industrial strategies If MS participate, with national/regional programmes and activities

On the basis of the evidence collected, the thematic impact assessments evaluate the effectiveness of the various policy options along three dimensions corresponding to the

different categories of likely impacts: scientific, economic and technological, and societal (including environmental). Each impact assessment considers to which extent the different policy options fulfil the desirable 'functionalities' and are therefore likely to produce the targeted impacts. In addition, where specific impacts (e.g. on fundamental rights) are relevant for a candidate Partnership, these are assessed in the corresponding report and according to the Better Regulation Guidelines and Toolbox. This analysis results in a scoring of the policy options with a three-point scale. Scores vary from + to +++, where + refers to low potential for reaching the likely impacts, ++ to a good potential, and +++ to a high potential. The effectiveness assessment of the different options does not use a compound score but concludes on as many scores as there are expected impacts. This is done to increase transparency and accuracy in the assessment of options. Qualitative and quantitative evidence is provided to motivate each score.

A similar approach is followed to evaluate the coherence of options with the overarching objectives of the EU's R&I policy, and distinguishes between **internal** and **external coherence**. Specifically, internal coherence corresponds to the consistency between a given implementation mode and the other actions under Horizon Europe. External coherence refers instead to the alignment with other initiatives at EU, national and international level beyond Horizon Europe that are relevant to a thematic area. Each option (implementation mode) is assessed following a three-point qualitative scale.

To compare the expected costs and benefits of each option (efficiency), the thematic impact assessments broadly follow a cost-effectiveness approach 19 to establish to which extent the intended objectives can be achieved for a given cost. A preliminary step in this process is to obtain a measure of the expected costs of the policy options, to be used in the thematic assessments. As the options correspond to different implementation modes, relevant cost categories generally include the costs of setting-up and running an initiative. For instance, set-up costs includes items such as the preparation of a European Partnership proposal and the preparation of an implementation structure. The running costs include the annual work programme preparation costs. Where a Partnership already exists, discontinuation costs and cost-savings are also taken into account²⁰. The table below provides an overview of the cost categories used in the impact assessment and a qualitative scoring of their intensity when compared to the baseline option (traditional calls). Providing a monetised value for these average static costs would have been misleading, because of the different features and needs of each candidate initiative. ²¹ The table shows the overall administrative, operational and coordination costs of the various options. These costs are then put into context in the impact assessments to reflect the expected co-financing rates and the total budget available for each of the policy options, assuming a common Union contribution (cost-efficiency):

The costs related to the baseline scenario (traditional calls under Horizon Europe) are
pre-dominantly the costs of implementing the respective Union contribution via calls
and project, managed by the executive agencies (around 4%, efficiency of 96% for

¹⁹ For further details, see Better Regulation Toolbox # 57.

²⁰ Discontinuation costs will bear winding down and social discontinuation costs and vary depending on e.g. the number of full-time-equivalent (FTEs) staff concerned, the type of contract (staff category and duration) and applicable rules on termination (e.g. contracts under Belgian law or other). If buildings are being rented, the cost of rental termination also apply. As rental contracts are normally tied to the expected duration of the current initiatives, these termination costs are likely to be very limited. In parallel, there would also be financial cost-savings related to the closing of the structure, related to operations, staff and coordination costs in particular. This is developed further in the individual efficiency assessments.

A complete presentation of the methodology developed to assess costs as well as the sources used is described in the external study supporting this impact assessment (Technopolis Group, 2020).

- the overall investment).
- For a Co-Programmed partnership the costs of preparation and implementation increase only marginally compared to the baseline (<1%), ²² but lead to an additional R&I investment of at least the same amount than the Union contribution ²³ (efficiency of 98% for the overall investment).
- For a Co-Funded partnership the additional R&I investment by Member States accounts for 2,3 times the Union contribution²⁴. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the national programmes, can be estimated at 6% of the Union contribution (efficiency of 98% related to the overall investment).²⁵
- For an Article 185 initiative the additional R&I investment by Member States is equal to the Union contribution²⁶. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the dedicated implementation structure, can be estimated at 7% of the Union contribution (efficiency of 96% related to the overall investment).
- For an Article 187 initiative the additional R&I investment by partners is equal to the Union contribution²⁷. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the dedicated implementation structure, can be estimated at 9% of the Union contribution (efficiency of 94% related to the overall investment).

Figure 2 - Intensity of additional costs compared with Horizon Europe Calls (for Partners, stakeholders, public and EU)

Cost items	Baseline: traditional calls	Option 1: Coprogrammed	Option 2 Co-funded	Option 3a - Art. 185	Option 3b -Art. 187
Preparation and set-up costs					
Preparation of a partnership proposal (partners and EC)	0		$\uparrow \uparrow$		
Set-up of a dedicated implementation structure		0		Existing: ↑ New: ↑↑	Existing: ↑↑ New: ↑↑↑
Preparation of the SRIA / roadmap	0		$\uparrow \uparrow$		
Ex-ante Impact Assessment for partnership		0		$\uparrow \uparrow$	↑
Preparation of EC proposal and negotiation		0		$\uparrow \uparrow$	↑
Running costs (Annual cycle of implementation)					
Annual Work Programme preparation	0		↑		

²² Specifically, some additional set-up costs linked for example to the creation of a strategic research and innovation agenda (SRIA) and additional running costs linked with the partners role in the creation of the annual work programmes and the Commission's additional supervisory responsibilities. A CPP will have lower overall costs than each of the other types of European Partnership, as it will function with a smaller governance and implementation structure than will be required for a Co-Funded Partnership or an Institutionalised Partnership and – related to this – its calls will be operated through the existing HEU agencies and RDI infrastructure and systems.

²³ Minimum contributions from partners equal to the Union contribution.

²⁴ Based on the default funding rate for programme co-fund actions of 30%, partners contribute with 70% of the total investment.

²⁵ These costs reflect set-up costs and additional running costs for partners, and the Commission, of the distributed, multi-agency implementation model.

²⁶ Based on the minimum requirement in the legal basis that partners contribute at least 50% of the budget.

²⁷ Based on the minimum requirement in the legal basis that partners contribute at least 50% of the budget.

Cost items	Baseline: traditional calls	Option 1: Coprogrammed	Option 2 Co-funded	Option 3a - Art. 185	Option 3b -Art. 187
Call and project implementation	0	0 In case of MS contributions: ↑	1	↑	↑
Cost to applicants	Comparable, unless there are strong arguments of major differences is oversubscription			fferences in	
Partners costs not covered by the above	0	↑	0	↑	↑
Additional EC costs (e.g. supervision)	0	\uparrow	↑	↑	$\uparrow \uparrow$
Winding down costs					
EC		0			$\uparrow\uparrow\uparrow$
Partners	0	↑	0	↑	↑

Notes: 0: no additional costs, as compared with the baseline; \uparrow : minor additional costs, as compared with the baseline; $\uparrow \uparrow$: medium additional costs, as compared with the baseline; $\uparrow \uparrow \uparrow$: higher costs, as compared with the baseline.

The cost categories estimated for the common model are then used to develop a scorecard analysis and further refine the assessment of options for each of the 12 candidate Institutionalised Partnerships. Specifically, the scores related to the set-up and implementation costs are used in the thematic impact assessments to consider the scale of the expected benefits and thereby allow a simple "value for money" analysis (**cost-effectiveness**). In carrying out the scoring of options, the results of fieldwork, desk research and stakeholder consultation undertaken and taken into account.

3. METHOD FOR IDENTIFYING THE PREFERRED OPTION – THE SCORECARD ANALYSIS

For the **identification of the preferred option**, a scorecard analysis is used to build a hierarchy of the options by individual criterion and overall in order to identify a single preferred policy option or in case of an inconclusive comparison of options, a number of 'retained' options or hybrid. This exercise supports the systematic appraisal of alternative options across multiple types of monetary, non-monetary and qualitative dimensions. It also allows for easy visualisation of the pros and cons of each option. Each option is attributed a score of the adjudged performance against each criterion with the three broad appraisal dimensions of effectiveness, efficiency and coherence.

This scorecard approach also relies on a standard cost model developed for the external study supporting the impact assessment, as illustrated in Figure 3. Specifically, the scores related to the set-up and implementation costs are used in the thematic impact assessments to consider the scale of the expected benefits and thereby allow a simple "value for money" analysis (**cost-effectiveness**). In carrying out the scoring of options, the results of fieldwork, desk research and stakeholder consultation undertaken and taken into account.

These costs essentially refer to the administrative, operational and coordination costs of the various options. The figure shows how the scoring of costs range from a value of 0, in case an option does not entail any additional costs compared to the baseline (traditional calls), to a score of (-) for options introducing limited additional costs relative to the baseline and a score of (-) when substantial additional costs are expected in comparison with the baseline. Should the costs of a policy option be lower than those of the baseline, (+) and (+ +) are used

It is considered that while there is a clear gradation in the overall costs of the policy options, the cost differentials are less marked when one takes into account the expected co-financing rates and the total budget available for each of the policy options, assuming a common

Union contribution. From this perspective, there are only one or two percentage points that split the most cost-efficient policy options – the baseline (traditional calls) and the Co-Programmed policy options – and the least cost-efficient – the Institutionalised Partnership option. A score of + is therefore assigned for **cost-efficiency** to the Co-Programmed and Co-Funded options, a score of 0 to the Article 185 option and a score of (-) for the Article 187 Institutionalised Partnership policy option²⁸.

Figure 3: Matrix on 'overall costs' and 'adjusted cost scoring'

	Baseline: Horizon Europe calls	Option 1: Co- programmed	Option 2: Co- funded	Option 3a: Institutionalised 185	Option 3b: Institutionalised 187
Administrative, operational and coordination costs	0	(0)	(-)	()	()
Administrative, operational and coordination costs adjusted per expected co-funding (i.e. cost- efficiency)	0	(+)	(+)	(0)	(-)

Notes: Score 0 = same costs as for the baseline; score (-) = limited additional costs compared to baseline; score (-) = substantial additional costs compared to baseline.; score (+) = lower costs compared to baseline

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²⁸ The baseline (traditional calls) is scored 0, as explained above.

Annex 5 Subsidiarity Grid

1. Can the Union act? What is the legal basis and competence of the Unions' intended action?

1.1 Which article(s) of the Treaty are used to support the legislative proposal or policy initiative?

This proposal is based on (1) Article 185 TFEU which stipulates that in implementing the multiannual framework programme, the Union may make provision, in agreement with the Member States concerned, for participation in research and development programmes undertaken by several Member States, including participation in the structures created for the execution of those programmes; and (2) Article 187 TFEU according to which the Union may set up joint undertakings or any other structure necessary for the efficient execution of Union research, technological development and demonstration programmes (both Articles are under Title XIX of the TFEU - Research and Technological Development and Space).

The proposal aims to implement Article 8 of the Commission proposal for Horizon Europe the future EU research and innovation (R&I) programme for 2021-2027, according to which, "European Partnerships shall be established for addressing European or global challenges only in cases where they will more effectively achieve objectives of Horizon Europe than the Union alone and when compared to other forms of support of the Framework programme". The Horizon Europe proposal has received the political agreement of the Council and the European Parliament.

1.2 Is the Union competence represented by this Treaty article exclusive, shared or supporting in nature?

Research is a shared competence between the EU and its Member States according to the TFEU. Article 4 (3) specifies that in the areas of research, technological development and space, the European Union can carry out specific activities, including defining and implementing programmes, without prejudice to the Member States' freedom to act in the same areas.

Subsidiarity does not apply for policy areas where the Union has **exclusive** competence as defined in Article 3 TFEU²⁹. It is the specific legal basis which determines whether the proposal falls under the subsidiarity control mechanism. Article 4 TFEU³⁰ sets out the areas where competence is shared between the Union and the Member States. Article 6 TFEU³¹ sets out the areas for which the Unions has competence only to support the actions of the Member States.

2. Subsidiarity Principle: Why should the EU act?

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https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12008E004&from=EN https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12008E006:EN:HTML

2.1 Does the proposal fulfil the procedural requirements of Protocol No. 2³²:

- Has there been a wide consultation before proposing the act?
- Is there a detailed statement with qualitative and, where possible, quantitative indicators allowing an appraisal of whether the action can best be achieved at Union level?

This proposal and the accompanying impact assessment were supported by a wide consultation of stakeholders, both during the preparation of the Horizon Europe proposal and - later on, all the candidates for European Partnerships. Member States were consulted via the Shadow Strategic configuration of the Horizon Europe Programme Committee. On candidates for institutionalised Partnerships based on Article 185/187 of the TFEU, an Open Public Consultation (OPC) was held between 11 September and 6 November 2019. Over 1 600 replies were received. In addition, targeted consultation activities were undertaken to prepare the present impact assessment. In particular, for each of the candidate partnerships, an external consultant interviewed a representative sample of stakeholders. The need for EU action as well as its added value were covered in those interviews.

The explanatory memorandum and the impact assessment (horizontal part, Section 3) contain a dedicated section on the principle of subsidiarity, as explained in question 2.2 below.

2.2 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the conformity with the principle of subsidiarity?

The impact assessment accompanying the proposal features a horizontal part on relevant common elements to all the candidate partnerships, including the conformity of the proposed initiative with the principle of subsidiarity (Section 3). Moreover, the individual assessments of each candidate partnership include additional details on subsidiarity, touching in particular on the specificities of a candidate partnership that could not be adequately reflected in the horizontal part of the impact assessment. This will also be reflected in the explanatory memorandum.

2.3 Based on the answers to the questions below, can the objectives of the proposed action be achieved sufficiently by the Member States acting alone (necessity for EU action)?

National action alone cannot achieve the scale, speed and scope of support to R&I needed for the EU to meet its long-term Treaty objectives, to deliver on the EU's strategic policy priorities (including the climate and energy goals set out in the Paris Agreement, and the European Green Deal), and to contribute to tackling global challenges and meeting the Sustainable Development Goals (SDGs).

³² https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12016E/PRO/02&from=EN

(a) Are there significant/appreciable transnational/cross-border aspects to the problems being tackled? Have these been quantified?

The thematic areas covered by the candidate partnerships feature a series of challenges in terms of cross-border/transnational aspects, need to pool resources, need for a critical mass to meet intended policy objectives, need to coordinate different types of actors (e.g. academia, industry, national and regional authorities) across different sectors of the economy and society, which cannot be tackled to the same degree by Member States alone. This is particularly true for the research and innovation (R&I) dimension of the proposed initiative: the importance of a multi-centre and interdisciplinary approach, cross-country data collection and research, and the need to develop and share new knowledge in a timely and coordinated manner to avoid duplication of efforts are key to achieve high quality results and impact. The Interim Evaluation of Horizon 2020 and the impact assessment of Horizon Europe provide extensive qualitative and quantitative evidence on the above points. In addition, Sections 1 and 2 of the individual impact assessments on the candidate partnerships include more detail on the necessity to act at EU-level in specific thematic areas. Finally, it is worth noting that not all Member States have the same capacity or R&I intensity to act on these challenges. As the desired policy objectives can be fully achieved only if the intended benefits are widespread across the Member States, this requires action at the EU-level.

(b) Would national action or the absence of the EU level action conflict with core objectives of the Treaty³³ or significantly damage the interests of other Member States?

As per Article 4(3) TFEU, national action does not conflict with core objectives of the Treaty in the area of R&I. The absence of EU level action in this area would however prevent the achievement of core objectives of the Treaty. Indeed, national action alone cannot achieve the scale, speed and scope of support to R&I needed for the EU to meet its long-term Treaty objectives on e.g. competitiveness, to deliver on the EU's strategic policy priorities, and to contribute to tackling global challenges and meet the Sustainable Development Goals (SDGs).

(c) To what extent do Member States have the ability or possibility to enact appropriate measures?

As foreseen by Article 4(3) TFEU, this proposal does not hamper Member States' ability to enact appropriate measures in the field of R&I. However, the scale and complexity of the policy objectives pursued by the present initiative cannot be fully addressed by acting at national level alone.

(d) How does the problem and its causes (e.g. negative externalities, spill-over effects) vary across the national, regional and local levels of the EU?

^{33 &}lt;u>https://europa.eu/european-union/about-eu/eu-in-brief_en</u>

As described in the horizontal part of the impact assessment accompanying the present proposal, several problems (e.g. on competitiveness, global challenges, demographic change) and their underlying causes affect the EU as a whole rather than individual Member States. Where important differences between Member States are present, these are described in Sections 1 and 2 of the individual impact assessments.

(e) Is the problem widespread across the EU or limited to a few Member States?

The problem of coordinating R&I efforts in the thematic areas covered by the candidate partnerships affects all Member States, albeit to different degrees. However, from a general EU perspective, available evidence shows that the EU as a whole needs to step up efforts and investments in thematic areas that are crucial to tackle present and future policy challenges on several fronts, e.g. ageing population, global technological trends, and climate change to name a few. The way these problems affect the EU and its Member States is described in the horizontal part of the impact assessment and in Sections 1 and 2 of the individual impact assessments.

(f) Are Member States overstretched in achieving the objectives of the planned measure?

As indicated in the horizontal part of the impact assessment and in Sections 1 and 2 of the individual assessments, the sheer scale, speed and scope of the needed support to R&I would overstretch national resources, without guaranteeing the achievement of the intended objectives. Acting at EU-level would achieve greater impact in a more effective and efficient manner.

(g) How do the views/preferred courses of action of national, regional and local authorities differ across the EU?

No specific differences between the views of national, regional and local authorities emerged from the stakeholder consultation.

2.4 Based on the answer to the questions below, can the objectives of the proposed action be better achieved at Union level by reason of scale or effects of that action (EU added value)?

EU funded R&I activities, including those covered by the present proposal, produce demonstrable benefits compared to the corresponding national and regional initiatives, due to the scale, speed and scope achievable by acting at the EU level. In addition, the proposed initiatives should be seen as complementary and reinforcing national and sub-national initiatives in the same area.

(a) Are there clear benefits from EU level action?

Quantitative and qualitative evidence of the benefits of EU level action are available in the interim evaluation of Horizon 2020 and in the impact assessment of Horizon Europe, among others. An analysis of the emerging challenges in each thematic areas, of the EU's competitive positioning, as well as feedback gathered from different types of stakeholders for the present impact assessment indicate that EU level action remains appropriate also for the present proposal. In addition, the benefits of acting at EU-level have been illustrated by the success and the impact achieved by the predecessors to the proposed initiative.

(b) Are there economies of scale? Can the objectives be met more efficiently at EU level (larger benefits per unit cost)? Will the functioning of the internal market be improved?

EU funded R&I activities, including those covered by the present proposal, produce demonstrable benefits compared to the corresponding national and regional initiatives, due to the scale, speed and scope achievable by acting at the EU level. This is the case both in terms of effectiveness in achieving intended policy objectives, but also in terms of efficiency. Positive impact is also visible in terms of competitiveness: recent data on EU funded R&I activities indicate that EU-funded teams grow 11.8% faster and are around 40% more likely to be granted patents or produce patents applications than non-EU funded teams. Efficiency gains are also visible in terms of dissemination of results to users beyond national borders, including SMEs and citizens. EU funded R&I is more effective in leveraging private investment. Finally, there are clear additionality benefits (i.e. EU R&I funding does not displace or replace national funding), as the EU focuses on projects that are unlikely to be funded at national or regional level. Overall, this is beneficial to the functioning of the internal market in several respects, including human capital reinforcement through mobility and training, the removal of barriers to cross-border activity for economic players including SMEs, easier access to finance and to relevant knowledge and research, and increased competition in the area of R&I.

(c) What are the benefits in replacing different national policies and rules with a more homogenous policy approach?

A homogeneous policy approach in the various thematic areas covered by the present proposal would reduce fragmentation and increase efficiency and effectiveness in meeting the intended policy objectives. Indeed fragmentation, persisting barriers in the internal market and differences in the resources available to Member States are some of the key problems that stand in the way of fully achieving the intended policy objectives and reaching the required critical mass to obtain tangible results. Specific detail on how these issues differ in each thematic area are illustrated in Sections 1 and 2 of the individual impact assessments, so as to reflect the specificities of each case.

(d) Do the benefits of EU-level action outweigh the loss of competence of the Member States and the local and regional authorities (beyond the costs and benefits of acting at national, regional and local levels)?

The proposed initiative does not lead to a loss of competence of the Member States. In fact,

the proposed initiative should be seen as complementary and reinforcing national and subnational initiatives in the same area. Previous quantitative and qualitative assessments of Horizon Europe and Horizon 2020 have shown that the proposed EU-level action do not displace national ones and tend to concentrate on initiatives that would not have been funded by the Member States themselves, or would not have reached the same scale and ambition without EU-level intervention, due to their complexity and trans-national nature.

(e) Will there be improved legal clarity for those having to implement the legislation?

Yes. The proposed initiatives will be implemented in line with the Horizon Europe single set of rules for participation; this will ensure increased clarity and legal certainty for end beneficiaries, other stakeholders and programme administrators. It will also reduce the administrative burden for beneficiaries, and for the Commission services. In addition, the accessibility and attractiveness of the broader Horizon Europe programme, in particular for applicants with limited resources, would be sustained.

3. Proportionality: How the EU should act

3.1 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the proportionality of the proposal and a statement allowing appraisal of the compliance of the proposal with the principle of proportionality?

The principle of proportionality underpins the entire analysis of the candidate partnerships. Specifically, the analysis included in the accompanying impact assessment is structured along the following logic: 1. Justification of the use of a partnership approach in a given area (including considerations on additionality, directionality, link with strategic priorities) instead of other forms of intervention available under Horizon Europe; 2. If the partnership approach is deemed appropriate, proportionality considerations guide the assessment of which type of partnership intervention (collaborative calls, co-programmed, co-funded or institutionalised partnership) is most effective in achieving the objectives. This will also be reflected in the explanatory memorandum.

3.2 Based on the answers to the questions below and information available from any impact assessment, the explanatory memorandum or other sources, is the proposed action an appropriate way to achieve the intended objectives?

The proposed initiative only focuses on areas where there is a demonstrable advantage in acting at the EU-level due to the scale, speed and scope of the efforts needed for the EU to meet its long-term Treaty objectives and deliver on its strategic policy priorities and commitments. In addition, the present proposal leaves full freedom to the Member States to pursue their own actions in the policy areas concerned. This will also be reflected in the explanatory memorandum.

(a) Is the initiative limited to those aspects that Member States cannot achieve

satisfactorily on their own, and where the Union can do better?

The proposed initiative only focuses on areas where there is a demonstrable advantage in acting at the EU-level due to the scale, speed and scope of the efforts needed for the EU to meet its long-term Treaty objectives and deliver on its strategic policy priorities and commitments.

(b) Is the form of Union action (choice of instrument) justified, as simple as possible, and coherent with the satisfactory achievement of, and ensuring compliance with the objectives pursued (e.g. choice between regulation, (framework) directive, recommendation, or alternative regulatory methods such as co-legislation, etc.)?

For each of the candidate partnerships, the analysis carried out in the accompanying impact assessment has explored several options for implementation. A comparative assessment of the merits of each option also included an analysis of the simplicity of the intervention, its proportionality and effectiveness in achieving the intended objectives. This is reflected in the fact that a tailored approach has been suggested for each candidate partnership, ranging from looser forms of cooperation to more institutionalised ones, depending on the intended policy objectives, specific challenges, and desired outcome identified in each case.

(c) Does the Union action leave as much scope for national decision as possible while achieving satisfactorily the objectives set? (e.g. is it possible to limit the European action to minimum standards or use a less stringent policy instrument or approach?)

The proposed approach leaves full freedom to the Member States to pursue their own actions in the policy areas covered by the present proposal.

(d) Does the initiative create financial or administrative cost for the Union, national governments, regional or local authorities, economic operators or citizens? Are these costs commensurate with the objective to be achieved?

The proposed initiatives do create financial and administrative costs for the Union, national governments and, depending on the chosen mode of implementation, for regional and local authorities. In addition, economic operators and other stakeholders potentially involved in the candidate partnerships will also incur some costs linked to implementation. The financial cost of the proposed initiative is covered under the Horizon Europe programme. Its exact amount is still subject to political decision. As regards the candidate partnerships and the different modes of implementation (co-programmed, co-funded, institutionalised), the relevant costs and benefits are assessed in the individual impact assessments covering each candidate partnership. The additional administrative costs of implementation via partnerships are limited, when compared to the administrative costs of implementation through traditional calls. As indicated by comparable experience with previous initiatives and in feedback provided by a variety of stakeholders, these costs are expected to be fully justified by the benefits expected from the proposed initiative. Where available, additional details on costs are provided in Annex 3 of the impact assessment.

(e) While respecting the Union law, have special circumstances applying in individual Member States been taken into account?

Where relevant, differences between Member States in capacity and stage of advancement of R&I in specific thematic areas have been taken into account in the individual impact assessments.



Brussels, 23.2.2021 SWD(2021) 37 final

PART 5/19

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT REPORT Accompanying the document

Proposal for a COUNCIL REGULATION establishing the Joint Undertakings under Horizon Europe

European Partnership on Innovative Health

{COM(2021) 87 final} - {SEC(2021) 100 final} - {SWD(2021) 38 final}

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Annex 6 Additional background information

1. BACKGROUND INFORMATION FOR ALL INITIATIVES

1.1. Selection criteria of European Partnerships

Partnerships based on Article 185 and 187 TFEU shall be implemented only where other parts of the Horizon Europe programme, including other forms of European Partnerships would not achieve the objectives or would not generate the necessary expected impacts, and if justified by a long-term perspective and high degree of integration. At the core of this impact assessment is therefore the need to demonstrate that the impacts generated through a Partnership approach go beyond what could be achieved with traditional calls under the Framework Programme – the Baseline Option. Secondly, it needs to assess if using the Institutionalised form of a Partnership is justified for addressing the priority.

The necessity test for a European Partnership (as set out in the Horizon Europe regulation) has two levels:

- 1. The justification for implementing a priority with a European Partnership to address Horizon Europe and EU priorities. This is linked to demonstrating that a European Partnership can produce added value beyond what can be achieved through other Framework Programme modalities, notably traditional calls in the work programmes (Option 0 Baseline).
- 2. The justification for the use of the form of Institutionalised Partnership: Once it has been demonstrated that a partnerships approach is justified, co-programmed and/or co-funded forms are considered for addressing the priorities as they are administratively lighter, more agile and easier to set-up (Options 1 and/or 2). As Institutionalised Partnerships require setting up a legal framework and the creation of a dedicated implementation structure, they have to justify higher set-up efforts by demonstrating that it will deliver the expected impacts in a more effective and efficient way, and that a long-term perspective and high degree of integration is required (Option 3).

The outcomes of the 'necessity test' is presented together with the preferred option.

Figure 1. Horizon Europe selection criteria for the European Partnerships

Common selection criteria & principles	Specifications
1. More effective	Delivering on global challenges and research and innovation objectives
(Union added value) clear impacts for the EU and	Securing EU competitiveness
its citizens	Securing sustainability
	Contributing to the strengthening of the European Research and Innovation Area
	Where relevant, contributing to international commitments
2. Coherence and synergies	Within the EU research and innovation landscape
	Coordination and complementarity with Union, local, regional, national and,

Common selection criteria & principles	Specifications
	where relevant, international initiatives or other partnerships and missions
3. Transparency and openness	Identification of priorities and objectives in terms of expected results and impacts
	Involvement of partners and stakeholders from across the entire value chain, from different sectors, backgrounds and disciplines, including international ones when relevant and not interfering with European competitiveness
	Clear modalities for promoting participation of SMEs and for disseminating and exploiting results, notably by SMEs, including through intermediary organisations
4. Additionality	Common strategic vision of the purpose of the European Partnership
and directionality	Approaches to ensure flexibility of implementation and to adjust to changing policy, societal and/or market needs, or scientific advances, to increase policy coherence between regional, national and EU level
	Demonstration of expected qualitative and significant quantitative leverage effects, including a method for the measurement of key performance indicators
	Exit-strategy and measures for phasing-out from the Programme
5. Long-term	A minimum share of public and/or private investments
commitment of all the involved parties	In the case of Institutionalised European Partnerships, established in accordance with article 185 or 187 TFEU, the financial and/or in-kind, contributions from partners other than the Union, will at least be equal to 50% and may reach up to 75% of the aggregated European Partnership budgetary commitments

1.2. Overview of potential functions for a common back office among Joint Undertakings

Functions	Current situation	Option of joint back-office	Comments
Organising calls for grant and proposal evaluations	Each JU organises this independently.	A central organisation of evaluation, logistics, contracting evaluators, managing the data of the evaluation results Central database of potential evaluators with domain expertise in thematic areas of partnerships	need to be supervised by the
Human Resources related matters	Each JU has own HR policy and resources Quite some resources spent on	More generic resources and expertise for HR matters	Ensuring consistency with EC HR policies is already in place

	recruitment in some JUs Some HR facilities are procured from external contractors Some JUs have a Service Level Agreement with COM for HR	More consistency in HR policy Shared HR investment for specialised expertise (IP and legal)	
Financial management	Each JU conducts own financial contract management; differences between JUs Each JU is audited separately. Auditing at project level more frequent than in other Horizon 2020 parts and outsourced by JUs thus differences ECA: too many audits on JUs	Financial management by one core team of financial staff Would reduce the number of interfaces for audits and simplifies the auditing of the all JUs Harmonisation of project auditing	Simplifies the harmonisation of financial management across JUs in line with Horizon Europe
Communication (internal and external)	Each JU has a separate communication strategies, teams and resources	A common back-office can support activities such as event organisation, dissemination of results, setting up website communication Can help create a more visible Partnership brand	A considerable share of communication activity is partnership specific (addressing particular target groups, synthesising project results) however there are generic communication activities that can be shared Needs to avoid duplication of efforts
Data management on calls, project portfolios, information on project results	Most JUs but not all use e- Corda for project data Overall IT integration of JUs still difficult	Harmonised data management Reduction of IT systems and support that is procured	This will need to happen regardless of the common back office but will likely be more smooth if managed centrally

2. BACKGROUND INFORMATION FOR THIS SPECIFIC INITIATIVE

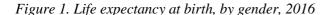
2.1. Health status in the EU and related main challenges

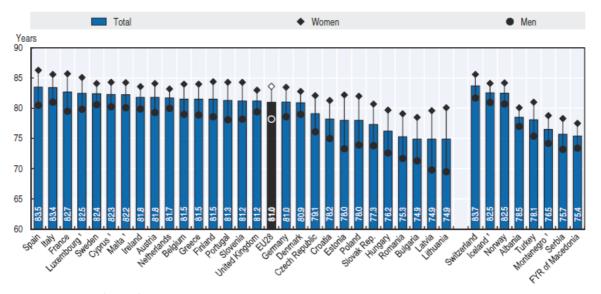
This Annex describes the health status of EU citizens based on the analysis provided in the most recent "Health at a Glance: Europe" report (2018)¹ developed by the Organisation for Economic Co-operation and Development (OECD) in cooperation with the European Commission. It includes recent trends in life expectancy, the main causes of death, health inequalities by gender and socioeconomic status, the occurrence of communicable and chronic diseases as well as the main challenges to improving the health of EU citizens.

HEALTH STATUS

Trends in life expectancy

Life expectancy² reaches 81 years on average across EU countries, exceeding 80 years in two-thirds of EU countries (Figure 1). Women live nearly 5 ½ longer than men although this gap has narrowed by one year since 2000. This gender gap is partly due to greater exposure to risk factors among men (tobacco consumption, excessive alcohol consumption and less healthy diet) resulting in higher death rates from heart diseases, various types of cancer and other diseases.





Three-year average (2014-16).
 Source: Eurostat Database.

Until recently, life expectancy was rising fairly rapidly and steadily across EU countries, but since 2011, the gains in life expectancy have slowed down markedly in several Western European countries, with even some reductions in certain years. This appears to have been driven by a slowdown in the rate of reduction of deaths from circulatory diseases and periodical increases in mortality rates among elderly people, due partly to bad flu seasons in some years. More than 80% of all deaths in the EU occur after the age of 65. The main cause of death for people under 65 is cancer, particularly among women (Eurostat, 2018).

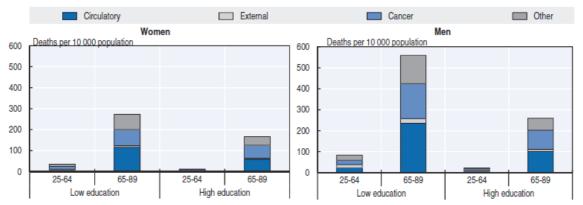
¹ https://ec.europa.eu/health/sites/health/files/state/docs/2018 healthatglance rep en.pdf

² Life expectancy measures the average number of remaining years of life for people at a specific age based on current mortality conditions

Inequalities in life expectancy

Large inequalities in life expectancy persist not only by gender but also by socioeconomic status. On average across EU countries, 30-year-old men with a low education level can expect to live about 8 years less than those with a university degree or the equivalent. The "education gap" among women is smaller, of about 4 years. This education gap in life expectancy is due to higher mortality rates among the least educated at different ages (Figure 2). A substantial part of the education gap in mortality is due to higher smoking rates, a very important risk factor for both circulatory diseases and different types of cancer.

Figure 2. Mortality rates by education level and causes, 10 European countries, 2011 (or nearest year)



Note: Countries covered are Belgium, the Czech Republic, Denmark, Finland, Hungary, Latvia, Norway, Poland, Slovenia and the United Kingdom (England).

Source: Murtin, F. et al. (2017).

Healthy life expectancy

Healthy life expectancy indicates whether any gains in life expectancy are lived in good health or with some health problems and disabilities. The main indicator of healthy life years used in the European Union is the number of years lived free of activity limitations due to health problems. On average across EU countries, people can expect to live about 80% of their lives free of disability (Figure 3). Whereas the gender gap in life expectancy at birth is about 5,5 years on average across EU countries, there is virtually no gender gap in healthy life expectancy (64,2 years for women compared with 63,5 years for men). Women in EU countries can expect to live over 19 years of their lives with some disabilities compared with less than 15 years for men. This is explained by the fact that women report more activity limitations due to health problems at any given age and also because women live longer.

Life expectancy with activity limitation Women Men 18% 21% 79.5 85.6 Italy 17% 81.0 84.4 Cyprus 1 18% 80.4 84.4 Finland Portugal 78.1 84.3 25% 78.2 Malta 1 10% 80.0 Austria 79.3 Sweden Belgium 84.1 13% 19% 79.0 84.0 23% 19% 78.9 EU28 83.6 17% Ireland 16% 79.9 Germany 78.6 83.5 22% 80.0 83.0 24% United Kingdom 21% 79.4 24% 82.2 28% Estonia 26% 73.3 82.1 Czech Rep 82.0 Poland 21% 17% 73.9 81.3 28% Crnatia 24% 75.0 Slovak Rep. 73.8 80.1 26% Lithuania 19% 69.5 72.6 79.7 25% 69.8 79.6 Latvia 17% 717 78.5 14% 10% 71.3 Bulgaria 11% 80.7 84.2 19% Norway 12% 25 75 75 50 25 50 100 100

Figure 3. Life expectancy and healthy life years at birth, by gender, 2016 (or nearest year)

Three-year average (2014-16 except for Iceland: 2013-15).
 Note: Data comparability is limited because of cultural factors and different formulations of question in EU-SILG.
 Source: Eurostat Database.

Main causes of mortality

The main causes of deaths across EU countries remain circulatory diseases, mainly heart attacks and strokes (over 1.8 million deaths in 2016) and cancers (1.3 million deaths), which together account for over 60% of all deaths (Figure 4). Indeed, diseases of the cardiovascular system were the main cause of deaths in all EU Member States, except in Denmark, France, the Netherlands and the United Kingdom where cancer was the main killer.³

also shows that the third main cause of death in the EU was diseases of the respiratory system, killing 422 000 (8% of all deaths in the EU). A significant share of deaths happened due to other external causes which include accidents, suicides, homicides and other violent causes of death (237 000 deaths, 5% of all deaths in the EU), diseases of the digestive system (222 000 deaths, 4%), mental and behavioural diseases such as dementia (220 000 deaths, 4%) and diseases of the nervous system including Alzheimer's (219 000 deaths, 4%)³⁶.

³ EUROSTAT News 2019 https://ec.europa.eu/eurostat/web/products-eurostat-news/-/DDN-20190716-1

Other causes of death. 13% Diseases of the Diseases of the circulatory system nervous system 4% Mental and behavioural diseases 4% Diseases of the digestive system Accidents and other external causes of deaths 5% Diseases of the respiratory system 8% Cancers

Figure 4. Causes of death in the EU by type, 2016 (as % of all deaths)

SOURCE EUROSTAT ICD10 2016 all deaths of residents in or outside their home country

Burden of diseases in the EU

Circulatory diseases

Circulatory diseases comprise a range of illnesses related to the circulatory system, including ischaemic heart diseases (notably heart attacks) and cerebrovascular diseases (such as strokes). Ischaemic heart diseases (IHD) and strokes caused more than one-fifth of all deaths in EU Member States in 2015.

26%

Death rates for IHD are over 80% higher for men than for women across EU countries, because of a greater prevalence of risk factors among men, such as smoking, hypertension and high cholesterol. Since 2000, mortality rates from IHD have declined in all countries, with an overall reduction of over 40% on average across the EU, although the reduction has slowed down in recent years. Reductions in risk factors such as tobacco consumption have contributed to reducing the incidence of IHD and consequently mortality rates. Improvements in medical care have also played an important role.

Strokes were responsible for some 430 000 deaths across the EU in 2015, accounting for about 8% of all deaths. In addition to being an important cause of mortality, the disability burden from stroke is substantial. The gender gap in mortality rates from stroke is not as large as for IHD (less than 20%). As with IHD, there are wide variations in stroke mortality rates across countries. Since 2000, stroke mortality rates have decreased by nearly 50% across the EU, although the gains have slowed down over the past five years. Again, as with IHD, the reduction in stroke mortality can be attributed at least partly to both a reduction in risk factors and improvements in medical treatments. Looking ahead, further progress in reducing mortality rates from IHD, strokes and other circulatory diseases may be hampered by a rise in certain risk factors such as obesity and diabetes (OECD, 2015).

Cancer

Cancer is the second leading cause of mortality after cardiovascular diseases, accounting for 25% of all deaths in 2015. Figure shows the main causes of cancer mortality among men and women.

Women Men 583 986 deaths 739 146 deaths 22 27 Others Colorecta Liver Others 69 199 281 453 Colorectal 17 967 219 204 38% 85 138 Liver 389 5% Pancreas 42 340 Pancreas 42 676 6% Lung 88 773 15% Luna Prostate Ovary 184 605 Breast 75 356 94 435

Figure 5. Main causes of cancer mortality among men and women in EU countries, 2015

Source: Eurostat Database.

In all countries, mortality rates from cancer are greater among men than women. Death rates from all types of cancer combined among men and women have declined at least slightly in most EU Member States since 2000, although the decline has been more modest than for circulatory diseases, explaining why cancer now accounts for a larger share of all deaths. In 2018, 3 million new cases of cancer were expected to be diagnosed in the EU (actual figures not yet available).⁴. Large variations in cancer incidence exist across EU countries, with Hungary, Ireland, Denmark, Belgium and France with the highest expected age-standardised incidence rate in 2018. Such variations in incidence rates mirror the variations in the real number of new cancers each year, but also variability in national screening policies to detect different types of cancer as soon as possible.

Respiratory diseases

Mortality from respiratory diseases is the third main cause of death in EU countries, accounting for 8% of all deaths in 2015. Most of these deaths (90%) were among people aged 65 and over. The main causes of death from respiratory diseases are chronic obstructive pulmonary disease (COPD), pneumonia, asthma and influenza. Death rates from respiratory diseases are on average 85% higher among men than among women in all EU countries. This is partly due to higher smoking rates among men. The prevalence and mortality from respiratory diseases are likely to increase in the coming years as the population ages and presently unreported cases of COPD begin to manifest, whether alone or in co-morbidity with other chronic diseases.

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⁴ Joint Research Centre (2018), Dataset Collection: European Cancer Information System, https://ec.europa.eu/jrc/en/publication/dataset-collection-european-cancer-information-system.

Diabetes

About 32.7 million adults were diabetics in the EU in 2017, up from an estimated 18.3 million adults in 2000 (Figure). In addition, some 12.8 million people were estimated to have undiagnosed diabetes in 2017. Diabetes is more common among older people. These upward trends are partly due to the rise in obesity and physical inactivity, and their interactions with population ageing.

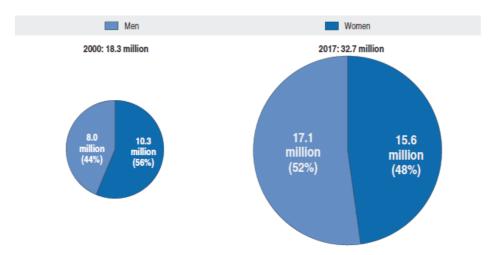


Figure 6. Number of people with diabetes in EU28, 2000 and 2017.

Note: Data include people aged 20-79 with Type1 or Type 2 diagnosed diabetes. The number of peoples with diabetes in 2000 has been estimated for some countries do to data gaps. Source IDF Atlas, 8^{th} edition, 2017 and OECD estimates.

The economic burden of diabetes is substantial. People with diabetes are at greater risk of developing cardiovascular diseases such as heart attack and stroke if the disease is left undiagnosed or poorly controlled. They also have higher risks of sight loss, foot and leg amputation, and renal failure. The health expenditure allocated to treat diabetes and prevent complications are estimated at about EUR 150 billion in 2017 in the European Union. Type 2 diabetes is largely preventable. A number of risk factors, such as overweight and obesity, nutrition and physical inactivity, are modifiable. However, the prevalence of overweight and obesity is increasing in most countries.

<u>Dementia</u>

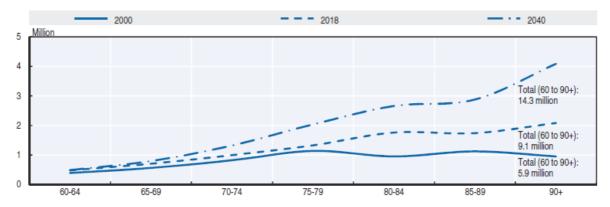
In 2017, Alzheimer's disease and other dementia represented 9.6% of all deaths in the EU, expressing an increase of 2.2% in annual change in comparison with 2016. In 2018 alone, an estimated 9.1 million people aged over 60 (around 7%) were living with dementia in the EU Member States, a significant increase from 5.9 million in 2000. Ageing populations mean that this number will continue to substantially grow in the future. Estimations indicate that in 2040, 14.3 million people aged over 60 could be living with dementia (Figure 7).

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⁵ GHB Compare https://vizhub.healthdata.org/gbd-compare/

⁶ OECD (2018), Care needed: Improving the lives of people with dementia, OECD Health Policy studies, OECD publishing, Paris, https://doi.org/10.1787/9789264085107-en

Figure 7. Estimated number of people with dementia in EU countries by age group, 2000, 2018, and 2040



Source: OECD analysis of data covering 28 EU countries from the World Alzheimer Report 2015 and the United Nations.

However, there is some evidence that the risk of dementia could be reduced through healthier lifestyles and preventive interventions. If such efforts are successful, the rise in prevalence may be less dramatic than these numbers suggest. Nonetheless, dementia will undoubtedly pose a growing challenge to all EU countries.

Communicable diseases

Communicable diseases, such as measles, hepatitis B and many others, pose major threats to the health of European citizens, although vaccination can efficiently prevent these diseases. 13 475 cases of measles were reported across the 30 EU/EEA countries from May 2017 to May 2018, up by nearly 60% over the preceding 12-month period. In most countries where vaccination coverage is high, very few cases of measles were reported.

CURRENT AND FUTURE CHALLENGES TO IMPROVING THE HEALTH OF EU CITIZENS

Ageing of the EU population

Population projections (Figure 8) suggest that there will be 66.1 million very old persons — defined here as those aged 80 years and over — in the EU-28 by 2080. This means the more than double the 2016 figure, which was 27.3 million very old persons. More so, the latest projections indicate that age dependency ratios (indicator which gives insight into the number of people of nonworking age) are likely to continue increasing. This highlights challenges for public expenditure in relation to pensions, health care and long-term care costs⁷.

 7 Eurostat: People in the EU: who are we and how do we live? 2015 edition

100+
90
Elderly
(d5 years and over)
90
80
90
10
Children
(thildren
(thildren
100+
100
0.75
0.50
0.25
0.00
0.25
0.50
0.75
1.00

Figure 8. Population pyramides (% of population), EU-28, 2016 (estimates) and 2080 (projections)

Source: Eurostat

In a context of an ageing society, non-communicable diseases are an active threat to public health. Even more so timely access to health care, prevention interventions and curative measures are of critical importance. Overall, the ageing process in the EU, allied with a substantial demand for health care, has been estimated to result in a significant increase in health care spending of 1–2 % of GDP in the EU Member States in total by 2050. On average, this would amount to an increase of 25% in health care spending⁸.

Health care spending in the EU

Increasing numbers of people living with dementia, as well as other chronic diseases, will bring new challenges to the national, regional and local health systems. This will impact the organisation of services, fiscal sustainability of the systems and financial protection of the populations they serve.

Across the EU as a whole, health spending per capita increased by around 1.9% each year between 2013 and 2017, compared with an annual growth rate of only 0.6% between 2009 and 2013. In 2017, spending in health care in the EU stood at 9.6% of gross domestic product (GDP) ranging from over 11% in France and Germany to less than 6% in Romania (Figure 9).

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⁸ Eurostat: Morbidity statistics – methodology – statistics explained 2015

Figure 9. Health expenditure as a share of GDP, 2017 (or nearest year)

Source: OECD Health Statistics 2018, https://doi.org/10.1787/health-data-en; Eurostat Database; WHO Global Health Expenditure Database

In 2016, EU Member States spent 60% of their health expenditure on curative and rehabilitative care services (inpatient⁹ and outpatient care), 20% on medical goods (mainly pharmaceuticals) while 13% were spent on health-related long-term care and the remaining 7% on collective services, such as prevention and public health (Figure 10).

⁹ Inpatient care refers to care for a patient who is formally admitted (or 'hospitalised') to an institution for treatment and/or care and stays for a minimum of one night in the hospital or other institution providing inpatient care [Source: OECD Health Data 2001: A Comparative Analysis of 30 Countries, OECD, Paris, 2001, data sources, definitions and methods]

Inpatient care* Outpatient care** Long-term care Medical goods 100 80 70 60 50 131 36 34 32 36 40 30 20 10 United Kingdom Finland Slovenik

Figure 10. Health expenditure by function, 2016 (or nearest year)

Note: Countries are ranked by the sum of inpatient and outpatient care as a share of current health expenditure. Source: OECD Health Statistics 2018, https://doi.org/10.1787/health-data-en; Eurostat Database.

Pharmaceuticals (excluding those used in hospitals) represented the third largest item of health care spending, accounting for a sixth of health expenditure in 2016. Differences in distribution channels, prevalence of generic drugs, as well as relative prices in different countries, can highly influence spending in this category. The total retail pharmaceutical bill across the EU was more than EUR 210 billion in 2016 and an increase of around 5% since 2010. Spending on pharmaceuticals used during hospital care can typically add another 20% to a country's pharmaceutical bill. The cost of pharmaceuticals is predominantly covered by government or compulsory insurance schemes. These schemes cover around 64% of all retail pharmaceutical spending, with out-of-pocket payments (34%) and voluntary private insurance (1%) financing the remaining part.

The challenge of unmet needs for medical care. Unmet needs for medical care demonstrate issues in health care accessibility for a number of reasons including cost, distance to the closest health facility and waiting times¹⁰. Unmet care needs may result in poorer health for people forgoing care and may increase health inequalities if such unmet needs are concentrated among poor people. There is significant variation in the EU regarding the percentage of people reporting unmet medical needs both across countries and income levels with the burden falling mostly in low-income groups (Figure 11).

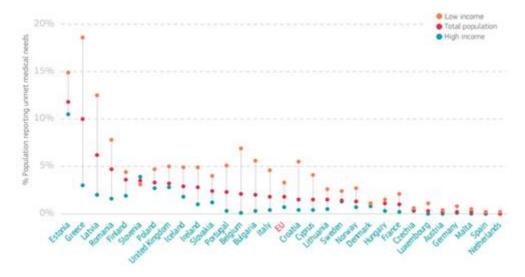
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^{*} Refers to curative-rehabilitative care in inpatient and day care settings.

^{**} Includes home care and ancillary services.

¹⁰ The share of persons declaring an unmet need for medical examination is also a core indicator for accessibility in the "social scoreboard" underpinning the European Pillar of Social Rights.

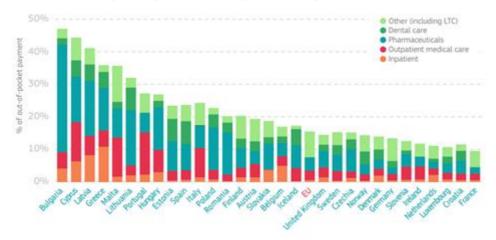
Figure 11. Unmet needs vary across countries and income groups.



Source: Adapted from OECD/European Observatory on Health Systems and Policies (2019), Country Health Profiles 2019, State of Health in the EU (data refer to 2017).

Out of the fourteen EU Member States with a reported level of unmet medical needs above the EU average, half revealed costs as the prominent reason. Across the EU, about 1.7% of citizens self-reported to have forgone treatment primarily for financial reasons. Of note, out-of-pocket spending varies across the EU, reaching more than twice the EU average in Bulgaria, Cyprus, Latvia, Greece, Malta and Lithuania (Figure 12):

Figure 12. Out-of-pocket payments by expenditure type



Source: Adapted from OECD/European Observatory on Health Systems and Policies (2019), Country Health Profiles 2019, State of Health in the EU (data refer to 2017). NOTE: Indicator captures how the out-of-pocket expenditure as a share of current expenditure on health is broken down by particular services and goods.

Figure also shows that out-of-pocket spending is highly driven by pharmaceutical expenditure, being the largest single cost component in the majority of the EU Member

¹² Out-of-pocket payments are expenditures borne directly by a patient where neither public nor private insurance cover the full cost of the health good or service. At an aggregate level, the share of out-of-pocket spending in total health spending reflects the degree of financial protection in a country.

States. More so, the emergence of new medical technologies is having an important impact on the determinants for access to these pharmaceuticals in national contexts.

2.2. Information about IMI JU & lessons learnt

In 2007, the European Commission released a proposal for the creation of the Innovative Medicines Initiative¹³ Joint Undertaking (IMI JU), a public-private partnership (PPP) between the European Community, represented by the European Commission, and the European Federation of Pharmaceutical Industries and Associations, EFPIA. The proposal was based on an article in the EU treaties (now Article 187 TFEU) allowing the EU to set up joint undertakings 'for the efficient execution of Union research, technological development and demonstration programmes'.

Under the Seventh Framework Programme (FP7), IMI JU had a budget of EUR 2 billion. Half of it came from the EU and the rest came in the form of in-kind contributions from EFPIA and its member companies who did not receive any EU funding. The overall goal of the IMI JU programme was to 'significantly improve the efficiency and effectiveness of the drug development process with the long-term aim that the pharmaceutical sector produce more effective and safer innovative medicines'.

IMI delivered 59 projects of approx. EUR 1.919 million total budget¹⁴ (cut-off date of the analysis: December 2019). The three most funded health areas were: 'infectious diseases' (EUR 719 million), 'drug discovery' (EUR 232 million) and 'other' (EUR 221 million) as shown in Figure 1.

Stakeholder analysis

Based on the analysis of IMI JU funded projects, overall 29.6% of the participants were private companies while 51.9% were academia, secondary and higher education establishments, and non-profit research organisations. 11.2% of beneficiaries receiving EU funding were SMEs, 5.7% came from an entity categorised as other and 1.6% represented patient organisations (see Table 1 below for types of organisations and the budget distribution for the 59 projects). It should be noted again in this context that EFPIA members did not receive EU funding.

¹³ For clarity, the term 'IMI JU' is used when referring to Innovative Medicines Initiative JU that started in 2007 under EP7, and the term 'IMI2 JU' is used to denote its successor initiative, operating under Horizon

²⁰⁰⁷ under FP7, and the term 'IMI2 JU' is used to denote its successor initiative, operating under Horizon 2020. The term 'IMI' is used when the two predecessors initiative are meant jointly.

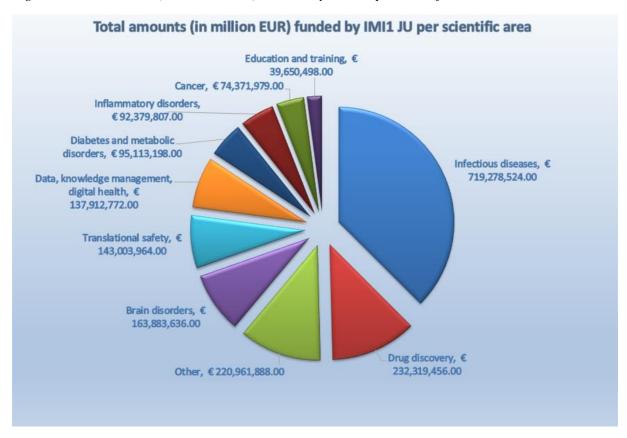
¹⁴ Jointly, for the EU financial contribution and the contribution of private JU Member, i.e. members of EFPIA or its constituent entities or their affiliated entities.

¹⁵ The Final Evaluation of the Innovative Medicines Initiative Joint Undertaking (2008-2016) operating under the 7th Framework Programme Experts Group Report.

Table 1. Types of organisations and the budget distribution for the 59 IMI JU projects

Type of organisation	Number of participations in IMI	Requested EU Contribution (EUR)	EFPIA in-kind contribution (EUR)
Academia, Research Organisations	888	802,395,744	0
EFPIA	507	0	953,144,739
Patient Organisations	26	5,672,638	0
SMEs	192	127,994,480	0
Others	98	29,793,249	0
Grand Total	1711	965,730,983	953,144,739

Figure 1. Total amounts (in million EUR) invested by IMI JU per scientific area



The total EU contribution (% share) to participations distributed over the different country categories was:

- EUR 907.3 million (93.9%) for EU-15;
- EUR 45.6 million (1.3 %) for Associated Countries;
- EUR 12.1 million (1.3%) for EU-13; and

• EUR 0.7 million (0.1%) for third countries.

An experts' analysis of IMI's first projects revealed that they were generating socio-economic impacts on a number of fronts: making concrete improvements to pharmaceutical R&D; leveraging funding; creating new knowledge and tools; and making Europe an attractive place to carry out research. The report noted that many of the projects' achievements would not have been possible without IMI. Feedback from project participants has also highlighted the benefits of taking part in IMI projects for all participants, including large pharmaceutical companies, universities, SMEs, and patient organisations¹⁶.

IMI JU projects in general contributed to novel scientific insights. The number of publications was impressive with 1,678 unique Web of Science publications linked to the Thomson Reuters citation databases (published between 2009 and 2015). There were 1,661 papers (articles and reviews; 99%); 17 other document types (13 editorials, two meeting abstracts, one letter and one news-item; 1%). Between 2009 and 2015, the citation impact for IMI project papers (1.93) was nearly twice the EU's citation impact (1.1) in similar journal categories.¹⁷

2.2.1. IMI JU Interim & Final evaluations

The Final Evaluation of the IMI JU⁵⁰ (published in June 2017) set out to address specific evaluation questions under the individual criteria of effectiveness, efficiency, relevance, coherence and added value. The expert group concluded that the IMI JU programme was relevant and justified and positive contributions on the drug development process have been realised. According to the final evaluation (similarly to IMI2 JU), "the main achievement of IMI JU on which there was general consensus, was that under IMI JU collaborations between different competing global companies, SME's and academia became possible. These collaborations created trust and new partnerships, including partners from different areas of expertise, such as with regulatory bodies, or with patient's representatives groups. Together with the available budget and long term strategy, this was considered an important asset for European pharmaceutical research". The evaluation recognised that since its origin in 2008, 'IMI may have contributed to resilience of the European pharmaceutical industry at the time of the crisis, as the number of clinical trials and research remained stable across Europe in the period following the crisis of 2008'. IMI actions have also contributed to access to research infrastructure. A major success was the development of an antimicrobial resistance infrastructure that provided access to external companies or the European Lead Factory (ELF) project, providing access to libraries of medicinal compounds.

One of the main criticisms, found both in the interim¹⁸ and final evaluations of IMI JU⁵⁰ was the lack of a performance measuring system with SMART (Specific, Measurable, Achievable, Relevant, Time-phased) Key Performance Indicators (KPIs) to measure not

¹⁶ IMI Socio-economic Impact <u>Assessment Expert Group Final Report</u> (May 2016).

¹⁷ The Final Evaluation of the Innovative Medicines Initiative Joint Undertaking (2008-2016) operating under the 7th Framework Programme. https://ec.europa.eu/research/health/pdf/imi final evaluation.pdf.

¹⁸ Second Interim Evaluation IMI - Innovative Medicines Initiative Joint Undertaking https://www.imi.europa.eu/sites/default/files/uploads/documents/reference-documents/2ndInterimEvaluationIMI.pdf

only scientific output, but also socio-economic impacts. A finally agreed set of KPIs was introduced in 2017, during the lifetime of IMI2 JU.

The second interim evaluation of IMI JU (published in July 2013) also provided recommendations for the future initiative, i.e. the IMI2 JU:

Recommendation 1: Baseline data should be obtained in parallel with the launch of IMI2 in order to allow for better benchmarking and assessment of IMI2 performance.

Recommendation 2: Industrial participants from other healthcare related sectors should be involved in IMI2. An integrated approach to healthcare will be required including prevention and diagnosis.

Recommendation 3: The Commission should ensure that IMI2 is transparent and has increased flexibility in terms of governance. It should be ensured that the roles and mandates of the governance and advisory bodies (in particular the Scientific Committee and the States Representatives Group) are clearly defined and the membership configured with the appropriate expertise to execute their mandate.

These recommendations have resulted, among others, in the following developments:

Ad 1) A set of ten SMART KPIs was introduced for IMI2 JU in December 2017¹⁹.

Ad 2) A small improvement has been achieved in involving other health care related sectors, mainly in diagnostics and medical technology companies (e.g. IMI2 JU Call 20 topic on 'Proton therapy'). However, under IMI2 JU, only the pharmaceutical sector was represented as the founding member and therefore, sizeable involvement of non-pharmaceutical entities under the current IMI2 JU structure and rules is unlikely to be achieved by the end of the IMI2 JU programme. The main reasons seem to consist in difficulties to attract big non-pharma industries to IMI2 topics because of the various current rules in place, including the intellectual property rules not responding to the needs of these industries. IHI is going to address this recommendation as it is designed to involve five health care industry sectors (pharma, medtech, biotech, imaging, vaccines) from the start.

Ad 3) IMI2 JU has generally improved definitions of its governance structures and advisory bodies and its communication between them. The governance structure was enshrined in the Regulation establishing IMI JU and as such, it was not modified during the lifetime of the initiative. The composition of the Scientific Committee and the States Representatives Groups was considered adequate for the tasks performed.

2.3. Information about IMI2 JU & lessons learnt

Under Horizon 2020, the overall budget for the Societal Challenge "Health, demographic change and wellbeing" was EUR 7.5 billion which included Joint Undertakings (JUs). The Innovative Medicine Initiative was one such JU that supported R&I in the health field, named as IMI2 JU for the period 2014-2020 to distinguish it from its predecessor, IMI JU, operating under FP7.

¹⁹ IMI2 JU Key Performance Indicators. https://www.imi.europa.eu/sites/default/files/uploads/documents/About-IMI/mission-objectives/IMI2 https://www.imi.europa.eu/sites/default/files/uploads/documents/About-IMI/mission-objectives/IMI2 https://www.imi.europa.eu/sites/default/files/uploads/documents/About-IMI/mission-objectives/IMI2 https://www.imi.europa.eu/sites/default/files/uploads/documents/About-IMI/mission-objectives/IMI2 https://www.imi.europa.eu/sites/

IMI2 JU's total budget of up to EUR 3.276 billion makes it the world's largest public-private partnership in life sciences. IMI has become a renowned brand, recognised globally. Half of its budget comes from Horizon 2020 and most of the rest comes from the European Federation of Pharmaceutical Industries and Associations (EFPIA) and its member companies in the form of in-kind contributions, for example time of staff working on joint projects (other minor contributors include technology providers, diagnostics companies, charities or data handlers). It is important to emphasise that EFPIA companies do not receive any EU funding via IMI; the EU funding goes to universities, research centres, small and medium-sized enterprises (SMEs), mid-sized companies, patient groups, and regulators²⁰.

In each IMI project, a number of big industry players (EFPIA members) participate and collaborate with public sector partners and smaller companies. The IMI office coordinates the selection of the most suitable public consortium (including mostly public research organisation and SMEs) for the projects through open, competitive calls. These partners are funded by the EU, while EFPIA members use their own resources.

A novelty of IMI2 JU compared to its predecessor was the introduction of Associated Partners (AP) that can support and contribute to (both financially and in-kind) the objectives of IMI. The AP category was created with the goal of expanding IMI2 JU activities to a wider range of stakeholders to address the entire life science research and innovation value chain and to actively involve organisations other than pharmaceutical companies (therefore also following the recommendations of the predecessor IMI JU evaluation). Examples of organisations that have become AP include philanthropic organisations and charities that run their own health research programmes, as well as organisations working in sectors related to health care such as ICT, imaging, diagnostics, etc. IMI2 JU already attracted several global players as APs, such as the Bill and Melinda Gates Foundation, the Wellcome Trust and the Coalition for Epidemic Preparedness Innovations (CEPI)²¹. In fact, the category of AP has been so successful in leveraging contributions to IMI2 JU, that the reserved maximum amount of EUR 213 million as set out in the regulation is expected to be fully used. The category of AP is expected to continue in the future IHI.

Calls under IMI2 JU resulted in more than 84 projects (figure based on the number of grant agreements signed by end December 2019). Some of these projects focus on specific health issues such as neurological conditions, diabetes, oncology, Ebola vaccine development and antimicrobial resistance. Others focus on broader challenges in drug development such as drug and vaccine safety, knowledge management, drug behaviour in the body, and research and clinical data sharing platforms. In addition to research projects, IMI2 JU supported a number of education and training projects.

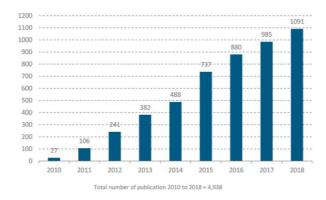
IMI projects delivered scientific breakthroughs that would not have been possible without IMI's public-private partnership model (see success stories below). Thomson Reuters is tracking the research papers coming out of IMI, revealing a rapid growth of scientific output (Figure 1), matched with high quality: the citation impact of IMI papers is twice the world average and significantly higher than the EU average. Articles accounted for the majority of publications (73.2%), followed by reviews (14%) and other (12.7%) in 2018. IMI projects

²¹ IMI2 JU full list of Associated Partners.

²⁰ Council of the European Union (2014), Council regulation (EU) No 557/2014 of 6 May 2014 establishing the Innovative Medicines Initiative 2 Joint Undertaking. Official Journal of the European Union 169, p. 54-76.

produced more publications in Pharmacology & Pharmacy than in other journal categories, followed by Neurosciences and Biochemistry & Molecular Biology²².

Figure 1. Number of Web of Science publications stemming from IMI.



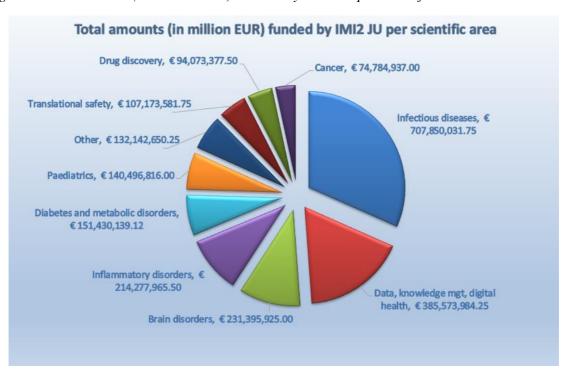
IMI2 project participant analysis

In terms of number and total budget of projects, the following data are available (up to December 2019):

• 84 projects of approx. EUR 1,832 million total budget²³

The three most funded health areas for IMI2 are: 'infectious diseases' (EUR 708 million), 'data, knowledge management, digital health' (EUR 386 million) and 'brain disorders' (EUR 232 million), as shown in Figure 2.

Figure 2. Total amounts (in million EUR) invested by IMI2 JU per scientific area



²² Bibliometric analysis of ongoing IMI projects (September 2019).

²³ Corresponding to IMI2 JU calls up to Call 14 (with further eight calls remaining to be signed/launched).

Stakeholder analysis

IMI2 JU project participants spanned a wide range of organisations including private companies (including SMEs), higher education institutions, public-funded research centres, public bodies and others (e.g. non-profit organisations, patient associations, etc.). Based on the analysis of IMI2 JU funded projects (until 2018), overall 39.20% of the participants were private companies while 33.65% were higher education institutions, 17.25% were research performing organisations and 3.53% were public bodies (see Figure 3). 15.4% of beneficiaries receiving EU funding are SMEs²⁴. It should be noted that EFPIA members do not receive EU funding.

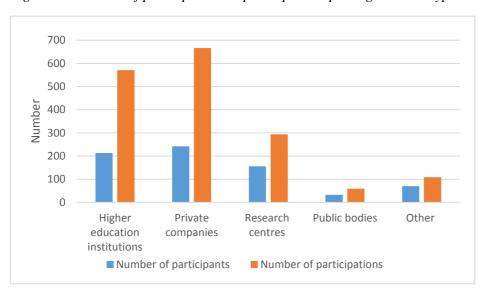


Figure 3. Overview of participants and participations per organisation type in IMI2 (2014-2018)

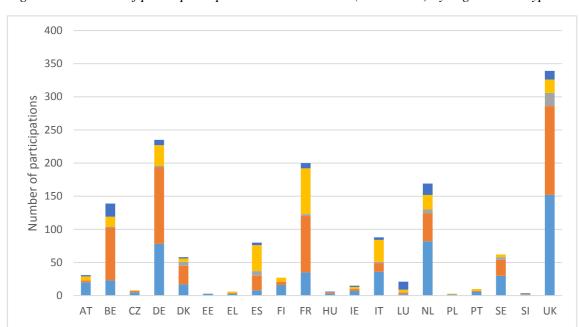
In terms of the size of funding, higher education institutions accounted for most of the received funding, totalling around EUR 447 million or 55% of the total net requested EU contributions between 2014 and 2018²⁵. This was followed by EUR 222 million (27%) for research centres, EUR 87 million (11%) for private companies, EUR 23 million (3%) for public bodies and EUR 40 million (5%) for other types of organisations. Since constituent and affiliated entities of EFPIA that participated in projects did not receive any reimbursement from the JU, their costs are not represented among these figures.

The highest number of participants (including all public and private sector participants and non-EU participants) were from the UK (19.95%, n=339) followed by Germany (13.83%, n=235), France (11.77%, n=200), the Netherlands (9.95%, n=169) and Belgium (8.18%, n=139) (see Figure 4). The EU15 Member States dominated the participation, accounting for 87% of participations and 90% of the total net requested EU contributions. In turn, EU13 accounted for only 2% of the participations and 1% of the total EU contributions. There was also participation from associated Member States (7% of participations, receiving 3% of contributions) and other international partners (4% of participations, receiving 5% of contributions).

²⁵ Technopolis analysis of IMI2 JU data

²⁴ IMI (2019) Annual Activity Report 2018. Available at:

https://www.imi.europa.eu/sites/default/files/uploads/documents/reference-documents/AAR2018 final.pdf



■ Higher education institutions ■ Private companies ■ Public bodies ■ Research centres ■ Other

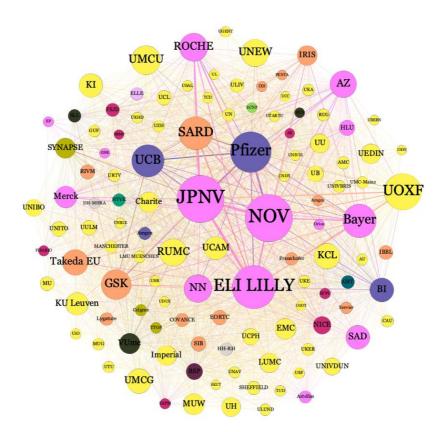
Figure 4: Overview of participants per EU MS in IMI2 JU (2014-2018) by organisation type

Based on IMI2 JU participation data, the level of participation of individual organisations was mapped. Figure 5 outlines a preliminary mapping of the IMI2 JU network according to organisations' NACE²⁶ industry sector (classified according to colour) with the bubble size indicating the frequency of participation (the bigger the bubble, the more frequent participation). The lines ('ties') between two organisations display the frequency of collaboration among the concerned organisations. The private companies, Janssen Pharmaceutica NV, Novartis Pharma AG, Eli Lilly and Company and Pfizer participated in the highest number of IMI2 JU projects (see JPNV, NOV, ELI LILLY and PFIZER in Figure 5 below). Again, it should be noted that as EFPIA members, these companies did not receive EU funding.

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²⁶ NACE (Nomenclature of Economic Activities) is the European statistical classification of economic activities. NACE groups organisations according to their business activities. Statistics produced on the basis of NACE are comparable at European level and, in general, at world level in line with the United Nations' International Standard Industrial Classification (ISIC).

Figure 5: Preliminary mapping of the network structure of IMI2 JU by NACE sector





Source: Technopolis Group

2.3.1. IMI2 JU Interim evaluation and recommendations for a future partnership

The interim evaluation of the IMI2 JU²⁷ (published in September 2017) came to the following main findings:

- The main achievement of IMI2 JU on which there was general consensus, was that since the joint undertaking started, collaborations between different competing global companies, SME's and academia became possible. These collaborations created trust and new partnerships, including partners from a number of expertise areas, such as patient representative groups or regulatory bodies, which are essential stakeholders for medicines to enter the market with quality, safety and efficacy guarantees and in the shortest possible time. Together with the available budget and long term strategy, these collaborations were considered an important asset for European pharmaceutical research.
- The large scale and ambition of the IMI2 JU projects, their long-term vision and strategy were viewed positively.
- The reasons to create a public-private partnership to strengthen the European pharma industry were valid and the goals were justified.
- Thanks to the joint undertaking, for the first time competing companies were collaborating in precompetitive research and deciding together, which call topics should be launched to address challenges that a single company could not tackle.
- IMI2 JU was considered to be a unique initiative that has no counterpart elsewhere.
- The process of developing the SRA and call topics was considered by many stakeholders to lack transparency and to be dominated by EFPIA partners.
- The added value for patients or society in general was hard to demonstrate at the time of mid-term evaluation, because of the early stage of IMI2²⁸.

Therefore, the experts drafting the evaluation identified several recommendations for a potential future partnership that were taken into consideration in the design of IHI (Table 2).

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²⁸ This finding could be attributed to the fact that mid-term evaluation report was published in 2017, only three years after the launch of the initiative in 2014.

²⁷ European Commission (2017) The Interim Evaluation of the Innovative Medicines Initiative 2 Joint Undertaking (2014-2016) operating under Horizon 2020. Experts Group Report. Luxembourg: Publications Office of the European Union.

Table 2. Recommendations of IMI2 JU interim evaluation for a future initiative and how they were used to design IHI

Recommendation	How it was taken into consideration in the design of IHI
Recommendation 1: Make a substantial adaptation to the collaborative and funding model to enable the active engagement of other industry sectors with the pharmaceutical industry to capitalise on their expertise in the development of new health care interventions.	IHI is designed as a cross-sectoral partnership between EU and five industry sectors (pharma, medtech, biotech, imaging, vaccines), rather than only pharmaceuticals as in IMI2 JU. The respective industry associations have indicated a strong preliminary interest in becoming members of such an Institutionalised Partnership.
Recommendation 2: Increase the transparency of in-kind contributions as well as the Strategic Research Agenda (SRA) and call topics generation to reflect European interest and interests of stakeholders other than EFPIA. Transparency on these issues will open up the programme for more creative and innovative thinking and trust amongst the potential participants and stakeholders.	Transparency of the initiative was maintained from the design phase, including via several public consultations (detailed in Annex 2). To address the request for broader involvement of stakeholders in IHI governance and for more openness, a separate body is planned to be created in its governance ('Innovation Panel'). It would be tentatively composed of the representatives of EU and member industry associations, as well as of various other stakeholders such as representatives of patients, health care professionals, patients, health care providers, academia, research and technology organisations, research infrastructures, other partnerships and ad-hoc members as necessary. The reporting of in-kind contribution will be handled according to the conditions laid down in the relevant legal texts.
Recommendation 3: Change the rules on the calculation of the in-kind contributions from non-European entities. To be consistent with the goal of increasing investments in Europe, in-kind contributions from activities that occur outside of the EU should not be accepted to match with the public funding, but may be accounted as additional contributions or leveraging effects.	During consultations on IHI, EU Member States expressed a strong wish to strengthen the competitiveness of Europe's health technology industry (more information in Annex 2 section 1.3.2). At the same time, the necessary global dimension of the partnership should be ensured. Therefore, the partnership should strive to attract and partially match investments from outside Europe to increase its international footprint, capture resources and expertise of global companies, benefit from other previous international investments or address a specific scope (such as e.g. disease prevalence in non-EU countries, with relevance for EU population), while maintaining a majority of activities in the EU.

The experts also identified a number of recommendations to improve effectiveness, efficiency, coherence and added value of the existing partnership. Even though these recommendations were meant to help in the final phase of IMI2 JU execution, they were also used as lessons learned to better design the Innovative Health Initiative (Table 3).

Table 3. Findings of IMI2 JU interim evaluation that could be implemented towards the end of IMI2 JU, and how they were used to design the Innovative Health Initiative.

Recommendation	How it was taken into consideration in the design of IHI
Recommendation 1: A renewed and stronger effort should be made to attract and integrate other industries than the pharmaceutical industry in the collaborative projects.	IHI will involve several industry sectors as founding members.
Recommendation 2: Create a better ecosystem to attract more SMEs. - Expand the scope of projects to attract SMEs developing innovative technologies to capture novel trends in the development of healthcare of the future; - Make topic description less prescriptive and allow more flexibility for SMEs to come with creative ideas.	Associations of medtech, biotech, imaging and vaccine industry sectors have indicated a strong preliminary interest in becoming members of such an Institutionalised Partnership, along with EFPIA's continued interest. The new associations have a larger number of SME partners, across various geographies. It is expected that a majority of topic will be less prescriptive single-stage, allowing a more bottom-up approach with more space for ideas coming from applicants.
Recommendation 3: An accountable Performance Measurement Framework, using SMART KPIs should be developed to assess the impacts and socio-economic benefits of the joint undertaking.	A set of KPIs aligned with the specific objectives of IHI is going to be in place from the start of the initiative.
Recommendation 4: Review the IP policy and make it more flexible to respond to the needs allowing negotiations on exclusive rights.	As a default, general Horizon Europe provisions will apply.
Recommendation 5: Improve and broaden access to project outcomes and assure their sustainability to increase impact. - Develop a platform for open dialogue with and between the different groups in the governance structure of the joint undertaking; - Develop a brokerage platform to stimulate that results from IMI2 projects and from other programmes are leading to applications. - Ensure communication to a wider audience to increase awareness of the programme results and outputs.	The measures to enssure the sustainability of project outcomes remain to be discussed. The initiative will strive to consider recommendations from IMI2 JU Scientific Committee on this matter ²⁹ . The process of future topic generation is foreseen to be made more transparent by revised governance structure with the Innovation Panel that will better incorporate the voice of various stakeholders, as explained above (Table 2, recommendation 2). The details of communication activities will be discussed later in the partnership preparation process.

https://www.imi.europa.eu/sites/default/files/uploads/documents/About-IMI/Governance/sc/SC Sustainability June2018.pdf.

²⁹ IMI Scientific Committee Recommendation. Sustainability solutions are important criteria determining project quality and output in IMI (2018).

The recommendations referred to above have resulted, among others, in a set of ten SMART KPIs introduced in December 2017³⁰. The KPIs focus on the following elements:

- 1) the coverage of the research portfolio, showing adequate implementation of the annual scientific priorities;
- the achievements of the assets during the course of the IMI programmes;
- the impact of the IMI programmes on the regulatory framework;
- 4) the ability of the IMI programs to set new standards (i.e. new taxonomies, new stratifications)
- 5) the rate of contribution of non-pharma actors to the IMI programmes (e.g. non-pharma industries, foundations, charities, professional organisations);
- the accessibility of the resources/outputs beyond the IMI consortia partners;
- 7) the level of co-authorships and cross-sector publications between European researchers;
- 8) the adoption of the novelty generated by the IMI programmes by the industrial partners;
- 9) the level of involvement of patients groups or healthcare professional association;
- 10) the level of collaboration and SME participation.

Data from IMI2 JU Annual Activity Report 2019³¹ demonstrate that IMI2 JU has already reached or almost reached the desired targets in more than half of the KPIs.

2.4. **IMI Success stories**

IMI has resulted in a range of outcomes and impacts on health care, health systems and patient wellbeing³². A selection of these success stories is presented below, followed by a case example from an SME.

Empowering patients

IMI2 made a significant step towards patient empowerment: the Patient Expert Training Course trained almost 100 patients from 32 countries across 58 disease areas, and the R&D toolbox has been used by more than 500,000 people worldwide. These were outputs of the European Patients' Academy on Therapeutic Innovation³³ project (EUPATI, budget EUR 10.9 million) that has helped address a key gap in patient and public knowledge by providing information on how medical R&D is conducted. Other outputs include guidance documents for the engagement of patient organisations, and annual conferences and workshops.

Responding to emerging health threats

In November 2014, IMI responded to the West Africa outbreak of Ebola by launching a comprehensive Ebola+ programme³⁴ to tackle a wide range of challenges in Ebola research,

³⁰ IMI2 JU Key Performance Indicators. https://www.imi.europa.eu/sites/default/files/uploads/documents/About- IMI/mission-objectives/IMI2 KPIs approved 14 DEC 2017.pdf.

⁽²⁰²⁰⁾ Available Annual Report at: https://www.imi.europa.eu/sites/default/files/events/IMI%20AAR%202019 FINAL.pdf.

³² An up-to-date list of success stories can be found at https://www.imi.europa.eu/projects-results/success- stories-projects.

33 https://www.imi.europa.eu/projects-results/project-factsheets/eupati.

https://www.imi.europa.eu/projects-results/project-factsheets/ebola.

including vaccines development, clinical trials, storage and transport, as well as diagnostics. Today, the Ebola+ programme has 12 projects with a total budget (joint EU and EFPIA / Associated Partner contributions) of close to EUR 300 million. In July 2020, the European Commission granted marketing authorisations to Janssen, a Johnson & Johnson company, for their vaccine against Ebola virus disease, whose development was supported by IMI's Ebola+ programme.

Better use of big data

20 years of clinical research on knee replacement were reviewed and analysed in just 5 days. It demonstrated the power of using electronic health data in replicating clinical trials, to generate information that could help patients and doctors make better decisions about their care (EHDEN project, budget EUR 28.9 million)³⁵. This was done as part of IMI's Big Data for Better Outcomes programme aiming to integrate detailed personal and biological data to uncover insights that will improve outcomes for patients.

Years of clinical research data on Alzheimer's earliest stages were made securely available to the scientific community – a move that can help go further with knowledge sharing and discovery of treatments. This was done through the 'European prevention of Alzheimer's dementia consortium', looking into innovative designs of clinical trials to deliver better results, faster and at lower cost³⁶ (EPAD project, budget EUR 59.9 million).

Faster diagnostics

Lengthy diagnostic was a major problem during the 2014-15 West Africa Ebola outbreak. To remedy this, a compact, easy-to-use diagnostic device was developed that deliver results in a little over an hour³⁷. The device is now validated and commercially available. The test can be used to diagnose Ebola and other *Filoviridae* such as Marburg virus. In the future, it may be expanded to other WHO priority pathogens such as dengue and Lassa fever. This was done under IMI's Mofina project (EUR 4.4 million), where partners reported that the collaboration between public and private stakeholders was key to their success.

Greener pharmaceuticals

A new tool was designed to embed 'green chemistry' in chemical development, for use in the early stages of drug development³⁸. The toolkit assesses how green a chemical reaction is by using a combination of qualitative and quantitative criteria. A range of new, cleaner catalysts were also delivered, now used by several pharmaceutical companies. This was done thanks to CHEM21 project (budget EUR 26.7 million) that addresses inefficiencies and sustainability in the manufacturing processes of pharmaceuticals.

Accelerating the development of new drugs and new treatments

Using patient reported outcomes and tools, the impact of chronic obstructive respiratory disease (COPD) on how patients experience physical activity was measured, achieving a qualification of European Medicines Agency (EMA) for novel methodologies. This opens

³⁵ https://www.ehden.eu/ehden-knee-replacement-study-results-published-in-lancet-rheumatology-truly-elevating-observational-data/.

³⁶ https://www.imi.europa.eu/projects-results/project-factsheets/epad.

https://www.imi.europa.eu/projects-results/project-factsheets/mofina.

https://www.imi.europa.eu/projects-results/project-factsheets/chem21.

the way for the development of more effective treatments (PRO-active project, budget EUR 15.6 million).

Pharmaceutical companies – who are market competitors – started to share their data on the toxicity of drug-like compounds, for the first time on a large scale. This happened through the creation of a large database, which can be mined, e.g. to try to predict whether or not a particular candidate drug is likely to have an adverse effect on patients. This data sharing can lower the failure rate in later phases of pharmaceutical development, significantly reduce the number of animal tests needed, and accelerate the development of new drugs³⁹ (eTOX project, budget EUR 18.7 million).

Stakeholder opinion



Dr Tamas Letoha, CEO Pharmacoidea Ltd

Pharmacoidea Ltd. is a Hungarian biotech SME specialising in preclinical drug discovery, founded in the 2000s' by a handful of talented scientists. The early years were characterized by struggling at a little domestic market until the company got into an IMI project as part of an international consortium. IMI was a game-changer for Pharmacoidea, it gained hands-on knowledge of the pharmaceutical R&D process, partnering with leading industry players and academic institutes. By understanding the industrial requirements of pharmaceutical drug discovery, the company acquired the skills for

world-class pharmaceutical innovation. As a result, Pharmacoidea's drug discovery platform was advanced, innovative target-specific bioassays and analytical methods were developed and Pharmacoidea established an advanced informatics platform and filed several novel patents. All strengthening the company's industrial capacities, business perspectives and improving its competitiveness within the biotech and pharmaceutical industry. IMI also opened up a vast network of potential clients, and the IMI participation put a quality stamp on the company. Pharmacoidea's revenues increased almost ten-fold from EUR 114,600 in 2012 (before joining IMI) to EUR 961,366 in 2018 and created several highly skilled jobs.

³⁹ https://www.imi.europa.eu/projects-results/project-factsheets/etox.



Brussels, 23.2.2021 SWD(2021) 37 final

PART 6/19

COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT REPORT

Accompanying the document

Proposal for a Council Regulation establishing the Joint Undertakings under Horizon Europe

European Partnership for Key Digital Technologies

{COM(2021) 87 final} - {SEC(2021) 100 final} - {SWD(2021) 38 final}

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Glossary

Term or acronym	Meaning or definition
AI	Artificial intelligence
ASIC	Application Specific Integrated Circuit
CAGR	Compound annual growth rate
CF	Co-funded partnership
CMOS	Complementary Metal Oxide Semiconductor
СР	Co-programmed partnership
CPS	Cyber-physical system
DAE	Digital Agenda for Europe
DEP	Digital Europe Programme
DSM	Digital Single Market strategy
ECS	Electronic Components and Systems
ECSEL JU	Electronic Components and Systems for European Leadership - Joint
	Undertaking
EDA	Electronic design automation
ELG	Electronics Leaders Group
EMS	Electronics manufacturing services
EPS	ECSEL Participating States
ETP	European Technology Platform
EP	European Partnerships
ES	Embedded software
FDSOI	Fully depleted silicon on insulator
FPGA	Field-Programmable Gate Array
HEI	Higher education institutions
HPC	High performance computing
IA	Innovation Actions (of ECSEL JU)
IC	Integrated Circuits
ICT	Information and Communication Technologies
IDM	Integrated Device Manufacturer
IoT	Internet of Things
IP A185	Institutionalised Partnership Art 185
IP A187	Institutionalised Partnership Art 187
IPCEI	Important Project of Common European Interest
IS	Intelligent Software
JTI	Joint Technology Initiative
KDT JU	Key Digital Technologies – Joint Undertaking
LIFE	Programme for Environment & Climate Action
MFF	Multi-annual Financial Framework
MS	Member States of the European Union
PS	Platform Software
RIA	Research and Innovation Actions (of ECSEL JU)
R&D	Research and Development
R&I	Research and Innovation

Silicon On Insulator	
Strategic Research and Innovation Agenda	

PART 1 - COMMON FOR ALL CANDIDATE INSTITUTIONALISED EUROPEAN PARTNERSHIPS

BACKGROUND AND CONTEXT TO EUROPEAN PARTNERSHIPS IN HORIZON EUROPE AND FOCUS OF THE IMPACT ASSESSMENT- WHAT IS DECIDED

1.1. Focus and objectives of the impact assessment

This impact assessment accompanies the Commission proposal for Institutionalised European Partnerships to be funded under Horizon Europe, the 2021-2027 Framework Programme for EU Research and Innovation (R&I). It sets out to help decide in a coordinated manner the right form of implementation for specific candidate initiatives based on a common approach and methodology to individual assessments². It also provides an horizontal perspective on the portfolio of candidate European Partnerships to identify further efficiency and coherence gains for more impact.

European Partnerships are initiatives where the Union, together with private and/or public partners (such as industry, public bodies or foundations) commit to support jointly the development and implementation of an integrated programme of R&I activities. The rationale for establishing such initiatives is to achieve the objectives of Horizon Europe more effectively than what can be attained by other activities of the programme.³

Based on the Horizon Europe Regulation, European Partnerships may be set up using three different forms: "Co-funded", "Co-programmed" and "Institutionalised". The setting-up of Institutionalised Partnerships involves new EU legislation and the establishment of dedicated implementing structures based on Article 185 or 187 of the Treaty on the Functioning of the EU (TFEU). This requires an impact assessment to be performed.

The Horizon Europe Regulation defines eight priority areas, scoping the domains in which Institutionalised Partnerships could be proposed⁴. Across these priority areas, 13 initiatives have been identified as suitable candidate initiatives for Institutionalised Partnerships because of their objectives and scope. This impact assessment aims to identify whether 12 of these initiatives⁵ need to be implemented through this form of implementation and would not deliver equally well with traditional calls of Horizon Europe or other lighter forms of European Partnerships under Horizon Europe. This means assessing whether each of these initiatives meets the necessity test set in the selection criteria for European Partnerships in the Horizon Europe Regulation, Annex III.

This assessment is done without any budgetary consideration, as the overall budget of the Multiannual Financial Framework of the EU – and hence of Horizon Europe – for the next financing period is not known at this stage.⁶

¹ Horizon Europe Regulation (common understanding), https://data.consilium.europa.eu/doc/document/ST-7942-2019-INIT/en/pdf

² Based on the European Commission Better Regulation framework (SWD (2017) 350) and supported by an external study coordinated by Technopolis Group (to be published in 2020).

³ For further details on these points, see below Section 1.2.2.

⁴ Set out in the Annex Va of the Horizon Europe Regulation (common understanding). https://data.consilium.europa.eu/doc/document/ST-7942-2019-INIT/en/pdf

Only 12 are subject to this impact assessment, as one initiative on High Performance Computing has already been subject to an impact assessment in 2017 (SEC(2018) 47).

⁶ EU budget commitments to the European Partnership candidates can only be discussed and decided following the political agreement on the overall Multiannual Financial Framework and Horizon Europe budgetary envelopes. The level of EU contribution for individual partnerships should be determined once there are agreed

1.2. The political and legal context

1.2.1. Shift in EU priorities and Horizon Europe framework

European priorities have evolved in the last decades, and reflect the social, economic, and environmental challenges for the EU in the face of global developments. In her Political Guidelines for the new European Commission $2019 - 2024^7$, the new Commission President put forward six overarching priorities, which reach well beyond 2024 in scope⁸. Together with the Sustainable Development Goals (SDGs), these priorities will shape future EU policy responses to the challenges Europe faces, and thus also give direction to EU research and innovation.

As part of the Multi-annual Financial Framework (MFF) 2021-27 the new EU Framework Programme for Research and Innovation Horizon Europe will play a pivotal role for Europe to lead the social, economic, and environmental transitions needed to achieve these European policy priorities. It will be more impact driven with a strong focus on delivering European added value, but also be more effective and efficient in its implementation. Horizon Europe finds its rationale in the daunting challenges that the EU is facing, which call for "a radical new approach to developing and deploying new technologies and innovative solutions for citizens and the planet on a scale and at a speed never achieved before, and to adapting our policy and economic framework to turn global threats into new opportunities for our society and economy, citizens and businesses." While Horizon Europe continues the efforts of strengthening the scientific and technological bases of the Union and foster competitiveness, a more strategic and impact-based approach to EU R&I investment is taken. Consequently, the objectives of Horizon Europe highlight the need to deliver on the Union strategic priorities and contribute to the realisation of EU objectives and policies, contribute to tackling global challenges, including the Sustainable Development Goals by following the principles of the Agenda 2030 and the Paris Agreement. 10

In this context, at least 35 % of the expenditure from actions under the Horizon Europe Programme will have to contribute to climate action. Furthermore, a Strategic Plan is co-designed with stakeholders to identify key strategic orientations for R&I support for 2021-2024 in line with the EU priorities. In the Orientations towards the first Strategic Plan for Horizon Europe, the need to strategically prioritise and "direct a substantial part of the funds towards the areas where we believe they will matter the most" is emphasised. The Orientations specify, that actions under Pillar II of Horizon Europe "Global Challenges and European Industrial Competitiveness" will target only selected themes of especially high impact that significantly contribute to delivering on the political priorities of the Union. Most of the candidate European Partnerships fall under this Pillar.

objectives, and clear commitments from partners. Importantly, there is a ceiling to the partnership budgets in Pillar II of Horizon Europe (the legal proposal specifies that the majority of the budget in pillar II shall be allocated to actions outside of European Partnerships).

⁷ https://ec.europa.eu/info/strategy/priorities-2019-2024 en

⁸ 1.A European Green Deal; An economy that works for people; A Europe fit for the Digital Age; Promoting our European way of life; A Stronger Europe in the World; and 6.A New push for European Democracy

⁹ EC (2018) A Modern Budget for a Union that Protects, Empowers and Defends. The Multiannual Financial Framework for 2021-2027. Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, COM(2018) 321 final

¹⁰ Article 3, Common understanding regarding the proposal for Horizon Europe Framework Programme.

1.2.2. Key evolutions in the approach to partnerships in Horizon Europe

Since their start in 1984 the successive set of Framework Programmes uses a variety of instruments and approaches to support R&I activities, address global challenges and industrial competitiveness. Collaborative, competition-based and excellence-driven R&I projects funded through Work Programmes are the most traditional and long-standing approach for implementation. Since 2002, available tools also include **partnerships**, whereby the Union together with private and/or public partners commit to jointly support the development and implementation of an R&I programme. These were introduced as part of creating the European Research Area (ERA) to align national strategies and overcome fragmentation of research effort towards an increased scientific, managerial and financial integration of European research and innovation. Interoperable and integrated national research systems would allow for better flows of knowledge, technology and people. Since then, the core activities of the partnerships consist of building critical mass mainly through collaborative projects, jointly developing visions, and setting strategic agendas.

As analysed in the **interim evaluation of Horizon 2020**¹¹, a considerable repertoire of partnership initiatives have been introduced over time, with 8 forms of implementation ¹² and close to 120 partnership initiatives running under Horizon 2020 - without clear exit strategies and concerns about their degree of coherence, openness and transparency. Even if it is recognised that these initiatives allow setting long-term agendas, structuring R&I cooperation between otherwise dispersed actors, and leveraging additional investments, the evaluation points to the complexity generated by the proliferation of instruments and initiatives, and their insufficient contribution to policies at EU and national level.

Box 1 *Key lessons from the interim evaluation of Horizon 2020 and R&I partnerships*

- The **Horizon 2020 Interim Evaluation** concludes that the overall partnership landscape has become overly complex and fragmented. It identifies the need for rationalisation, improve their openness and transparency, and link them with future EU R&I missions and strategic priorities.
- The **Article 185 evaluation** finds that these public-public partnerships have scientific quality, global visibility and networking/structuring effects, but should in the future focus more on the achievement of policy impacts. From a systemic point of view, it found that the EU public-to-public cooperation (P2P) landscape has become crowded, with insufficient coherence.
- The **Article 187 evaluation** points out that Public-Private Partnership (PPP) activities need to be brought more in line with EU, national and regional policies, and calls for a revision of the Key Performance Indicators. As regards the **contractual PPPs (cPPPs)** their reviews identified challenges of coherence among cPPPs and the need to develop collaborations and synergies with other relevant initiatives and programmes at EU, national and regional level.

Over 80% of respondents to the Open Public Consultation (OPC) indicated that a significant contribution by future European Partnerships is 'fully needed' to achieve climate-related goals, to develop and effectively deploy technology, and for EU global competitiveness in specific sectors/domains. Views converged across all categories of respondents, including citizens, industry and academia.

¹¹ Interim evaluation of Horizon 2020, Commission Staff Working Document, SWD(2017)221 and 222 Interim evaluation of the Joint Undertakings operating under Horizon 2020 (Commission Staff Working Document, SWD(2017) 339); Evaluation of the Participation of the EU in research and development programmes undertaken by several Member States based on Article 185 of the TFEU, Commission Staff Working Document, SWD (2017)340)

¹² E.g. initiatives based on Article 187 (Joint Technology Initiatives), Article 185 TFEU, Contractual Public-Private Partnerships (cPPPs), Knowledge & Innovation Communities of the European Institute of Innovation & Technology (EIT-KICs), ERA-NETs, European Joint Programmes, Joint Programming Initiatives.

The impact assessment of Horizon Europe identifies therefore the need to **rationalise the EU R&I funding landscape**, in particular with respect to partnerships, as well as to **re-orient partnerships towards more impact** and delivery on EU priorities. To address these concerns and to realise the higher ambition for European investments, Horizon Europe puts forward **a major simplification and reform for the Commission's policy on R&I partnerships**¹³. Reflecting its pronounced systemic nature aimed at contributing to EU-wide 'transformations' towards the sustainability objectives, Horizon Europe indeed intends to make a more effective use of these partnerships with a **more strategic, coherent and impact-driven approach**. Key related changes that apply to all forms of European Partnerships encapsulated in Horizon Regulation are summarised in the Box below.

Box 2 Key features of the revised policy approach to R&I partnerships under Horizon Europe based on its impact assessment

- ✓ **Simpler architecture & toolbox** by streamlining 8 partnership instruments into 3 implementation forms (Co-Funded, Co-Programmed, Institutionalised), under the umbrella 'European Partnerships'
- ✓ More systematic and transparent approach to selecting, implementing, monitoring, evaluating and phasing out all forms of partnerships (criteria for European Partnerships):
 - The selection of Partnerships is embedded in the strategic planning of Horizon Europe, thereby ensuring coherence with the EU priorities. The selection criteria require that partnerships are established with stronger ex-ante commitment and higher ambition.
 - The implementation criteria stipulate that initiatives adopt a systemic approach in achieving impacts, including broad engagement of stakeholders in agenda-setting and synergies with other relevant initiatives to promote the take-up of R&I results.
 - A harmonised monitoring & evaluation system will be implemented, and ensures that progress is analysed in the wider context of achieving Horizon Europe objectives and EU priorities.
 - All partnerships need to develop an exit strategy from Framework Programme funding. This new approach is underpinned by principles of openness, coherence and EU added value.

✓ Reinforced impact orientation:

- Partnerships are established only if there is evidence they support achieving EU policy objectives
 more effectively than other Horizon Europe actions, by ensuring alignment with an R&I agenda
 (directionality) and securing leveraging effects (additionality).
- European Partnerships are expected to provide mechanisms based on a concrete roadmap to join up R&I efforts between a broad range of actors towards the development and uptake of innovative solutions in line with EU priorities, serving the economy and society, as well as scientific progress.
- They are expected to develop close synergies with national and regional initiatives, acting as dynamic change agents, strengthening linkages within their respective ecosystems and along the value chains, as well as pooling resources and efforts towards the common EU objectives.

Under Horizon Europe, a 'European Partnership' is defined as "an initiative where the Union, prepared with early involvement of Member States and/or Associated Countries, together with private and/or public partners (such as industry, universities, research organisations, bodies with a public service mission at local, regional, national or international level or civil society organisations including foundations and NGOs), commit to jointly support the development and implementation of a programme of research and innovation activities, including those related to market, regulatory or policy uptake."

The Regulation further specifies that European Partnerships shall adhere to the "principles of Union added value, transparency, openness, impact within and for Europe, strong leverage effect on sufficient scale, long-term commitments of all the involved parties, flexibility in implementation, coherence, coordination and complementarity with Union, local, regional, national and, where relevant, international initiatives or other partnerships and missions."

¹⁴ Article 8 and Annex III of the Horizon Europe Regulation (common understanding))

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¹³ Impact assessment of Horizon Europe, Commission Staff Working Document, SWD(2018)307.

1.3. Why should the EU act

1.3.1. Legal basis

Proposals for Institutionalised European Partnerships are based on:

- 1) Article 185 TFEU which allows the Union to make provision, in agreement with the Member States concerned, for participation in research and development programmes undertaken by several Member States, including participation in the structures created for the execution of those programmes; or
- 2) Article 187 TFEU according to which the Union may set up joint undertakings or any other structure necessary for the efficient execution of Union research, technological development and demonstration programmes.¹⁵

1.3.2. Subsidiarity

The EU should act only in areas where there is demonstrable advantage that the action at EU level is more effective than action taken at national, regional or local level. Research is a shared competence between the EU and its Member States according to the TFEU. Article 4 (3) specifies that in the areas of research, technological development and space, the EU can carry out specific activities, including defining and implementing programmes, without prejudice to the Member States' freedom to act in the same areas. The candidate initiatives focus on areas where there is a demonstrable value added in acting at the EU level due to the scale, speed and scope of the efforts needed for the EU to meet its long-term Treaty objectives and deliver on its strategic policy priorities and commitments. In addition, the proposed initiatives should be seen as complementary and reinforcing national and subnational activities in the same area. Overall European Partnerships find their **rationale in addressing a set of systemic failures**¹⁶:

- Their primary function is to create a platform for a strengthened **collaboration** and knowledge exchange between various actors in the European R&I system and an enhanced **coordination** of strategic research agendas and/or R&I funding programmes. They aim to address **transformational failures** to better align agendas and policies of public and private funders, pool available resources, create critical mass, avoid unnecessary duplication of efforts, and leverage sufficiently large investments where needed but hardly achievable by single countries.
- The concentration of efforts and pooling of knowledge on common priorities to solve multi-faceted societal and economic challenges is at the core of these initiatives. Specifically, enhanced cross-disciplinary and cross-sectoral collaboration and an improved integration of value chains and ecosystems are among the key objectives of these instruments. In the light of Horizon Europe, the aim is to drive system transitions and transformations towards EU priorities.
- Especially in fast-growing technologies and sectors such as ICT, there is a need to **react to emerging opportunities** and address systemic failures such as shortage in skills or critical mass or cross-sectoral cooperation along the value chains that would hamper attainment of future European leadership and/or strategic autonomy.
- They also aim to address **market failures** predominantly to enhancing industry investments thanks to the sharing of risks.

¹⁵ Both Articles are under Title XIX of the TFEU - Research and Technological Development and Space.

¹⁶ The Interim Evaluation of Horizon 2020 and the impact assessment of Horizon Europe provide qualitative and quantitative evidence on these points. Sections 1 and 2 of each impact assessment on candidate European Partnerships include more detail on the necessity to act at EU level in specific thematic areas.

2. THE CANDIDATE EUROPEAN PARTNERSHIPS – WHAT NEEDS TO BE DECIDED

2.1. Portfolio of candidates for Institutionalised European Partnerships

The new approach for more objective-driven and impactful European Partnerships is reflected in the way candidate Partnerships have been identified. It involved a co-design exercise aiming to better align these initiatives with societal needs and policy priorities, while broadening the range of actors involved. Taking into account the 8 areas for Institutionalised European Partnerships set out in the Horizon Europe Regulation 17, a co-design exercise as part of the Strategic Planning process of Horizon Europe lead to the identification of 49 candidates for Co-funded, Co-programmed or Institutionalised European Partnerships 18. Out of these, 13 were identified as suitable candidate Institutionalised Partnerships because of their objectives and scope 19. Whilst the Co-Funded and Co-Programmed Partnerships are linked to the comitology procedure (including the adoption of the Strategic Plan and the Horizon Europe Work Programmes), Institutionalised Partnerships require the adoption of legislation and are subject to an impact assessment. The Figure below gives an overview of all candidate European Partnerships according to their primary relevance to Commission priorities for 2019-2024.

Figure 1 - Overview of the candidates for Co-Funded, Co-Programmed and Institutionalised European Partnerships according to Horizon Europe structure

Cluster 1: Health	Cluster 4: Digital, Industry &	Cluster. 5: Climate, Energy &	Cluster 6: Food, Bioeconomy, Agriculture,		
	Space	Mobility			
Innovative	Key digital technologies	Clean Hydrogen	Circular Bio-based Europe		
Health Initiative	Smart networks & services	Safe & automated road transport	Safe & sustainable food		
EU-Africa Global Health	High-Performance Computing	Transforming EU's rail system	system		
Large-scale	European Metrology	Clean Aviation	Climate-neutral, sustainable & productive blue bio-		
innovation & transformation of	AI-Data-Robotics	Integrated Air Traffic Management	economy		
health systems	Photonics	European industrial battery value	Animal Health		
Personalised	Made in Europe	chain	Water4All		
Medicine	Clean steel – low-carbon	Zero-emission waterborne	Accelerating farming systems transitions		
ERA for Health	steelmaking	transport			
Rare diseases	Carbon neutral & circular industry	Zero-emission road transport	Environmental observations		
One-Health Anti	Global competitive space	Built environment & construction	for sustainable agriculture		
Microbial Resistance	systems	Clean energy transition	Rescuing biodiversity		
Chemicals risk	Geological Service for Europe	Sustainable, smart & inclusive cities & communities	EIT Food		
assessment	EIT Digital	EIT Climate	Cluster 2: Culture, Creativity		
EIT Health	EIT Manufacturing	EIT InnoEnergy	& Inclusive Society		
EIT Raw Materials		EIT Urban Mobility	EIT Cultural and Creative Industries		
Horizon Europe Pillar III - Cross-Pillars Innovative Europe					
Innovative SMEs European Open Science Cloud					

Source: Technpolis group (2020)

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¹⁷ Horizon Europe Regulation (common understanding), Annex Va.

Shadow configuration of Strategic Programme Committee for Horizon Europe. The list of candidate European Partnerships is described in "Orientations towards the Strategic Plan of Horizon Europe" - Annex 7 Only 12 are subject to this impact assessment, as one initiative on High Performance Computing has already been subject to an impact assessment in 2017 (SEC(2018) 47)

There are only three partnerships for which implementation as an Institutionalised Partnership under Article 185 is an option, i.e. European Metrology, the EU-Africa Global Health partnership, and Innovative SMEs. Ten partnerships are candidates for Institutionalised Partnerships under Article 187. Overall the initiatives can be categorised into 'horizontal' partnerships and 'vertical' partnerships.

The 'horizontal' partnerships have a central position in the overall portfolio, as they are expected to develop methodologies and technologies for application in the other priority areas, ultimately supporting European strategic autonomy in these areas as well as technological sovereignty. These 'horizontal' partnerships are typically proposed as Institutionalised or Co-programmed Partnerships, in addition to a number of EIT KICs, they cover mainly the digital field in addition to space, creative industries and manufacturing, but also the initiative related to Innovative SMEs. 'Vertical' partnerships are focused on the needs and development of specific application areas, and are primarily expected to support enhanced environmental sustainability thereby addressing Green Deal related objectives. They also deliver on policies for more people centred economy, through improved wellbeing of EU citizen and the economy, like health related candidate European Partnerships.

2.2. Assessing the necessity of a European Partnership and possible options for implementation

Horizon Europe Regulation Article 8 stipulates that Institutionalised European Partnerships based on Article 185 and 187 TFEU shall be implemented only where other parts of the Horizon Europe programme, including other forms of European Partnerships would not achieve the objectives or would not generate the necessary expected impacts, and if justified by a long-term perspective and high degree of integration. At the core of this impact assessment is therefore the need to demonstrate that the impacts generated through a Partnership approach go beyond what could be achieved with traditional calls under the Framework Programme – the Baseline Option. Secondly, it needs to assess if using the Institutionalised form of a Partnership is justified for addressing the priority.

For all candidate Institutionalised European Partnerships the options considered in this impact assessment are the same, i.e.:

- Option 0 Baseline option Traditional calls under the Framework Programme
- Option 1 Co-programmed European Partnership
- Option 2 Co-funded European Partnership
- Option 3 Institutionalised Partnership
 - o Sub-option 3a Institutionalised Partnerships based on Art 185 TFEU
 - o Sub-option 3b Institutionalised Partnerships based on Art 187 TFEU

2.2.1. *Option 0 - Baseline option – Traditional calls*

Under this option, strategic programming for R&I in the priority area will be done through the mainstream channels of Horizon Europe. The related priorities will be implemented through **traditional calls** of Horizon Europe covering a range of actions, mainly R&I and/or innovation actions but also coordination and support actions, prizes or procurement. Most actions involve consortia of public and/or private actors in ad hoc combinations, while some actions are single actor (mono-beneficiary). There will be no dedicated implementation structure and no support other than what is foreseen in the related Horizon Europe Work Programme. This means that discontinuation costs/benefits of predecessor initiatives should be factored in for capturing the baseline situation when relevant.

Under this option, strategic planning mechanisms in the Framework Programme will allow for a high level of flexibility in the ability of traditional calls to respond to particular needs over time, building upon additional input in co-creation from stakeholders and programme committees involving Member States. The Union contribution to addressing the priority covers the full duration of the initiative, during the lifetime of Horizon Europe. Without a formal EU partnership mechanism, it is less likely that the stakeholders will develop a joint Strategic Research Agenda and commit to its implementation or agree on mutual commitments and contributions outside their participation in funded projects.

2.2.2. European Partnerships

Under this set of options, three different forms of implementation are assessed: Co-funded, Co-Programmed, Institutionalised European Partnerships. These have **commonalities that cannot serve as a distinguishing factor in the impact assessment process**. They are all based on agreed objectives and expected impacts and underpinned by Strategic Research and Innovation Agendas / roadmaps that are shared and committed to by all partners in the partnership. They all have to follow the same set of criteria along their lifecycle, as defined in the Horizon Europe Regulation (Annex III), including ex ante commitment from partners to mobilise and contribute resources and investments. The Union contribution is defined for the full duration of the initiative for all European Partnerships. The Horizon Europe legal act introduces few additional requirements for Institutionalised Partnerships, e.g. the need for long-term perspective, strong integration of R&I agendas, and financial contributions.

Figure 2 - Key differences in preparation and implementation of European Partnerships

Туре	Legal form	Implementation			
Co-Programmed	Contractual arrangement / MoU	Division of labour , whereby Union contribution is implemented through Framework Programme and partners' contributions under their responsibility.			
Co-Funded	Grant Agreement	Union provides co-funding for an integrated programme with distributed implementation by entities managing and/or funding national research and innovation programmes			
Institutionalised based on Article 185/187 TFEU	Basic act (Council regulation, Decision by European Parliament and Council)	Integrated programme with centralised implementation			

The main differences between the different forms of European Partnerships are in their preparation and in the way they function, as well as in the overall impact they can trigger. The Co-Programmed form is assessed as the simplest, and the Institutionalised the most complex to prepare and implement. The functionalities of the different form of Partnerships – compared to the baseline option – are presented in Figure 3. They relate to the types of actors Partnerships can involve and their degree of openness, the types of activities they can perform and their degree of flexibility, the degree of commitment of partners and the priority setting system, and their ability to work with their external environment (coherence), etc. These key distinguishing factors will be at the basis of the comparison of each option to determine their overall capacity to deliver what is needed at a minimised cost.

Figure 3 Overview of the functionalities provided by each form of European Partnerships, compared to the traditional calls of Horizon Europe (baseline)

Baseline: Horizon Europe calls	Option 1: Co- Programmed	Option 2: Co-Funded	Option 3a: Institutionalised Art 185	Option 3b: Institutionalised Art 187
Type and composition	of actors (including openn	ness and roles)		
Partners: N.A., no common set of actors that engage in planning and implementation Priority setting: open to all, part of Horizon Europe Strategic planning Participation in R&I activities: fully open in	Partners: Suitable for all types: private and/or public partners, foundations Priority setting: Driven by partners, open stakeholder consultation, Member States in comitology Participation in R&I activities: fully open in	Partners: core of national funding bodies or govern-mental research organisations Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: limited, according to national	governmental research organisation Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: fully open in line with Horizon	Partners: Suitable for all types: private and/or public partners, foundations Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: fully open in line with Horizon Europe rules, but possible
line with Horizon	line with Horizon Europe	rules of partner	Europe rules, but	derogations
Europe rules	rules	countries	possible derogations	
	vities (including additiona			
Activities: Horizon Europe standards that allow broad range of individual actions Additionality: no additional activities and investments outside the funded projects Limitations: No systemic approach beyond individual actions	Activities: Horizon Europe standard actions that allow broad range of individual actions, support to market, regulatory or policy/ societal uptake Additionality: Activities/investments of partners, National funding Limitations: Limited systemic approach beyond individual actions	Activities: Broad, according to rules/programmes of participating States, State-aid rules, support to regulatory or policy/societal uptake Additionality: National funding Limitations: Scale & scope depend on participating programmes, often smaller in scale	Activities: Horizon Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to systemic approach Additionality: National funding	Activities: Horizon Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to systemic approach (portfolios of projects, scaling up of results, synergies with other funds. Additionality: Activities/investments of partners/ national funding
Priority-setting process	s and directionality			
Priority setting: Strategic Plan and annual work programmes, covering max. 4 years. Limitations: Fully taking into account existing or to be developed SRIA/ roadmap	Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Input to FP annual work programme drafted by partners, finalised by EC (comitology) Objectives & commitments set in contractual arrangement Iorizon Europe) & externa	Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Annual work programme drafted by partners, approved by EC Objectives & commitments set in Grant Agreement	Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Annual work programme drafted by partners, approved by EC Objectives & commitments set in legal act mes. national program	Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Annual work programme drafted by partners, approved by EC (vetoright in governance) Objectives & commitments set in legal act
`	* ′			
Internal: Coherence between different parts of the FP Annual Work programme can be ensured by EC External: Limited for other Union programmes, no synergies with national/regional programmes & activities	Internal: Coherence among partnerships & with parts of the FP Annual Work programme can be ensured by partners & EC External: Limited synergies with other Union programmes & industrial strategies. If Member States participate, with national/regional programmes &	Internal: Coherence among partnerships & with parts of the FP Annual Work programme can be ensured by partners & EC External: Synergies with national/ regional programmes & activities	Internal: Coherence among partnerships & with parts of the FP Annual Work programme can be ensured by partners & EC External: Synergies with national/regional programmes & activities	Internal: Coherence among partnerships & with parts of the FP Annual Work programme can be ensured by partners & EC External: Synergies with other Union programmes and industrial strategies If Member States participate, with national/regional programmes &

2.2.2.1. Option 1 - Co-programmed European Partnership

This form of European Partnership is **based upon a Memorandum of Understanding or a Contractual Arrangement** signed by the Commission and the private and/or public partners. Private partners are represented by industry associations, which also support the daily management of the partnership. This type of partnership would allow for a large degree of flexibility for the activities, partners and priorities to continuously evolve. The commitments of partners are political efforts described in the contractual arrangement and the contributions from partners are provided in kind more than financially. The priorities for the calls, proposed by the Partnership's members for integration in the Horizon Europe's Work Programmes, are subject to further input from Member States (comitology) and Commission services. The Union contribution is implemented within the executive agency managing Horizon Europe calls for research and innovation projects proposals. The full array of Horizon Europe instruments can be used, ranging from research and innovation (RIA) types of actions to coordination and support actions (CSA) and including grants, prizes, and procurement.

2.2.2.2. Option 2 – Co-funded European Partnership

The Co-funded European Partnership is **based on a Grant Agreement** between the Commission and a consortium of partners, resulting from a specific call in the Horizon Europe Work Programme. This form of implementation only allows to address public partners at its core. Typically these provide co-funding to a common programme of activities established and/or implemented by entities managing and/or funding national R&I programmes. The recipients of the EU co-funding implement the initiative under their responsibility, with national funding/resources pooled to implement the programme with co-funding from the Union. The expectation is that these entities would cover most if not all EU Member States. Calls and evaluations would be organised centrally, beneficiaries in selected projects would be funded at national level, following national funding rules.

2.2.2.3. Option 3 – Institutionalised European Partnership

This type of Partnership is the most complex and high-effort arrangement, and requires meeting additional requirements. Institutionalised European Partnership are based on a Council Regulation (Article 187 TFEU or a Decision by the European Parliament and Council (Article 185 TFEU) and are implemented by dedicated structures created for that purpose. These regulatory needs limit the flexibility for a change in the core objectives, partners, and/or commitments as these would require amending legislation. The basic rationale for this type of partnership is the need for a strong integration of R&I agendas in the private and/or public sectors in the EU in order to address a strategic challenge. It is therefore necessary to demonstrate that other forms of implementation would not achieve the objectives or would not generate the necessary expected impacts, and that a long-term perspective and high degree of integration is needed. For both Article 187 and 185 initiatives, contributions from partners can be in the form of financial and in-kind contributions. Eligibility for participation and funding follows by default the rules of Horizon Europe, unless a derogation is introduced in the basic act.

Option 3a - Institutionalised Partnerships based on Article 185 TFEU

Article 185 of the TFEU allows the Union to participate in programmes jointly undertaken by Member States and limits therefore the scope to **public partners** which are Member States and Associated Third Countries. This type of Institutionalised Partnership aims therefore at reaching the greatest possible impact through the integration of national and EU

funding, aligning national strategies in order to optimise the use of public resources and overcome fragmentation of the public research effort. It brings together R&I governance bodies of most if not all EU Member States (legal requirement: at least 40% of Member States) as well as Associated Third Countries that designate a legal entity (Dedicated Implementation Structure) of their choice for the implementation. By default, participation of non-associated Third Countries is not foreseen. Such participation is possible only if it is foreseen in the basic act and subject to conclusion of an international agreement.

Option 3b - Institutionalised Partnerships based on Article 187 TFEU

Article 187 of the TFEU allows the Union to set up joint undertakings or any other structure necessary for the efficient execution of EU research, technological development and demonstration programmes. This type of Institutionalised Partnership brings together a stable set of **public and private partners** with a strong commitment to taking a more integrated approach and requires the set-up of a dedicated legal entity (Union body, Joint Undertaking (JU)) that carries full responsibility for the management of the Partnership and implementation of the calls. Different configurations are possible:

- Partnerships focused on creating strategic industrial partnerships where, most often, the partner organisations are represented by one or more industry associations, or in some cases individual private partners;
- Partnerships coordinating national ministries, public funding agencies, and governmental research organisations in the Member States and Associated Countries;
- Or a combination of the two: the so-called tripartite model.

Participation of non-associated Third Countries is only possible if foreseen in the basic act and subject to conclusion of an international agreement.

2.3. Overview of the methodology adopted for the impact assessment

The methodology for each impact assessment is based on the Commission Better Regulation Guidelines²⁰ to evaluate and compare options with regards to their **efficiency**, **effectiveness** and coherence. This also integrates **key selection criteria for European Partnerships**.

Box 3 Summary of European Partnerships selection criteria²¹

- *Effectiveness* in achieving the related objectives and impacts of the Programme;
- Coherence and synergies of the European Partnership within the EU R&I landscape;
- *Transparency* & *openness* as regards the identification of priorities and objectives and the involvement of partners & stakeholders from the entire value chain, backgrounds & disciplines;
- Ex-ante demonstration of *additionality* and *directionality*;
- Ex-ante demonstration of the partners' *long term commitment*.

2.3.1. Overview of the methodologies employed

In terms of **methods and evidence used**, the impact assessments draw on an external study covering all candidate Institutionalised European Partnerships in parallel to ensure a high level of coherence and comparability of analysis, in addition to a horizontal analysis.²² For all initiatives, the understanding of the overall context of the candidate institutionalised

²¹ For a comprehensive overview of the selection criteria for European Partnerships, see Annex 6.

²⁰ European Commission (2017), Better Regulation Guidelines (SWD (2017) 350)

²² Technopolis Group (2020), Impact Assessment Study for Institutionalised European Partnerships under Horizon Europe, Final Report, Study for the European Commission, DG Research & Innovation

European Partnerships relied on desk research, including among others the lessons learned from previous partnerships. This was complemented by the analysis of a range of quantitative and qualitative evidence, including evaluations of past and ongoing initiatives; foresight studies; statistical analyses of Framework Programmes application and participation data, and Community Innovation Survey data; analyses of science, technology and innovation indicators; reviews of academic literature; sectoral competitiveness studies and expert hearings. The analyses included a portfolio analysis, a stakeholder and social network analysis in order to profile the actors involved as well as their co-operation patterns, and an assessment of the partnerships' outputs (bibliometric and patent analysis). A cost modelling exercise was performed in order to feed into the efficiency assessments of the partnership options, as described below. Public consultations (both open and targeted) supported the comparative assessment of the policy options. For each initiative, up to 50 relevant stakeholders were interviewed by the external contractor (policymakers, business including SMEs and business associations, research institutes and universities, and civil organisations, among others). In addition, the analysis was informed by the results of the Open Public Consultation run between September and November 2019, the consultation of Member States through the Strategic Programme Committee and the online feedback received on the Inception Impact Assessments of the set of initiatives.

A more detailed description of the methodology and evidence base that were mobilised, completed by thematic specific methodologies, is provided in Annexes 4 and 6.

2.3.2. *Method for identifying the preferred option*

The first step of the assessments consisted in scoping the problems that the initiatives are expected to solve given the overall economic, technological, scientific and social context, including the lessons to be learned from past and ongoing partnerships on what worked well and less well. This supported the identification of the objectives of the initiative in the medium and long term with the underlying intervention logic – showing how to get there.

Given the focus of the impact assessment on comparing different forms of implementation, the Better Regulation framework has then been adapted to introduce "key functionalities needed" - making the transition between the definition of the objectives and what would be crucial to achieve them in terms of implementation. The identification of "key functionalities needed" for each initiative as an additional step in the impact assessment is based on the distinguishing factors between the different options (see Section 2.2.1). In practical terms, each option is assessed on the basis of the degree to which it would allow for the key needed functionalities to be covered, as regards e.g. the type and composition of actors that can be involved ('openness'), the range of activities that can be performed (including additionality and level of integration), the level of directionality and integration of R&I strategies; the possibilities offered for coherence and synergies with other components of Horizon Europe, including other Partnerships (internal coherence), and the coherence with the wider policy environments, including with the relevant regulatory and standardisation framework (external coherence). This approach guides the identification of discarded options while allowing at the same time a structured comparison of the options not only as regards their effectiveness, efficiency and coherence, but also against a set of other key selection criteria for European Partnerships (openness, transparency, directionality)²³.

In line with the Better Regulation Framework, the assessment of the effectiveness, efficiency and coherence of each option is made compared to the baseline. Therefore, for

²³ The criterion on the ex-ante demonstration of partners' long term commitment depends on a series of factors that are unknown at this stage, and thus fall outside the scope of the analysis.

each of these aspects the performance of using traditional calls under Horizon Europe is first estimated and scored 0 to serve as a reference point. This includes the discontinuation costs/benefits of existing implementation structures when relevant. The policy options are then scored compared to the baseline with a + and - system with a two-point scale, to show a slightly or highly additional/lower performance compared to the baseline. A scoring of 0 of a policy option means that it would deliver as much as the baseline option.

On the basis of the evidence collected, the intervention logic of each initiative and the key functionalities needed, the impact assessments first evaluate the **effectiveness** of the various policy options to deliver on their objectives. To be in line with the Horizon Europe impact framework, the fulfilment of the specific objectives of the initiative is translated into 'expected impacts' - how success would look like -, differentiating between scientific, economic/ technological, and societal (including environmental) impacts. Each impact assessment considers to which extent the different policy options provides the 'key functionalities needed' to achieve the intended objectives. The effectiveness assessment does not use a compound score but shows how the options would deliver on the different types of expected impacts. This is done to increase transparency and accuracy in the assessment of options²⁴.

A similar approach is followed to evaluate the coherence of options with the overarching objectives of the EU's R&I policy, and distinguishes between **internal** and **external coherence**. Specifically, internal coherence covers the consistency of the activities that could be implemented with the rest of Horizon Europe, including European Partnerships (any type). External coherence refers to the potential for synergies and/or complementarities (including risks of overlaps/gaps) of the initiative with its external environment, including with other programmes under the MFF 2021-27, but also the framework conditions at European, national or regional level (incl. regulatory aspects, standardisation).

To compare the expected costs and benefits of each option (efficiency), the thematic impact assessments broadly follow a cost-effectiveness approach²⁵ to establish to which extent the intended objectives can be achieved for a given cost. A preliminary step in this process is to obtain a measure of the expected costs of the policy options, to be used in the thematic assessments. As the options correspond to different implementation modes, relevant cost categories generally include the costs of setting-up and running an initiative. For instance, set-up costs includes items such as the preparation of a European Partnership proposal and the preparation of an implementation structure. The running costs include the annual work programme preparation costs. Where a Partnership already exists, discontinuation costs and cost-savings are also taken into account²⁶. The table below provides an overview of the cost categories used in the impact assessment and a qualitative scoring of their intensity when compared to the baseline option (traditional calls). Providing a monetised value for these average static costs would have been misleading, because of the different features and needs

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²⁴ In the thematic impact assessments, scores are justified in a detailed manner to avoid arbitrariness and spurious accuracy. A qualitative or even quantitative explanation is provided of why certain scores were given to specific impacts, and why one option scores better or worse than others.

²⁵ For further details, see Better Regulation Toolbox # 57.

²⁶ Discontinuation costs will bear winding down and social discontinuation costs and vary depending on e.g. the number of full-time-equivalent (FTEs) staff concerned, the type of contract (staff category and duration) and applicable rules on termination (e.g. contracts under Belgian law or other). If buildings are being rented, the cost of rental termination also apply. As rental contracts are normally tied to the expected duration of the current initiatives, these termination costs are likely to be very limited. In parallel, there would also be financial cost-savings related to the closing of the structure, related to operations, staff and coordination costs in particular. This is developed further in the individual efficiency assessments.

of each candidate initiative.²⁷ The table shows the overall administrative, operational and coordination costs of the various options. These costs are then put into context in the impact assessments to reflect the expected co-financing rates and the total budget available for each of the policy options, assuming a common Union contribution (cost-efficiency):

- The costs related to the baseline scenario (traditional calls under Horizon Europe) are pre-dominantly the costs of implementing the respective Union contribution via calls and project, managed by the executive agencies (around 4%, efficiency of 96% for the overall investment).
- For a Co-Programmed partnership the costs of preparation and implementation increase only marginally compared to the baseline (<1%), but lead to an additional R&I investment of at least the same amount than the Union contribution²⁸ (efficiency of 98% for the overall investment).
- For a Co-Funded partnership the additional R&I investment by Member States accounts for 2, 3 times the Union contribution²⁹. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the national programmes, can be estimated at 6% of the Union contribution (efficiency of 98% related to the overall investment).
- For an Article 185 initiative the additional R&I investment by Member States is equal to the Union contribution³⁰. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the dedicated implementation structure, can be estimated at 7% of the Union contribution (efficiency of 96% related to the overall investment).
- For an Article 187 initiative the additional R&I investment by partners is equal to the Union contribution³¹. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the dedicated implementation structure, can be estimated at 9% of the Union contribution (efficiency of 94% related to the overall investment).

Figure 4 - Intensity of additional costs compared with Horizon Europe Calls (for Partners, stakeholders, public and EU)

Cost items	Baseline: traditional calls	Option 1: Coprogrammed	Option 2 Co-funded	Option 3a - Art. 185	Option 3b -Art. 187
Preparation and set-up costs					
Preparation of a partnership proposal (partners and EC)	0		$\uparrow \uparrow$		
Set-up of a dedicated implementation structure		0		Existing: ↑ New: ↑↑	Existing: ↑↑ New: ↑↑↑
Preparation of the SRIA / roadmap	0		$\uparrow \uparrow$		
Ex-ante Impact Assessment for partnership		0		↑ ↑	↑
Preparation of EC proposal and negotiation		0		↑ ↑	↑
Running costs (Annual cycle of implementation)					
Annual Work Programme preparation	0		↑		

²⁷ A complete presentation of the methodology developed to assess costs as well as the sources used is described in the external study supporting this impact assessment (Technopolis Group, 2020).

²⁸ Minimum contributions from partners equal to the Union contribution

²⁹ Based on the default funding rate for programme co-fund actions of 30%, partners contribute with 70% of the total investment.

³⁰ Based on the minimum requirement in the legal basis that partners contribute at least 50% of the budget.

³¹ Based on the minimum requirement in the legal basis that partners contribute at least 50% of the budget.

Cost items	Baseline: traditional calls	Option 1: Coprogrammed	Option 2 Co-funded	Option 3a - Art. 185	Option 3b -Art. 187	
Call and project implementation	0	0 In case of Member States contributions: ↑	↑	1	1	
Cost to applicants	Comparable, unless there are strong arguments of major differences in oversubscription					
Partners costs not covered by the above	0	↑	0	↑	↑	
Additional EC costs (e.g. supervision)	0	\uparrow	↑	↑	$\uparrow \uparrow$	
Winding down costs						
EC		0			$\uparrow\uparrow\uparrow$	
Partners	0	↑	0	↑	↑	

Notes: 0: no additional costs, as compared with the baseline; \uparrow : minor additional costs, as compared with the baseline; $\uparrow \uparrow \uparrow$: medium additional costs, as compared with the baseline; $\uparrow \uparrow \uparrow \uparrow$: higher costs, as compared with the baseline.

The cost categories estimated for the common model are then used to develop a scorecard analysis and further refine the assessment of options for each of the 12 candidate Institutionalised Partnerships. Specifically, the scores related to the set-up and implementation costs are used in the thematic impact assessments to consider the scale of the expected benefits and thereby allow a simple "value for money" analysis (cost-effectiveness)³². In carrying out the scoring of options, the results of fieldwork, desk research and stakeholder consultation undertaken and taken into account.

For the **identification of the preferred option**, the scorecard analysis builds a hierarchy of the options by individual criterion and overall in order to identify a single preferred policy option or in case of an inconclusive comparison of options, a number of 'retained' options or hybrid. This exercise supports the systematic appraisal of alternative options across multiple types of monetary, non-monetary and qualitative dimensions. It also allows for easy visualisation of the pros and cons of each option. Each option is attributed a score of the adjudged performance against each criterion with the three broad appraisal dimensions of effectiveness, efficiency and coherence.

As a last step, the alignment of the preferred option with key criteria for the selection of European Partnerships is described, reflecting the outcomes of the 'necessity test'. The monitoring and evaluation arrangements are concluding the assessment, with an identification of the key indicators to track progress towards the objectives over time.

2.4. Horizontal perspective on candidate Institutionalised European Partnerships

Overall impact orientation, coherence and efficiency needs

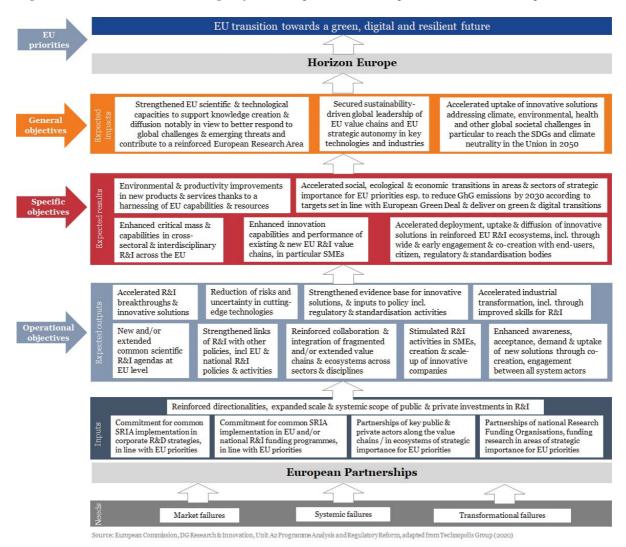
The consolidated **intervention logic** for the set of candidate Institutionalised European Partnerships in the Figure below builds upon the objectives as reported in the individual impact assessments.

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³² More details on the methodology can be found in Annex 4.

³³Certain aspects of the selection criteria will be further addressed/ developed at later stages, notably in the context of preparing basic acts (e.g. Openness and Transparency; Coherence and Synergies), in the Strategic Research and Innovation Agendas (e.g. Directionality and Additionality), and by collecting formal commitments (Ex-ante demonstration of partners' long-term commitment).

Figure 5 – Overall intervention logic of the European Partnerships under Horizon Europe



When analysed as a package the 12 candidate Institutionalised European Partnerships are expected to support the achievement of the European policy priorities targeted by Horizon Europe by pursuing the following joint general objectives:

- a) Strengthening and integrating EU scientific and technological capacities to support knowledge creation and diffusion notably in view to better respond to global challenges and emerging threats and contribute to a reinforced European Research Area;
- b) Securing sustainability-driven global leadership of EU value chains and EU strategic autonomy in key technologies and industries; and
- c) Accelerate the uptake of innovative solutions addressing climate, environmental, health and other global societal challenges contributing to Union strategic priorities, in particular to reach the Sustainable Development Goals and climate neutrality in the Union in 2050.

In terms of specific objectives, they jointly aim to:

- a) Enhance the critical mass and scientific capabilities in cross-sectoral and interdisciplinary research and innovation across the Union;
- b) Accelerate the social, ecological and economic transitions in areas and sectors of strategic importance for Union priorities, in particular to reduce greenhouse gas

- emissions by 2030 according to the targets set in line with the European Green Deal, and deliver on the green and digital transition;
- c) Enhance the innovation capabilities and performance of existing and new European research and innovation value chains, in particular SMEs;
- d) Accelerate the deployment, uptake and diffusion of innovative solutions in reinforced European R&I ecosystems, including through wide and early engagement and co-creation with end-users, citizen and regulatory and standardisation bodies;
- e) Deliver environmental and productivity improvements in new products and services thanks to a harnessing of EU capabilities and resources.

In terms of their operations, taking a horizontal perspective on all initiatives allows for the identification of further possible collective efficiency and coherence gains for more impact:

- Coherence for impact: The extent and speed by which the expected results and impacts will be reached, will depend on the scale of the R&I efforts triggered, the profile of the partners involved, the strength of their commitments, and the scope of the R&I activities funded. To be fully effective it comes out clearly that future partnerships need to operate over their whole life cycle in full coherence with their environment, including potential end users, regulators and standardisation bodies. This relates also to the alignment with relevant EU, national or regional policies and synergies with R&I programmes. This needs to be factored in as of the design stage to ensure a wide take-up and/or deployment of the solutions developed, including their interoperability.
- Collaboration for impact: Effectiveness could also be improved collectively through enhanced cross-disciplinary and cross-sectoral collaboration and an improved integration of value chains and ecosystems. An adequate governance structure appears in particular necessary to ensure cross-fertilisation between all European Partnerships. This applies not only to initiatives where similar R&I topics are covered and/or the same stakeholders involved or targeted, but also to the interconnections needed between the 'thematic' and the 'vertical' Partnerships, as these are expected to develop methodologies and technologies for application in EU priority areas. Already at very early stages of preparing new initiatives, Strategic Research and Innovation Agendas and roadmaps need to be aligned, particularly for partnerships that develop enabling technologies that are needed in other Partnerships. The goal should be to achieve greater impacts jointly in light of common challenges.
- Efficiency for impact: Potential efficiency gains could also be achieved by joining up the operational functions of Joint Undertakings that do not have a strong context dependency and providing them through a common back-office³⁴. A number of operational activities of the Joint Undertakings are of a technical or administrative nature (e.g. financial management of contracts), or procured from external service providers (e.g. IT, communication activities, recruitment services, auditing) by each Joint Undertaking separately. If better streamlined this could create a win-win situation for all partners leading to better harmonization, economies of scales, and less complexity in supervision and support by the Commission services.
 - 2.4.1. Analysis of coherence of the overall portfolio of candidate initiatives at the thematic level

Looking at the coherence of the set of initiatives at the thematic level, the "digital centric"

³⁴ See Annex 6 for an overview of key functions/roles that could be provided by a common back office.

initiatives have a strong focus on supporting the digital competitiveness of the EU ecosystem. Their activities are expected to improve alignment and coordination with Member States and industry for the development of world-competitive EU strategic digital technology value chains and associated expertise. Addressing the Key Digital Technologies, the 5G and 6G connectivity needs as part of a Smart Networks and Services initiative and the underlying supercomputing capacities through a European High Performance Computing initiative present potential for synergies that can be addressed through cooperative actions (e.g. joint calls, coordinated support activities, etc.). They may as well profit from and contribute to Partnerships envisaged for Photonics, AI, data, robotics, Global competitive space system and Made in Europe, together with the EIT Digital. Synergies between these initiatives and several programmes (Digital Europe and Connecting Europe as well as cohesion programmes) are needed in areas where EU industry has to develop leadership and competitiveness in the global digital economy. They are expected to impact critical value chains including on sectors where digital is a strong enabler of transformation (health, industrial manufacturing, mobility/transport, etc.).

The transport sector face systemic changes linked to decarbonisation and digitisation. Large scale R&I actions are needed to prepare the transition of these complex sectors to provide clean, safer, digital and economically viable services for citizens and businesses. Past decades have shown that developing and implementing change is difficult in transport due to its systemic nature, many stakeholders involved, long planning cycles and large investments needed. A systemic change of the air traffic network through an Integrated Air Traffic Management initiative should ensure safety and sustainability of aviation, while a Clean Aviation initiative should focus on the competitiveness of tomorrow's clean aircrafts made in Europe. The initiative for Transforming Europe's rail system would comprehensively address the rail sector to make it a cornerstone in tomorrow's clean and efficient door-to-door transport services, affordable for every citizen as well as the most climate-friendly mode of transport for freight. Connected and Automated Mobility is the future of road transport, but Europe is threatened to fall behind other global regions with strong players and large harmonised markets. The initiative Safe and Automated Road Transport would bring stakeholders together, creating joint momentum in digitalising road transport and developing new user-based services. Stronger links and joint actions will be established between initiatives to enable common progress wherever possible. The Clean Hydrogen initiative would be fundamental to that regard. Synergies would also be sought with partnerships driving the digital technological developments.

To deliver a deep decarbonisation of highly emitting industrial sectors such as the steel, transport and chemical industries would require the production, distribution and storage of **hydrogen** at scale. The candidate hydrogen initiative would have a central positioning in terms of providing solutions to the challenges for sustainable mobility and energy, but also is expected to operate in synergies with other industry related initiatives. The initiative would interact in particular with initiatives on the zero emission road and water transport, transforming Europe's railway system, clean aviation, batteries, circular industry, clean steel and built environment partnerships. There are many opportunities for collaboration for the delivery and end-use of hydrogen. However, the Clean Hydrogen initiative would be the only partnership focused on addressing hydrogen production technologies.

Metrology, the science of measurement, is an enabler across all domains of R&I. It supports the monitoring of the Emissions Trading System, smart grids and pollution, but also contributes to meeting demands for measurement techniques from emerging digital technologies and applications. More generally, emerging technologies across a wide range of fields from biotechnologies, new materials, health diagnostics or low carbon technologies are giving rise to demands requiring a world-leading EU metrology system.

The initiative for a **Circular Bio-based Europe** is intended to solve a shortage of industry investments in the development of bio-based products whose markets do not have yet certain long-term prospects. The **Innovative Health Initiative** and **EU-Africa Global Health** address the lack of investments in the development of solutions to specific health challenges. The initiative on **Innovative SMEs** supports innovation-driven SMEs in participating in international, collaborative R&I projects with other innovative firms and research-intensive partners. As a horizontal initiative it is expected to help innovative SMEs to grow and to be successfully embedded in global value chains by developing methodologies and technologies for potential application in the other partnership areas or further development by the instruments of the European Innovation Council.

The description of the interconnections between all initiatives for each Horizon Europe cluster is provided in the policy context of each impact assessment and further assessed in the coherence assessment for each option.

PART 2 - THE CANDIDATE EUROPEAN PARTNERSHIP ON KEY DIGITAL TECHNOLOGIES

1. INTRODUCTION: POLITICAL AND LEGAL CONTEXT

Digital technologies are transforming the world at unprecedented speed. They have changed how we communicate, live and work. They have changed our societies and our economies: they contribute to productivity and efficiency as well as to broader socio-economic development. The digital transformation affects all sectors of the economy and it will continue to expand and deepen. It will further determine our capacity to address key societal challenges, from the respect of fundamental rights to our environmental objectives. The digital transformation has been empowered by exponentially growing computing power, through what we call 'key digital technologies'. Key Digital Technologies, in this document, refers to **electronic components and systems** that underpin all digital products and services today. They are viewed as **key** because they are the **basic building blocks** of digital systems.

Electronic components refer to miniaturised physical devices (chips) that fulfil precise functions. They are based on semiconductor technology and come in many families (microprocessors, microcontrollers, memory chips, sensors).

Electronic systems³⁵ refer to sets of interconnected chips that perform more complex functions (various forms of sensing and actuating, process control, navigation etc).

Electronic components and systems include software for enhanced functionality and flexibility.

Electronic components and systems are **the fundamental enablers of innovation** in a number of "vertical" economic sectors such as automotive, manufacturing, healthcare, aerospace and defence, and can be the determinant of first mover advantage for companies active in those sectors. Crucially, they also play a foundational role in shaping how digital transformation unfolds. The Commission has made it a top priority for Europe to lead a digital transformation that goes hand in hand with a green transformation, that delivers to European values such as privacy and trust, security and safety, and that does not threaten citizens' well-being or disrupt critical infrastructures and wider security interests. ³⁶

Often in need of working in close collaboration with segments of vertical industries, the value chain of electronic components and systems is complex and R&I intensive. It spans a significant number of specialised tasks performed by a variety of companies. Strengthening the relevant industrial fabric is crucial to pursuing the digital transformation in a European way and will require, amongst others, improving Europe's capabilities in the design and production of the most critical parts of the supply chain, and thereby reducing dependencies on other parts of the globe.

This document focuses on assessing the most effective, efficient and coherent way of implementing an R&I initiative which would focus on joint European research and innovation activities in electronics components and systems under Horizon Europe.

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³⁵ A simple electronic system is the anti-lock brake system (ABS) in a car. ABS combines a sensing component that measures acceleration (accelerometer), a microprocessor that analyses the changes in acceleration over time and a hydraulic valve that acts on the car brakes. Sudden changes in acceleration (e.g. braking sharply in front of a close obstacle) are detected and trigger the system to act intermittently on the brakes, assisting the driver to be in control of the car. Similar systems are used to trigger airbag deployment in case of car collision.

³⁶ Shaping Europe's Digital Future. COM(2020) 67

1.1. Emerging challenges in the field

The production of electronic components and systems counts among the most R&I-intensive activities (see Fig 6). Over the last 20 years, the annual R&I expenditure as a percent of revenues has been consistently between 15 and 20%. They are characterised by rapid technological change fuelled by constant R&I at all stages of the value chain, from the materials, fabrication equipment and design tools, through the processes of chip and system **design** and **manufacturing**, to the **test and packaging** of chips and **assembly into** systems. As components and systems become increasingly complex, the trade-off between the use of hardware and software to meet performance requirements has also become an important R&I challenge.

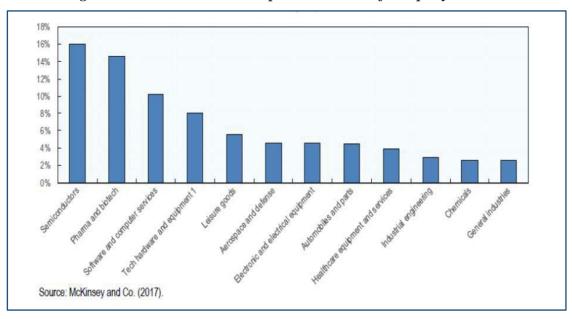


Figure 6. Research and Development % share of company revenue

This elaborate process translates to a complex and global supply chain and high investment costs with large economies of scale: the cost of designing and developing an advanced chip can be on the order of $1 \text{ B} \in$, a leading-edge fab (where fabrication takes place) costs up to $20 \text{ B} \in$. No single country or company dominates all of the stages of the value chain.

In recent years, and with the entry of China as an ever more prominent actor in the semiconductor business, global competition has intensified. This is evidenced in part by the growing numbers of **acquisitions** by companies, serving to build up the capacities they need to capture new markets.³⁹

Global trade has increasingly been affected by measures serving national or regional policy agendas. ⁴⁰ The COVID-19 pandemic has further ignited **geopolitical tensions**, stirring up competition between regions and unleashing measures to support local industrial ecosystems

³⁷ The annual R&I expenditure as a percent of revenues has been consistently between 15 and 20% over the last 20 years: Semiconductor Industry Association - Factbook 2020

³⁸ Measuring distortions in international markets: The semiconductor value chain. OECD Dec 2019

³⁹ Industrials Executive Mergers and Acquisitions Report. Kearny. 2019

⁴⁰ Illustrative cases include the US-China trade dispute over the licensing of Android operating system to Huawei, the US's prohibition on exports of critical electronic components to Iran, export control of essential semiconductor materials from Japan to South Korea, and more recently, the recent US intervention to block the export of critical EU semiconductor manufacturing equipment to China.

while minimising dependencies on imports.⁴¹ While China is investing 150 B\$ in the semiconductor industry over a 10 year period, including for R&I, until 2025, the US has recently⁴² announced subsidies of 25 B\$ to strengthen domestic production, including R&I into "cutting edge semiconductor" production.

The global demand for electronic components and systems⁴³ is being increasingly shaped by digital transformation as these technologies penetrate more and diverse sectors of the economy. While applications in automotive, manufacturing, healthcare, consumer, aerospace and defence account nowadays for roughly 40% of the semiconductor market, growth rates are forecast to be higher than for the computing and communications segments. This translates into a diversity of challenges to be met by electronics components and systems, such as computing speed, low energy consumption, security, real-time constraints and others.

As explained in the European data strategy⁴⁴, the **volume of data** produced in the world is growing rapidly, by a factor of five from 2018 to 2025. Processing such data at the speed needed to capture widely its benefits will require an important shift in the way we conceive and produce electronic components and systems. Scaling up the computing performance with today's component technologies will simply make computing one of the biggest energy consuming activities. Future components and systems should therefore exhibit radically **lower energy consumption** to be able to harness the benefits of data growth. Electronic components and systems delivering on energy efficiency will help the digital sector reduce carbon emissions⁴⁵ and contribute to the green transformation of the using sectors.

Moreover, safety, security and respect of privacy are fundamental objectives in the development of technologies permeating sectors such as healthcare. During the COVID-19 pandemic, for example, it has become clear that the costs associated with the health service infrastructure can be alleviated by remote medical assistance and personal healthmonitoring. Wearable devices will require low-power consumption and **secure electronic components** and systems will be instrumental in ensuring that **privacy is preserved**. **Security, privacy and safety** have therefore become increasingly important challenges in the EU digitised society. Secure hardware and software components will need further development to cater for increasing use of online digital identity, to prevent hacking and manipulation of data, and to ensure GDPR compliance in future networked systems ⁴⁶. Computing systems that are increasingly embedded in all types of artefacts will be often operating under real-time constraints ⁴⁷ and have to be **highly dependable and safe**.

To satisfy these challenges there are two main technological trends, **miniaturisation** and **emerging computing paradigms**, including edge computing.

For decades the industry has been driven forward by Moore's law, according to which capabilities of a chip of a given size double every two years. Using very advanced photolithographic techniques developed and industrialised in Europe, the number of transistors that can be packed into a chip today is on the order of ten billion (see fig. 7).

⁴¹ Trump and Chip Makers Including Intel Seek Semiconductor Self-Sufficiency WSJ. 11.05.2020

⁴² U.S. Lawmakers Propose \$25 Billion to Help Chip Industry, Bloomberg 10 June 2020

⁴³ The annual growth rate of the global market is estimated at 5.6% until 2025

⁴⁴ COM (2020) 66. A European strategy for data. 19 February 2020

⁴⁵ Nowadays the ICT sector is responsible for about 3% of global carbon emissions

⁴⁶ HiPEAC. (2019). *HiPEAC Vision 2019*.

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⁴⁷ Real-time systems guarantee a response within a specified time constraint, usually in the order of milliseconds.

While the dimensions of transistors may be squeezed further to 3 and 2 nanometer, Moore's Law is reaching physical (and economic) limits and remains a major R&I challenge. This **progressive miniaturisation** has had the added advantage of increasing computing speed. So-called microprocessors and memory chips resulting from these developments have driven the successive generations of computing and communication devices which account for roughly 60% of the semiconductor component market today.

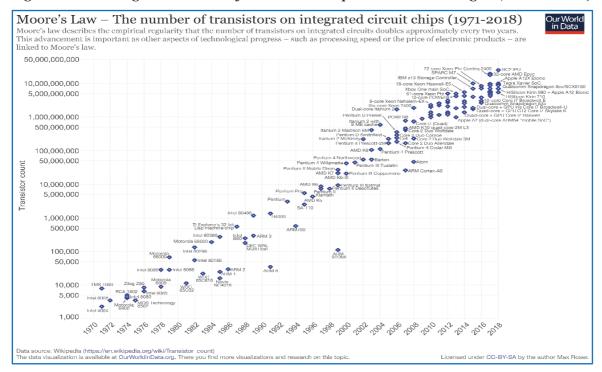


Figure 7. Technological evolution of semiconductor production technologies (Moore's Law)

As Moore's law reaches its physical limits, alternative computing paradigms are beginning to emerge. Today's main contenders are neuromorphic computing (based on neural networks), spintronics and quantum computing – areas where European research organisation are sought after for their know-how. While the first chips have been developed, the full ecosystem of design methodologies and tools, software simulation and fabrication equipment are still in development. Neuromorphic computing, for example, offers great promise for achieving 2-3 orders of magnitude improvements in energy efficiency for data processing tasks and it is particularly suited to power Artificial Intelligence. Further industrialisation of emerging technologies, their integration with sensing and connectivity, will open a window of opportunity. Building out the ecosystem will require new know-how and expertise, new approaches and new collaborations between research and industrial actors.

Finally, many applications in a variety of sectors today make intensive use of data processing and Artificial Intelligence – process automation in manufacturing for example. Given the large volumes of data that can be collected today - thanks inter alia to the variety of sensors that exist - data processing often takes place in remote data centres ('the cloud'). Innovative electronic components such as very low-power microprocessors, accelerators and embedded memory can enable more and more processing to take place close to the user – so-called **edge computing**⁴⁹. While cloud and edge computing will likely co-exist, edge

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⁴⁸ For a meaningful Artificial Intelligence. Cédric Villani. 2018 (pp. 51-52)

⁴⁹ Emerging compute paradigm whereby processing is done close to the user rather than in remote data centres

computing for AI is on the one hand a huge opportunity for Europe to leverage existing strengths in specific vertical markets. On the other hand, the possibility to avoid transfer of data to the central cloud, improving speed, **energy efficiency**, **privacy and security**, makes edge computing an attractive proposition from economic, environmental, and fundamental rights perspectives. Electronic components and systems will be important enablers of the transformation.

Stakeholder opinion

In their feedback to the Open Public Consultation to the KDT inception impact assessment, respondents representing industry asked for a broadening of the scope with respect to the ECSEL JU. In particular the need to integrate semiconductor-based photonics, selected software technologies (beyond embedded software) and focus on electronic value chains was highlighted by the industry associations.

A minority of views from industrial representatives expressed concerns with a broader scope. In particular with the fact that an extension of the scope would add complexity to the running of the initiative.

A majority of interviewees⁵⁰, including from large companies, industry associations, SMEs, RTOs and universities equally stressed the importance of AI, computer architectures, software engineering and silicon-based photonics for the KDT initiative.

1.2. EU relative position in the field

The electronics value-chain is made up: of i) manufacturing equipment, raw materials, and software-based design tools; ii) chip design and semiconductor manufacturing; iii) packaging, test and assembly; iv) embedded systems. See Figure 8.

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⁵⁰ Interviews taken place in the context of the study « Impact Assessment Study for Institutionalised European Partnerships under Horizon Europe - Candidate Institutionalised European Partnership on Key Digital Technologies ». Technopolis Group. January 2020

Manufacturing Equipment Raw material Semiconductor Embedded Packaging, tests Chip design (Silicon wafers) manufacturing and assembly Systems Vertical sectors Software Communication **Design Tools** Computers Industry **Functions** Automotive - Computing Aeronautics - Networking Defence - Embedded Security KDT scope Intelligence Healthcare Home appliances Covered by Consumer other partnerships Energy

Figure 8. The electronics components and systems value-chains

Manufacturing equipment, raw materials, and design tools: Europe accounts for 17% (or 24 B€) of the global market⁵¹. Europe is the leading provider of advanced photolithography equipment that enables miniaturization of transistors to dimensions of 2 to 3 nanometres. There is significant know-how in Europe's research and technology organisations which have supported development of equipment process technologies. Europe has a vibrant ecosystem of smaller actors, active in equipment such as wafer processing and wafer handling.

Europe also leads in the production of Silicon-on-Insulator (SOI) wafers and process technologies which are increasingly important for communications as well as for applications requiring low power consumption. A process technology based on SOI wafers (FDSOI⁵²) was developed in research labs in Europe and transferred to industry.

While Europe has some industrial players in design tools for components, boards and electronic systems it is largely dependent today on US companies for its design needs.

Chip design and Semiconductor manufacturing: EU-headquartered companies accounted for 9% - or 40 B€ - in 2018⁵³ of this fiercely competitive 456 B€ market, with three European vendors⁵⁴ in the top-15 global ranking.⁵⁵ Although revenue growth in Europe has been constant over the last decade - at 4.6% - Korean, Taiwanese and Chinese companies are gaining market share. US, Korean and Taiwanese companies, now dominate the top-15.

⁵¹ European Commission. (2019). Study on Emerging technologies in electronic components and systems (ECS) - Opportunities ahead. SMART 2018-0005

⁵² Fully-depleted Silicon on Insulator

⁵³ European Commission. (2019). Study on Emerging technologies in electronic components and systems (ECS) - Opportunities ahead. SMART 2018-0005

⁵⁴ STM, NXP and Infineon are ranked at 11, 12 and 13 in the 2018 Semiconductor vendors ranking. Reference: "Measuring distortions in international markets: The semiconductor value chain", *OECD Trade Policy Papers*, No. 234, OECD Publishing, Paris.

⁵⁵ A first indication of the 2019 semiconductor market has been published on April 1st, 2020. Two European vendors are in the top-10 (STM, number 8th, and Infineon, number 10th). With currently available information European share of global semiconductor production is estimated at 10%.

In terms of **market segments**, EU companies are strong in automotive, industrial manufacturing, aerospace, defence and security, and healthcare. The European industrial ecosystem in semiconductor components is regaining strengths in manufacturing since 2016 after a long period of stagnation. In particular, important investments made in pilot lines for production, have helped bridge the innovation gap and accelerated the move of innovative technologies from the lab to the fab capitalising on Europe's R&D strengths.

Despite limited industrial presence in **computing and communications** segments, which require large investments in both design and manufacturing⁵⁷, European research competencies are strong in these domains in terms of know-how. A number of SMEs – many of which spin-offs from academia – also participate actively in leading-edge research initiatives, such as the European Processor Initiative.⁵⁸ Europe hosts the world's best research labs⁵⁹ in semiconductor technology with leading⁶⁰ capabilities in chips for neuromorphic⁶¹ and in-memory computing, quantum computing and spintronics.

Packaging, test and assembly: Packaging, test and assembly,⁶² traditionally labour-intensive activities located to a large extent in South-East Asia (Malaysia, Thailand, Philippines). Packaging may become more strategically important as the phasing out of Moore's Law calls for new approaches to functional integration and miniaturisation of electronic components and systems. Increasing levels in process automation and growing added-value justifies to relocate in Europe some of the advanced packaging activities. Europe has specific strengths in high-end and niche markets, as well as in academia, and there is scope to develop these further.

Embedded systems: refer to electronic systems that perform specific functions within a larger mechanical/electrical system. They are used in applications in specific market segments, such as adaptive cruise control or lane-warning systems in vehicles, process control systems in industrial machinery, diagnostic systems in medical equipment, and autopilot systems in planes. These segments are dynamic and grow faster than computing and communications, where growth has been showing signs of saturation and where competiveness is driven largely by processor and memory performance (presently the dominion of US and Asian players). Europe is a strong player in embedded electronics and software both in research and in its exploitation by industry where it is world leading in the field of real-time systems for safety critical applications in automotive, manufacturing and aeronautics. The Important Project of Common European Interest on microelectronics marked a turning point for Europe. Its approval in December 2018 led to private investments of more than 6B€ in first industrial deployment and related R&I, including the first

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⁵⁶ European Commission. (2019). Study on the Electronics Ecosystem – Overview, Developments and Europe's Position in the World. Final Report. SMART 2016/0007.

⁵⁷ Advanced microprocessors cost between 400 M€ and 3B€ to develop. The construction of advanced fabrication facilities cost on the order of 20B€.

⁵⁸ https://www.european-processor-initiative.eu/

⁵⁹ Imec in Belgium, CEA-Leti in France, Fraunhofer Institute for Microelectronics in Germany

⁶⁰ Self-learning-neuromorphic-chip-that-composes-music, Phys.org, May.2017

Neuromorphic refers to computing approaches making use of electronic circuits that mimic neuro-biological architectures such as those present in nervous systems.

⁶² **Packaging** is the process to encapsulate the silicon chip to protect it from the environment. **Testing** assesses the quality and functioning of packaged chips discarding the failures. **Assembly** is the process to mount and interconnect chips onto boards.

greenfield investment in manufacturing in well over a decade. Its main focus was on low-power technology, sensors and power management for electric vehicles. ⁶³

SUPPORT TO THE FIELD IN THE PREVIOUS FRAMEWORK PROGRAMME – KEY STRENGTHS AND WEAKNESS IDENTIFIED

The proposed **initiative builds on the on-going** (2014-20) **ECSEL Joint Undertaking** based on Art. 187⁶⁴, with the participation of the European Commission, ECSEL Participating States (EPS)⁶⁵ and industry. It addresses the research and innovation challenges of electronics components and systems.

The overall strategic orientation and operations of the ECSEL JU are the responsibility of the Governing Board (GB). The GB is composed of representatives of the Commission, the Participating States and the private members representing industry, universities and research institutes. Each member appoints its representatives and a lead delegate who holds the voting rights of that member in the GB.

The financial contribution to the ECSEL JU from the Commission, the Participating States and the private partners is set out in the Council Regulation establishing the partnership.

In practice this is implemented on annual basis. Following confirmation of the proposed Commission contribution at the beginning of each year, each EPS announces their commitments. They are then published in the call work programme. Once projects have been evaluated and selected, fine-tuning of the contributions is always feasible (as EPS can decide to augment theirs).

In the period 2014-2018, total contributions from the Commission, EPS and private partners amounts to 822,2, 731,7 and 1795,6 M€⁶⁶, respectively. The private partners' contribution takes account of all beneficiaries in projects (both members and non-members of the industrial associations). Approximately, 30% of ECSEL beneficiaries are not members of associations, what gives an idea of the openness of the partnership.

The contribution of industry and research organisations to ECSEL projects is mostly in-kind (e.g. personnel, infrastructure) subject to audit. In the period 2014-18, the ratio of the **audited** in kind contribution of private members to the Commission contribution has been **2.18:1**. The ratio of **EPS** to Commission contributions in the same period is **0.9:1**. ⁶⁷

The leveraging of the Commission's contribution by a factor of three has enabled a **critical** mass of resources to be mobilised that is essential for large-scale collaborative efforts (on the order of 100 M€) around major industry objectives, such as **pilot lines on new** component technology and software platforms and related standardisation efforts. This

 $^{^{63}}$ In 2018, the Commission gave its approval for an Important Project of Common European Interest (IPCEI) on Microelectronics. Under this IPCEI, DE, FR, IT and the UK jointly support transnational cooperation of 29 companies to maintain and further expand European competencies in the electronics ecosystem. It combines €1.75 billion of national aid with €6.25 billion of private investment addressing innovation and first industrial deployment of technologies developed within European R&D initiatives.

⁶⁴ Council Regulation (EU) No 561/2014 establishing the ECSEL Joint Undertaking. 6 May 2014

ECSEL Participating States comprise 25 Member States (Cyprus and Croatia excluded) and four Associated
 States within the Horizon 2020 programme (Switzerland, Norway, Israel and Turkey).
 ECSEL Annual Activity Report 2018.

⁶⁷ The Council Regulation establishing the JU, in its recital 21, foresees that all contributions are taken into account when measuring the impact: "In assessing the overall impact of the ECSEL Joint Undertaking, investments from all legal entities other than the Union and the states participating in the ECSEL Joint Undertaking (the 'ECSEL Participating States') contributing to the objectives of the ECSEL Joint Undertaking should be taken into account. Those overall investments are expected to amount to at least EUR 2 340 000 000."

streamlining of priorities and strategies, and synchronisation of funding decisions to mobilise resources, would otherwise not have been possible⁶⁸.

What has or is being achieved so far

ECSEL has become instrumental for the European stakeholders and a key pillar of Europe's industrial R&I strategy.⁶⁹ Major technological achievements enabled by large scale initiatives include:

- Extreme UV lithography: development of the world's most advanced process equipment for ultimate miniaturisation of semiconductor components.
- FDSOI: Innovative technology for the production of components with reduced energy consumption (a factor of two compared to competing processes) and high performance for radio frequency (RF). It is being rolled-out for Internet of Things applications.
- Advanced power electronics: using alternatives to conventional Silicon (e.g. SiGe, GaN). Europe is leading the world in devices for power management and conversion indispensable for electric vehicles, smart energy grids and industry 4.0.
- Safety-critical embedded systems: has become a recognised European strength in applications for which safety is a primary concern such as automotive and avionics.
- Smart miniaturised systems: development of a new generation of minimally invasive smart catheters with integrated intelligence.

ECSEL has focused on areas in which the societal impact is particularly strong, such as clean mobility, energy efficient industry and sustainable healthcare. ⁷⁰ From the perspective of scientific impact, in the period 2014 to 2018, 66% of publications from ECSEL JU participants were in the top 25% ranked journals in their respective fields. When it comes to patents, ECSEL JU has so far a total of 46 patents registered for 400 Million Euro of paid effort as projects continue.

In a growing competitive environment with increasing societal and environmental challenges and a very rapid technological evolution, the intended KDT initiative would build on ECSEL achievements and take them to a higher level, while adapting to the new technological, industrial and geopolitical reality.

Key areas for improvement and unmet challenges – Lessons learnt

The ECSEL interim assessment⁷¹ identifies areas for improvement and put forward specific recommendations:

- to place greater emphasis on a strategic approach with a stronger alignment to EU priorities. The current partnership was considered as being too bottom-up in its approach, and the Commission and Participating States were encouraged to play a stronger role in priority setting.
- a broader coverage of electronic value chains including participation of systems houses⁷². This was in part intended to encourage better working together of the components and systems communities, but also that R&D is well-aligned with industrial needs – whether

⁶⁸ European Commission. (2018). Interim Evaluation of the ECSEL Joint Undertaking (2014-2016) Operating under Horizon 2020. Final report.

69 'Study on the impact of ECSEL funded actions'. Deloitte, Valdani Vicari and Associati. February 2020.

⁷⁰ 'Study on the impact of ECSEL funded actions'. Deloitte, Valdani Vicari and Associati. February 2020.

⁷¹ European Commission. (2018). Interim Evaluation of the ECSEL Joint Undertaking (2014-2016) Operating under Horizon 2020. Final report.

⁷² End user industries with capability to design and produce systems

longer or shorter term - from day1. A slight expansion of the scope to higher layers of software would also help facilitate this.

- to aim at **better harmonisation of national** administrative practices and procedures with a view to **simplification**. This regards practices related to the rules and conditions to participants across Participating States, which can be simplified. The application and reporting processes in particular should not be more complex than they would be for the regular Horizon 2020/Europe calls.

and

- to strive for **further integration of SMEs** and start-ups in the electronics innovation ecosystem. Though participation of SMEs represented up to 30% in terms of numbers, in terms of funding share – currently 17% - there is still scope to play a more active role in the partnership and exploit their full potential.

The proposed initiative in KDT takes account of these lessons learnt in its scope, objectives and implementation. The need of a closer alignment with EU priorities, a broad coverage of value-chains and the better integration of SMEs are part of the intervention logic ('problem drivers') of this initiative and they are addressed in its specific objectives. The harmonisation and simplification of national practices and procedures is to be addressed in the setting and implementation of a potential partnership⁷³ (currently in discussion with national authorities).

More details are provided in Section 2 (Problems) and Section 4 (Objectives).

1.3. EU policy context beyond 2021

The proposed initiative can be set in the context of a number of recently announced European policies and priorities. These policies would inform the Strategic Research and Innovation Agendas (SRIA) of a future initiative on Key Digital Technologies and be taken into account in work programmes that form the basis for calls for proposals:

Artificial Intelligence: Recent progress in AI has been driven by the ever-increasing processing power of semiconductor chips. The White Paper on Artificial Intelligence⁷⁴ acknowledges that advanced low-power processors, a market currently dominated by non-EU players, will be essential for Europe to be creators and not just users of AI. This situation can be turned around by initiatives such as the European Processor Initiative, which develops a low-power processor for supercomputing, and a future initiative on Key Digital Technologies which would address the computational requirements of AI (notably deep learning) and their implications for processor design. The Paper also identifies neuromorphic solutions, where Europe is strong today, as being suited to tasks which deploy AI.

The Data strategy⁷⁵: The aim is to enable the data economy for the coming five years. Processing and storage of data, computing power and cybersecurity are among the essential issues to be tackled, if the EU is to acquire a leading role in the data economy. In this perspective, the EU needs to reduce its technological dependencies on secure, energy-efficient, affordable and high-quality data processing capacities. A future KDT initiative would address the R&D needed to master these capacities.

⁷⁵ A European strategy for data, COM(2020) 66 final, 19.2.2020

⁷³ An on-going EC-Member States dialogue is addressing harmonisation and simplification.

⁷⁴ European Commission White Paper on Artificial Intelligence, COM(2020)65 final, 19.2.2020

Industrial Strategy⁷⁶: The new strategy stresses the need for Europe to pool its strengths to do collectively what no one can do alone. It cites microelectronics as an example of the value of pooling resources to reverse a downward trend. This is in large part due to the current ECSEL JU and an Important Project of Common European Interest (IPCEI) on Microelectronics, and the investments they have triggered in the development and production of electronics components and systems. In the same context the Communication underlines that the EU will continue to support the development of key enabling technologies *i.e.* microelectronics that are strategically important for Europe's industrial future and announces possible follow-up to the first IPCEI on microelectronics. The R&D programme of a future initiative could complement the innovation roadmap of a second IPCEI.

Recovery Plan for Europe⁷⁷: The Commission has proposed a reinforced EU budget to help repair the economic and social damage brought about by the coronavirus pandemic and kick start the recovery. The Commission estimates that investment needs amount to at least 3.5 trillion euros in 2020-2021. Investment in key sectors and technologies is considered crucial. The Communication highlights that strong interdependencies between electronic value chains and other industrial value chains, including digital and automotive, make electronics one of the most important industrial ecosystems in Europe. An annual investment gap of 17B€ has been estimated for semiconductor technologies. Support to Member States and mobilisation of private investment will be crucial to increased investment in key value chains, such as microelectronics, necessary to Europe's future resilience and strategic autonomy in the context of the green and digital transitions. The future initiative will also be instrumental in this sense.

Green Deal: the Communication⁷⁸ points explicitly to the potential of digital technologies to bring efficiencies on the one hand and the need to reduce the environmental footprint on the other, including that of electronics components and systems.⁷⁹ A future initiative would need to embrace this two-pronged approach by focussing on the development of low power technologies and their applications.

Research and Innovation: under the proposed Horizon Europe programme, Pillar II Cluster "Digital, Industry and Space" aim to make concrete contributions to three overarching EU policies: 'A Europe fit for the Digital Age', 'An economy that works for people', and 'A European Green Deal'. Horizon Europe would cover the earlier stages of research on electronic component and systems technologies with emphasis on high quality scientific outcomes. Mechanisms for interaction between the initiative and Horizon Europe would be put in place such as the setup of technology clusters and the follow up of specific projects ('from lab to fab').

The three candidate Institutionalised Partnerships covering digital technologies, i.e. *Key Digital Technologies, Smart Network and Services* and *EuroHPC*, together with partnerships *Photonics* and *AI, data technologies and robotics*⁸⁰, are intended to enable Europe to prepare for the continued massive use of data – much of which is coming from devices and premises at the edge of the network (wearables, autonomous vehicles, factories, hospitals, etc.).

⁷⁹ A new Circular Economy Action Plan, COM(2020) 98 final. 03.03.2020

⁷⁶ A New Industrial Strategy for Europe, COM(2020)102 final, 10.3.2020,

⁷⁷ Identifying Europe's recovery needs, SWD(2020) 98 final, 27.5.2020

⁷⁸ The European Green Deal, COM(2019) 640, 19.12.2019

⁸⁰ Photonics' and 'AI, data technologies and robotics' are co-programme candidate partnerships.

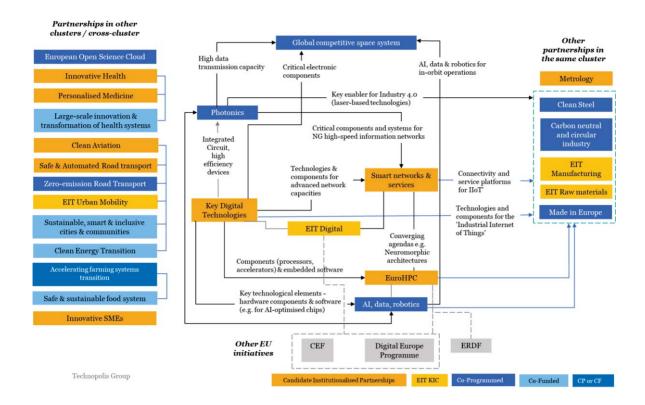
As alluded to in sections 1.1 and 1.2, the proposed KDT initiative covers advances (design, manufacturing, embedded systems) in the underpinning electronic components and systems technologies that can provide enhanced performance or additional functionality at the application level. The networking (Smart Network and Services), computing (EuroHPC) and integrated intelligence (AI, data technologies and robotics) functions build on these advances. More specifically:

- **Smart Network and Services**: electronic components and systems feed both the network infrastructure (base stations, routers, servers) and the terminals. Network speed, capacity and reliability largely depend on key components (application specific circuits, net processors, radio-frequency devices, smart antennas) that would be expected to be developed by the KDT initiative.
- **EuroHPC**: Supercomputers require high-performance electronic components (processors, accelerators) to be developed by the initiative in KDT.
- AI, Data and Robotics: AI systems and robots make use of advanced components (sensors, processors, actuators, embedded memories, power devices) to perform increasingly complex tasks. Data processing is enabled by chips with high computation power which are essential for autonomous, real-time decisions, as requested in robots. Essential components for AI and robotics, such as those mentioned, would be developed in the KDT initiative.
- **Photonics**: Photonics exploits the properties of light and covers a broad range of technologies (such as laser-based 3D printing, optical communications, new types of light sources, multi-sensing, etc.). Photonics include Photonics Integrated Circuits (PICs) which are based on semiconductor technology and, therefore, would be addressed by such an initiative in KDT.

It will thus be important for a future KDT initiative to **build and maintain strategic links** with these partnerships and their stakeholder communities. This is foreseen in the draft Impact Assessment for the candidate European Partnership for Smart Networks and Services (p.32). EuroHPC and ECSEL JUs are currently developing their strategic roadmaps in coordination with each other, and with the involvement of respective Commission and Participating States representatives.

Beyond digital, strategic links with partnerships on mobility, health, manufacturing, space and energy are also envisaged. This is work in progress. Specific targets in this context would be to make use of testbeds (whether vehicles, networks, robots or other) in which components and systems developed in an initiative relating to KDT could be assessed and validated in close-to-real-life scenarios before eventual commercial deployment.

Figure 9: Envisaged European Partnerships in the Digital, Space & industry cluster.

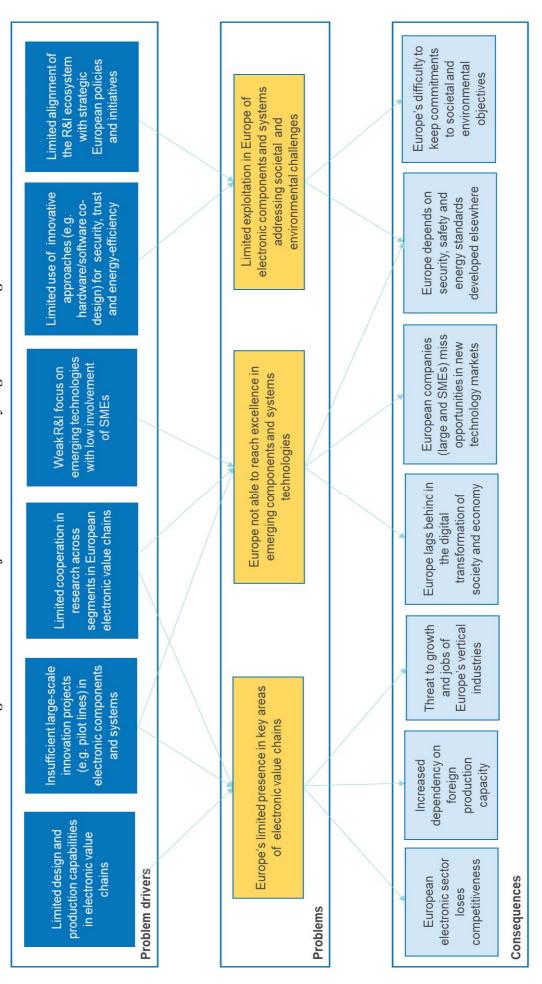


2. PROBLEM DEFINITION

Given the scale of the challenges entailed by the digital transformation, the current scientific, technological and economic positioning of Europe in the field, and the EU policy context, a set of problems have been identified where EU research and innovation in electronic components and systems has a specific role to play.

A problem tree portraying related problems, their drivers and consequences is presented in Figure 10. They are described in detail in the following sections.

Figure 10: Problem tree for the initiative on Key Digital Technologies



2.1. What are the problems?

The predecessor initiative ECSEL was set up to achieve further miniaturisation, higher computing or communication speeds, better energy performance, improved security, safety, reliability, or cost reductions. Despite a considerable number of achievements by ECSEL in these areas, further progress is necessary to stay at the technological forefront and maintain Europe globally competitive in the field of electronics components and systems. Also a number of unmet objectives and shortcomings identified at the interim evaluation of ECSEL need to be addressed.

Main identified problems are:

2.1.1 Europe's limited presence in key areas of electronic value chains

European electronic components and systems suppliers have a strong position in global vertical markets, including automotive, industrial equipment, aerospace, security and healthcare⁸¹. However, not all stages of development and production take place in the EU. **Manufacturing** of electronic components and systems mostly takes place in **Asia** and circuit **design** is dominated by US and, more recently, by Asian companies. R&I effort would be required to develop the necessary design and manufacturing competences. Additionally Europe has **very limited presence** in high-volume **computing and communications markets**, which currently account for 60% of global components market. Limited presence in key areas affects electronics value chains and undermines EU sovereignty.

The current **COVID-19 crisis** has put additional strain on supply chain resilience and has illustrated the critical importance of **access** to electronic components^{82,83} and Europe's ability to develop them.

2.1.2 Europe not able to reach excellence in emerging components and systems technologies

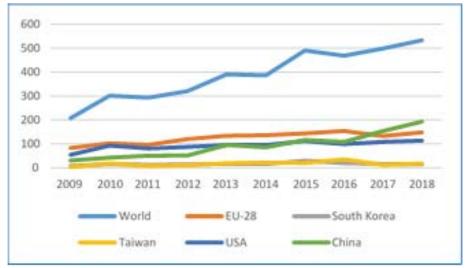
Analysis of the number of research publications in microelectronics in the period 2009-18 (Fig. 11) shows that Europe has been leading, although its leadership has been taken over by China in 2017 and is closely followed by the US. Steep increases in research capacity and R&D investments in these regions are threatening Europe's ability to seize emerging opportunities.

⁸¹ Europe is a leading global supplier of electronic technologies for automotive, industrial equipment, aerospace, defence & security, and healthcare sectors (See 2018 data in Table 1, Annex 6)

⁸² The Commission has identified microelectronics as a crucial sector for the EU economy and has addressed its challenges linked to the crisis

⁸³ EC proposal for a COVID-19 recovery plan.

Figure 11: Production of research publications on microelectronics per country and year — number of publications (2009-2018)



Source: Calculations by Technopolis Group based on Scopus data

Moreover, the uptake of research output by industry in Europe has been slow, mostly because of its fragmentation and smaller footprint when compared with US and China. Finally, European R&D actors, **SMEs and start-ups** are often particularly strong in emerging domains, but can **lack the connection to a broader ecosystem** to develop partnerships, grow their knowledge and eventual customer base, limiting Europe's ability to capitalise on the excellence of the research output.

2.1.3 Limited exploitation in Europe of electronic components and systems addressing societal and environmental challenges

In the development of electronic components and systems, focus has traditionally been on performance and costs. More recently the pressure to extend the autonomy of mobile devices and the increasing attention to environmental impacts have made **reduced energy consumption** a key criteria in technology development. **Safety and security** considerations have also grown in importance following increasing cybersecurity concerns, as well as the societal demand for **trust and privacy** in respect to fundamental rights. However, as enduser companies to date have primarily relied on software-based solutions to achieve higher - but still insufficient - levels of energy efficiency and security, the potential of hardware is as yet unexploited.

Stakeholder opinion

The large majority of stakeholders responding in the **open public consultation** recognised the importance of addressing innovation in electronic components and systems at European level. All stakeholder types expressed the need to make a significant contribution to the global competitiveness of Europe's KDT industries (134 out of 154 respondents, or 87% indicated this as 'relevant' or 'very relevant'). A stronger focus on the development and exploitation of innovative technologies was noted by all consulted stakeholder types (131 out of 150 respondents, or 87%) and notably SMEs.

A minority of stakeholders (mostly industrial representatives) expressed concerns of overlapping of the KDT partnership with the Horizon Europe programme and with related initiatives (e.g. Smart Networks and Services, Connected and Automated Mobility).

2.2. What are the problems drivers?

2.2.1. Limited design and production capabilities in electronic value chains

With every technology generation, the complexity and costs of **design and fabrication** of electronic components increase. Without a coordinated R&I effort to develop key competences in design and production, Europe risks limited presence in these segments, and features gaps in electronics value chains.

Within the electronics value-chain, a growing number of stakeholders ('fabless') focus on chip design and outsources manufacturing to third parties ('foundries'). The most prominent 'fabless' vendors are from the US and Taiwan, with only one European company ranked amongst the world's top ten⁸⁴. Europe lacks a robust **design ecosystem** that can support its own **chip development capabilities.** Such ecosystem would provide incentives for the creation of intellectual property, access to design libraries and EDA⁸⁵ tools, and risk-sharing among design houses, Integrated Device Manufacturers (IDMs), research centres and user companies.

The 2019 global market share of semiconductor components that are manufactured in Europe is 9-10%. This, and does not reflect Europe's economic standing and research excellence in the field. In particular, the lack of manufacturing facilities in Europe for advanced digital circuits is a matter of concern as it limits the ability to capture important markets such as data processing and communications. Europe needs, therefore, to strengthen its production capability to bring it in line with its potential for development of digital systems and services, and avoid disproportionate dependence on other regions.

2.2.2. Insufficient large-scale innovation projects (e.g. pilot lines) in electronic components and systems

Large-scale projects are essential to the development of technologies from the **early stages of research to maturity**. For example, **pilot lines** of production at high Technology Readiness Levels (TRLs) enable testing of new components and process technology by a large variety of users before industrial deployment. Another example is **large-scale demonstrators** of embedded software and systems, where experimentation by a large set of users in a variety of application environments is essential before commercial exploitation. An R&I setting with EU and national diverging priorities, is not suitable to launch projects of large scale that bring together a broad set of stakeholders to address ambitious objectives.

2.2.3. Limited cooperation in research across segments in European electronic value chains

Intense competition and **fast technological evolution** make the role of electronics value chains ever more important. Keeping pace with this evolution requires intense R&I effort; however, today the various segments of the supply chain (design, manufacturing, packaging, ..) address research in disconnected ways. This makes the role of technology integration arduous and inefficient. The dynamic nature of value chains requires **close collaboration of technology stakeholders across segments**, for example through a common research roadmap.

85 EDA (Electronic Design Automation) are software tools supporting efficient chip design

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⁸⁴ Dialog (UK) is 10th on the 2Q2019 world ranking of IC design companies. Source: TrendForce. Global Top Ten IC Design Companies for 2Q19. Press release August 29th, 2019

Stakeholder opinion

According to the **Open Public Consultation**, a majority of stakeholders, especially from SMEs, universities and RTOs, considered that the co-creation of solutions with downstream sectors has high relevance (132 out 151 respondents, or 87% indicated this as 'relevant' or 'very relevant').

Minority views: A few **interviewees**, especially from large companies, highlighted the importance of the transition towards more complex value networks and the fast-evolving nature of digital technologies and the application sectors.

2.2.4. Weak R&I focus on emerging technologies with low involvement of SMFs

To **respond to future challenges and retain its innovation potential**, Europe needs to develop capabilities in emerging technologies that expand its traditional strengths and offer new opportunities. Despite Europe's lead in specific segments today (see section 1.2 EU relative position in the field), its leadership is threatened by massive investments by the US, China and other regions in new areas. ⁸⁶ Scientific excellence in promising domains is the base for future leadership. Assessment and identification of these domains, based on European capabilities in a global context and their potential for future impact (technoeconomic, societal and environmental) is essential.

Emerging technologies open new markets and offer new opportunities to industry, in particular to dynamic **SMEs and start-ups** who can contribute with specific competences and benefit from the value emerging technologies create.

Stakeholder opinion

The need to build technological capabilities in emerging technologies was stressed by several **interviewees** from Member States, large companies, SMEs, business associations, universities and RTOs.

It was frequently mentioned by interviewees that no single European country on its own could take up the competition with the likes of the US and China on emerging technologies.

Some views (mainly from research organisations) in the public consultation suggest to attract more SMEs through a higher involvement of RTOs in the initiative.

2.2.5. Limited use of innovative approaches (e.g. hardware/software codesign) for security, trust and energy-efficiency

Europe's technological capabilities in secure and trusted components do not always find their way into systems and final products. Similarly for energy-efficient devices. Addressing security and environmental issues is often done at software level in the latest stages of development with suboptimal results. Solutions addressing hardware-software codesign early in product development provide more efficient results but they require the adoption of innovative technologies and methodologies by the users.

As electronic components and systems are embedded in most of the smart products and services we use today, ensuring a supply of **trusted**, **secure**, **energy-efficient and reliable components** addressing specific environmental and societal requirements is of paramount importance for Europe.

⁸⁶ The 'Made in China 2025' initiative plans \$150 billion in semiconductors investments by 2025. The US Networking and Information Technology Research & Development (NITRD) has made \$4 billion available, for high capability computing systems, data management and software design.

Stakeholder opinion

At the **open public consultation** stakeholders put forward that the KDT initiative is highly relevant for securing access to trusted electronics components and systems (127 out of 154 respondents, or 82%, indicated this as 'relevant' or 'very relevant'). This view was especially supported by industry associations, universities, RTOs, Member States and large companies, while it was shared to a lesser extent by SMEs.

A minority of stakeholders (mostly from industry) stressed the importance of security and indicated that the initiative should place a higher emphasis on technologies for security.

2.2.6. Limited alignment of the electronic R&I ecosystem with strategic European policies and initiatives

The ECSEL Interim assessment⁸⁷ recommends **a more strategic approach** of the partnership in the development of electronic components and systems, and a closer link to the digital transformation of the EU economy. Limited alignment to policies reduces the strategic impact of an R&I initiative and it is a source of inefficiencies. The support to the societal and environmental objectives of the Union would need to be embedded in the agenda of the future initiative. To this end the **Commission** and the **Participating States** would need to **play a strong role in setting** and monitoring progress towards **strategic objectives**.

2.3. How will the problems evolve?

If action is not taken the problems identified will persist and risks will materialise. Europe will head to a situation from which it will very difficult or not possible to recover.

Without action addressing the risks and problems, it is anticipated that Europe

- will **lose scientific leadership** in terms of R&I in electronic components and systems technologies in which it excels today.
- can **lose competitiveness** by weakening its ability to develop electronic components and systems technologies in which it is strong today(semiconductor equipment and materials, low energy consumption microelectronics, power components, embedded software).
- will put at **risk its leadership in critical industries** and services (automotive, avionics, industrial, machinery, healthcare, security). Performance requirements (whether energy consumption, security, reliability or cost) that determine their position in the market might not be met. The losses in those sectors will be progressively important as they become increasingly digitised.
- will **miss out on opportunities** that new technologies (e.g. Artificial Intelligence, new forms of computing) may create for the sector of electronic components and systems. It will be increasingly difficult to enter new markets and grow with them.
- will be **dependent on other regions** (US, Asia) for key technologies, with limited choice and exposed to unilateral trade decisions on technology access and conditions.
- will **not be able to shape the digital future according to its values** (privacy, security, ethics). Electronic components and systems coming from abroad do not commonly meet the EU high standards for privacy and transparency.

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⁸⁷ European Commission. (2018). Interim Evaluation of the ECSEL Joint Undertaking (2014-2016) Operating under Horizon 2020. Final report

• will **not be able to fully implement key policies**, such as environmental, data and industrial strategies. Digitisation and technological innovation are integral elements of policies, lack of access to advanced digital technologies within the EU will be a major drawback for their implementation.

Over time, with market consolidation and technological maturity these effects would intensify. Their combination can lead to a situation where **Europe is irrelevant as a digital technology driver and becomes a mere technology consumer.**

The development of the necessary technological capabilities requires investments of industry in production capacity for electronics components and systems in Europe within the next 5 to 10 years to provide a solid base for European companies to effectively respond to the challenges ahead. Investments in production capacity in Europe is not in the scope of a KDT initiative that focuses on R&I. However, support to R&D and innovation activities, such as piloting and validation of technologies, are important elements for industries as they federate and lower risks of private investments. The recent IPCEI in microelectronics, addressing innovation and first industrial deployment of technologies developed in European R&D initiatives, ECSEL in particular, is a good example of R&I actions leading to private investments.

Stakeholder opinion

The fast-evolving nature of key emerging digital technologies, including their influence on industries and technological areas, were stressed by **interviewees** from industry associations, large companies and SMEs.

The need for a policy action, and the implications of 'no action' for critical industries, was underlined by all interviewed stakeholder types.

3. WHY SHOULD THE EU ACT?

3.1. Subsidiarity: Necessity of EU action

Electronics value chains are vast and complex, expanding across regions and industrial sectors. Rapid technological progress, increasing investments by growth of large vertically-integrated companies in the US and Asia⁸⁸ in developing their own chips⁸⁹, and the massive investments by these competing regions in know-how and production capacity, demand a rapid and coordinated response of the EU to maintain and further improve its competitive position in electronics components and systems, and related industries.

Moreover the impact of geopolitical tensions on the global industrial and technology landscapes with no end yet in sight, calls for an enhanced effort by the EU in close partnership with the Member States, industrial and research actors to agree a coherent strategic agenda with an appropriate level of ambition.

In order to be able to **shape the digital future according to European values** (privacy, security, ethics, respect for the environment), closer collaboration with Member States is needed to agree an appropriate framework at European level including standards and

⁸⁸ Tesla, Google, Huawei, Samsung, Baidu, etc.

⁸⁹ tesla-new-self-driving-chip-is-here-and-this-is-your-best-look-yet, The Verge, Apr. 2019; google-rattles-tech-world-new-ai-chip, wired, May 2017; samsung-to-make-baidus-new-ai-chips, ZDNet, Dec. 2019

certification schemes for electronic components and systems that will ensure those values can be adhered to.

Electronic components and systems also are increasingly important for Europe's vertical industries in their digital transition. The reinforcing of industrial ecosystems and value chains that provide for the research and innovation needs of those industries will necessarily involve a variety of actors from across the Union.

The experience of the ECSEL JU confirms that a sustained and coordinated effort under a common structure can lead to positive achievements.

3.2. Subsidiarity: Added value of EU action

Evolution in technology and innovation affects the way stakeholders interact in value chains. A fast-changing environment requires coordinated initiatives that bring together suppliers and users addressing hardware and software technologies, aligning European, national and industry efforts.

Companies alone or single countries cannot meet the scale and the intensity of investments by major competing regions (US, China, South Korea, Taiwan and Japan). Only a European mobilisation and coordination of investments could ensure the necessary critical mass.

Similarly Europe has many strengths at different parts of the electronics value chain which are scattered across different Member States. Consolidation would reinforce those strengths and thereby Europe's global position. Coordinated actions at EU level would stimulate the creation of ecosystems in which SMEs and start-ups can progress and grow faster.

Stakeholder opinion

The results of the **Member States consultation** on Horizon Europe Partnerships⁹⁰ confirm strongly the overall relevance of the proposed initiative in Key Digital Technologies (KDT). 96% of Member States consider electronic components and systems relevant for their national policies and priorities, as well as for their industry, research organisations and universities.

All **interviewed** stakeholder groups noted the need for alignment and policy coordination on research agendas; interviewees from industry commented that the level of investment by the US and China in electronic components and systems technologies cannot be matched by any individual European country and, as a result, coordination and critical mass at EU level are required.

4. OBJECTIVES: WHAT IS TO BE ACHIEVED?

4.1. General objectives of the initiative

Three general objectives corresponding to the main problems discussed in Section 2.1 are identified:

1. Reinforce Europe's **technology sovereignty** in electronic components and systems to support future **needs of vertical industries** and the economy at large

Ensuring that Europe stays at the technological forefront in advanced electronic components and systems would contribute to strong strategic value chains. Gaps in the

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⁹⁰ European Partnerships under Horizon Europe: results of the structured consultation of Member States. Shadow Configuration of the Strategic Programme Committee. 27 June 2019

value chain can become problematic in the presence of global crises, as dependence on technologies developed in other regions can deprive user industries of first mover advantage and limit their capacity to innovate. This is of particular importance in the transition of industry to digital and it will be increasingly critical as digital technologies become more pervasive across sectors. European strengths in specific segments of electronic components and systems (e.g. equipment and materials, low-power semiconductors, power electronics, embedded software) have a positive impact on the sectors they serve. European concerted action is required to develop leading-edge technologies, to accelerate their uptake and reinforce EU industries where they are strong.

A reinforced EU sovereignty should materialised in doubling the value of the design and production of electronic components and systems in Europe by 2030, in line with the weight of the EU in products and services.

2. Establish EU scientific excellence and innovation leadership in emerging components and systems technologies

Further miniaturisation towards physical limits, the rapid penetration of artificial intelligence, the emergence of edge computing and of alternative computing paradigms (such as neuromorphic, quantum computing) open new opportunities for electronics components and systems and their applications. A solid scientific base in emerging areas can enable Europe to seize such opportunities. An early involvement of industry stakeholders in specific promising areas in the research cycle will speed time-to-market, boost leadership and innovation, and maximise social and economic impacts. Moreover it will facilitate a more prominent role by Europe in standards setting, allowing European needs to be reflected. SMEs and start-ups who, in Europe, are generally strong in emerging technologies, can benefit from and help give shape to new ecosystems, supported by simplified administrative procedures.

As a target for an initiative on KDT, SMEs should represent at least one third of the total number of participants while at least 20% of public funding should go to SMEs.

3. Ensure that components and systems technologies address Europe's societal and environmental challenges

Public and private sectors need to pool resources to address EU societal and environmental challenges and objectives to build know-how and capacity in **areas that are currently missing or not sufficiently developed**. Specific components and systems technologies to which Europe needs to step up in these areas would be identified and addressed in the initiative together with standards setting.

Technologies considered essential for Europe will be tailored to **reflect European** values in their application. In particular technologies that provide the right levels of trust and privacy, as well as those contributing to the EU environmental objectives.

The initiative would align with the EU policy on energy efficiency. The target is to reduce energy consumption 32.5% by 2030. This target would be revised upwards by the Commission in 2023.⁹¹

⁹¹ Directive (EU) 2018/2002 of the European Parliament and of the Council of 11 December 2018 amending Directive 2012/27/EU on energy efficiency

Each of the three general objectives of the KDT initiative contributes to the objectives of Horizon Europe to deliver respectively techno-economic, scientific and societal impact from the Union's investments in research and innovation. They would strengthen the scientific and technological base of the Union and foster its industrial competitiveness at global level.

4.2. Specific objectives of the initiative

To better achieve the general objectives, six specific objectives are defined. These specific objectives respond to each of the problem drivers discussed in Section 2.2.

a. Establish design and production capabilities in Europe for strategic application areas

Strengthen and extend current European design and manufacturing capabilities in specific areas (such as power electronics, digital devices, etc.) to critical domains such as communication, computing and intelligent systems. Establishing new capabilities in Europe requires long-term planning and a firm commitment of public and private stakeholders. Interaction with relevant digital partnerships (SNS and EuroHPC for example) and initiatives addressing applications (such as healthcare and automotive) will be necessary to ensure coherence of action along the respective value chains. While R&I for production will involve mainly large semiconductor companies and research labs, the design activities will attract mostly SMEs and start-ups.

b. Launch large-scale projects supporting the fast transfer of technologies from the lab to the fab

This specific objective would support large scale projects, such as pilot lines of production and real scale demonstrators that bring together technology suppliers and users. These actions mobilise a high volume of resources and require the combination of public (European and national) and private resources under a common scheme. Large-scale projects bring specific value to the implementation of a long-term strategic planning. These projects should be open to SMEs - in addition to large companies and research organisations - providing unique opportunities for small companies and start-ups to get access to such facilities.

c. Build a dynamic EU-wide ecosystem based on digital value-chains with simplified access to newcomers

Establish an ecosystem that facilitates interaction between stakeholders and makes cooperation within and across value chains more efficient. The ecosystem will serve semiconductor and software producers, large and small, RTOs and academia, as well as technology users (systems manufacturers, service providers) to set common agendas and technology roadmaps and establish relations that go beyond research cooperation.

The administration and procedures for participation in the initiative would be simplified to make it accessible and attractive to new organisations. The target is to streamline administrative practices to sensibly reduce the complexity, eliminating any double EU and national intervention at all level of the operations (proposals, projects, audits).

d. Strengthen EU scientific excellence and exploit the potential of SMEs and start-ups in emerging technologies

Strengthen current capabilities and develop new knowledge and technological competence in emerging areas such as novel computing paradigms, and support emerging trends and opportunities such as edge AI. This objective would require the mobilisation of new stakeholders, mainly SMEs and start-ups active in emerging technological areas. To stimulate their participation, efforts to simplify the administrative requirements linked to participation – with respect to those of the current partnership - will be important.

e. Enhance component technologies that guarantee security, trust and energy-efficiency for critical infrastructures and sectors in Europe

Reinforce electronic components and systems technologies to guarantee the supply (design and production capacity) of secure, trusted and low energy components. Drive standards setting and support their integration into critical infrastructures (energy, data, transport,...) and systems, ensuring that they respond to future needs.

f. Ensure alignment of the new initiative with European policy priorities

Establish coherence between the Strategic R&I Agenda of the initiative and EU policies so that electronics components and systems technologies contribute efficiently. This objective would require a long-term roadmap that complements R&D with security certification⁹² and standardisation actions. The alignment of projects and the initiative as a whole with EU policies would be monitored and reported regularly.

Stakeholder opinion

The **open public consultation** showed a broad consensus about KDT making a significant contribution to global competitiveness of key European industries (112 out of 162 respondents, or 69% indicated this as 'very relevant'). Establishing the link between KDT and application sectors was perceived as fully needed by four out of five respondents from business associations, large companies, SMEs, universities, RTOs and public authorities. Promote leadership in emerging technologies and secure technological sovereignty and globally competitive presence in key digital technologies were equally stressed as important by all **interviewed** stakeholder groups.

A majority of stakeholders to the **open public consultation** indicated the need to 'focus more on bringing about transformative change towards sustainability' (67 respondents indicated this as 'needed', and 63 respondents as 'fully needed', with a combined 67%) and to make a 'significant contribution to the EU efforts to achieve climate-related goals' (respectively 64 and 61 respondents indicated this as 'needed' or 'fully needed', combined 64%).

A minority of stakeholders (13 respondents or 8%), mainly academia and citizens, indicated that the KDT initiative was moderately needed or not needed for EU global competitiveness.

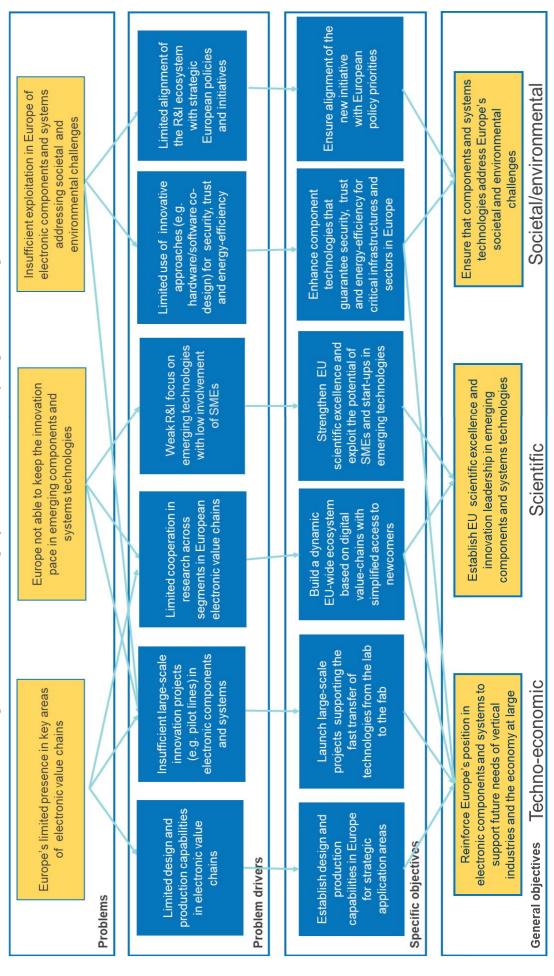
the first scheme being prepared under the Framework is based on the so-called "Common Criteria" (standards that have been applied with great success in the EU to the certification of smart cards, integrated circuits, hardware security modules and other similar technologies).

The KDT activities on security and trust would have a direct impact on the EU's ability to attain its political goals in this area and specifically in the following initiative: Development of cybersecurity certification schemes developed under the European Cybersecurity Certification Framework that was established by the Cybersecurity Act (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L...2019.151.01.0015.01.ENG&toc=OJ:L:2019:151:TOC). In particular, the first scheme being prepared under the Framework is based on the so-called "Common Criteria"

4.3. Intervention logic for the initiative

The relationship between the general and specific objectives of the potential initiative on Key Digital Technologies is shown in Figure 12.

Figure 12: Intervention logic for an initiative on Key Digital Technologies



How would success look like?

Should the initiative deliver on its specific objectives, it is expected that it would translate in practice into the following impacts:

Scientific impacts

- Europe reinforces its **scientific** capabilities in emerging fields of electronic components and systems, maintaining **excellence** in publications and attracting best talents.
- ➤ Improved cross-border and cross-sector **scientific cooperation** that strengthen the exchange of knowledge across the ecosystem

The following specific objectives would contribute to these impacts:

- Strengthen scientific excellence in emerging technologies would contribute to extend Europe's leadership (see ranking of research publications in Figures 1-4 in Annex 6) to new research areas.
- Build a dynamic EU-wide ecosystem with an extensive network of national research organisations and universities spread across Europe facilitates cross-disciplinary and cross-sector dissemination and application of scientific results.

Stakeholder opinion

A majority of stakeholders from business associations, universities, large companies and SMEs identified in the **open public consultation** scientific impact as most relevant for the KDT initiative. More than half of public authorities and more than three-quarters of universities and RTOs consulted found it 'very relevant'.

Regarding minority views, two respondents (a business association and an academic organisation) indicated scientific impact as 'not relevant'.

Economic/technological impacts

- European electronics components and systems industry strengthens its **technological leadership** and its **global competitive position**, creating jobs and aligning its design and production capabilities with the EU's needs and economic weight.
- > Strengthen **digital transformation** in vertical sectors through electronic components and systems technologies developed in Europe
- > Create a dynamic **ecosystem of innovation** in electronic components and systems with higher and more active involvement of SMEs

The following specific objectives would contribute to these impacts:

- Establish design and production capabilities in Europe for strategic application areas
- Launch large-scale projects supporting the fast transfer of technologies from the lab to industrial settings.
- Build a dynamic EU-wide ecosystem with the involvement of users will help accelerate the market readiness of emerging technologies and facilitate the integration of SMEs.

Stakeholder opinion

According to the **open public consultation**, 'a more innovative, sustainable and competitive electronics and systems industries' was deemed as the most important impact by stakeholders (95 out of 154 respondents, or 62% indicated this as 'very relevant'); an overall majority of universities, RTOs, companies, business associations and public authorities found it relevant or highly relevant.

To facilitate economic impact through the 'development and exploitation of innovative technology paradigms' was also considered to be highly relevant (80 out 150 respondents, or 53%), although to a slightly lower extent.

A minority view, two respondents (a business association and an academic/research organisation) indicated economic/technological impact as 'not relevant'. In particular for the options 'a more innovative, sustainable and competitive electronics and systems industries' and the 'development and exploitation of innovative technology paradigms'.

Societal impacts

- European applications and services provide high levels of **privacy and security** through the use of European components and systems
- ➤ Implementation of EU policies (green and digital transition, technology sovereignty) takes place according to European values and ambitions

Specific objectives contributing to societal impacts:

- Enhanced component technologies that guarantee security and trust for critical European infrastructures and sectors.
- Alignment of the initiative with European policy priorities would favour the development of digital technologies that meet European standards.

Environmental impacts

➤ Electronic component and systems industries and vertical industries progressively reduce their negative environmental impact

Specific objectives with expected contribution to the environmental impacts are:

- Enhance technologies that guarantee energy-efficiency including the design and manufacturing of low consumption components,
- Alignment with the EU policy priorities and in particular with the European Green Deal and the Circular Economy Action Plan

Expected impacts on fundamental rights

Research and innovation on secure and trusted components, systems, software and related applications will contribute to the protection of sensitive personal information⁹³. This will have an impact on the fundamental right to privacy, essential to human autonomy and protection, serving as the foundation upon which other human rights are built.

This impact is linked to the specific objectives on access to secure and trusted components and alignment to EU policy priorities.

Stakeholder opinion

According to the **open public consultation**, delivering 'enabled safety and security' was among the most important impacts for stakeholders (94 out of 153 respondents, or 61% indicated this as 'very relevant'). It was followed by the need to ensure the 'provision of trusted electronics components and systems to the public and businesses' (86 respondents out of 154 respondents, 56%). On the other hand, 'contribution to more functional, efficient, economical and accessible electronics systems' was by a smaller number of respondents indicated as 'very relevant' (70 out of 152 respondents or 46%).

⁹³ Charter of Fundamental Rights of the European Union (2012/C 326/02). Article 8. Protection of personal data.

With efforts maintained over time, all impacts are expected to be materialised within the time framework of the new initiative.

4.4. What is needed to achieve the objectives – Key functionalities needed

Given the focus of the impact assessment on comparing different forms of implementation, the identification of "key functionalities needed" allows making the transition between the definition of the objectives and what would be crucial to achieve them *in terms of implementation*. These functionalities relate to the type and composition of actors that have to be involved, the type of range of activities that should be performed, the degree of directionality needed and the linkages needed with the external environment.

4.4.1. Type and composition of the actors to be involved

Collaboration among stakeholders of the ecosystem, representing all segments of the value chains, is essential for the development of new technologies and the fast market uptake of innovation. The scope of the candidate initiative in terms of technology coverage would need to be broader than ECSEL JU, and the need for integrating relevant stakeholders would be even more relevant. **Openness and flexibility** to integrate players from emerging and/or adjacent technologies and to encourage SMEs participation is also vital.

The involvement and commitment of the following actors is necessary to achieve the intended objectives:

- **Industrial technology suppliers**. Industrial actors from the various segments of the value-chain: Manufacturing equipment and material suppliers, design centres, integrated device manufacturers, software developers. They are the core partners in the initiative and play a central role in its implementation.
- Industrial users (vertical industries). They set the system and service requirements, assess technological choices and play an active role in their validation and demonstration.
- **SMEs and start-ups.** In relation to both previous categories, they would contribute with specific know-how and expertise, and benefit in multiple ways from the involvement in the initiative. Based on the interim evaluation of ECSEL, a lesson to be learned is in terms of the need to enable an increased participation of SMEs, including from the financial point of view, to help achieve both scientific and economic impacts.
- Research and academic organisations. They range from world-class RTOs, to national research organisations and universities. Their cooperation with industry to develop innovative solutions is an essential element for the success of the initiative.
- **Participating States**. Member and Associated States would provide guidance on setting the priorities, ensure the coherence of national and EU programmes and strategies, and stimulate the involvement of relevant national partners. Their financial contribution ⁹⁴ allows to raise significantly the ambitions of the initiative.
- **European Commission.** Together with Participating States, the Commission ensures that public societal and environmental priorities are fully considered, integrates the

⁹⁴ From ongoing discussions with Member States it is expected that they will collectively match the EU contribution to the partnership (as it is currently with ECSEL)

initiative in the context of the EU Framework Programme and supervises the proper setup and running of the candidate initiative in the form of a partnership.

Finally, a high level of participation and balance of sectors, technologies and type of partners, should be achieved - improving current ECSEL levels⁹⁵- to guarantee an open initiative and prevent unjustified concentration on specific technologies or sectors to the benefit of a reduced set of organisations.

4.4.2. Type and range of activities needed

This section concerns the types of activities that the initiative is intended to encourage, so as to respond effectively to the challenges and problems described in Chapter 2.

To deliver in its objectives, the initiative would need to support activities ranging from the formulation of the technology concept (Technology Readiness Level⁹⁶, TRL2) to the completion and qualification of systems (TRL8). The type of activities include:

- Collaborative R&I actions that foster academia-industry, industry-industry and cross-sectoral collaborations.
- Innovation actions to accelerate the maturity of new technology generations for their rapid integration in vertical industries.
- Large-scale projects, such as pilot lines for validation and demonstration of technologies in close to real-life environments.
- Technology platforms where suppliers and users can assess and optimise new technological approaches.
- Research actions addressing the design and manufacturing challenges of critical cross-cutting technologies, such as smart networking and high-performance computing.
- Research and Innovation actions for developments in emerging technological
- Coordination and support actions for the production of common research agendas, mobilisation of stakeholders (e.g. SMEs) and their integration in the ecosystem; coordination with relevant European and national initiatives; and contribution to standardisation activities.
- Coordinated activities between Participating States, Commission, and private members to address security and energy-efficiency aspects in technology and application roadmaps. They would include certification and standardisation activities.
- Coordination with other European initiatives (e.g. IPCEI, European Processor Initiative) for complementary investments on design and production capacities of secure and trusted components.

⁹⁶ Technology Readiness Level (TRL) gives an indication of the maturity of a technology in a scale from TRL1

⁹⁵ The total number of different entities participating in ECSEL in the period 2014-19 is 2681. ECSEL Annual Activity Report 2019. Pending publication.

⁽basic principles observed) to TRL9 (competitive manufacturing)

4.4.3. Priority setting system and level of directionality required

It has been argued in the problem analysis in section 2.1 and the analysis of drivers in section 2.2 that for Europe to compete with China and US especially in emerging technologies, significant investments and resources need to be mobilised. To meet the objective of technological sovereignty and address the problem of Europe's dependence on critical technologies, making sure that Europe has access to technology that respects its values, a broad agreement on a roadmap of activities is necessary. The high ambitions for technological sovereignty and economic leadership imply the development of a shared **European vision** implemented through a **unified research agenda** with strategic objectives reflecting EU priorities and supported by a critical mass of resources (financial, infrastructure and human resources) from the members of the initiative. Thus, the highest possible leverage of resources from industry and Member States under the shared vision is critical to be able to tackle the objectives and deliver on impacts.

The strategic vision should be implemented by the stakeholders along the value chain through the preparation of a common Strategic Research and Innovation Agenda (SRIA). Under the existing partnership ECSEL this has been an open exercise that has involved hundreds of representatives from research, industry and administrations. The priorities of technologies and application sectors in the SRIA has been the result of a broad consensus of participants. The SRIA is in a first instance produced by the private partners and submitted for comments and inputs to the partnership members (EC, Participating States) and approved by the Governing Board.

Responding to shortcomings identified in the interim evaluation of the ECSEL partnership, the Commission and the Participating States in the future initiative would need to steer the agenda towards strategic objectives that are aligned with the policy priorities of the Union. This multi-stakeholder process will aim at producing a balanced agenda that takes account of industry priorities, research challenges and EU and national policies, and making it difficult for a small set of partners to wield undue influence. The monitoring of the initiative would need to ensure that this balance is maintained. An updated SRIA would need to be produced annually, following a broader consultation, which is open and involves a larger amount of stakeholders than nowadays, including innovative smaller companies, to ensure that the scope and priorities of the initiative align as necessary with fast-changing developments.

The sectors and technologies identified in this report are presented as examples based on current context and trends.

The interim evaluation of ECSEL JU recognises the significance of coordination, common vision and research agendas. The experience from ECSEL JU shows that the leverage effect could reach a ratio of 1:3, meaning that for every Euro of EU funding, Participating States and industry could contribute 3 Euros. The ECSEL experience with ratios of 1€ from EU, 0,9€ from Participating States and 2,18€ from private members in the period 2014-18 is encouraging. 8

Recent declarations from industry associations⁹⁹ and from national authorities¹⁰⁰ confirm their intention to continue the current tri-partite scheme with the same relative contributions

⁹⁷ European Commission. (2018). *Interim Evaluation of the ECSEL Joint Undertaking (2014-2016) Operating under Horizon 2020*. Final report.

⁹⁸ ECSEL Annual Activity Report 2018.

⁹⁹ Declaration of the ECSEL Industry Associations

¹⁰⁰ Declarations from Member States

(1€ from EU, 1€ from participating states, 2€ from private members 101). Commitments from the initiative's members would need to be reflected in the future Council Regulation. The implementation details are still pending internal discussion.

The KDT initiative, object of this impact assessment, would aim at a more challenging set of objectives and with a broader impact than the current ECSEL JU. At the time of writing this impact assessment the level of financial support to the KDT initiative is uncertain. Despite the fact that the three members of the initiative (European Commission, Participating States and Industry) consider KDT as an area with far-reaching impact on the EU economy and society, the COVID-19 crisis may limit available resources. In case of a reduced budget, a decision by its members (via a shadow governing board) on the prioritisation of objectives and rationalisation of activities would be necessary to ensure that its ambitions can be realistically achieved.

Given the importance of establishing robust electronics value chains, the consolidation of an ecosystem would be a priority for coordination, especially at the early stages of the candidate initiative.

The above conclusions are also supported by the interviews with the ECSEL JU industry associations and downstream stakeholders. The consensual view is that coordination of research agendas among EU, Member States and industry allows a more effective R&I response in a fast-moving market and with a higher level of impact.

4.4.4. Coherence needed with the external environment

Alignment with strategic EU policies and initiatives is a major recommendation from the ECSEL Interim evaluation and one of the problem drivers for the intervention logic of the future initiative. "The European Green Deal", "A Europe fit for the digital age" and "An economy that works for people", but also the most recent "Recovery Package" are major EU priorities to which the initiative should provide valuable contributions. Access to secure and energy-efficient components for strategic European infrastructure and sectors and ensuring technological sovereignty would be objectives of the candidate initiative closely related to the objectives of these EU initiatives.

Participation of Member States would facilitate alignment with national programmes and strategies, reducing overlap and fragmentation of efforts, and importantly, ensuring critical mass and synergies can be built.

As indicated earlier, the enabling character of electronic components and systems argues in favour of coordination with other partnerships and initiatives in digital sector (see section 1.3). The 'digital cluster' of partnerships is expected to coordinate with Member States and industry for a comprehensive EU digital strategy. Coordination is also expected with partnerships addressing other verticals such as space (Global competitive space system) and manufacturing (Made in Europe) sectors as well as health (IMI), mobility and energy.

Synergies with the Digital Europe Programme (DEP)¹⁰³ would need to be exploited with testing facilities, skills development and capacity building activities in specific digital domains. Similar synergies would need to be explored with Connecting Europe Facilities

¹⁰¹ These relative contributions are based in ECSEL experience. Matching of public funding by the private members takes account of contributions from all project beneficiaries (members and non-members of industrial associations)

Europe's moment: Repair and Prepare for the Next Generation. COM(2020) 456

DEP (Digital Europe Programme) has been proposed by Commission as part of the EU long-term budget 2021-27. https://ec.europa.eu/digital-single-market/en/news/digital-europe-programme-proposed-eu92-billion-funding-2021-2027

(CEF)¹⁰⁴ that supports investments in European infrastructure networks for transport, energy and digital.

The achievement of EU technological sovereignty would need to be facilitated by the coordination of the KDT initiative with a future IPCEI on digital technologies. There are indications 105 that efforts could be made towards combined national and private investments for first industrial deployment, building the required capacity for production in Europe of advanced components for edge-computing.

Finally, the interim evaluation of ECSEL JU stressed the importance and potential for coordination with local, regional, national and European initiatives. ¹⁰⁶ Coordination with regional clusters such as Silicon Europe, Silicon Saxony (Dresden), Minalogic (Grenoble), and DSP Valley (Leuven-Eindhoven) could contribute to the mobilisation of stakeholders, especially SMEs, and their integration in the ecosystem.

5. WHAT ARE THE AVAILABLE POLICY OPTIONS?

This section describes the specific functionalities that could be provided under the baseline scenario of traditional calls and the various options of different types of European partnerships.

5.1. What is the baseline from which options are assessed?

The baseline scenario used in this impact assessment is a situation without a Partnership and only traditional calls of Horizon Europe. Given that there is a predecessor Partnership as well as other funding sources in the area, these will continue generating effects even if there is no new Partnership. In particular it is expected that these already existing initiatives will still create effects in the area of digital technologies. This is taken into account in the effectiveness assessment.

In parallel, the baseline situation means that the current implementation structure of the Article 187 would be closed, which bears winding down and social discontinuation costs. There would also be financial cost-savings related to the closing of the structure, related to operations, staff and coordination costs in particular. This is taken into account in the efficiency assessment.

The baseline (Option 0) for the functioning of this research and innovation initiative in the field of electronic components and systems is to make use of mainstream channels of Horizon Europe. The related priorities would be implemented through traditional calls under the Framework Programme. Table 1 presents the key characteristics of the baseline.

Table 1: Key characteristics of the baseline situation – Traditional calls

Implications of option
 Enabling appropriate profile of
 Consortia of public and/or private actors in ad hoc combinations are eligible. Specific actions can be for a single actor (mono-beneficiary).

CEF (Connecting Europe Facilities) has been proposed by the Commission as part of the EU Multi-financial Framework 2021-27. https://ec.europa.eu/commission/presscorner/detail/en/IP_18_4029

Electronics Leaders Group. (2018). Boosting Electronics Value Chains in Europe: A report to Commissioner Gabriel.

¹⁰⁶ European Commission. (2018). Interim Evaluation of the ECSEL Joint Undertaking (2014-2016) Operating under Horizon 2020. Final report.

participation (actors involved)

- Calls are open for participation of entities from Member and Associated States.
 Organisation from third countries can participate under specific conditions. Partners from industrialised countries are not eligible for funding.
- Systematic and structured engagement of Member States limited to the participation in the programme committees.

Supporting implementation of R&I agenda (activities)

- Supported activities include Horizon Europe standard actions that allow a broad range of individual actions covering the whole spectrum of activities that are required for the digital technologies achieving the objectives of the KDT initiatives (TRL2 to TRL8).
- Combination of activities into a portfolio of actions for achieving a common objective is not
 possible.
- Leverage of additional activities or investments beyond the direct scope of the funded actions is not possible.

Ensuring alignment with R&I agenda (directionality)

- The strategic programming through the programme committees of Horizon Europe involving a wide range of stakeholders (who are not necessarily aware of, relevant to, or interested in the objectives of the KDT initiative) implies a lower level of directionality and a lower weight of industry's voice in shaping the priorities compared to other options.
- There is possibility to develop an SRIA or roadmaps. However, without a formal EU partnership mechanism, it is less likely that the stakeholders will develop a joint Strategic Research Agenda and commit to its implementation or agree on mutual financial commitments beyond the single project participation.
- The strategic planning mechanisms of Horizon allow for a high level of flexibility and responsiveness to changing needs.
- Coordination with national or regional initiatives difficult to achieve in practice.
- Coordinated implementation and funding linked to concrete objectives and roadmap is not
 possible as the funded projects are part of much broader project portfolio managed by an
 agency or EC services.
- Support of priorities cannot continue over the four years of the strategic plan and budget and therefore it is less likely that the funding will be used for supporting long term objectives.
- The coherence of funded activities in the area of electronic components and systems with other parties of the Annual Work programme is ensured by the EC.
- Coordination and exploitation of synergies with other programmes beyond the FP and industrial strategies is limited as it requires more structured approaches which are not available in Horizon Europe.

Securing leveraging effects

(additionality)

- Member States do not contribute to the budget. Thus, the resources that could be mobilised
 are sensibly lower compared with other options.
- Substantial industry contribution, mostly in-kind (e.g. researchers, labs), of 50% of the total cost of the initiative, will not be possible.

Key differences compared to the current situation

- Moving from the current ECSEL JU to Horizon Europe calls (baseline option) would entail the dismantling of the JU with the following consequences:
 - The development and implementation of a common vision with the partners in the area and the achievement of objectives would not be possible to the same extent
 - A stable structure encompassing Participating States, the industry associations and the EC for R&I cooperation would disappear
 - Large scale R&I actions (pilots, platforms) could not be implemented in a coordinated way
 - The initiative would be fully financed by the EU. Participating States and Industry would not be able to contribute at programme level (but at project level)
 - The overall budget of the initiative, including contributions by industry and Member

5.2. Description of the policy options

5.2.1. Option 1 - Co-programmed European Partnership

This form of European Partnership is based upon a *Memorandum of Understanding* or a *Contractual Arrangement* signed by the European Commission and industrial associations representing the private partners. The formal commitments from partners are not legally binding and subject to "best efforts". Table 2 presents the key characteristics of the option.

Table 2: Key characteristics of Option 1- Co-programmed European Partnership

Table 2: Key characteristics of Option 1- Co-programmed European Partnership					
	Implications of option				
Enabling appropriate profile of participation (actors involved)	 Suitable for the participation of a large community of stakeholders able to contribute to the definition and implementation of the Strategic R&I agenda. Private members (industry, RTOs) represented by associations that provide limited administrative support. The calls are included in the FP Work programme. Horizon Europe rules for participation apply. 				
Supporting implementation of R&I agenda (activities)	 Union contribution is implemented via calls for proposals published in the Work Programmes of Horizon Europe based on the input from partners (adopted via comitology). R&I activities follow 2-year Work programmes, with risk of discontinuity of actions and limited long-term financial stability to pursuit the partnership objectives Implementation of actions and administration by Commission services or relevant executive agency. A broad range of coordinated activities from low TRL to demonstration are possible under the standard actions of Horizon Europe. The associations representing private partners allow some level of coordination, including activities related to regulation and standardisation and developing synergies with other initiatives. 				
Ensuring alignment with R&I agenda (directionality)	 The strategic R&I agenda/roadmap is agreed between partners and EC. The objectives and commitments are set in the contractual arrangement. The input to FP work programme is drafted with the inputs from partners and finalised by EC (comitology). The commitments are political/best effort. Coherence among partnerships and with different parts of the Work programme of Horizon Europe can be ensured by partners and EC, however exploitation of synergies with other programmes is limited. Coordination with national or regional initiatives difficult to achieve in practice. Coordinated implementation and funding linked to concrete objectives and roadmap is not possible as the funded projects are part of much broader project portfolio managed by an agency or EC services. Synergies with industrial strategies is ensured through the industrial partners. Synergies with national and regional programmes and activities can be explored. 				
Securing leveraging effects (additionality)	 Leveraging target defined and agreed from the onset but agreement to commit resources from the involved stakeholders remains "best efforts" Under this type of partnership in-kind contribution of industry is possible and it would be included in the Contractual Agreement. Member States: This option allows only for light coordination of efforts with R&I in the field at the national level but no financial contribution to the budget of the initiative 				

Key differences compared to the current situation

- Moving from the current ECSEL JU to Co-Programme partnership (Option 1) would entail the dismantling of the JU with the following consequences:
 - The implementation of a common vision and achievement of objectives would be less efficient and take longer
 - A stable structure encompassing Participating States, the industry associations and the EC for R&I cooperation would disappear
 - Large scale integrated R&I actions (pilots, platforms) could not be implemented
 - Important contributions (financial) from Participating States and industry would not materialise and the EU would have to bear a higher share of the cost.
 - The overall budget of the initiative, including contribution by industry, Member States, would likely be substantially reduced
 - Substantial discontinuation cost, with a 4-year winding down period for the current JU (see rationale at 6.2 Efficiency)

5.2.2. Option 2 – Co-funded European Partnership

See table with key characteristics of Option 2 in Annex 6 (Impact Assessment, Part 2)

5.2.3. Option 3 – Institutionalised European Partnership

a) Institutionalised Partnerships under Art. 185 TFEU

See table with key characteristics of Option 3a in Annex 6 (Impact Assessment, Part 2)

b) Institutionalised European Partnership under Art 187 TFEU

An Art 187 TFEU partnership is based on a Council Regulation and implemented by dedicated structures created for that purpose. It can be implemented only where other parts of the Horizon Europe programme, including other forms of European Partnerships would not achieve the objectives or would not generate the necessary expected impacts, and if justified by a long-term perspective and high degree of integration.

Table 3: Key characteristics of Ontion 3: Institutionalised Partnership under Art 187 TFEU

Table 3: Key characteristics of Option 3: Institutionalised Partnership under Art 18/1FEU					
	Implications of option				
Enabling appropriate profile of participation (actors involved)	 This option is suitable for the participation of all types of partners contributing to the definition and the delivery of the SRIA The upfront commitments and long-term planning of this option are attractive to a large set of participants. The involvement of Participating States contributes to the mobilisation and participation of national actors. In response to emerging challenges and evolving priorities, the SRIA can be defined to attract new relevant partners. Horizon Europe rules apply by default, so any legal entity can apply to partnership calls. In addition to Participating States, companies and research organisations from other countries can participate but subject to policy considerations. Non-associated third countries can only be included as partners if foreseen in the basic act and subjected to conclusion of dedicated international agreements. Basic act can foresee exceptions for participation in calls / eligibility for funding. 				
Supporting implementation	• The standard actions of Horizon Europe that allow to build a portfolio with a broad range of research, innovation and demonstration activities.				

of R&I agenda (activities)

- The dedicated administrative structure of the JU can efficiently implement, monitor and report results of an integrated portfolio of projects.
- The option allows the combination of national and Union funding for the joint financial support of activities. It enables the achievement of critical mass of investments in a common agenda across the EU.
- Communication and dissemination activities can be supported by the partnership structure.

Ensuring alignment with R&I agenda (directionality)

- The Strategic R&I Agenda setting the objectives and priorities of the partnership is agreed between Participating States, the industry associations and the EC.
- The annual work programme is adopted by the Governing Board of the partnership.
- The voting majority of EU and national members in the partnerships facilitates the alignment of the partnership with public policy priorities.
- The objectives and commitments are set in the legal base. Changes require modification of the Regulation and approval by the Council.

Securing leveraging effects (additionality)

- Commitments include the obligation for financial and in-kind contributions of partnership members, including contributions to the administrative costs. Commitments would be legally established in the basic act.
- For the KDT JU where a tripartite model is envisaged, contribution of industry to the operational running of the partnership is expected to be 50% of the aggregated partnership budget. Contribution of Participating States is expected to maintain the current ECSEL level and match the EU contribution (25% of the aggregated budget)

Key differences compared to the current situation

- The JU structure of ECSEL would be taken over by the KDT partnership
- Modifications will be introduced in administrative procedures and practices to ensure that
 operations are lean and as efficient as possible

5.3. Options discarded at an early stage

The Co-Funded partnership and the Institutionalised Partnership created under Article 185 of the TFEU are not considered relevant for the impact assessment of the initiative on Key Digital Technologies.

Based on the objectives of the KDT initiative, the direct beneficiary is the industry. Therefore, the objectives can be only achieved if industry plays a pivotal role in the setting of the agenda, implementation and mobilisation of resources. This precondition is not satisfied by Co-Funded or Art 185 partnerships:

- The Co-Funded partnership allows only public partners at its core and the industry cannot make formal commitments or contributions to it, nor to participate in the setting of the research agenda.
- The participation in Art 185 TFEU is limited to Member States.

6. How do the different policy options compare to achieve the expected impacts?

Based on the objectives pursued by the initiative and the key functionalities identified to be able to achieve them, each option for implementation is assessed in terms of effectiveness, efficiency and coherence compared to the baseline scenario of traditional calls. The analysis is primarily based on the degree to which the different options would cater for the key needed functionalities. All options are compared to the baseline situation of traditional calls, which is thus consistently scored at 0 to serve as reference point.

6.1. Effectiveness

To be in line with the Horizon Europe impact framework, the fulfilment of the specific objectives of the initiative is translated into 'expected impacts' - how success would look like -, differentiating between scientific, economic/ technological, and societal (including environmental) impacts. This section considers to which extent the different policy options would allow delivering these expected impacts – confronting what is needed (functionalities) with what each form of implementation can provide in practice. The assessments in this section set the basis for the comprehensive comparative assessment of all retained options against all dimensions in Section 6.4, based on a scoring system 107.

Scientific Impacts

- Europe reinforces its scientific capabilities in emerging fields of electronic components and systems, maintaining excellence in publications and attracting best talents.
- Improved cross-border and cross-sector scientific cooperation that strengthen the exchange of knowledge across the ecosystem

Scientific impacts would be generated by collaborative actions of **interdisciplinary research** teams. The active **involvement of industry** is necessary, as well as a good degree of **coordination** and a significant **volume of resources**, to ensure that scientific advances are supported through the innovation cycle and eventually transferred to industrial environments. These elements are part of a strategic approach characterised by directionality towards common objectives, alignment of individual projects, and participation of industrial partners.

Baseline: Horizon Europe traditional calls

Option 0 with traditional calls under the Framework Programme can effectively attract **high-quality research** teams particularly in emerging and less established technologies. This option allows to define a technology roadmap, however, it is **less attractive to industry, including to SMEs and start-ups, due to the difficulty of long-term planning** to align research activities with industrial priorities. This option therefore does not ensure the participation of all necessary actors as a partnership would.

The uncertainty of industry involvement and the absence of financial contribution from Participating States makes this option **unlikely to mobilise a critical volume of resources**. Furthermore, the use of open calls, with limited coordination, to address research priorities is likely to involve a considerable **degree of inefficiency** due to the risk of different projects addressing similar issues.

Finally, Horizon Europe traditional calls are **well suited to address cross-sector research** by multi-disciplinary teams. This option, however, **would not mobilise important stakeholders** (large companies and SMEs) to support scientific cooperation towards common objectives. As a consequence, this option would have a **limited contribution** to a dynamic **ecosystem**.

Option 1: Co-Programmed European Partnership

Option 1 can address research challenges as a part of a strategic agenda that aligns with industrial objectives. It can attract the participation of academia and research

A more in depth and detailed analysis of each policy option is provided in the "Impact Assessment Study for Institutionalised European Partnerships under Horizon Europe – Candidate Institutionalised European Partnership on Key Digital Technologies". Technopolis Group (2020)

stakeholders to address scientific challenges in emerging fields, and provide a **good level of coordination** to support industrial commitments.

In this option industry associations can mobilise a **broad range of stakeholders**, including SMEs, and ensure a **good coverage** of the value chains, including research organisations and technology users. Also, they can contribute more systematically in the building of a **collaborative multidisciplinary ecosystem**, facilitating the exchange of knowledge across sectors. However, the lack of participation of Participating States in this option **limits both directionality and the volume of resources** necessary to implement large-scale actions supporting the transfer of scientific outcomes to industrial settings, limiting the involvement of user industries.

Therefore, the potential of the option to generate the expected scientific impacts is good (+) compared to the baseline.

Option 3: Institutionalised European Partnership under Article 187 TFEU

Option 3 can attract and engage in research activities the different types of stakeholders, in a strategic agenda that aligns research effort with industrial and policy priorities. The participation of the industry is expected to be high as this option provides the highest possible commitment and a coordinated long-term strategic planning. The launching of open calls, as in the other options, provides opportunities to attract new participants with the necessary competences to address emerging challenges. Further harmonisation and simplification of administrative procedure will also facilitate participation. Therefore, it is considered that the potential of this option to attract the necessary mix of stakeholders to research activities is high.

The tripartite model of this option with the **involvement of Participating States** would attract national research organisations and ensure the highest level of coordination with **national research** programmes. On the assumption that the Commission financial contribution would be similar to other options, the tripartite model of this option would **mobilise a substantially higher volume of resources** by combining Commission, national and private contributions, as proven in the existing ECSEL JU. It enables the design and implementation of a common agenda across the EU with the necessary resources to build a dynamic European ecosystem for electronic components and systems.

The existence of a **central coordination** mechanism which can proactively mobilise different types of stakeholders, including national research organisations, can provide the highest possible coverage of value chains. The central coordination of this option also offers the flexibility and enables the implementation of follow-up activities to disseminate **knowledge across sectors and stakeholders** (e.g. SMEs) sustaining and **reinforcing the ecosystem**.

Therefore, the potential of the option to generate the expected scientific impacts is high (++) compared to the baseline.

Table 4: Overview of the options' effectiveness compared to the baseline - Scientific impacts

Impacts	Baseline: Horizon Europe calls	Option 1: Co- programmed	Option 3: Institutionalised Art 187
Europe reinforces its scientific capabilities in emerging fields of electronic components and systems maintaining leadership excellence in publications and attracting best talents.	0	+	++
Improved cross-border and cross-sector cooperation that strengthen the exchange of knowledge across the ecosystem	0	+	++

Notes: Score ++: Option presenting a *high* potential compared to baseline; Score +: Option presenting a *good* potential compared to baseline; Score 0: Potential of the baseline.

Economic/Technological impacts

- European electronics components and systems industry strengthens its **technological leadership** and its **global competitive position** aligning its design and production capabilities with the EU's needs and its economic weight.
- > Strengthen digital transformation in vertical sectors through electronic components and systems technologies developed in Europe
- > Create a dynamic ecosystem of innovation in electronic components and systems with higher and more active involvement of SMEs

Achievement of the expected impacts requires the ability to support technology development from the initial phases of R&D until technology maturity. This implies the combined use of research actions and large-scale pilots at the appropriate points in time.

It will require a strategic approach endorsed by private and public sector actors and their commitment to mobilise a critical mass of resources over the longer term. It will necessarily imply achieving a coherent alignment between industrial priorities and public sector policies.

Moreover it requires **moving rapidly from low to higher TRLs** and achieving a high level of integration, with the involvement of users in the early phases of the technology development. SMEs and start-ups should be involved as providers of new ideas for innovations.

Baseline: Horizon Europe traditional calls

Under the baseline option the development of a strategic research and innovation agenda with the participation of the industry is possible, but the degree of alignment with industry priorities over time is likely to be limited.

The absence of any steering and any financial contribution from the Member States limits the potential of this option to establish coherence with national policies and the possibility to mobilise the required volume of resources that would be needed in particular for large-scale pilots.

Horizon Europe calls do not have the mechanism to support successive phases of technological development nor the creation of industrial consortia to accelerate technologies maturity from low to higher TRLs.

Traditional calls in Horizon Europe can attract the participation of SMEs but with considerable risk of discontinuity of effort. The **low level of coordination** offered would not support the creation of an ecosystem where SMEs and start-ups can interact with relevant stakeholders beyond research cooperation.

Option 1: Co-Programmed European Partnership

Under Option 1, the **industry associations could provide coordination** to their members and mobilise the necessary mix of stakeholders.

Option 1 offers the possibility of aligning the partnership with the strategies of industry and the development of an agenda of activities.

However the **industrial commitment may be limited** to 'best effort' which may affect a long-term planning necessary to support technologies along the full R&I cycle from low to higher TRLs.

The interest of industry and their participation in projects contributing to the digital transformation would **stimulate industrial investments**. However, absent national public support, this Option is **unlikely to mobilise the necessary public and private resources** to support large-scale pilot and demonstration projects required for the validation of technologies in specific sectors.

The industry associations can mobilise stakeholders and ensure the participation of relevant organisations from across the value chain, including SMEs, and is open to newcomers according to emerging needs. The industry associations will facilitate and steer appropriate collaboration among their members.

Although the Option offers higher coordination compared to the baseline, the building of the ecosystem that stimulates the involvement of SMEs requires flexibility and feedback mechanisms: flexibility to design and implement calls according to the needs, feedback loops that facilitate learning and adaptation of the activities to fit the changing needs best. These possibilities are only partially covered due to the **absence of a central coordination and management system.**

Therefore, the potential of the Option to generate the expected impact compared to the baseline is high (++) for 'Strengthen digital transformation in vertical sectors through electronic components and systems technologies developed in Europe' and it is good (+) for the rest.

Option 3: Institutionalised European Partnership under Article 187 TFEU

The Institutionalised Partnership Art 187 is subject to a legal framework set out in a Council Regulation. As the other options do, it provides the opportunity to any organisation to participate through open calls. Therefore, in terms of the **participation of the necessary mix of partners**, the potential is high.

Option 3 offers the ability to generate integrated portfolios of projects through activities supporting technology acceleration, scale-up and validation and allows the pooling of private and public resources and the implementation of large-scale projects bringing together technology suppliers and users.

Option 3 offers the **highest directionality** among the various options. The partnership is built around a common European strategic research and innovation agenda agreed among the Commission, the Participating States and the industry represented by industry associations, and implemented through work programmes that can be updated annually.

The legal basis offers a stable framework for long-term planning and financial commitments compared to other Options and facilitates the alignment of the partnership with EU, national and industrial priorities.

The central coordination of this option offers the **flexibility to design specific activities to adapt to emerging areas and to attract and integrate SMEs** It also provides the highest possible directionality and leverage and the ability to design and implement a portfolio of activities that can support the building of the ecosystem that can attract and sustain SMEs and start-ups. **Further harmonisation of procedures across Participating States and simplification of administrative procedures** (currently in place in ECSEL) will further contribute to the increased participation of SMEs.

Therefore, the overall potential of the option to generate the expected impact is high (++).

Table 5: Overview of the options' effectiveness compared to the baseline - Economic/technological impacts

	Baseline: Horizon Europe calls	Option 1: Coprogrammed	Option 3: Institutionalised Art 187
European electronic components and systems industry strengthens its technological leadership and its global competitive position aligning its design and production capabilities with the EU's needs and its economic weight	0	+	++
Strengthen digital transformation in vertical sectors through electronic components and systems technologies developed in Europe	0	++	++
Create a dynamic ecosystem of innovation in electronic components and systems with higher and more active involvement of SMEs	0	+	++

Notes: Score ++: Option presenting a *high* potential compared to baseline; Score +: Option presenting a *good* potential compared to baseline; Score 0: Potential of the baseline.

Societal and environmental impacts

- European systems and services providing high levels of **privacy and security** through the use of European digital technologies
- Implementation of **EU policies** (digital transition, technology sovereignty) according to the **European values and ambitions**
- ➤ Electronic components and systems industries and vertical industries progressively reduce their negative environmental impact

Baseline: Horizon Europe traditional calls

Under Horizon Europe, the prioritisation by the Commission and the Member States (through the Programme Committee and the work programmes) is likely to place **high emphasis on societal and environmental impacts**. This emphasis would be accentuated as the European Commission has declared Horizon Europe a key instrument to achieve the Green Deal objectives¹⁰⁸.

High-quality research results are, therefore, expected regarding the optimisation of security and privacy as well as the environmental characteristics of electronic components and systems. However, the generation of the expected impacts depends on the final uptake of relevant digital technologies by the vertical industries. Horizon Europe would be effective in the generation of the research results through stand-alone projects and early prototyping, but it would be less effective in facilitating industrial uptake at later stages of technology maturity. The scale and scope of research impacts would therefore be limited.

Due to the lack of a critical mass of resources and the limited alignment with industry priorities, it is unlikely that this Option would achieve the intended mitigation of environmental impacts (which requires industry wide adoption of technologies).

Similarly, **lack of coordination** across low and high TRL stages would limit the alignment of the area with EU societal and environmental policies.

Option 1: Co-Programmed European Partnership

Under the Co-Programmed partnership, more emphasis will be given to later stages of the research process compared to traditional calls in Horizon Europe. This option can **balance**

¹⁰⁸ 'Mobilising Research and fostering innovation'. The European Green Deal. COM(2019) 640. 11 December 2019

social/environmentally-driven research and activities supporting the use of research results in sectors and services of interest.

The environmental impacts of the initiative is related to its potential to **reduce the energy consumption** of the applications by making use of greener components and systems technologies.

Further to commercial interests, industry will take into account environmental impacts as the workprogramme is established by the Commission. Therefore, the improvement of energy efficiency and the development of **environmentally friendly technologies** is expected to be a high priority.

In Option 1 the **coordination necessary to align** industry with other EU policies and commit to their implementation might be limited.

The overall potential of the Option to generate societal and environmental impacts is expected to be high (++) compared to the baseline with the exception of impact 'Implementation of EU policies (green and digital transition, technology sovereignty) according to the European values and ambitions' which is expected to be good (+) compared to the baseline. See table 6.

Option 3: Institutionalised European Partnership under Article 187 TFEU

An institutionalised Art. 187 partnership with a **long-term strategy** agreed between public and private members can ensure that **societal and environmental** aspects are addressed in the later stages of R&D and in the preparation for industrialisation.

Joint public-private priorities of societal relevance include the development of technologies supporting security, safety and trust, ensuring their availability in the digital transition of systems and services.

The **portfolio approach** of this option would support a balanced coverage of **citizen-centred technological solutions** together with others that focus on performance, sustainability, etc.

Public-private priorities of societal relevance also include skills and education policies. There is a clear shortage of engineering and ICT skills in microelectronics that needs to be addressed. Increased collaboration between academia and industry can facilitate on-the-job learning; research ministries can facilitate support programs for Masters, PhDs, and internships in these areas.

A **tripartite model** with the participation of Member States would bring to an institutionalised partnership national experiences, **expanding and diversifying the scope** of societal challenges addressed and approaches taken.

In addition to commercial interests, **the strong coordination and central management** of this option and the key role of the Commission and the Participating States would enable closer alignment to EU policies, including by establishing coordination with relevant partnerships and, improving on the current experience in ECSEL, by steering the SRIA towards those policy objectives.

As shown in the existing ECSEL JU, the **high volume of public and private resources** that this option can mobilise will help the development of technologies and their integration in a broad number of sectors and applications.

Therefore, the overall potential of the Option to generate both societal and environmental impacts related to security and alignment with EU policies is expected to be high (++) compared to the baseline.

Summary

Table 6 below lists the scores assigned for each of the policy options to reach the various impacts. Scores are based on the assessments above, as well as on the views expressed by the different stakeholders.

Table 6: Overview of the options' effectiveness compared to the baseline - Societal impacts

	Option 0: Horizon Europe calls	Option 1: Coprogrammed	Option 3: Institutionalised Art 187
European systems and services providing high levels of privacy and security through the use of European digital technologies	0	++	++
Implementation of EU policies (green and digital transition, technology sovereignty) according to the European values and ambitions	0	+	++
Electronic components and systems industries and vertical industries progressively reduce their negative environmental impact	0	++	++

Notes: Score ++: Option presenting a *high* potential compared to baseline; Score +: Option presenting a *good* potential compared to baseline; Score 0: Potential of the baseline.

Assessment of directionality and additionality

As argued in the problems and drivers sections for both the European electronic ecosystem and the vertical industries that depend on these technologies for their competitiveness, the main challenge is Europe's ability to retain leadership and address technological sovereignty while facing severe competition from other regions, in particular China and US. The KDT initiative is expected to play a pivotal role in tackling the challenge by strengthening technological leadership of Europe in electronic components and systems, ensuring the supply of secure and energy-efficient components and systems for critical infrastructures and sectors, and ensuring the coordination and integration of R&I efforts by companies, national research communities and ecosystems that connect their long-term investment to the European and global value chains and networks. The development of a shared European vision, set together with the Commission and the Participating States, with a coordinated research agenda and a central management system aligned with EU, national and industry priorities and strategies is necessary for exploiting synergies. Also the commitment of the initiative members to enable the pooling of resources and the leverage effects is necessary to support the activities that would generate the expected impacts. Thus, the option that offers the highest level of directionality and additionality will maximise the economic and technological impacts of the initiative.

6.2. Efficiency

In order to compare the policy options consistently in terms of their efficiency, a standard cost model was developed for the external study supporting the impact assessment for the set of candidate Institutionalised Partnerships. The model and the underlying assumptions and analyses are set out in the Common Part of this impact assessment, Section 2.3.2 and in the Methodology Annex 4. A dedicated Annex 3 also provides more information on who is affected and how by this specific initiative in line with the Better Regulation framework. The scores related to the costs set out in this context allow for a "value for money" analysis (cost-effectiveness) in the final scorecard analysis in Section 6.4.

In addition, for this specific initiative under the baseline scenario of traditional calls, there would be winding down and social discontinuation costs for the existing implementation

structure of the current Article 187 initiative ECSEL. The JU statutes¹⁰⁹ foresee a 4-year winding down period to manage projects launched in the last phase of the JU and running beyond 31st December 2020.¹¹⁰

There would be also 'intangible costs' associated to the JU discontinuity. It will be difficult to justify a lower intensity of EU support in R&I to the components and systems industry at a moment in which access in Europe to key digital technologies is becoming critical and when other regions (China, US, Korea) are receiving substantial public support that goes beyond R&I.

Discontinuity of the ECSEL JU will represent administrative savings of €5.53 million/year (of which 50% contribution by the EC), with the exception of the 2021-24 period as indicated above. It is estimated that the overall longer term cost savings from using traditional calls (or a co-programme model) instead of an existing Article 187 initiative would considerably exceed the costs incurred for winding down operations. This overall situation is set as the starting point for the comparison of options. The score of this baseline scenario (traditional Horizon Europe calls) is set to 0 to be used as a reference point.

On this basis, the scores for the costs of the different options range from a value of 0, in case an option does not entail any additional costs compared to the baseline, to a score of (-) when an option introduces limited additional costs when compared to the baseline and a score of (-)(-) when substantial additional costs are expected in comparison with the baseline. In case the scores are lower than for the baseline scenario, (+) and (+)(+) are used.

The intensity of additional costs for specific items for the various options as compared to the baseline, i.e. Option 0 (Horizon Europe calls) is presented in Figure 4 in the overview of the methodology (Section 2.3. in the common part of this report).

It is considered therefore that there is a clear gradation in the **overall costs** of the policy options, this is reflected in the scores assigned to baseline (0), co-programme (0) and Article 187 (-)(-) scenarios. The cost differentials, however, are less marked when one takes into account the expected co-financing rates and the total budget available for each of the policy options, assuming a common Union contribution. From this perspective, there are only one or two percentage points that split the most cost-efficient policy options – the baseline (traditional calls) and the Co-Programmed policy options – and the least cost-efficient – the Institutionalised Partnership option. Indeed, in terms of cost-efficiency, the Co-Programmed Partnership (Option 1) is 2 percentage points more efficient than the baseline; and an Article 187 Partnership is 2 percentage points less cost-efficient than the baseline. A score of (+) is therefore assigned for **cost-efficiency** to the Co-Programmed options and a score of (-) for the Institutionalised Partnership policy option¹¹¹.

It should be noted that the potential for the creation of crowding-in effects for industry has been taken into account when assessing the effectiveness of the policy options, above.

When assessing efficiency, the financial contribution of Member States to the candidate KDT JU as well as the industrial commitment need to be taken into account. Based on the existing JU experience¹¹² and on-going consultation with Member States and Industry Associations, it is intended (see sub-section 4.4.3) that the envisaged initiative in KDT

-

Council Regulation (EU) No 561/2014 of 6 May 2014 establishing the ECSEL Joint Undertaking

The administrative cost planned for the management of ECSEL legacy in the period 2021-24 is €10.4 million, to be equally shared by EC and industry members.

¹¹¹ The baseline (traditional calls) is scored 0, as explained above.

 $^{^{112}}$ ECSEL leverage ratios in the period 2014-18: 1€ from EU, 0,9€ from participating states and 2,18€ from private members. ECSEL Annual Activity Report 2018

would generate a leverage effect of 1:3, enabling a critical volume of resources to support actions at the right scale to generate the foreseen impacts.

Table 7 summarises the cost scores.

Table 7: Matrix on 'overall costs' and 'cost-efficiency'

	Baseline: Horizon Europe calls	Option 1: Co- programmed	Option 3: Institutionalised Art 187
Overall cost	0	0	(-)(-)
Cost-efficiency	0	(+)	(-)

Notes: Score 0 = same costs as for the baseline; score (-) = limited additional costs compared with the baseline; score (-)(-) = substantial additional costs compared with the baseline.

6.3. Coherence

6.3.1. Internal coherence

In this section we assess the extent to which the policy options show the potential of ensuring and maximising coherence with other programmes and initiatives under Horizon Europe, in particular European Partnerships.

Option 0: Horizon Europe calls (baseline)

Under this option, coherence between activities in the area of electronic components and systems with activities under Cluster 4 of the Horizon Europe and the other initiatives presented are ensured by the Commission. However, exploitation of synergies between the KDT and other initiatives, such as exchange of knowledge and experience at the level of projects and stakeholders, is limited as it requires an extra layer of coordination beyond the Programme Committees.

Option 1: Co-Programmed

Under the Co-Programmed option, the exploitation of synergies can go beyond the possibilities offered by the baseline option. The Commission can ensure coordination at the level of the research agendas, while the industry associations can proactively bring together projects and stakeholders from various initiatives to work together on common problems or exploit together common challenges.

Therefore, the potential of the Option to generate the expected impact is good (+) compared to the baseline

Option 3: Institutionalised Art 187

The Institutionalised Art 187 partnership can provide the highest level of coordination, as in addition to the role of the Commission, the Participating States and the industry associations there is a central coordination mechanism which can increase the effectiveness of the effort. Since the central management of the partnership (i.e. the Governing Board, with representation of all members) decides on the actions, calls and funding allocation, the KDT partnership could set together with other initiatives joint activities of common interest.

Therefore, the potential of the Option to generate the expected impact is high (++) compared to the baseline

6.3.2. External coherence

In this section we assess the extent to which the policy options show the potential of ensuring and maximising coherence with EU-level programmes and initiatives beyond the Framework Programme and/or national and international programmes and initiatives.

Option 0: Horizon Europe calls (baseline)

In section 4.4.4 several opportunities for collaboration and development of synergies with initiatives and programmes beyond Horizon Europe have been identified. Under this option, some coordination with other European Commission activities is possible at the level of priorities. However, coordination at the level of implementation is somewhat limited or even not feasible.

Collaboration with national or regional initiatives such as national programmes for the support of KDT or a close coordination with regional clusters is difficult to achieve under this option.

Option 1: Co-Programmed European Partnership

Under this option, limited synergies can be established with other Union programmes and industrial strategies. For example, 35% of the budget of Horizon Europe will be supporting the Green Deal.

Therefore, the potential of the Option to generate the expected impact is good (+) compared to the baseline

Option 3: Institutionalised European Partnership under Article 187

The central coordination of this option provides the best scenario for exploitation of synergies with initiatives outside the framework programme, including international programmes. The participation of Member States provides the opportunity for coordination with national programmes and regional clusters. The close interaction in this option between Member States and private partners can support the coordination of national and industry efforts to set up a new IPCEI contributing to EU technological sovereignty, as announced in the Industrial strategy¹¹³.

Beyond Horizon Europe, the Digital Europe Programme (DEP) is of particular interest to the KDT initiative. The central management and the up-front member commitments of an institutionalised partnership would facilitate the planning and coordination of the R&I activities of the envisaged partnership and the capacity building, technology deployment and skills development activities foreseen in the Digital Europe Programme.

Therefore, the potential of the Option to generate the expected impact is high (++) compared to the baseline

Based on the above analysis, table 8 summarise the scores assigned to the various options on internal and external coherence.

Summary

Table 8: Overview of the options' potential for ensuring and maximizing coherence

	Baseline: Horizon Europe calls	Option 1: Coprogrammed	Option 3: Institutionalised Art 187
Internal coherence	0	+	++

EU Industrial Strategy. A new Industrial Strategy for a green and digital Europe. 10 March 2020. https://ec.europa.eu/info/strategy/priorities-2019-2024/europe-fit-digital-age/european-industrial-strategy en

	Baseline: Horizon Europe calls	Option 1: Coprogrammed	Option 3: Institutionalised Art 187
External coherence	0	+	++

Notes: Score ++: Option presenting a *high* potential compared to baseline; Score +: Option presenting a *good* potential compared to baseline; Score 0: Potential of the baseline.

6.4. Tabular comparison of options and identification of preferred option

Table 9 below, lists the scores assigned for each of the policy options, based on the assessments above, and taking into account the views expressed by the different stakeholders.

Table 9: Scorecard of the policy options for all criteria

	Criteria	Baseline: Horizon Europe calls	Option 1: Co- programmed	Option 3: Institutionalised Art 187
	Sc	ientific impacts		
	Europe reinforces its scientific capabilities in emerging fields of electronic components and systems	0	+	++
	Improved cross-border & cross-sector scientific cooperation that strengthen the exchange of knowledge across the ecosystem	0	+	++
	Economic	c/technological impacts		
	European electronic components and systems industry strengthens its technological leadership and its global competitive position	0	+	++
Effectiveness	Strengthen digital transformation in vertical sectors through electronic components and systems technologies developed in Europe	0	++	++
Effe	Create a dynamic ecosystem of innovation in electronic components and systems with higher and more active involvement of SMEs	0	+	++
	Se	ocietal impacts		
	European systems and services providing high levels of privacy and security through the use of European digital technologies	0	++	++
	Implementation of EU policies according to the European values and ambitions	0	+	++
	Electronic components and systems industries and vertical industries progressively reduce their negative environmental impact	0	++	++
ence	Internal coherence	0	+	++
Coherence	External coherence	0	+	++
ency	Overall cost	0	0	(-)(-)
Efficiency	Cost-efficiency	0	(+)	(-)

Notes: Scores for effectiveness and coherence: Score ++: Option presenting a *high* potential compared to baseline; Score +: Option presenting a *good* potential compared to baseline; Score 0: Potential of the baseline Scores for efficiency: Score 0 = same costs as for the baseline; score (-) = limited additional costs compared with the baseline; score (-)(-) = substantial additional costs compared with the baseline

According to the scorecard in Table 9 the baseline option (Option 0) performs less well against the criteria of effectiveness and coherence compared to Options 1 (Co-Programme) and Option 3 (Institutionalised Art. 187). The higher score of Option 0 in the criterion of overall cost does not weight up against its low scores in all the other dimensions.

When compared with Option 1, Option 3 received the highest scores in effectiveness for most criteria on scientific and economic/technological impacts (in one economic/technological impact at the same level as Option 1). On the criteria for societal/environmental impacts Options 1 and Option 3 have the same scores in two impacts and Option 3 higher in one impact. We can conclude that Option 3 maximises the benefits compared to the other two options.

Option 3 received the lowest score in terms of cost-efficiency. However, the difference with the other two options is not significant (one to two percentage points) and it is largely compensated with the clear benefits in all other criteria.

Weights can be associated to the different criteria to reflect their relative importance in the objectives of the initiative. For this initiative a very important success factor is its impact on the vertical industries. This suggests that higher weights be given to societal/environmental and economic/technological impacts.

On societal and economic/technological impacts, Option 3 scores at the same level or higher than Option 1 and significantly better that Option 0. A higher weight for this impact, therefore, will not change the conclusion that Option 3 offers the highest benefits.

Compared to the other options, Option 3 would:

- Provide a more appropriate structure than the other options to implement a common vision and to achieve the objectives more efficiently (in terms of time and resources).
- Generate overall higher level of all impacts.
- Provide higher levels on internal and external coherence.
- Support integrated large-scale actions (pilots, platforms) with involvement of a large variety of users.
- Stronger involvement of technology users will generate spillover effects on the vertical "user" industries.
- Support a tri-partite model (EU, Participating States and Industry) with financial contributions from the EU and Participating States, mobilising a volume of resources not possible with Horizon Europe calls or a co-programmed partnership.
- Provide greater effectiveness through higher leverage and structuring effects in the ecosystem, creating a critical mass of financial and human resources, attracting more SMEs.
- Improve coherence beyond Horizon Europe and a co-programmed partnership through better coordination with European, national or regional initiatives at the level of priorities and implementation, as well at the level of individual projects or stakeholders.

When considering Option 3 (Institutionalised partnership based on Art. 187) in a bi-partite approach with European Commission and Industry as members (i.e. excluding Member States), it is concluded that the following benefits will be severely limited or fully disappear:

✓ The volume of R&I resources (public funding and industry contribution) supporting the initiative would be reduced to 50%. This would substantially limit the ambitions of the KDT initiative, and in particular the industrial actors, in a scenario of increasing competition from other regions.

- ✓ The integration of European and national priorities in electronic components and systems under a unified strategy at EU level will not be fully implementable.
- ✓ The coherence of the initiative at the European (Horizon Europe and beyond) and national levels would diminish in scope and efficiency.
- ✓ The needs of users will not be taken into account
- ✓ Enhancing technology sovereignty which requires a critical mass of efforts at both demand and supply sides will no longer be realistic as a goal.
- ✓ The coexistence of EU and national initiatives in the area will create fragmentation of actions and stakeholders, and will weaken the ecosystem of electronics components and systems technologies which is critical to maintain a strong industrial base in Europe.
- ✓ The contribution of the initiative to EU political priorities, notably to 'A Europe fit for the Digital Age' and to the 'European Green Deal', would be lowered if Member States are not actively involved in the initiative.

The above assessment concludes that Option 3, Institutionalised Partnership based on TFEU Article 187 in a tri-partite configuration with European Commission, Participating States and Industry is the preferred option, showing higher levels of impacts and coherence than the other options that largely compensate the lower cost-efficiency of the Option.

The Institutionalised Partnership Art 187 is subject to a legal framework set out in a Council Regulation, which defines the objectives and the resources contributed by partners in relation to the proportion of EU funding. The partnership is steered by a governing board with representation of all partners, i.e. the private sector, represented by industry associations, representatives of all Participating States and the Commission. The operation is managed by a central structure supporting, among other things, the development of a long-term strategy and the specification of annual work programmes delivered through projects through open calls.

As it was unanimously agreed by stakeholders interviewed, Option 3 can ensure the highest possible commitment of industry and Member States around a strategic agenda. At the same time, the alignment with the EU policy is ensured by the participation of the Commission in the management of the partnership. The calls are designed by the management of the partnership according to the work programme with the highest possible alignment with the industry's strategy. The central coordination of the selection of the projects will result in a stronger and more coherent research portfolio. Therefore, the potential to achieve the required directionality is high.

Based on the assessment in chapter 6, we conclude that Institutionalised Partnership based on Article 187 TFEU is the preferred option for the KDT initiative.

This option

- ensures that the electronic components and systems industry, including all segments of the European ecosystem, is taking a leading role and it is fully engaged in the implementation of the initiative.
- ensures the highest possible coordination of research agendas (including national ones) and mobilisation of resources that are necessary for the creation of the critical mass that is necessary for achieving the ambitious initiative objectives.
- provides the highest level of commitments from public and private members
- provides a stable structure and simplified administrative procedures to sustain a long-term planning that attracts major stakeholders as well as SMEs

- offers the highest possible coordination and coherence with other initiatives of Horizon Europe, as well as external initiatives.
- favours the alignment of the initiative with the EU priorities through the involvement of European and national authorities

Finally the preferred option provides flexibility in the definition and implementation of priorities through the annual revision of the strategic agenda and the efficient decision process through a central management. This makes the Institutionalised Partnership based on Article 187 TFEU best suited for the KDT initiative to respond to future technological changes and to new political priorities.

Comparison between the preferred option & the current partnership existing in the area taking into account lessons from past evaluations

What continues	What is different
 A focus on electronics components and systems An industry-driven R&I programme High-quality science and research actions A tri-partite (EC, Participating States, Industry) model A governance model with a Public Authorities Board (EC and PS) and a Governing Board (EC, PS and Industry) The Joint Undertaking support office The combination of EU and national financing (50/50) The industrial commitment to match public funding 	 A broader coverage of electronic value-chains, involving technology supply- and user-sides A more effective participation of SMEs and start-ups A more active involvement of users in early phases of research A more strategic approach to R&I actions following a set of priorities established by industry, Commission and Participating States A closer alignment to European political priorities such as environment, societal and digital transformation objectives Increased flexibility in addressing technology change A stronger focus on emerging technologies A closer follow-up of project impacts A stronger interaction with relevant partnerships A larger set of Participating States* A simplified set of rules and participation criteria for the Participating States * Currently in discussion with Member States
	Currently in discussion with Member States

7. The preferred Option – How will actual impacts be monitored and evaluated?

7.1. The preferred option

In Table 10, below, the alignment of the preferred option of Institutionalised European Partnership under Article 187 TFEU with the selection criteria for European Partnerships defined in Annex III of the Horizon Europe Regulation is depicted. Seeing that the design process of the candidate Institutionalised Partnerships is not yet concluded and several of the

related topics are still under discussion, the criteria of additionality/directionality and long-term commitment are covered in terms of *expectations* rather than ex-ante demonstration.

Table 10: Alignment with the selection criteria for European Partnerships

Criterion	Alignment of the preferred option
Higher level of effectiveness	According to the assessment in chapter 6, an Article 187 TFEU partnership will be more effective in increasing the competitive position of the electronic components and systems and the downstream industries, establish the European leadership in emerging technologies and securing the technological sovereignty of Europe
Coherence and synergies	Article 187 TFEU partnership provides the necessary conditions for coordination and creating synergies with other internal or external initiatives and also for developing the electronic ecosystem. The participation of the EC in the governance structure of the partnership ensures the alignment of the objectives with the Horizon Europe objectives and the EU priorities, while the central management structure can effectively coordinate with other partnerships and European initiatives.
Transparency and openness	The management framework and the tripartite character of the partnership ensure transparency and openness in terms of participation.
	The partnership would be able to assemble contributions from the EU, Participating States and private members in a tripartite model. This would create the critical mass of resources necessary to address the ambitious objectives of the partnership.
Additionality and directionality	The partnership would also be able to develop a coherent, long-term European strategy for the development of the electronic ecosystem and its technological capabilities. The ambition is to establish leadership in emerging technologies, secure the sovereignty of Europe in electronic components and systems and further strengthen its competitive position in strategic sectors that rely on electronic components and systems.
Long-term commitment	The partnership would encourage long-term commitment of financial and in-kind resources from Participating States and private members. Based on the experience of ECSEL and on-going consultations the partnership is expected to ensure a financial contribution from Participating States up to 25% and a contribution from the private sector at least equal to 50% of the aggregated European Partnership budget.

7.2. Objectives and corresponding monitoring indicators

Operational objectives

The Figure 13 identifies a broad range of activities and operational objectives that can be implemented under Horizon Europe. This reflects the definition of European Partnerships in the Horizon Europe Regulation as initiatives for which the Union and its partners "commit to jointly support the development and implementation of a programme of research and innovation activities, including those related to market, regulatory or policy uptake."

Figure 13: Operational objectives of the initiative

Coordinat	Coordination and Support Actions (CSA)	tions	ouul	Innovation Actions (IA)		Research and Innovation actions (RIA)	ation actions
Activities							
		Align	Support		Localin	Develop key digital	Support innovative technological
Develop capabilities for	support large scale projects	build synergies	aiming at	Create an R&I	leading-edge	secure applications	approaches
application-	(e.g.	with MS to	integrating	environment	research on	and critical	contributing to
specific designs in strategic areas	production pilot lines)	private resources	around sectoral value networks	מנוומכוועם נס סועובא	technologies	energy, telecom, transport	and environmental protection
Operational objectives	S						
200							1
Establish design and production capabilities in Europe for strategic application areas		Launch large-scale projects supporting the fast transfer of technologies from the lab to the fab	Build a dynamic EU-wide ecosystem based on digital value-chains with simplified access to newcomers	Strengthen EU scientific excellence and exploit the potential of SMEs and start-ups in emerging technologies		Enhance component technologies that guarantee security, trust and energy-efficiency for critical infrastructures and sectors in Europe	Ensure alignment of the new initiative with European policy priorities
Specific objectives							
				/			
	XX			7		1	
Reinfor electronic con support:	Reinforce Europe's position in electronic components and systems to support future needs of vertical industries and the economy at large	n in stems to tical t large	Establish EU innovation le components ar	Establish EU scientific excellence and innovation leadership in emerging components and systems technologies	0	Ensure that components and systems technologies address Europe's societal and environmental challenges	nts and systems ss Europe's onmental
General objectives	Techno-economic	nomic		Scientific		Societal/environmental	onmental

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Monitoring indicators

In addition to Key Impact Pathways indicators set centrally in the Regulation of Horizon Europe, a number of short, medium and long-term monitoring indicators have been identified to measure progress of the partnership towards its objectives. See Table 11.

Table 11: Monitoring indicators in addition to the Horizon Europe key impact pathway indicators

	3		<i>y</i> 1 1 <i>y</i>	
Objectives	Impacts	Short-term (typically as of year 1+)	Medium-term (typically as of year 3+)	Long-term (typically as of year 5+)
Establish EU scientific excellence and innovation leadership in emerging components and systems technologies	Scientific impact – Europe reinforces its scientific capabilities in emerging fields of electronic components and systems	Number of projects with one or more publications Number of peer reviewed publications produced by the partnership	Share of publications produced by the partnership in journals within the upper 25% based on Field-weighted Citation index	Number and share of peer reviewed publications from the partnership projects that are core contribution to the scientific field
	Scientific impact – Improved cross-border and cross-sector cooperation that strengthen the exchange of knowledge across the ecosystem	Number of peer reviewed publications with co- authoring from industry and academia (Universities, research organisations)	Field-weighted citation index of peer reviewed publication with co- authoring from industry and academia	Number and share of peer reviewed publications from projects that are core contributions to scientific field with co-authoring from industry and academia
ronic components f vertical industries rge	Technological / economic impact – Strengthen digital transformation in vertical sectors through electronic components and systems technologies developed in Europe	Number of IPs, new products or services digitised with European technologies	Number/Share of supported companies successfully launched new digitised products and services	World market share of Europe in the supported segments due to the initiative
Reinforce Europe's position in electronic components and systems to support future needs of vertical industries and the economy at large	Technological / economic impact - European electronics components and systems industry strengthened its technological leadership and its global competitive position	Contribution of the initiative to the various market segments of electronic components and systems	Global market share of Europe in the various market segments of electronic components and systems	Evolution of world market share of Europe in electronic components and systems segments due to the initiative
Reinforce Europe and systems to sup an	Technological / economic impact – Create a dynamic ecosystem of innovation in electronic components and systems with higher and more active involvement of SMEs	Number of SMEs involved in research and innovation actions in the initiative and associated funding	Participation (number of partners) and percentage of funding to SMEs in the initiative	Market share differential of SMEs through their participation in the KDT initiative
chnologies address al challenges	Societal impact – European systems and services providing high levels of privacy and security through the use of European digital technologies	Number of technologies (chips, components, systems, applications) with high levels of security and privacy developed in selected projects	Number of technologies in the value chains (chips, components, systems, applications) with reduced consumption of energy developed by supported projects and reached the market	Market share of new products with enhanced security and privacy
Ensure that components and systems technolog Europe's societal and environmental chall	Societal impact – Implementation of EU policies (digital transition, technological sovereignty) according to the European values and ambitions	Number of projects with a direct link to the EU policy objectives	Number of project outcomes making a specific and measurable contribution to EU policies	Share of products and services specifically developed to align with EU priorities and policies
ponents a ocietal an	Environmental impact – Vertical industries	Number of projects with reduction in energy	Maximum level of energy efficiency achieved in	Overall energy efficiency gain due to projects results
Ensure that corr Europe's s	progressively reduce their negative environmental impact	consumption Number of projects addressing improvement of the environmental characteristics of technologies.	Number of applications and services adopting technologies with improved environmental performance	Share of vertical industries with highly reduced environmental impact through the use of European electronic components and systems supported in projects

7.3. Evaluation framework

The evaluation of the Partnership will be done in full accordance with the provisions laid out in Horizon Europe Regulation Article 47 and Annex III, with external interim and ex-post evaluations feeding into the overall Horizon Europe evaluations. As set in the criteria for European Partnerships, the evaluations will include an assessment of the most effective policy intervention mode for any future action; and the positioning of any possible renewal of the Partnership in the overall European Partnerships landscape and its policy priorities. In the absence of renewal, appropriate measures will be developed to ensure phasing-out of Framework Programme funding according to conditions and timeline agreed with the legally committed partners ex-ante.



Brussels, 23.2.2021 SWD(2021) 37 final

PART 7/19

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT

Accompanying the document

Proposal for a COUNCIL REGULATION establishing the Joint Undertakings under Horizon Europe

European Partnership for Key Digital Technologies

{COM(2021) 87 final} - {SEC(2021) 100 final} - {SWD(2021) 38 final}

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Annex 1 Procedural Information

1. LEAD DG, DECIDE PLANNING REFERENCES

Co-Lead DG: Directorate-General for Communications Networks, Content and Technology (CNECT), Directorate-General for Research and Innovation (RTD)

Decide number: PLAN/2019/5389

2. ORGANISATION AND TIMING

Institutionalised partnerships are foreseen in Articles 185 and 187 of the Treaty on the Functioning of the European Union (TFEU). The preliminary agreement on Horizon Europe contained a list of possible areas for institutionalised partnerships based on Article 185 and 187. For each of these areas the Commission considered 12 potential institutionalised partnerships. Their set up involves new EU legislation and the establishment of dedicated implementing structures and therefore an impact assessment for each of these initiatives.

Following political validation in June 2019, the impact assessment process started with the publication of inception impact assessments for each initiative in August 2019.

An inter-service steering group (ISSG) on research and innovation partnerships under Horizon Europe was set up in May 2019 and held 4 meetings before submission of the Staff Working Document to the Regulatory Scrutiny Board (7 May 2019, 19 June 2019, 5 December 2019, 20 January 2020). The ISSG consisted of representatives of the Secretariat-General, Directorate-General for Budget, Directorate-General for Research and Innovation, Directorate-General for Communications Networks, Content and Technology, Directorate-General for Mobility and Transport, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, Directorate-General for Energy, Directorate-General for Environment, Directorate-General for Climate Action, and the Legal Service.

An online public stakeholder consultation was launched between September and November 2019, gathering 1635 replies for all 12 initiatives.

3. CONSULTATION OF THE RSB

Two upstream meetings with the Regulatory Scrutiny Board were held on 10 July 2019 and 30 September 2019.

The Staff Working Document was submitted to the Regulatory Scrutiny Board for a hearing that took place on 13 May 2020. In accordance with the feedback received from the Regulatory Scrutiny Board on 15.05.2020 the Staff Working Document has been revised as presented in Figure 1. These revisions were endorsed by the Inter Service Steering Group on 10 June 2020.

4. EVIDENCE, SOURCES AND QUALITY

To ensure a high level of coherence and comparability of analysis for all candidate initiatives, an external study was procured to feed into the impact assessments of the 12 candidate

institutionalised partnerships¹. It consisted of a horizontal analysis and individual thematic analyses for each of the initiatives under review.

For all initiatives, the evidence used includes desk research partly covering the main impacts and lessons learned from previous partnerships. A range of quantitative and qualitative data sources complement the evidence base, including evaluations; foresight studies; statistical analyses of Framework Programmes application and participation data and Community Innovation Survey data; analyses of science, technology and innovation indicators; reviews of academic literature; sectoral competitiveness studies and expert hearings. The analyses included a portfolio analysis, a stakeholder and social network analysis in order to profile the actors involved as well as their co-operation patterns, and an assessment of the partnerships' outputs (bibliometrics and patent analysis). A cost modelling exercise was performed in order to feed into the efficiency assessments of the partnership options. Public consultations (open and targeted) supported the comparative assessment of the policy options. For each initiative up to 50 relevant stakeholders were interviewed by the external contractor (policymakers, business including SMEs and business associations, research institutes and universities, and civil organisations, among others). In addition, the analysis was informed by the results of the Open Public Consultation (Sep - Nov 2019), the consultation of the Member States through the Strategic Programme Committee and the online feedback received on the Inception Impact Assessments of the set of candidate Institutionalised European Partnerships.

A more detailed description of the methodology and evidence base used, completed by thematic specific methodologies, is provided in Annexes 4 and 6.

Figure 1 Modifications to the draft Staff Working Document based on comments received from the Regulatory Scrutiny Board

Comments from the Regulatory Scrutiny Board	Actions taken for the Staff Working Document
The report pre-selects certain sectors and technologies for support, instead of setting out the best partnership approach for promoting a competitive innovation environment.	The revised text in section 4 (Objectives) makes clear that there are no preselected priorities, neither for specific technologies nor specific sectors. It describes the preparation of what would constitute the Strategic Research and Innovation Agenda (SRIA). This is where sectors, technologies and applications would be identified and updated annually based on technological trends and political priorities. The preparation itself would be done through an inclusive and multi-stakeholder participative process.
The dividing lines between this partnership and other initiatives that support research and innovation in the ICT sector are not clear.	The differences in scope and the interactions foreseen with relevant partnerships and initiatives, both digital-centric and related applications, are now addressed in section 1.3. The strategic importance of building and maintaining these interactions under the current and future European policies and

¹ Technopolis Group, 2020, forthcoming.

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	priorities is highlighted.
The report does not sufficiently integrate the mid-term evaluation findings of the existing Joint Undertaking into the problem description and the intervention logic.	Conclusions and recommendations from the mid-term evaluation of the existing JU are described in the box "Support to the field in the previous Framework Programme – Key strengths and weaknesses identified". They have been taken into consideration, and integrated into the problem definition and intervention logic (sections 2.1, 4.3 and 4.4). Moreover, specific actions are identified addressing the main findings of the mid-term evaluation.
The report does not score the options in a consistent way. It does not justify how it weighs the different impacts when arriving at the preferred option.	The justifications and the accompanying scores corresponding to the various impacts in the analysis of options have been reviewed (in both the text and the tables section 6) and checked for consistency. The section includes an updated comprehensive comparative assessment of all options under consideration.
Additional comments How would the partnership differ from the existing Joint Undertaking?	Actions taken for the Staff Working Document The table in Section 6 describing the differences between the envisaged initiative and the existing JU ('what continues' and 'what is different' columns) have been updated. In section 1 and throughout the report the differences between the candidate KDT and existing ECSEL are also highlighted.
What ways are envisaged to help materialise a co-financing of 1:3, given the uncertainties surrounding the overall budget and design of the partnerships? How can these risks be mitigated?	The 1:3 leverage target is based on the ECSEL experience and feedback received in recent consultations with Member States and industry associations. The report now describes how the 1:3 leverage is achieved in ECSEL (section 1.2). The ambition is that the KDT initiative achieve a similar target (Sections 4.4 and 6.2). This depends ultimately on how this can be implemented under HE and is still pending internal discussion.
The IA should report stakeholders' views, in particular those of relevant minorities. It should also appropriately treat the views of respondents considered as participating in a 'campaign'.	A 'campaign' of 20 respondents has meanwhile been identified in the open public consultation (OPC). These responses have been omitted in the OPC analysis. They have been treated and reported separately. Stakeholder opinions from OPC and interviews are included in relevant parts of the Impact Assessment, now including minority views with indication of type of supporting stakeholders.

Recommendations accompanying positive opinion	Actions taken for the Staff Working Document
Substantiate further the societal impacts of the preferred option and its scoring	The societal impacts associated to the long-term planning, the portfolio approach and tripartite model of the preferred option (institutionalised partnership based on Art. 187) have been elaborated further. They cover joint public-private societal priorities, a balanced set of projects that address societal challenges, and the contribution to the initiative of national societal impacts through the involvement of Participating States. The scoring associated to the preferred option (++ Option presenting a high potential compared to the baseline) has been further justified on the basis of the elements provided in the analysis of societal impacts for the various options. See Pages 66-68.
Clarify interactions with projects and recently announced EU policies and priorities	Details have been included on interaction with specific policies announced recently (data strategy, industrial strategy) and initiatives (recovery plan for Europe). Also the interactions with Horizon Europe have been elaborated further as well as with relevant partnerships (AI, data and robotics). See P. 33-34
Address uncertainties of funding level and ways to cope with potential lower financing	The fact that the financing level is uncertain at the time of writing the assessment is addressed by proposing ways to ensure a sound match between the scope and objectives of the initiative and the overall amount of resources allocated. See P. 55
Report in a more consistent way the minority views	Stakeholder opinions are included throughout the assessment. This includes views expressed by stakeholders in response to the open public consultation or at interviews conducted in the context of the supporting study. Minority views (with indication of type of stakeholders) have been more consistently reported next to the dominating opinions. See the blue boxes throughout the document

The table above summarises modifications introduced in the revised KDT Impact Assessment to address the comments received with the RSB Opinion and issues raised at the Impact Assessment Quality Checklist as well as comments received at the RSB hearing.

Stakeholder Consultation Annex 2

1. OVERVIEW FOR ALL CANDIDATE INSTITUTIONALISED EUROPEAN PARTNERSHIPS

1.1. Introduction

In line with the Better Regulation Guidelines,² the stakeholders were widely consulted as part of the impact assessment process of the 12 candidates for institutionalised partnerships, including national authorities, the EU research community, industry, EU institutions and bodies, and others. These inputs were collected through different channels:

- A feedback phase on the inception impact assessments of the candidate initiatives in August 2019, gathering 350 replies for all 12 initiatives on the "Have your say" web portal during a period of 3 weeks;
- A structured consultation of Member States performed by the EC services over 2019 through the Shadow Strategic Configuration of the Programme Committee of Horizon Europe (in line with the Article 4a of the Specific Programme of Horizon Europe). This resulted in 44 possible candidates for European Partnerships identified as part of the first draft Orientations Document towards the Strategic Plan for Horizon Europe (2021-2024), taking into account the areas for possible institutionalised partnerships defined in the Regulation.
- An online public stakeholder consultation administered by the EC, based on a structured questionnaire, open between September and November 2019, gathering 1635 replies for all 12 initiatives;
- A targeted consultation run by the external study contractors with a total of 608 interviews performed as part of the thematic studies by the different study teams between August 2019 and January 2020.

1.2. **Horizontal results of the Open Public Consultation**

The consultation was open to everyone via the EU Survey online system.³ The survey contained two main parts to collect views on general issues related to European partnerships (in Part 1) and specific responses related to one or more of the 12 candidate initiatives (as selected by a participant). The survey was open from 11 September till 12 November 2019. The consultation was available in English, German and French and advertised widely through the European Commission's online channels as well as via various stakeholder organisations.

1.2.1. Profile of respondents

In total, 1635 respondents filled in the questionnaire of the open public consultation. Among them, 272 respondents (16.64%) were identified to have responded to the consultation as part of a campaign (coordinated responses). Based on the Better Regulation Guidelines, the groups of respondents where at least 10 respondents provided coordinated answers were labelled as 'campaigns', segregated and analysed separately and from other responses. In total 11 campaigns were identified, the largest of them includes 57 respondents⁴. In addition, 162

² https://ec.europa.eu/info/files/better-regulation-guidelines-stakeholder-consultation_en https://ec.europa.eu/eusurvey/runner/ConsultationPartnershipsHorizonEurope

⁴ The candidate Institutionalised Partnership Clean Hydrogen has the highest number of campaigns, namely 5. A few initiatives, such as Innovative SMEs, Smart Networks and Systems, were not targeted by campaigns. Some campaign respondents decided to provide opinions about several partnerships.

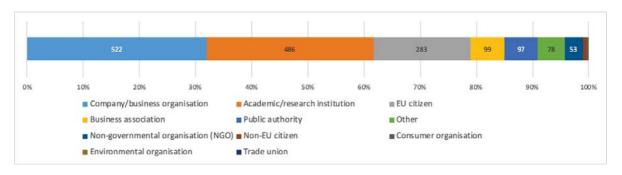
respondents in the consultation also display similarities in responses but in groups smaller than 10 respondents. Hence, these respondents were not labelled as campaigns and therefore were not excluded from the general analysis.

Table 1: Country of origin of respondents (N=1635)

Country	Number of	Percentage of
Country	respondents	respondents
Germany	254	15.54%
Italy	221	13.52%
France	175	10.70%
Spain	173	10.58%
Belgium	140	8.56%
The Netherlands	86	5.26%
Austria; United Kingdom	61	3.73%
Finland	49	3.00%
Sweden	48	2.94%
Poland	45	2.75%
Portugal	32	1.96%
Switzerland	28	1.71%
Czechia	24	1.47%
Greece	23	1.41%
Norway; Romania	22	1.35%
Denmark	20	1.22%
Turkey	19	1.16%
Hungary	14	0.86%
Ireland	12	0.73%
United States	11	0.67%
Estonia; Slovakia; Slovenia	10	0.61%
Bulgaria; Latvia	9	0.55%
Bosnia and Herzegovina	7	0.43%
Lithuania	4	0.24%
Canada; Croatia; Israel	3	0.18%
China; Ghana; Iceland; Japan; Luxembourg; Morocco	2	0.12%
Bhutan; Botswana; Cyprus; Iran; Malta; Mexico; Moldova; Mongolia; Palestine; Russia; Serbia; South Africa; Tunisia; Ukraine; Uruguay	1	0.06%

As shown in Figure 2, the three biggest **categories of respondents** are representatives of companies and business organisations (522 respondents or 31.9%), academic and research institutions (486 respondents or 29.7%) and EU citizens (283 respondents or 17.3%). Among the group of respondents that are part of campaigns, most respondents are provided by the same groups of stakeholders, namely company and business organisations (121 respondents or 44.5%), academic and research institutions (54 respondents or 19.8%) and EU citizens (42 respondents or 15.4%).

Figure 2 Type of respondents (N=1635) - For all candidate initiatives



Among all consultation respondents, 1303 (79.69%) have been **involved in the on-going research and innovation framework programme** Horizon 2020 or the preceding Framework Programme 7, while 332 respondents (20.31%) were not. In the group of campaign respondents, the share of those who were involved in these programmes is higher (245 respondents out of 272 or 90.07%) than in the group of non-campaign respondents (1058 out of 1363 or 77.62%). When respondents that participated in the Horizon 2020 or in the preceding Framework Programme 7 were asked to indicate in which capacity they were involved in these programmes, the majority stated they were a beneficiary (1033 respondents) or applicant (852 respondents). The main stakeholder categories, e.g. companies/business organisation, academic/research institutions, etc., show a similar distribution across the capacities in which they 'have been involved in Horizon 2020 or in the Framework Programme 7' as the overall population of consultation respondents.

Among those who have been involved in Horizon 2020 or the preceding Framework Programme 7, 1035 respondents (79.43%) are/were involved in a partnership. The share of respondents from campaigns that are/were involved in a partnership is higher than for non-campaign respondents, 89.80% versus 77.03% respectively. The list of partnerships under Horizon 2020 or its predecessor Framework Programme 7 together with the numbers, percentages of participants is presented in Table 4, the table also show the key stakeholder categories for each partnership. Most consultation respondents participated in the following partnerships: Fuel Cells and Hydrogen 2 (FCH2) Joint Undertaking, Clean Sky 2 Joint Undertaking, European Metrology Programme for Innovation and Research (EMPIR) and in Bio-Based Industries Joint Undertaking. The comparison between the non-campaign and campaign groups of respondents shows that the overall distribution is quite similar. However, there are some differences. For the campaign group almost a half of respondents is/was involved in the Fuel Cells and Hydrogen 2 (FCH2) Joint Undertaking, a higher share of campaign respondents is/was participating in Clean Sky 2 Joint Undertaking and in Single European Sky Air Traffic Management Research (SESAR) Joint Undertaking.

When respondents were asked in which **role**(s) **they participate**(d) in a **partnership**(s), over 40% indicated that they act(ed) as partner/member/beneficiary in a partnership. The second largest group of respondents stated that they applied for funding under a partnership. The roles selected by non-campaign and campaign respondents are similar.

Table 4: Partnerships in which consultation respondents participated (N=1035)

Name of the partnership	Number and % of respondents from both groups (n=1035)	Number and % of respondents from a non-campaign group (n=815)	Academic/researc h institutions	Business associations	Company/busines s organisations	Company/busines s organisations	EU citizens	NGOs	Public authority
Fuel Cells and Hydrogen 2 (FCH2) Joint Undertaking	354 (33.33%)	247 (30.31%)	97	9	37	43	41	8	5
Clean Sky 2 Joint Undertaking	195 (18.84%)	145 (17.79%)	57	2	10	27	37	1	7
European Metrology Programme for Innovation and Research (EMPIR)	150 (14.49%)	124 (15.21%)	64	0	13	9	14	2	19
Bio-Based Industries Joint Undertaking	142 (13.72%)	122 (14.97%)	39	8	20	27	14	1	6
Shift2Rail Joint Undertaking	124 (11.98%)	101 (12.40%)	31	7	5	31	14	3	7
Electronic Components and Systems for European Leadership (ECSEL) Joint Undertaking	111 (10.72%)	88 (10.80%)	42	2	7	20	12	0	5
Single European Sky Air Traffic Management Research (SESAR) Joint Undertaking	66 (6.38%)	46 (5.64%)	10	3	3	20	3	2	3
5G (5G PPP)	53 (5.12%)	47 (5.77%)	20	1	6	14	5	0	1
Eurostrars-2 (supporting research-performing small and medium-sized enterprises)	44 (4.25%)	40 (4.91%)	17	0	6	1	7	0	6
Innovative Medicines Initiative 2 (IMI2) Joint Undertaking	37 (3.57%)	35 (4.29%)	18	2	3	3	2	4	3
Partnership for Research and Innovation in the Mediterranean Area (PRIMA)	28 (2.71%)	26 (3.19%)	15	0	3	1	2	0	2
European and Developing Countries Clinical Trials Partnership	25 (2.42%)	24 (2.94%)	12	0	1	2	3	3	2
Ambient Assisted Living (AAL 2)	22 (2.13%)	21 (2.58%)	11	2	1	1	3	0	3
European High- Performance Computing Joint Undertaking (EuroHPC)	22 (2.13%)	18 (2.21%)	6	0	2	3	5	0	2

For the remaining of the consultation, respondents could provide their views on each/several of the candidate initiatives. The majority of respondents (31.4%) provided their views on the

Clean Hydrogen candidate partnership. More than 45% of respondents from the campaigns selected this partnership. Around 15% provided their views for European Metrology, Clean Aviation and Circular Bio-based Europe. The share of respondents in the campaign group that chose to provide views on the Clean Aviation candidate partnership is of 20%. The smallest number of respondents provided opinions on the candidate initiative 'EU-Africa research partnership on health security to tackle infectious diseases – Global Health'.

Table 5: Candidate Institutionalised Partnerships for which consultation respondents provide responses (N=1613)

Name of the candidate Institutionalised European partnership	Number and % of respondents from both groups (n=1613)	Number and % of respondents from a non-campaign group (n=1341)
Clean Hydrogen	506 (31.37%)	382 (28.49%)
European Metrology	265 (16.43%)	225 (16.78%)
Clean Aviation	246 (15.25%)	191 (14.24%)
Circular bio-based Europe	242 (15%)	215 (16.03%)
Transforming Europe's rail system	184 (11.41%)	151 (11.26%)
Key Digital Technologies	182 (11.28%)	162 (12.08%)
Innovative SMEs	111 (6.88%)	110 (8.20%)
Innovative Health Initiative	110 (6.82%)	108 (8.05%)
Smart Networks and Services	109 (6.76%)	107 (7.98%)
Safe and Automated Road Transport	108 (6.70%)	102 (7.61%)
Integrated Air Traffic Management	93 (5.77%)	66 (4.92%)
EU-Africa research partnership on health security to tackle infectious diseases – Global Health	49 (3.04%)	47 (3.50%)

1.2.2. Characteristics of future candidate European Partnerships

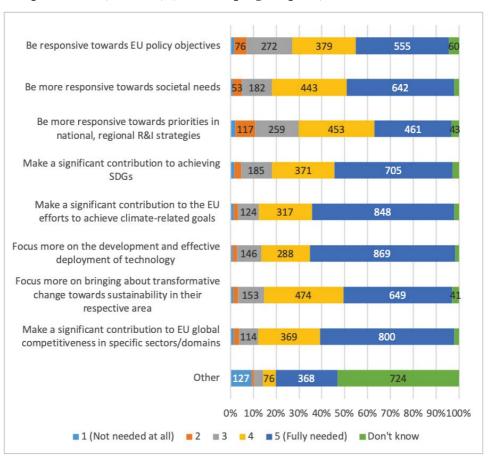
Respondents were asked to assess what areas, objectives, aspects need to be in the **focus of the future European Partnerships** under Horizon Europe and to what extent. According to Figure 6, a great number of respondents consider that a significant contribution by the future European Partnerships is 'fully needed' to achieve climate-related goals, to the development and effective deployment of technology and to EU global competitiveness in specific sectors/domains. Overall, respondents' views reflect that many aspects require attention of the Partnerships. The least attention should be paid to responding towards priorities of national, regional R&D strategies, including smart specialisation strategies, according to respondents.

Overall, only minor differences can be found between the main stakeholder categories. Academic/research institutions value the responsiveness towards EU policy objectives and focus on development and effective deployment of technology a little less than other respondents. Business associations, however, find that the future European Partnerships under Horizon Europe should focus a little bit more on the development and effective deployment of technology than other respondents. Furthermore, business associations, large companies as well as SMEs value the role of the future European Partnerships for significant contributions to EU global competitiveness in specific sectors domains a little higher than other

respondents. Finally, both NGOs and Public authorities put a little more emphasis on the role of the future European Partnerships for significant contributions to achieving the UN SDGs. The views of citizens (249, or 18.3%) do not reflect significant differences with other types of respondents. However, respondents that are/were directly involved in a partnership under Horizon 2020 or its predecessor Framework Programme 7 assign a higher importance of the future European Partnerships to be more responsive towards EU policy objectives and to make a significant contribution to achieving the UN's Sustainable Development Goals.

A qualitative analysis of the "other" answers highlights the importance of collaboration and integration of relevant stakeholders to tackle main societal challenges and to contribute to policy goals against which fragmentation of funding and research efforts across Europe should be avoided. Additionally, several respondents suggested that faster development and testing of technologies, acceleration of industrial innovation projects, science transfer and market uptake are needed. Next to that, many respondents provided answers related to the hydrogen and the energy transition, which corresponds to the high number of respondents that provided answers to the candidate initiative on this topic.

Figure 6: To what extent do you think that the future European Partnerships under Horizon Europe need to (N=1363) (non-campaign replies) For all candidate initiatives



1.2.3. Main advantages and disadvantages of Institutionalised European Partnerships

An open question asked to outline the main advantages and disadvantages of participation in an Institutionalised European Partnership (as a partner) under Horizon Europe (1551 respondents). The advantages mentioned focus on the development of technology, overall collaboration between industry and research institutions, and the long-term commitment. Disadvantages mentioned are mainly administrative burdens. An overview is provided below.

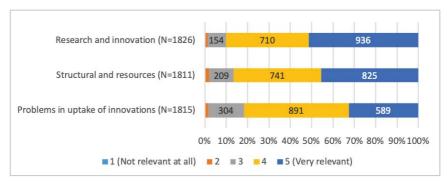
Advantages mentioned: Long term commitment, stability, and visibility in financial, legal, and strategic terms; Participation of wide range of relevant stakeholders in an ecosystem (large/small business, academics, researchers, experts, etc.); Complementarity with other (policy) initiatives at all levels EU, national, regional; Efficient and effective coordination and management; High leverage of (public) funds; Some innovative field require high levels of international coordination/standardisation (at EU/global level); Ability to scale up technology (in terms of TRL) through collaboration; Networking between members; Direct communication with EU and national authorities.

Disadvantages mentioned: Slow processes; System complexity; Continuous openness to new players should be better supported as new participants often bring in new ideas/technologies that are important for innovation; Lower funding percentage compared to regular Horizon Europe projects; Cash contributions; Administrative burdens; Potential for IPR constraints.

1.2.4. Relevance of EU level to address problems in Partnerships' areas

Respondents were asked to rate the relevance of research and innovation efforts at EU level efforts to address specific problems in the area of partnerships. Research and innovation related problems were rated as most relevant across all candidate initiatives, followed by structural and resources problems and problems in the uptake of innovations. Overall, all three areas were deemed (very) relevant across the partnerships, as more than 80% of respondents found these challenges (very) relevant. Only minor differences were found between stakeholder categories. Research and innovation problems were found slightly more relevant by academic/research institutions, yet slight less relevant by large companies and SMEs. Structural and resource problems were indicated as slightly more relevant by NGOs, but slightly less by academic/research institutions. While both NGOs and public authorities find slightly more relevant to address problems in uptake of innovation than other respondents. The views of citizens are not differing significantly. Respondents that are/were directly involved in a current/preceding partnership find, however, the need to address problems related to the uptake of innovations slightly more relevant than other respondents.

Figure 9: To what extent do you think this is relevant for research and innovation efforts at EU level to address the following problems in relation to the candidate partnership in question? (non-campaign replies) Aggregation of responses of all candidate initiatives



Respondents were asked to indicate how these challenges could be addressed through Horizon Europe intervention. Just over 50% of all respondents indicated that institutionalised partnerships were the best fitting intervention, with relatively strong differences between stakeholder categories. The use of Institutionalised Partnership was indicated more by business associations and large companies, but less by academic/research institutions and SMEs. While academic/research institutions valued traditional calls more often, this was not the case for business associations, large companies and public authorities. Public authorities indicated a co-programmed intervention more often than other respondents. Citizens indicated slightly less often that institutionalised partnerships were the best fitting intervention. Respondents that are/were directly involved in a current/preceding partnership, selected the institutionalised partnership intervention in far higher numbers (nearly 70%).

Figure 10: In your view, how should the specific challenges described above be addressed through Horizon Europe intervention? (non-campaign replies) For all candidate initiatives



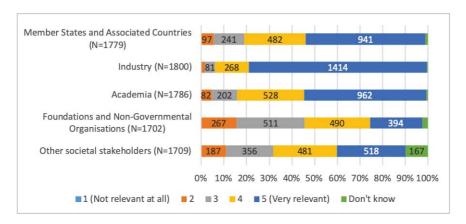
When asked to reflect on their answers, respondents that pointed to the need for using institutionalised partnership mentioned the long-term commitment of collaboration, a common and ambitious R&I strategy as well as the overall collaboration between industry and research institutions. Others shared positive experiences with other modes of interventions:

- Traditional calls, because of their flexibility and integration of a wide range of actors, as long as the evaluation panels do not deviate from the policy focus. This was mentioned by 94 participants, including companies (25), academics (26) and EU citizens (25).
- Co-funded partnership, as a mechanism to ensure that all participants take the effort seriously, while allowing business partnerships to develop. This approach was deemed suitable based on previous experiences with ERANETs. This was raised by 84 participants, 36 of them academic respondents, 18 companies and 16 EU citizens.
- Co-programmed partnerships, to tackle the need to promote and engage more intensively with the private sector. This was mentioned by 97 participants, most of them companies (34), followed by academics (22), business associations (15) and EU citizens (11).
 - 1.2.6. Relevance of a set of elements and activities to ensure that the proposed European Partnership would meet its objectives

Setting joint long-term agendas

Respondents were asked how relevant it is for the proposed European Partnerships to meet their objectives to have a strong involvement of specific stakeholder groups in setting joint long-term agenda. All respondents see stakeholders from industry as the most relevant, followed by academia and governments. The involvement of foundations and NGOs as well as other societal stakeholders were, however, still found to be (very) relevant by more than 50% of the respondents. Most respondents indicated the stakeholder group they belong to themselves or that represent them as relevant to involve.

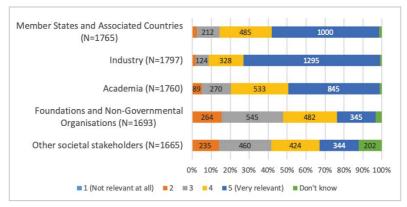
Figure 11: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives - Setting joint long-term agenda with strong involvement of: (non-campaign replies) For all candidate initiatives



<u>Pooling and leveraging resources through coordination, alignment and integration with stakeholders</u>

Respondents were asked how relevant it is for the proposed European Partnership to meet its objectives to pool and leverage resources (financial, infrastructure, in-kind expertise, etc.) through coordination, alignment and integration with specific groups of stakeholders. Respondents see stakeholders from industry as the most relevant, followed by academia and governments (Member States and Associated Countries). The involvement of foundations and NGOs as well as other societal stakeholders are also still found to be (very) relevant for more than 50% of the respondents. Similarly as described for the question on setting joint long-term agendas, most stakeholder categories valued their own involvement higher than other respondents – although also here differences between stakeholder categories were minor.

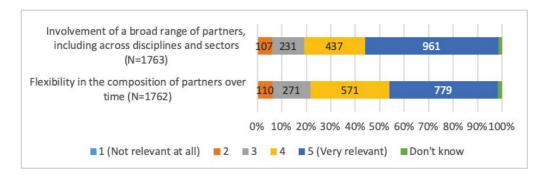
Figure 12: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives – Pooling and leveraging resources (financial, infrastructure, in-kind expertise, etc.) through coordination, alignment and integration with: (non-campaign replies) For all candidate initiatives



Composition of the partnerships

Regarding the composition of the partnership most respondents indicated that for the proposed European Partnership to meet its objectives the composition of partners needs to be flexible over time and that a broad range of partners, including across disciplines and sectors, should be involved (see Figure 13). When comparing stakeholder groups only minor differences were found. Academic/research institutions and public authorities found the involvement of a broad range of partners and flexibility in the composition of partners over time slightly more relevant than other respondents, while large companies found both less relevant. SMEs mainly found the flexibility in the composition of partners over time less relevant than other respondents, while no significant differences were found regarding the involvement of a broad range of partners. Citizens provided a similar response to noncitizens. Respondents that are/were directly involved in a current/preceding partnership, when compared to respondents not involved in a current/preceding partnership, indicated a slightly lower relevance of the involvement of a broad range of partners and flexibility in the composition of partners over time.

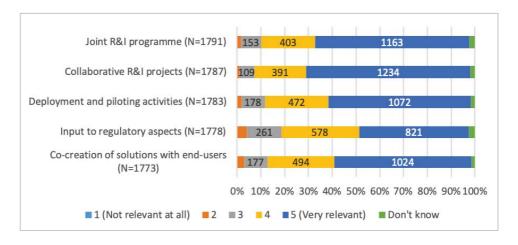
Figure 13: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives – Partnership composition (non-campaign replies) Aggregation of responses of all candidate initiatives



Implementation of activities

Most respondents indicated that implementing activities like a joint R&I programme, collaborative R&I projects, deployment and piloting activities, providing input to regulatory aspects and the co-creation of solutions with end-users are all (very) relevant for the partnerships to be able to meet its objectives. Minor differences were found between the main stakeholder categories, the differences found were in line with their profile. As such, academic/research institutions found joint R&I programme & collaborative R&I projects slightly more relevant and deployment and piloting activities, input to regulatory aspects and co-creation with end-users slightly less relevant than other respondents. For SMEs an opposite pattern is shown. Large companies, however, also found collaborative R&I projects slightly more relevant than other respondents, as well as input to regulatory aspects. The views of citizens are similar to non-citizens. Respondents that are/were directly involved in a current/preceding partnership, when compared to respondents not involved in a current/preceding partnership, show a slightly higher relevance across all activities.

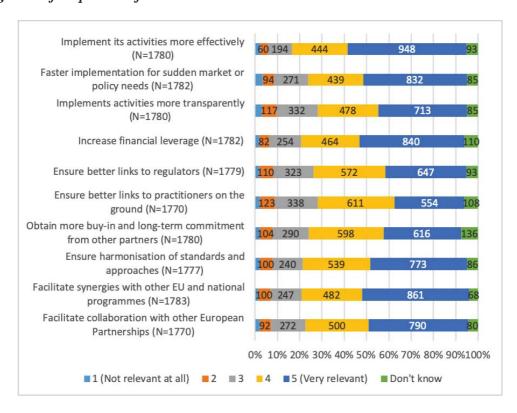
Figure 14: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives – Implementing the following activities (non-campaign replies) For all candidate initiatives



1.2.7. Relevance of setting up a legal structure (funding body) for the candidate European Partnerships to achieve improvements

Respondents were asked to reflect on the relevance of setting up a legal structure (funding body) for achieving a set of improvements, as shown in the Figure below. In general, 70%-80% of respondents find a legal structure (very) relevant for these activities. It was found most relevant for implementing activities in a more effective way and least relevant for ensuring a better link to practitioners on the ground, however differences are small.

Figure 15: In your view, how relevant is to set up a specific legal structure (funding body) for the candidate European Partnership to achieve the following? (non-campaign replies) Aggregation of responses of all candidate initiatives

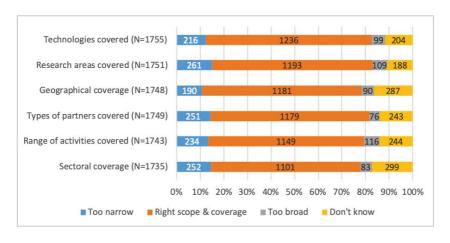


When comparing stakeholder categories there are only minor differences. Academic/research institutions indicated a slightly lower relevance for transparency, better links to regulators as well as obtaining the buy-in and long-term commitment of other partners. SMEs also indicated a lower relevance regarding obtaining the buy-in and long-term commitment of other partners. Large companies showed a slightly higher relevance for implementing activities effectively, ensure better links to regulators, obtaining the buy-in and long-term commitment of other partners, synergies with other EU/MS programmes and collaboration with other EU partnerships. NGOs find it slightly more relevant to implement activities faster for sudden market or policy needs. Public authorities, however, find it slightly less relevant to facilitate collaboration with other European Partnerships than other respondents. The views of citizens show a slightly lower relevance for a legal structure in relation to implementing activities in an effective way. Respondents that are/were directly involved in a current/preceding partnership indicated a higher relevance across all elements presented.

1.2.8. Scope and coverage of the candidate European Partnerships based on their inception impact assessments

Consulted on the scope and coverage for the partnerships, based on their inception impact assessments, the large majority feels like the scope and coverage initially proposed in the inception impact assessments is correct. However, about 11% to 15% of the respondents indicated the scope and coverage to be too narrow. About 11%-17% of respondents answered "Don't know". Overall, differences between the main stakeholder categories were found to be minor. Academic/research institutions indicated slightly more often that the research area was "too narrow" then other respondents. SMEs on the other hand indicated slightly more often that the research area and the geographical coverage were "too broad". NGOs and public authorities, however, found the geographical coverage slightly more often "too narrow". Large companies found the range of activities slightly more often "too broad" and the sectoral focus slightly more often "too narrow" when compared to other respondents. The views of citizens are the same as for other respondents. Respondents that are/were directly involved in a current/preceding partnership more often indicated that the candidate institutionalised European Partnership have the "right scope & coverage".

Figure 16: What is your view on the scope and coverage proposed for this candidate institutionalised European Partnership, based on its inception impact assessment? (non-campaign replies) Aggregation of responses of all candidate initiatives



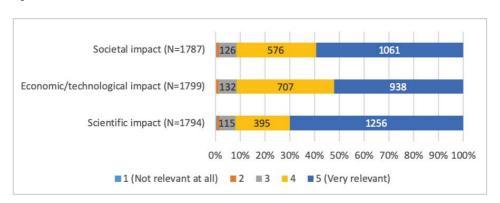
1.2.9. Scope for rationalisation and alignment of candidate European Partnerships with other initiatives

When asked whether it would be possible to rationalise a specific candidate European Institutionalised Partnership and its activities, and/or to better link with other comparable initiatives, nearly two thirds of respondents answered "Yes" (1000, or 62%), while over one third answered "No" (609, or 39%). Nearly no differences were found between stakeholder categories, only large companies and SMEs indicated slightly more often "Yes" in comparison to other respondents. The views of citizens are the same as for other respondents. Respondents that are/were directly involved in a current/preceding partnership, indicated "No" more often, the balance is about 50/50 between "Yes" and "No" for this group.

1.2.10. Relevance of European Partnerships to deliver targeted scientific, economic/technological and societal impacts

Finally, respondents were asked to rate the relevance of partnership specific impacts in three main areas: Societal; Economic/technological; and Scientific impacts. All three areas were deemed (very) relevant across the candidate partnerships. Scientific impact was indicated as the most relevant impact, more than 90% of respondents indicated that this as (very) relevant. Only minor difference between stakeholder groups were found. Academic/research institutions found scientific impacts slightly more relevant, while large companies found economic and technological impacts slightly more relevant than other respondents. NGOs found societal impact slightly more relevant, while SMEs found this slightly less important. Citizens did not a significantly different view when compared to other respondents. Respondents that are/were directly involved in a current/preceding partnership find all impacts slightly more relevant than other respondents.

Figure 17: In your view, how relevant is it for the candidate European Institutionalised Partnership to deliver on the following impacts? (non-campaign replies) Aggregation of responses of all candidate initiatives



1.3. Stakeholder consultation results for this specific initiative

1.3.1. Scope of the consultation

Key Digital Technologies (KDT) have been identified as one of the Commission's research and innovation initiatives under the Horizon Europe 'Digital, Industry and Space' cluster (Pillar II-Cluster 4). It is proposed to be supported by one of the European Partnerships in the envisaged partnership area of "Advancing key digital and enabling technologies and their use, including but not limited to novel technologies such as Artificial Intelligence, photonics and quantum technologies" (Area 2).

The Commission conducted a series of stakeholder consultations with various stakeholder groups of different levels (e.g. Member S2tates, R&I funding beneficiaries, industry associations, citizens, etc.) to seek views on EU Research and Innovation (R&I), and on the proposed KDT Partnership. In particular, the consultation activities focused on the need for, the scope and coverage, the type and the planned focus of this partnership.

1.3.2. Whom has the Commission consulted

The Commission consulted a wide range of stakeholders (e.g. public authorities, companies, business organisations, academia, research organisations and end-users) to anticipate a broad involvement of interested participants in the partnership. The consultation activities included but were not limited to those which applied for and/or received funding from the current Framework Programme or the interrelated partnership in Electronic Components and Systems for European Leadership (ECSEL), stakeholders from the European ICT and technological domains (current and emerging), and from vertical application areas. These targeted stakeholders were complemented by the identification of additional relevant stakeholders to be consulted, based on an external study undertaken to feed into the impact assessment for each of the potential institutionalised European Partnerships.

In summary, the following type of stakeholders have been consulted:

- The research community, consisting of academic/research institutions such as universities, public government-funded organisations, independent organisations or private research centres.
- The industrial community, which includes large companies, SMEs and Start-ups, material suppliers and equipment manufacturers.
- Public authorities, such as ministries and national bodies for research, EU institutions and bodies.
- EU citizens responding on their own behalf.
- Interested independent authorities and platforms.

representing a vast research, development and user community of nanoelectronics, embedded intelligent systems, smart system integration, semiconductor manufacturing, photonics and integrated software; a convergence of areas of research in KDT.

1.3.3. How has the Commission consulted?

The Commission launched a structured consultation of Member States through the Shadow Strategic Configuration of the Programme Committee Horizon Europe, which provided early

input⁵ into the preparatory work and resulted in 44 possible candidates for European Partnerships, taking into account the identified areas for possible institutionalised partnerships.

In addition, an open public consultation that covered all 12 potential institutionalised partnerships based on Articles 185 and 187 TFEU was launched. This consultation collected input from a broad range of stakeholders, across Europe and associated countries, on both the overall approach and the individual candidates for institutionalised partnerships.

Furthermore, a combination of written consultation tools and direct interactions with stakeholders were put in place, seeking input, views, ideas and experiences. Several (targeted) meetings and stakeholder workshops on the specific issues covered by the proposed partnership were organized to discuss and gather detailed input on various policy options. The identified option in the impact assessment largely builds on the outcome of these consultations with stakeholders.

1.3.4. Feedback received on the Inception Impact Assessment

The inception impact assessment⁶ of the initiative was published for feedback from 30 July 2019 to 27 August 2019, with the aim to seek initial feedback. Seventeen reactions were received on the inception impact assessment, notably from industry associations dealing with electronics components and systems, academic/research institutions, private business organisations, public authorities and citizens.

In summary, the majority of the reactions stressed the need for and emphasized support to such an initiative. According to the feedback received, several respondents asked for a broadening of the scope of the proposed KDT Partnership – e.g. the need to integrate semiconductor-based integrated photonics, selected software technologies (beyond embedded software) and their applications to cover full value chains and networks.

1.3.5. Meetings & Workshops with Stakeholders

From the private sector (Industry, Research, and Academia)

A series of meetings and workshops between the European Commission and key European private organisations have taken place, to discuss potential activities to be covered under a KDT partnership, the requirements and links between suppliers and users of digital technologies, the KDT value chains and application areas where these technologies play an essential role:

On February 1, 2018 in Brussels, high-level representatives of companies and research and technology organisations (RTOs) active in semiconductor technology met with Mariya Gabriel, the Commissioner for Digital Economy and Society, to discuss a consolidated set of strategic measures for electronics value chains in Europe. The outcome of this meeting – together with a series of specific KDT value chain workshops/consultations (March-April 2018) on automotive, health, space/aeronautics, security, hardware for AI, robotics and automation - resulted in a report: 'Boosting Electronic Value Chains in Europe'. The report

⁵ European Partnerships under Horizon Europe: results of the structured consultation of Member States (Report)

⁶ https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2019-4972315 en

⁷ https://ec.europa.eu/digital-single-market/en/news/boosting-electronics-value-chains-europe

sets out an updated strategy for the electronics sector in Europe, and makes the case for a change in approach and outlines a set of actions intended to set the basis for future European policy.

<u>In June 2019</u>, a draft Implementation Plan (IP), as a direct development of the aforementioned report on 'Boosting Electronics Value Chains in Europe', was presented by key industrial organisations to the European Commission. This Implementation Plan included a specific chapter on a KDT partnership.

<u>In September and November 2019</u> the European Commission met with Integrated Device Manufacturers (IDMs) to discuss a strategic cooperation between key European nanoelectronics companies, that would ensure leadership in KDT for edge computing, including specific activities that would potentially be covered under such a Partnership.

<u>In October 2019</u> a workshop with KDT System Houses took place in Brussels, to specifically address the requirements of users of digital technologies. It covered mostly the demand side of KDT value chains and addressed applications where these technologies play an essential part.

<u>In November 2019</u> at the European Forum for Electronic Components and Systems - EFECS2019⁸ in Helsinki, a High-level meeting took place between CONNECT Deputy Director General Khalil Rouhana and representatives of main Nanoelectronics companies, to further discuss a renewed strategy in Europe under the new Commission. It addressed the actions proposed in the implementation plan and the specific role of private members in a future KDT partnership.

From the Public sector (Members States)

<u>In April and May 2019</u>, two meetings took place with Member State representatives, building upon a consultation process on a potential follow-up Joint Undertaking (JU) to the current ECSEL JU, under Horizon Europe.

<u>In May/June 2019</u>, a Member State consultation was realised on the proposed portfolio of European Partnerships under Horizon Europe. 30 countries (all Member States, Iceland and Norway) provided feedback, which has been analysed by the Commission services and summarised (overall and per partnership candidate) in a report⁹. In summary, the overall feedback was positive on the proposed portfolio, with a general satisfaction to the thematic coverage.

On the proposed KDT Partnership, opinions strongly supported its high relevance in the national context, while also raising the importance of the scope of partners and relevant stakeholders, the need to provide strong support to and impact on SMEs, and the limitation of activities related to photonics and to those that require a very strong integration with electronic devices. Synergies with other partnerships within and outside the cluster would need to be ensured.

The results of the Member State consultation strongly confirmed the KDT partnership approach in addressing the specific priority and the overall relevance, also in line with

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⁸ https://efecs.eu/

⁹ European Partnerships under Horizon Europe: results of the structured consultation of Member States (Report)

national policies, priorities and R&I strategies, as well as for industry, research organisations and universities.

<u>In October 2019</u>, Member State representatives met with the EC to discuss their involvement in a potential KDT Partnership and the desired complementary steps to improve efficiency of implementation of an improved tri-partite model.

<u>In November</u> 2019, the Commission organised three workshops with Member State representatives on European Partnerships, to obtain a better understanding of the possible benefits of a collaboration between Member States and the candidate European Partnerships with industry, and its format. The discussions with the MS representatives were important to early detect opportunities to align on joint priorities, as well as to consider in design and preparation of implementation of the partnerships, thus ensuring discussions would be embedded in policy developments of a concrete field and high engagement of sectoral ministries.

One of the three workshops was on Digital Technologies, in which KDT was featured, highlighting its foundation of an existing and solid collaboration with Member States under ECSEL JU, and underlining the aim to ensure EU/national alignment through combined financing, as well as increase collaboration in testing of components. Overall, the digital-centric partnership was considered of high-relevance, since Europe has a dynamic and innovative digital industry.

1.3.6. Open Public Consultation

An online public consultation took place from 11 September 2019 to 12 November 2019, with the aim to seek the views of EU research and innovation stakeholders and citizens on the 12 proposed institutionalised European partnerships under the future Horizon Europe Research and Innovation programme (2021-2027). The consultation was available in English, German and French. It was advertised widely the European Commission's online channels as well as via various stakeholder organisations.

The consultation focused on the overall need for and the planned focus of these potential European partnerships, and had a part with specific questions on the proposed KDT Partnership.

Characteristics of Respondents

For the KDT Partnership, 182 respondents provided their views of which 20 were identified as belonging to a campaign. These campaign contributions were analysed separately and are not part of the actual analysis with a number of 162 responses.

Out of these 162 non-campaign responses, 55 (33.95%) of the respondents were representatives of academic and research institutions, 42 (25.93%) were company/business organisations, 35 respondents (21.60%) were citizens. Public authorities (4,32%) and NGOs (3,08%) also participated in the consultation.

The majority of respondents, namely 124 (76.54%), have been involved in the on-going research and innovation framework programme, while 84 respondents (67.74%) were directly involved in a partnership under Horizon 2020 or its predecessor Framework Programme 7.

Results on General Questions by non-campaign respondents

Relevance of efforts of the candidate European Partnership to address problems

At the beginning of the consultation, the respondents of this partnership indicated their views of the needs of the future European Partnerships under Horizon Europe. Overall, respondents indicated that many of these needs were fully required. The needs where most respondents indicated this, was making a significant contribution to EU global competitiveness in specific sectors and/or domains (112 respondents or 69.14%) and focusing more on the development and effective deployment of technology (101 respondents or 62.35%). These identified needs are in line with its proposed focus of the Partnership. No statistical differences were found between the views of citizens and other respondents for most needs.

Main advantages and disadvantages of participation in the Institutionalised European Partnership

The respondents were asked what they perceived to be the main advantages and disadvantages of participation in an Institutionalised European Partnership (as a partner) under Horizon Europe. A key-word analysis showed that respondents viewed collaboration as the main advantage, in addition to a strategic research agenda and leadership in Europe. The subsequent administrative burden was identified as a disadvantage.

Results on candidate European Partnership Specific Questions by non-campaign respondents

Relevance of research and innovation efforts at the EU level to address problems in relation to key digital technologies

In the consultation, respondents were asked to provide their view on the relevancy (5-point scale) of research and innovation efforts at EU level to address the following problems in relation to key digital technologies:

- Problems in uptake of digital innovations

With regard to the problems in uptake of digital innovations, the majority of respondents have picked either a 4 or a 5 on the 5-point relevancy scale. Respondents indicated that the most relevant problem is when the regulatory framework lags behind technology developments (106 respondents or 67.95% indicated this as a 'relevant' or 'very relevant' problem). The options that have received the least 5 ('very relevant') answers, out of all the problems presented, are the lack of consideration of societal or user needs (37 respondents or 23%) followed by the barriers to exploitation due to limited access to capital data or intellectual property (37 respondents or 24%).

- Structural and resource problems

With regard to structural and resource problems, the limited collaboration and pooling of resources between Member States, European Commission, Industry and Research organisations (Universities, RTO's) is clearly considered as a very relevant problem for research and innovation efforts at EU level to address (65 respondents or 42% indicated a 5 on the 5-point relevancy scale).

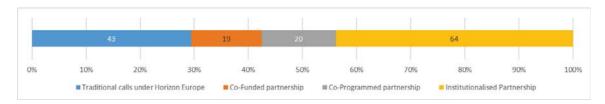
- Research and innovations problems

Finally, respondents have indicated that research and innovation problems are considered the most relevant, as all of the problems presented in this category have received more 5 (very relevant) responses than any of the other problems. The rapid change including big data and the emergence of new computing paradigms is considered the most relevant, with 105 respondents selecting 'very relevant' on this problem (66%).

Addressing the specific challenges through Horizon Europe intervention

- Type of partnership

Respondents were asked to indicate how these challenges could be addressed through Horizon Europe intervention. As shown in the figure below, just over 40% of respondents indicated that an Institutionalised Partnership would be the best fitting intervention to address these problems.



Respondents that selected an institutionalised partnership as the best fitting intervention mentioned for example that it is the most suitable instrument to "bring together the critical mass of public and private resources needed to ensure Europe's competitiveness, sovereignty and autonomy in the strategic domain of KDT". Furthermore, several respondents signalled its suitability to implement a long-term vision and to provide "substantial and long-term guidance on the R&I activities in the EU", the "broad impact and wide range of stakeholders" in the key digital technologies area, and the importance of "aligning national strategies on digital technologies into a single EU strategy".

Respondents who did not select institutionalised partnership as their preferred intervention (N=76) mentioned traditional calls, public private sector and the development of new technology.

Relevance of elements and activities to ensure that the proposed European Partnership would meet its objectives

Involvement of actors in setting joint long-term agenda

Respondents were asked how relevant the involvement of actors is in setting a joint long-term agenda to ensure that the proposed European Partnership would meet its objectives. A high number of respondents (120 respondents or 77%) indicated that a strong involvement of industry is very relevant actor for setting a joint long-term agenda. The role of academia and Member States, Associated Countries is also considered very relevant by many respondents (respectively 95 respondents or 61.29%, and 76 respondents or 51.35% indicated their role of as 'very relevant'). A strong involvement of foundations, NGOs and other stakeholders is considered less relevant by respondents (respectively 30 respondents or 20.69%, and 18 respondents or 13.24% indicated their role as 'very relevant'). Respondents that are/were involved in a current/preceding partnership indicated that industry and government (Member States and Associated Countries) are more relevant compared to other respondents.

- Pooling and leveraging resources

Respondents were asked to assess the relevance of different actors in pooling and leveraging resources (such as financial, infrastructure, in-kind expertise) through coordination, alignment or integration to meet Partnership objectives. The role of industry is considered as very relevant, as 104 respondents out of 154 (68%) indicated that their involvement is very relevant for the above-listed purpose. The involvement of foundations, NGOs and other stakeholders is seen as less important (respectively 25 respondents or 18% indicated the role of foundations/NGOs, and 20 respondents or 15% indicated the role of other stakeholders as very relevant).

A slight statistical difference was found between the views of citizens and other respondents. Citizens found the relevance of academia in pooling and leveraging resources through coordination, alignment or integration slightly less relevant. Similarly, respondents that are/were involved in a current/preceding partnership indicate a slightly higher relevance of industry.

- The partnership composition

Respondents were asked about the relevance of certain elements of the Partnership composition, such as flexibility in the composition of partners over time and involvement of a broad range of partners (including across disciplines and sectors), to reach objectives of the KDT Partnership.

A high share of respondents (117 or 77%) view that flexibility in composition of partners over time is relevant by giving a score of 4 and 5 on the indicated scale. The large majority of respondents (125 or 82%) also indicated that ensuring involvement of a broad range of partners is relevant to ensure that proposed European Partnership would meet its objectives.

- Implementation of activities

Respondents were asked to provide opinions on the relevance of implementation of several activities for meeting objectives of the Partnership. According to the analysis, a high number of respondents view that joint R&I programme, collaborative R&I projects, deployment and piloting of activities, as well as, co-creation of solutions with end-users is very relevant for meeting the objectives. Over 85% of respondents assessed listed activities as relevant or very relevant, giving a score of 4 and 5 on the indicated scale. In comparison, only 37 respondent out 152 (24.34%) consider that the input to regulatory aspects is very relevant for meeting objectives of the KDT Partnership.

Relevance of setting-up a specific legal structure (funding body) for the candidate European Partnership to meet objectives

Respondents were asked to assess the relevance of a specific legal structure (funding body) for the candidate European Partnership to achieve several objectives. According to the feedback, a large number of respondents suggested that setting-up a specific legal structure would be very relevant to implement activities more effectively (70 respondents or 46%), to implement activities faster to respond to sudden market or policy needs (62 respondents or 42%), to facilitate synergies with other EU and national programmes (62 respondents or 41%) and to facilitate collaboration with other relevant European Partnerships (60 respondents or 41%). On the other hand, a lower number of respondents (24 or 16%) indicated that the legal structure would be very relevant to ensure better links to regulators. Respondents that

are/were involved in a current/preceding partnership indicate a slightly higher relevance of setting up a specific legal structure to facilitate collaboration with other relevant European Partnerships.

Scope and coverage proposed for candidate institutionalised European Partnership

Respondents were asked to assess the scope and coverage proposed for the Key Digital Technology Partnership, based on its inception impact assessment. Overall, the majority of respondents consider that the scope and coverage are right in terms of technologies, research areas, geographical coverage, types of partners, range of activities and sectors. However, a significantly smaller number of respondents consider it too narrow for the research areas (22 respondents or 15%) and type of partners covered (20 respondents or 14%).

Alignment of the European Partnership with other initiatives

The majority of respondents (100 or 76%) consider that it would be possible to rationalise the candidate European Institutionalised Partnership and its activities, and/or to better link it with other comparable initiatives.

Relevance of the Candidate European Partnership to deliver impacts

Respondents were asked to assess the relevance of the candidate European Institutionalised Partnership to deliver on listed societal, economic/technological and scientific impacts.

The majority of respondents indicated that the Partnership would be 'very relevant' to deliver on the following societal impacts: provision of trusted electronics components and systems to the public and businesses (86 respondents or 55.84%), enabled safety - automotive, avionics, and security - transactions, communications (94 respondents or 61.44%). On the other hand, contribution to more functional, efficient, economical and accessible electronics systems was by a smaller number of respondents indicated as 'very relevant' (70 respondents or 46.05%).

Among economic/technological impacts that were suggested, a large number of respondents indicated that the Partnership would be 'very relevant' for more innovative, sustainable and globally competitive electronics and systems industries – including SMEs (95 respondents or 61.89%), and for the development and exploitation of innovative technology paradigms (80 respondents or 53.33%).

A large number of respondents, namely 102 out of 153 (66.66%), indicated that the Partnership would be 'very relevant' for the mentioned scientific impact: new scientific knowledge and reinforcement of EU research and innovative capabilities in Key Digital Technologies.

Summary of open question responses by non-campaign respondents

To complement and personalise further the answers to the multiple-choice questions in the Open Public Consultation, respondents were given the opportunity to provide feedback in an open-type format. The main consequent messages were:

In general, a future European Institutionalised partnership was the clear choice to bring together the critical mass of public and private resources needed to ensure Europe's competitiveness, sovereignty and autonomy in the strategic domain of KDT and act on the

basis of an industry-driven, truly pan-European common strategy, especially in light of the success of the current ECSEL Joint Undertaking.

Some respondents preferred the options of a co-funded or co-programed partnership, due to the low complexity level, as this would lead to higher success rates due to the dedicated work amongst partners that have collaborated in the past, whilst also providing a relational flexibility among eligible stakeholders to participate in a European project. With a view to SME access in such programs, playing a key part in the innovation development, it is the opinion that co-fund or co-programmed has proven to be successful in attracting interest towards open innovation.

For others, traditional calls were the preferred option, due to their familiarity. It is the opinion that the introduction of new rules, model agreements, procedures etc. would put participants in another learning curve. From the long line of framework programmes, they have shown that they offer simplicity, functionality and high potential of collaboration and results.

Respondents also noted that, experience from the current partnership in this domain has illustrated a further need to extend R&I efforts to related aspects of technologies. Some respondents also noted that cybersecurity, should be part of the future partnership on key digital technologies. Addressing lower technology readiness levels, would also provide the ability to innovate and address the unprecedented complexity of future digital technologies, requiring dedicated research efforts and collaboration across multiple industrial and academic domains.

Finally, as the majority of respondents agreed on the technological scope of the KDT partnership, it was also highlighted that these technologies and applications would act as main drivers in the digital transformation of the European economy and society.

Summary of campaign responses

Further to this, a single campaign (campaign #10 - 20 respondents) was identified for the current candidate Partnership. The participants of the campaign were strongly in favour of an institutionalised partnership.

An overview of the campaign responses can be seen in table 1.

Table 1: Overview of responses of campaign participants

Question category	Summary of responses
Research and innovation problems	All categories are considered mostly 'very relevant' (score 5).
Structural and resource problems	The categories "Limited availability of testbeds for novel computing components and systems" and "Sky-rocketing costs of equipment" are considered 'relevant' (score 4) and 'very relevant' (score 5). In contrast, "Limited collaboration and pooling of resources between Member States, European Commission, Industry and Research organisations (Universities, RTOs)" received an average score.
Problems in uptake of digital innovations	The category "Insufficient market size or inappropriate business models" is considered 'relevant', while other categories in this group of questions received a low score (namely, 2 and 3).
Preferred Horizon Europe intervention	Institutionalised Partnership was selected by all respondents. When respondents were asked to explain their choice, all of them used the following quote: "Only an institutionalised European Partnership based on Article 187 TFEU will bring together the critical mass of public

	and private resources needed to ensure Europe's competitiveness, sovereignty and autonomy in the strategic domain of KDT and act on the basis of an industry-driven, truly pan-European common strategy. A JU will create a long-term dedicated implementing structure representing the deepest level of integration, engagement and up-front commitment from public and private partners".
Relevance of actors for setting join long-term agenda	Involvement of Member States and Associated Countries, Industry and Academic is considered 'very relevant' by all respondents, while other categories received a low score (namely, 2 or 3).
Relevance of actors for pooling and leveraging resources	Involvement of Member States and Associated Countries, Industry and Academic is considered 'very relevant' by almost all respondents, while other categories received a low score (namely, 2 or 3).
Partnership composition	Mostly low score (on average, 3) on both answer categories ("Flexibility in the composition of partners over time" and "Involvement of a broad range of partners, including across disciplines and sectors").
Implementation of activities	Joint R&I programme, collaboration R&D projects and deployment, piloting activities, and co-creation of solutions with end-users are considered 'very relevant' and 'relevant' by most respondents. In contrast, "input to regulatory aspects" received a low score.
Relevance of the legal structure	Most answer categories received a high score with exception of "ensure better links to regulators", "ensure better links to practitioners on the ground" and "ensure harmonisation of standards and approaches".
Scope and coverage of the candidate Partnership	Almost all respondents considered that listed components of the candidate Partnership have right scope and coverage. Respondents were offered an opportunity to provide comments on the proposed scope and coverage of the Institutionalised Partnership. Several of them included the following quote: "Experience from ECSEL has illustrated a need to extend R&I efforts to related aspects of photonics and software, advanced computing technologies (such as neuromorphic computing and edge computing), biosensors and flexible electronics, all of which are featuring increasingly in the digital transformation of the economy and society and now need to be cointegrated to build complex systems and open up new avenues of application".
Rationalisation of the candidate Partnership and linking to other initiatives	Respondents consider that it would not be possible to rationalise the candidate Partnership and its activities, and/or to better link it with other comparable initiatives. Respondents were asked to explain their answer, most of them inserted a following quote: "The technologies of the KDT partnership and their applications will be key in addressing multiple global challenges such as transport & smart mobility, health & wellbeing, energy, digital industry and digital life, as well as driving the digital transformation of multiple sectors of Europe's economy and society. Whereas the KDT partnership will collaborate closely with comparable initiatives focusing on one specific challenge or sector, it cannot be linked or merged with only one of them".
Societal impact	Almost all respondents considered that the candidate Partnership would be 'very relevant' to deliver on listed impacts.
Economic/technological impact	Almost all respondents considered that the candidate Partnership would be 'very relevant' to deliver on listed impacts.
Scientific impact	All respondents considered that the candidate Partnership would be 'very relevant' to deliver on listed impacts.

1.3.7. Interviews (IA Study)

As part of the stakeholder consultation efforts, the impact assessment study on the candidate partnership performed interviews with a carefully balanced sample of relevant stakeholders covering five different categories. In summary, 51 stakeholders have been interviewed in the

framework of this partnership: around one third of interviews were conducted with large companies (31%), followed by industry associations (25%), RTOs and universities (14%), Member States (14%), SMEs (12%) and European Commission services (4%). Concerning geographical location, around half were from Western Europe (49%), followed by Eastern Europe (10%), Southern Europe (8%), the Nordics (4%) and international (6%). Finally, gender balance was at 76.5% male and 23.5% female.

The interviews were required to cover, among others, research, development, supply and enduser organisations as well as representatives from the KDT value chain, from equipment, design and production to systems integration and end-product. The segments sought covered, for example, electronics, semiconductors, foundries, systems, software, application areas (automotive, MedTech, energy, manufacturing, etc.), engineering and photonics. To obtain information about the envisaged set up and measures, it was equally sought to carry out interviews with executive level and board members of the current JU, in addition to Member State representatives, to scope the opinions and interest.

These interviews confirmed the strong need for a partnership in this domain, in line with the outcome of the open public consultation analysis. As it was apparent overall, the preferred option would be that of an Institutionalised Partnership (option 3), given its ability to ensure commitment of industry and MS around a strategic agenda, alignment with industry strategies, coordination of research agendas and mobilisation of funding. This appears to be linked to the existence of the current ECSEL JU, which was also successful in a form equivalent to an Institutionalised Partnership.

Option 0 – Traditional Calls

Interviewees mainly from MS, business organisations and RTOs supported the conclusion that traditional calls are effective in generating scientific impact and in targeting lower TRLs. However, it was also pointed out by MS and industry associations that traditional calls are less suited for aligning with the industrial demand/user side or in generating scientific impact in areas aligned with industry needs. Some interviewees also highlighted that calls are unlikely to mobilise a level of investment equivalent to other options, for example given the absence of national funding. In this context, the lack of formal mechanism of commitment and uncertainty concerning the level of financial contribution by industry was highlighted.

According to interviewees, traditional calls have a relatively low capacity to ensure long-term commitment, leverage resources and to build upon results of previous projects, thereby restricting it from strengthening technological leadership and competitiveness of Europe's KDT industry. This would require the alignment of strategies and coordination, something which traditional calls cannot deliver according to several interviewed organisations.

Option 1 - Co-programmed partnership

In general, the co-programmed partnership was found to allow for a high level of flexibility and agility in the organisation and involvement, while also having the capacity to facilitate commitment from both public and private partners as well as mobilise funding. In comparison to traditional calls, it was found to have a more aligned format to industry needs combined with a high level of flexibility and openness – both perceived to be conducive to achieving technological and industrial impact.

Option 3 - Institutionalised Partnership

Overall it was emphasised that an Institutionalised Partnership is mostly capable of addressing and building the KDT ecosystem and value chains, with a long term perspective on coordination and collaboration, supportive in addressing fragmentation and strengthening integration and cooperation in European value chains. Moreover, an Institutional Partnership is likely to contain a broad coverage of TRLs, thereby providing a broad coverage of the value chain. The tripartite nature and centralised structure of an Institutionalised Partnership offers a strong incentive for making synchronised funding decisions taking into account national and industry developments.

Through this partnership option, the alignment with the EU policy is ensured by the participation of the EC in the management of the partnership, according to the interviewees. The calls are designed by the management of the partnership according to the work programme with the highest possible alignment with the industry's strategy. The central coordination of the selection of the projects will result in a stronger and more coherent research portfolio. Therefore, the potential to achieve the required directionality is high. By comprising a centralised coordination and management, it is anticipated to provide a higher level of internal coherence.

It was also mentioned that the Institutional Partnership has a long-term perspective on collaboration and accordingly more effective in strengthening the exchange of knowledge within the value networks, given that traditional calls limit participation in a single project with low possibilities for continuation of the collaboration in follow-up calls.

Several interviewees highlighted that this partnership option has the highest relevance for achieving industrial impact and competitiveness and for developing strategic technologies; this viewpoint is based on that the option provides the strongest type of commitment, long-term stability and critical mass. It offers a better format for addressing alignment and ensuring coordination, relevant for agreeing on priorities of technological importance and for achieving technological sovereignty.

An Institutionalised Partnership has a relatively high capacity to ensure coordination and alignment with other national and European policies in the field, as stated by interviewees, also indicating potential links in relation to key application areas, such as automotive, energy, health, manufacturing and mobility/transport, in need of KDT solutions.

Annex 3 Who is affected and how?

1. Practical implications of the initiative

This annex describes the practical implications of the preferred option identified in the Impact Assessment: the establishment of an institutionalised partnership based on Article 187 to support and reinforce Europe's industrial, technological and innovation capacities in Key Digital Technologies, for directly or indirectly affected stakeholder groups.

2. SUMMARY OF COSTS AND BENEFITS

Overview of benefits (for all stakeholder groups)

Member States

The preferred option will provide the means to build up research, innovation and production capabilities in Key Digital Technologies, where no single Member State would have the industrial or economic potential to achieve similar results on its own.

The institutionalised partnership will not only enhance the investments at European level, but also make their returns proportionally higher, as the access to upgraded facilities starts to bear fruit. Additionally, funding through the partnership will stimulate MS support to KDT industry through appropriated instrument(s) such as IPCEI.

The initiative will allow Member States to anticipate requirements early enough in order to facilitate the deployment of key digital technologies at national and European levels. An effective tri-partite model will provide for greater synergies between the Member States, the Commission and the private sector and enable implementing a clear strategy for the sector at European level and merging expertise and resources to develop the necessary means and infrastructures, what would otherwise bear the cost or require effort, exceeding capacity of a single Member State.

The increased coherence and synergies between different funding mechanisms (Horizon Europe, Digital Europe Program, PENTA¹⁰ and IPCEI) would also have a positive impact on the efficiency of the EU budget to which Member States contribute, with an evident reduction of the fragmentation of research effort.

Businesses

European companies at large, both from the demand and supply side of nanoelectronics, embedded intelligent systems, smart system integration, semiconductor manufacturing, photonics and integrated software will be among the most affected stakeholder groups. Key companies from vertical application areas (transport and mobility, communications, manufacturing, health & care, energy, to name a few) will complement this comprehensive demand-supply approach, which will cover the value chains in full. With such an ambition, cross-industry cooperation will combine hardware and software, design and manufacturing

PENTA is a EUREKA initiative launched in 2016 to replace CATRENE with the aim to catalyse research, development and innovation in the areas of micro and nanoelectronics enabled systems and applications where there is shared high national and industrial interest.

and provide a basis for collaborative work, whilst creating ecosystems along the relevant value and supply chains.

Further to this, research efforts aiming directly at industrial needs will benefit from such a collaboration between research and industry, which will indirectly support the deployment of European leading-edge KDT products and solutions across the market.

SMEs

SMEs are the key players in emerging and less established key digital technologies. They will thus experience direct and indirect economic benefits from the initiative. The KDT partnership will open up opportunities to SMEs with a more tailored implementing structure, as research topics clearly become more market oriented. The cost of designing new products will decrease, since SMEs, which usually lack or look outside of their current market for the necessary infrastructure and resources, will gain easier access – through co-participation of large industrial actors - to a high-level scientific capacity, manufacturing equipment and materials. It is also expected that this initiative will open up new product and application markets for European SMEs active in the field of KDT, as novel computing paradigms (neuromorphic), AI and related software, support.

Research community

European research and development organisations, both on the supply and demand side, will benefit from improved coordination, pooling of resources and greater access to advanced methodologies and tools, such as pilot lines and platforms and testing and experimentation facilities, supported by the partnership. They will be able to attain the critical mass for longerterm projects of common strategic interest and perspective. Furthermore, the institutionalised partnership option will ensure coordination between research and industry, resulting in new technologies, devices and systems, and ensuring that a broad scope of innovations benefit from standardisation of underlying technologies, thus bringing down the costs of reaching the market. The tri-partite dimension will help the research community to accurately direct efforts towards concrete industrial needs, introducing applicable and marketable solutions that various industries and public authorities can easily take up. The research community would also experience cross-fertilisation amongst the various KDT stakeholder groups under the common overarching focus of several EU research programmes, as researchers learn about new avenues to pursue and developers learn about new possibilities for products. Creating the necessary conditions, via the partnership, to enhance every aspect of KDT research, will in turn give further visibility to the already globally leading EU excellence.

Citizens

Citizens will benefit from the institutionalised partnership as the new solutions and products are developed and delivered to make their lives safer and easier, such as safe autonomous vehicles, seamless and secure means of communication, as well as novel healthcare techniques and devices. Enhanced European expertise in KDT will also contribute to tackling societal problems, such as climate change or ageing society, as finding solutions for them will become easier with AI enabled computing derived from the combination of efficient, powerful and trusted electronics and advanced sensors.

The technologies developed under the KDT partnership will improve energy efficiency, make use of renewable energy sources, and look at new (edge) computing paradigms for data

processing. As downstream industries, through KDT, will progressively reduce the energy consumption of their products, develop technologies and applications of higher energy efficiency, and substitute existing with more environmentally friendly materials, the positive impact on the environment and sustainability will become more and more pronounced.

EU institutions, agencies and bodies

The EU institutions, agencies and bodies will benefit both from the outcome of the research, development and strategic actions of the initiative, whilst attaining state of the art methodologies and tools for the future. Cross-links with other domains open opportunities for synergies with multiple other bodies of EU relevance, such as with partnerships targeting enabling technologies, i.e. EuroHPC, SNS, Photonics, AI data & robotics, Global competitive space system and Made in Europe, together with the EIT Digital which will contribute to the development of skills and the boosting of digital entrepreneurship.

All stakeholder groups

Overall, the preferred option will benefit all stakeholders, as it will help to deal with the complexity of the research and innovation landscape in the development of digital products/services, where no single organisation or MS can master all required technologies. The collaborative functionalities of the initiative will enable stakeholders to expand collaborations, and develop innovations, and ultimately mature, as Europe-wide KDT cutting-edge projects, pilot lines and platforms become available, retaining the best talents in the EU and attracting highly skilled professionals from third countries.

A summary of the benefits can be seen in the table below:

I	. Overview of Benefits (total for all provisions) – P	referred Option				
Description	Estimation (quantitative or qualitative)	Comments				
Direct benefits						
Build-up of KDT research, innovation and production capabilities in Europe	Combined resources would effectively address the main objectives, where no single Member or Associated State would have the industrial or economic capacity to realise on its own.	anticipate requirements early enough in				
Joint R&I strategy	Collaboration across the EU will enable R&I stakeholders to further build collaborations, develop new innovations, and ultimately mature, as Europe-wide KDT pilot lines and platforms become accessible.	entails that no single entity can master all				
Economic growth particularly for SMEs	SMEs would directly benefit from such a specific collaborative environment, as market oriented research topics make use of a more tailored implementing structure, with a large capacity of manufacturing equipment and materials via participation of key large industrial enterprises	evident, especially for SMEs, which are the key role players in emerging and less established technologies, such as novel				
Societal	Citizens would benefit from the introduction of KDT in areas of interest, as safe autonomous					

	vehicles and seamless and secure means of communication are realised, as well as novel healthcare techniques and devices.	1 0
Environmental	KDTs would contribute to sustainability and in protecting the environment, as technologies developed would improve energy efficiency, make use of renewable energy sources, and look at new low-power (edge) computing paradigms for data processing.	would progressively reduce the energy consumption of their products, develop technologies and applications of high energy

Overview of costs – For the preferred option

With the assumption that the partnership will maintain the internal structure of the current ECSEL Joint Undertaking, it can be implicit that this option is considered closest to a 'costneutral' setup, as there is a likely continuation of the existing structure, building rental, HR, etc.

Under this assumption and in the case of JU discontinuity, the estimated cost and benefits are analysed. ECSEL statutes foresee a 4-year winding-up period to manage projects launched in the last phase of the Joint Undertaking that will be running beyond 31st December 2020. The administrative cost planned for the management of ECSEL legacy in the period 2021-24 is €10,4 million, to be equally shared by EC and industry members.

There would be also 'intangible costs' associated to the JU discontinuity. It will be difficult to justify a lower intensity of EU support in R&I to the components and software industry at a moment in which access in Europe to key digital technologies is becoming critical and when other regions (China, US, Korea) are receiving substantial public support that goes beyond R&I.

Finally, a tri-partite JU structure enables the mobilisation of a critical amount of resources as it supports the combined contributions of EU, Participating States and Industry.

II. Overview of direct and indirect costs – Preferred option							
		Citizens/Consumer s		Businesses		Administrations	
		One- off	Recurrent	One- off	Recurrent	One- off	Recurrent ¹¹
Management/ Administrative costs	Direct costs						Running cost €2.29 million ¹² /year (EC 50%)
Administrative costs	Indirect costs						
Personnel costs	Direct costs						€ 3.24 million /year - 30 full time equivalent staff (EC 50%)
	Indirect costs						
Coordination costs (or transaction costs)							

¹¹ Commitment appropriations

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¹² These are the costs of running the ECSEL JU according to the 2018 Annual Activity Report.

Budget expenditure/				
investment costs				

REFIT Cost savings table

Not applicable for the proposed KDT Partnership. The initiative will benefit from the existing organisation/structure (e.g. the Programme Office) already in place for the ECSEL JU. There are no additional regulatory costs associated, and no specific simplification measures apply in this case.

Annex 4 Analytical Methods

The methodology for each impact assessment is based on the Commission Better Regulation Guidelines¹³ to evaluate and compare options with regards to their **efficiency**, **effectiveness** and **coherence**. This is complemented by integrating the **conditions and selection criteria** for European Partnerships, as well as requirements for setting up Institutionalised Partnerships.¹⁴

1. OVERVIEW OF THE METHODOLOGIES EMPLOYED

In terms of **methods and evidence used**, the set of impact assessments for all candidate Institutionalised European Partnerships draw on an external study covering all initiatives in parallel to ensure a high level of coherence and comparability of analysis¹⁵.

All impact assessments mobilised a mix of qualitative and quantitative data collection and analysis methods. These methods range from desk research and interviews to the analysis of the responses to the Open Consultation, stakeholder analysis and composition/portfolio analysis, bibliometrics/patent analysis and social network analysis, and a cost-effectiveness analysis.

The first step in the impact assessment studies consisted in the definition of the context and the problems that the candidate partnerships are expected to solve in the medium term or long run. The main data source in this respect was desk research. This includes grey and academic literature to identify the main challenges in the scientific and technologic fields and in the economic sectors relevant for the candidate partnerships, as well as the review of official documentations on the policy context for each initiative.

In the assessment of the problems to address, the lessons to be learned from past and ongoing partnerships were taken into account, especially from relevant midterm or ex-post evaluations.

The description of the context of the candidate institutionalised European Partnerships required a good understanding of the corresponding research and innovation systems and their outputs already measured. Data on past and ongoing Horizon 2020 projects, including the ones implemented through Partnerships, served as basis for descriptive statistic of the numbers of projects and their respective levels of funding, the type of organisations participating (e.g. universities, RTOs, large enterprises, SMEs, public administrations, NGOs, etc.) and how the funding was distributed across them. Special attention was given to analysing the participating countries (and groups of countries, such as EU, Associated Countries, EU13 or EU15) and industrial sectors, where relevant. The sectoral analysis required enriching the eCORDA data received from the European Commission services with sector information extracted from ORBIS, using the NACE codification up to level 2. These data enabled the identification of the main and, where possible, emerging actors in the relevant systems, i.e. the organisations, countries and sectors that would need to be involved (further) in a new initiative.

¹⁴ A pivotal element of the present analysis is the so-called two-step 'necessity test' for European Partnerships, used to establish: step 1) the need for a partnership approach in the first place, followed by step 2) a justification for the form of Institutionalised Partnership. The necessity test is described in Annex 6. This impact assessment focuses on the second step of the test.

¹³ European Commission (2017), Better Regulation Guidelines (SWD (2017) 350)

¹⁵ Technopolis Group (2020), Impact Assessment Study for Institutionalised European Partnerships under Horizon Europe.

A Social Network Analysis was performed by the contractors using the same data. It consisted in mapping the collaboration between the participants in the projects funded under the ongoing R&I partnerships. This analysis revealed which actors – broken down per type of stakeholders or per industrial sector – collaborate the most often together, and those that are therefore the most central to the relevant research and innovation systems.

The data provided finally served a bibliometric analysis run by the contractor aimed at measuring the outputs (patents and scientific publications) of the currently EU-funded research and innovation projects. A complementary analysis of the Scopus data enabled to determine the position and excellence of the European Union on the international scene, and identify who its main competitors are, and whether the European research and innovation is leading, following or lagging behind.

A cost modelling exercise was performed in order to feed into the efficiency assessments of the partnership options.

The conclusions drawn from the data analysis were confronted to the views of experts and stakeholders collected via three means:

- The comments to the inception impact assessments of the individual candidate institutionalised European Partnerships;
- The open public consultation organised by the European Commission from September to November 2019;
- The interviews (up to 50) conducted by each impact assessment study team conducted between August 2019 and January 2020 (policymakers, business including SMEs and business associations, research institutes and universities, and civil organisations, among others).

The views of stakeholders (and experts) were particularly important for determining the basic functionalities (see further below) that the future partnerships need to demonstrate to achieve their objectives as well as their most anticipated scientific, economic and technological, and societal impacts. The interviews allowed more flexibility to ask the respondents to reflect about the different types of European Partnerships. Furthermore, as a method for targeted consultation, it was used to get insights from the actors that both the Study Teams and the European Commission were deemed the most relevant. For the comparative assessment of impacts, the external contractors confronted the outcomes of the different stakeholder consultation exercises to each other with a view of increasing the validity of their conclusions, in line with the principles of triangulation.

Annex 2 includes also the main outcomes of the stakeholder consultation exercises.

2. METHOD FOR ASSESSING THE EFFECTIVENESS, EFFICIENCY AND COHERENCE OF EACH OPTION - THE USE OF FUNCTIONALITIES

Given the focus of the impact assessment on comparing different forms of implementation, the Better Regulation framework has been adapted to introduce "key functionalities needed" – so as to link the intended objectives of the candidate European Partnerships and what would be crucial to achieve them *in terms of implementation*. The identification of "key functionalities needed" for each initiative as an additional step in the impact assessment is based on the distinguishing factors between the different options (see Section 2.2.1 in the main body of the impact assessment). In practical terms, each option is assessed on the basis of the degree to which it would allow for the key needed functionalities to be covered, as

regards e.g. the type and composition of actors that can be involved ('openness'), the range of activities that can be performed (including additionality and level of integration), the level of directionality and integration of R&I strategies; the possibilities offered for coherence and synergies with other components of Horizon Europe, including other Partnerships (internal coherence), and the coherence with the wider policy environments, including with the relevant regulatory and standardisation framework (external coherence). This approach guides the identification of discarded options. It also allows for a structured comparison of the options as regards their effectiveness, efficiency and coherence, and also against a set of other key selection criteria for European Partnerships (openness, transparency, directionality)¹⁶.

Figure 3 Overview of key functionalities of each form of implementation of European Partnerships

Baseline: Horizon Europe calls	Option 1: Co- programmed	Option 2: Co- funded	Option 3.1: Institutionalised Article 185	Option 3.2: Institutionalised Article 187
Type and compositi	on of actors (including	openness and roles)		
Partners: N.A., no common set of actors that engage in planning and implementation Priority setting: open to all, part of Horizon Europe Strategic planning Participation in R&I activities: fully open in line with standard Horizon Europe rules	Partners: Suitable for all types: private and/or public partners, foundations Priority setting: Driven by partners, open stakeholder consultation, MS in comitology Participation in R&I activities: fully open in line with standard Horizon Europe rules	Partners: core of national funding bodies or governmental research organisations Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: limited, according to national rules of partner countries	Partners: National funding bodies or governmental research organisation Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: fully open in line with standard Horizon Europe rules, but possible derogations	Partners: Suitable for all types: private and/or public partners, foundations Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: fully open in line with standard Horizon Europe rules, but possible derogations
••	ctivities (including add	•	<u> </u>	
Activities: Horizon Europe standards that allow broad range of individual actions Additionality: no additional activities and investments outside the funded projects Limitations: No systemic approach beyond individual actions	Activities: Horizon Europe standard actions that allow broad range of individual actions, support to market, regulatory or policy/ societal uptake Additionality: Activities/investment s of partners, National funding Limitations: Limited systemic approach beyond individual actions.	Activities: Broad, according to rules/programmes of participating States, State-aid rules, support to regulatory or policy/ societal uptake Additionality: National funding Limitations: Scale and scope depend on the participating programmes, often smaller in scale	Activities: Horizon Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to systemic approach Additionality: National funding	Activities: Horizon Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to systemic approach (portfolios of projects, scaling up of results, synergies with other funds. Additionality: Activities/investment of partners/ national funding
Directionality				
Priority setting: Strategic Plan and	Priority setting: Strategic R&I	Priority setting: Strategic R&I	Priority setting: Strategic R&I	Priority setting: Strategic R&I

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¹⁶ The criterion on the ex-ante demonstration of partners' long term commitment depends on a series of factors that are unknown at this stage, and thus fall outside the scope of the analysis.

Baseline: Horizon Europe calls	Option 1: Co- programmed	Option 2: Co- funded	Option 3.1: Institutionalised Article 185	Option 3.2: Institutionalised Article 187
annual work programmes, covering max. 4 years. <u>Limitations:</u> Fully taking into account existing or to be developed SRIA/ roadmap	agenda/ roadmap agreed between partners and COM, covering usually 7 years, including allocation of Union contribution Input to FP annual work programme drafted by partners, finalised by COM (comitology) Objectives and commitments are set in the contractual arrangement.	agenda/ roadmap agreed between partners and COM, covering usually 7 years, including allocation of Union contribution Annual work programme drafted by partners, approved by COM Objectives and commitments are set in the Grant Agreement.	agenda/ roadmap agreed between partners and COM, covering usually 7 years, including allocation of Union contribution Annual work programme drafted by partners, approved by COM Objectives and commitments are set in the legal base.	agenda/ roadmap agreed between partners and COM, covering usually 7 years, including allocation of Union contribution Annual work programme drafted by partners, approved by COM (veto-right in governance) Objectives and commitments are set in the legal base.
Coherence: internal industrial strategies	(Horizon Europe) and	external (other Union	programmes, national	programmes,
Internal: Between different parts of the Annual Work programme can be ensured by COM External: Limited for other Union programmes, no synergies with national/regional programmes and activities	Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Limited synergies with other Union programmes and industrial strategies If MS participate, with national/regional programmes and activities	Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Synergies with national/regional programmes and activities	Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Synergies with national/regional programmes and activities	Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Synergies with other Union programmes and industrial strategies If MS participate, with national/regional programmes and activities

In line with the Better Regulation Framework, the assessment of the effectiveness, efficiency and coherence of each option is made in comparison to the baseline. Therefore, for each of the above criteria, the performance of using traditional calls under Horizon Europe is first estimated and scored 0 to serve as a reference point. When relevant, this estimation also includes the costs/benefits of discontinuing existing implementation structures. The policy options are then scored compared to the baseline with a + and – system along a two-point scale, to indicate limited (+ or -) or high (++ or --) additional/lower performance compared to the baseline. When a policy option is scored 0, this means that its impact is expected to be roughly equal to the baseline option.

On the basis of the evidence collected, the intervention logic of each initiative and the key functionalities needed, the impact assessments first evaluate the **effectiveness** of the various policy options to deliver on their objectives. To be in line with the Horizon Europe impact framework, the fulfilment of the specific objectives of the initiative is translated into 'expected impacts' - how success would look like -, differentiating between scientific, economic/ technological, and societal (including environmental) impacts. Each impact

assessment considers to which extent the different policy options provides the 'key functionalities needed' to achieve the intended objectives. The effectiveness assessment does not use a compound score but shows how the options would deliver on the different types of expected impacts. This is done to increase transparency and accuracy in the assessment of options¹⁷.

A similar approach is followed to evaluate the coherence of options with the overarching objectives of the EU's R&I policy, and distinguishes between **internal** and **external coherence**. Specifically, internal coherence covers the consistency of the activities that could be implemented with the rest of Horizon Europe, including European Partnerships (any type). External coherence refers to the potential for synergies and/or complementarities (including risks of overlaps/gaps) of the initiative with its external environment, including with other programmes under the MFF 2021-27, but also the framework conditions at European, national or regional level (incl. regulatory aspects, standardisation).

To compare the expected costs and benefits of each option (efficiency), the thematic impact assessments broadly follow a cost-effectiveness approach to establish to which extent the intended objectives can be achieved for a given cost. A preliminary step in this process is to obtain a measure of the expected costs of the policy options, to be used in the thematic assessments. As the options correspond to different implementation modes, relevant cost categories generally include the costs of setting-up and running an initiative. For instance, setup costs includes items such as the preparation of a European Partnership proposal and the preparation of an implementation structure. The running costs include the annual work programme preparation costs. Where a Partnership already exists, discontinuation costs and cost-savings are also taken into account¹⁹. The table below provides an overview of the cost categories used in the impact assessment and a qualitative scoring of their intensity when compared to the baseline option (traditional calls). Providing a monetised value for these average static costs would have been misleading, because of the different features and needs of each candidate initiative.²⁰ The table shows the overall administrative, operational and coordination costs of the various options. These costs are then put into context in the impact assessments to reflect the expected co-financing rates and the total budget available for each of the policy options, assuming a common Union contribution (cost-efficiency):

- The costs related to the baseline scenario (traditional calls under Horizon Europe) are pre-dominantly the costs of implementing the respective Union contribution via calls and project, managed by the executive agencies (around 4%, efficiency of 96% for the overall investment).
- For a Co-Programmed partnership the costs of preparation and implementation

¹⁷ In the thematic impact assessments, scores are justified in a detailed manner to avoid arbitrariness and spurious accuracy. A qualitative or even quantitative explanation is provided of why certain scores were given to specific impacts, and why one option scores better or worse than others.

¹⁸ For further details, see Better Regulation Toolbox # 57.

¹⁹ Discontinuation costs will bear winding down and social discontinuation costs and vary depending on e.g. the number of full-time-equivalent (FTEs) staff concerned, the type of contract (staff category and duration) and applicable rules on termination (e.g. contracts under Belgian law or other). If buildings are being rented, the cost of rental termination also apply. As rental contracts are normally tied to the expected duration of the current initiatives, these termination costs are likely to be very limited. In parallel, there would also be financial cost-savings related to the closing of the structure, related to operations, staff and coordination costs in particular. This is developed further in the individual efficiency assessments.

²⁰ A complete presentation of the methodology developed to assess costs as well as the sources used is described in the external study supporting this impact assessment (Technopolis Group, 2020).

increase only marginally compared to the baseline (<1%),²¹ but lead to an additional R&I investment of at least the same amount than the Union contribution²² (efficiency of 98% for the overall investment).

- For a Co-Funded partnership the additional R&I investment by Member States accounts for 2,3 times the Union contribution²³. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the national programmes, can be estimated at 6% of the Union contribution (efficiency of 98% related to the overall investment).²⁴
- For an Article 185 initiative the additional R&I investment by Member States is equal to the Union contribution²⁵. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the dedicated implementation structure, can be estimated at 7% of the Union contribution (efficiency of 96% related to the overall investment).
- For an Article 187 initiative the additional R&I investment by partners is equal to the Union contribution²⁶. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the dedicated implementation structure, can be estimated at 9% of the Union contribution (efficiency of 94% related to the overall investment).

Figure 4 - Intensity of additional costs compared with Horizon Europe Calls (for Partners, stakeholders, public and EU)

Cost items	Baseline: traditional calls	Option 1: Coprogrammed	Option 2 Co-funded	Option 3a - Art. 185	Option 3b -Art. 187
Preparation and set-up costs					
Preparation of a partnership proposal (partners and EC)	0		$\uparrow \uparrow$		
Set-up of a dedicated implementation structure		0		Existing: ↑ New: ↑↑	Existing: ↑↑ New: ↑↑↑
Preparation of the SRIA / roadmap	0		$\uparrow \uparrow$		
Ex-ante Impact Assessment for partnership	0			↑	
Preparation of EC proposal and negotiation		0		$\uparrow \uparrow$	↑
Running costs (Annual cycle of implementa	ntion)				
Annual Work Programme preparation	0		1		
Call and project implementation	0	0 In case of MS contributions: ↑	↑	1	↑
Cost to applicants	Comparable, unless there are strong arguments of major differences in oversubscription			fferences in	

²¹ Specifically, some additional set-up costs linked for example to the creation of a strategic research and innovation agenda (SRIA) and additional running costs linked with the partners role in the creation of the annual work programmes and the Commission's additional supervisory responsibilities. A CPP will have lower overall costs than each of the other types of European Partnership, as it will function with a smaller governance and implementation structure than will be required for a Co-Funded Partnership or an Institutionalised Partnership and – related to this – its calls will be operated through the existing HEU agencies and RDI infrastructure and systems

²² Minimum contributions from partners equal to the Union contribution.

²³ Based on the default funding rate for programme co-fund actions of 30%, partners contribute with 70% of the total investment

These costs reflect set-up costs and additional running costs for partners, and the Commission, of the distributed, multi-agency implementation model.

²⁵ Based on the minimum requirement in the legal basis that partners contribute at least 50% of the budget.

²⁶ Based on the minimum requirement in the legal basis that partners contribute at least 50% of the budget.

Cost items	Baseline: traditional calls	Option 1: Coprogrammed	Option 2 Co-funded	Option 3a - Art. 185	Option 3b -Art. 187
Partners costs not covered by the above	0	\uparrow	0	\uparrow	↑
Additional EC costs (e.g. supervision)	0	\uparrow	\uparrow	↑	$\uparrow \uparrow$
Winding down costs					
EC		0			$\uparrow\uparrow\uparrow$
Partners	0	\uparrow	0	\uparrow	↑

Notes: 0: no additional costs, as compared with the baseline; \uparrow : minor additional costs, as compared with the baseline; $\uparrow \uparrow$: medium additional costs, as compared with the baseline; $\uparrow \uparrow \uparrow$: higher costs, as compared with the baseline.

The cost categories estimated for the common model are then used to develop a scorecard analysis and further refine the assessment of options for each of the 12 candidate Institutionalised Partnerships. Specifically, the scores related to the set-up and implementation costs are used in the thematic impact assessments to consider the scale of the expected benefits and thereby allow a simple "value for money" analysis (**cost-effectiveness**). In carrying out the scoring of options, the results of fieldwork, desk research and stakeholder consultation undertaken and taken into account.

3. METHOD FOR IDENTIFYING THE PREFERRED OPTION – THE SCORECARD ANALYSIS

For the **identification of the preferred option**, a scorecard analysis is used to build a hierarchy of the options by individual criterion and overall in order to identify a single preferred policy option or in case of an inconclusive comparison of options, a number of 'retained' options or hybrid. This exercise supports the systematic appraisal of alternative options across multiple types of monetary, non-monetary and qualitative dimensions. It also allows for easy visualisation of the pros and cons of each option. Each option is attributed a score of the adjudged performance against each criterion with the three broad appraisal dimensions of effectiveness, efficiency and coherence.

This scorecard approach also relies on a standard cost model developed for the external study supporting the impact assessment, as illustrated in Figure 5. Specifically, the scores related to the set-up and implementation costs are used in the thematic impact assessments to consider the scale of the expected benefits and thereby allow a simple "value for money" analysis (**cost-effectiveness**). In carrying out the scoring of options, the results of fieldwork, desk research and stakeholder consultation undertaken and taken into account.

These costs essentially refer to the administrative, operational and coordination costs of the various options. The figure shows how the scoring of costs range from a value of 0, in case an option does not entail any additional costs compared to the baseline (traditional calls), to a score of (-) for options introducing limited additional costs relative to the baseline and a score of (-) when substantial additional costs are expected in comparison with the baseline. Should the costs of a policy option be lower than those of the baseline, (+) and (++) are used.

It is considered that while there is a clear gradation in the overall costs of the policy options, the cost differentials are less marked when one takes into account the expected co-financing rates and the total budget available for each of the policy options, assuming a common Union contribution. From this perspective, there are only one or two percentage points that split the most cost-efficient policy options – the baseline (traditional calls) and the Co-Programmed policy options – and the least cost-efficient – the Institutionalised Partnership option. A score of + is therefore assigned for **cost-efficiency** to the Co-Programmed and Co-Funded options,

a score of 0 to the Article 185 option and a score of (-) for the Article 187 Institutionalised Partnership policy option 27 .

Figure 5: Matrix on 'overall costs' and 'adjusted cost scoring'

	Baseline: Horizon Europe calls	Option 1: Co- programmed	Option 2: Co- funded	Option 3a: Institutionalised 185	Option 3b: Institutionalised 187
Administrative, operational and coordination costs	0	(0)	(-)	()	()
Administrative, operational and coordination costs adjusted per expected co-funding (i.e. cost- efficiency)	0	(+)	(+)	(0)	(-)

Notes: Score 0 = same costs as for the baseline; score (-) = limited additional costs compared to baseline; score (-) = substantial additional costs compared to baseline.; score (+) = lower costs compared to baseline

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 $^{^{27}}$ The baseline (traditional calls) is scored 0, as explained above.

Subsidiarity Grid Annex 5

1. Can the Union act? What is the legal basis and competence of the Unions' intended action?

1.1 Which article(s) of the Treaty are used to support the legislative proposal or policy initiative?

This proposal is based on (1) Article 185 TFEU which stipulates that in implementing the multiannual framework programme, the Union may make provision, in agreement with the Member States concerned, for participation in research and development programmes undertaken by several Member States, including participation in the structures created for the execution of those programmes; and (2) Article 187 TFEU according to which the Union may set up joint undertakings or any other structure necessary for the efficient execution of Union research, technological development and demonstration programmes (both Articles are under Title XIX of the TFEU - Research and Technological Development and Space).

The proposal aims to implement Article 8 of the Commission proposal for Horizon Europe the future EU research and innovation (R&I) programme for 2021-2027, according to which, "European Partnerships shall be established for addressing European or global challenges" only in cases where they will more effectively achieve objectives of Horizon Europe than the Union alone and when compared to other forms of support of the Framework programme". The Horizon Europe proposal has received the political agreement of the Council and the European Parliament.

1.2 Is the Union competence represented by this Treaty article exclusive, shared or supporting in nature?

Research is a shared competence between the EU and its Member States according to the TFEU. Article 4 (3) specifies that in the areas of research, technological development and space, the European Union can carry out specific activities, including defining and implementing programmes, without prejudice to the Member States' freedom to act in the same areas.

Subsidiarity does not apply for policy areas where the Union has exclusive competence as defined in Article 3 TFEU²⁸. It is the specific legal basis which determines whether the proposal falls under the subsidiarity control mechanism. Article 4 TFEU²⁹ sets out the areas where competence is shared between the Union and the Member States. Article 6 TFEU³⁰ sets out the areas for which the Unions has competence only to support the actions of the Member States.

https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12008E004&from=EN https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12008E006:EN:HTML

²⁸ https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12008E003&from=EN

2. Subsidiarity Principle: Why should the EU act?

2.1 Does the proposal fulfil the procedural requirements of Protocol No. 2³¹:

- Has there been a wide consultation before proposing the act?
- Is there a detailed statement with qualitative and, where possible, quantitative indicators allowing an appraisal of whether the action can best be achieved at Union level?

This proposal and the accompanying impact assessment were supported by a wide consultation of stakeholders, both during the preparation of the Horizon Europe proposal and - later on, all the candidates for European Partnerships. Member States were consulted via the Shadow Strategic configuration of the Horizon Europe Programme Committee. On candidates for institutionalised Partnerships based on Article 185/187 of the TFEU, an Open Public Consultation (OPC) was held between 11 September and 6 November 2019. Over 1 600 replies were received. In addition, targeted consultation activities were undertaken to prepare the present impact assessment. In particular, for each of the candidate partnerships, an external consultant interviewed a representative sample of stakeholders. The need for EU action as well as its added value were covered in those interviews.

The explanatory memorandum and the impact assessment (horizontal part, Section 3) contain a dedicated section on the principle of subsidiarity, as explained in question 2.2 below.

2.2 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the conformity with the principle of subsidiarity?

The impact assessment accompanying the proposal features a horizontal part on relevant common elements to all the candidate partnerships, including the conformity of the proposed initiative with the principle of subsidiarity (Section 3). Moreover, the individual assessments of each candidate partnership include additional details on subsidiarity, touching in particular on the specificities of a candidate partnership that could not be adequately reflected in the horizontal part of the impact assessment. This will also be reflected in the explanatory memorandum.

2.3 Based on the answers to the questions below, can the objectives of the proposed action be achieved sufficiently by the Member States acting alone (necessity for EU action)?

National action alone cannot achieve the scale, speed and scope of support to R&I needed for the EU to meet its long-term Treaty objectives, to deliver on the EU's strategic policy priorities (including the climate and energy goals set out in the Paris Agreement, and the European Green Deal), and to contribute to tackling global challenges and meeting the

³¹ https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12016E/PRO/02&from=EN

Sustainable Development Goals (SDGs).

(a) Are there significant/appreciable transnational/cross-border aspects to the problems being tackled? Have these been quantified?

The thematic areas covered by the candidate partnerships feature a series of challenges in terms of cross-border/transnational aspects, need to pool resources, need for a critical mass to meet intended policy objectives, need to coordinate different types of actors (e.g. academia, industry, national and regional authorities) across different sectors of the economy and society, which cannot be tackled to the same degree by Member States alone. This is particularly true for the research and innovation (R&I) dimension of the proposed initiative: the importance of a multi-centre and interdisciplinary approach, cross-country data collection and research, and the need to develop and share new knowledge in a timely and coordinated manner to avoid duplication of efforts are key to achieve high quality results and impact. The Interim Evaluation of Horizon 2020 and the impact assessment of Horizon Europe provide extensive qualitative and quantitative evidence on the above points. In addition, Sections 1 and 2 of the individual impact assessments on the candidate partnerships include more detail on the necessity to act at EU-level in specific thematic areas. Finally, it is worth noting that not all Member States have the same capacity or R&I intensity to act on these challenges. As the desired policy objectives can be fully achieved only if the intended benefits are widespread across the Member States, this requires action at the EU-level.

(b) Would national action or the absence of the EU level action conflict with core objectives of the Treaty³² or significantly damage the interests of other Member States?

As per Article 4(3) TFEU, national action does not conflict with core objectives of the Treaty in the area of R&I. The absence of EU level action in this area would however prevent the achievement of core objectives of the Treaty. Indeed, national action alone cannot achieve the scale, speed and scope of support to R&I needed for the EU to meet its long-term Treaty objectives on e.g. competitiveness, to deliver on the EU's strategic policy priorities, and to contribute to tackling global challenges and meet the Sustainable Development Goals (SDGs).

(c) To what extent do Member States have the ability or possibility to enact appropriate measures?

As foreseen by Article 4(3) TFEU, this proposal does not hamper Member States' ability to enact appropriate measures in the field of R&I. However, the scale and complexity of the policy objectives pursued by the present initiative cannot be fully addressed by acting at national level alone.

(d) How does the problem and its causes (e.g. negative externalities, spill-over effects) vary across the national, regional and local levels of the EU?

³² https://europa.eu/european-union/about-eu/eu-in-brief_en

As described in the horizontal part of the impact assessment accompanying the present proposal, several problems (e.g. on competitiveness, global challenges, demographic change) and their underlying causes affect the EU as a whole rather than individual Member States. Where important differences between Member States are present, these are described in Sections 1 and 2 of the individual impact assessments.

(e) Is the problem widespread across the EU or limited to a few Member States?

The problem of coordinating R&I efforts in the thematic areas covered by the candidate partnerships affects all Member States, albeit to different degrees. However, from a general EU perspective, available evidence shows that the EU as a whole needs to step up efforts and investments in thematic areas that are crucial to tackle present and future policy challenges on several fronts, e.g. ageing population, global technological trends, and climate change to name a few. The way these problems affect the EU and its Member States is described in the horizontal part of the impact assessment and in Sections 1 and 2 of the individual impact assessments.

(f) Are Member States overstretched in achieving the objectives of the planned measure?

As indicated in the horizontal part of the impact assessment and in Sections 1 and 2 of the individual assessments, the sheer scale, speed and scope of the needed support to R&I would overstretch national resources, without guaranteeing the achievement of the intended objectives. Acting at EU-level would achieve greater impact in a more effective and efficient manner.

(g) How do the views/preferred courses of action of national, regional and local authorities differ across the EU?

No specific differences between the views of national, regional and local authorities emerged from the stakeholder consultation.

2.4 Based on the answer to the questions below, can the objectives of the proposed action be better achieved at Union level by reason of scale or effects of that action (EU added value)?

EU funded R&I activities, including those covered by the present proposal, produce demonstrable benefits compared to the corresponding national and regional initiatives, due to the scale, speed and scope achievable by acting at the EU level. In addition, the proposed initiatives should be seen as complementary and reinforcing national and sub-national initiatives in the same area.

(a) Are there clear benefits from EU level action?

Quantitative and qualitative evidence of the benefits of EU level action are available in the

interim evaluation of Horizon 2020 and in the impact assessment of Horizon Europe, among others. An analysis of the emerging challenges in each thematic areas, of the EU's competitive positioning, as well as feedback gathered from different types of stakeholders for the present impact assessment indicate that EU level action remains appropriate also for the present proposal. In addition, the benefits of acting at EU-level have been illustrated by the success and the impact achieved by the predecessors to the proposed initiative.

(b) Are there economies of scale? Can the objectives be met more efficiently at EU level (larger benefits per unit cost)? Will the functioning of the internal market be improved?

EU funded R&I activities, including those covered by the present proposal, produce demonstrable benefits compared to the corresponding national and regional initiatives, due to the scale, speed and scope achievable by acting at the EU level. This is the case both in terms of effectiveness in achieving intended policy objectives, but also in terms of efficiency. Positive impact is also visible in terms of competitiveness: recent data on EU funded R&I activities indicate that EU-funded teams grow 11.8% faster and are around 40% more likely to be granted patents or produce patents applications than non-EU funded teams. Efficiency gains are also visible in terms of dissemination of results to users beyond national borders, including SMEs and citizens. EU funded R&I is more effective in leveraging private investment. Finally, there are clear additionality benefits (i.e. EU R&I funding does not displace or replace national funding), as the EU focuses on projects that are unlikely to be funded at national or regional level. Overall, this is beneficial to the functioning of the internal market in several respects, including human capital reinforcement through mobility and training, the removal of barriers to cross-border activity for economic players including SMEs, easier access to finance and to relevant knowledge and research, and increased competition in the area of R&I.

(c) What are the benefits in replacing different national policies and rules with a more homogenous policy approach?

A homogeneous policy approach in the various thematic areas covered by the present proposal would reduce fragmentation and increase efficiency and effectiveness in meeting the intended policy objectives. Indeed fragmentation, persisting barriers in the internal market and differences in the resources available to Member States are some of the key problems that stand in the way of fully achieving the intended policy objectives and reaching the required critical mass to obtain tangible results. Specific detail on how these issues differ in each thematic area are illustrated in Sections 1 and 2 of the individual impact assessments, so as to reflect the specificities of each case.

(d) Do the benefits of EU-level action outweigh the loss of competence of the Member States and the local and regional authorities (beyond the costs and benefits of acting at national, regional and local levels)?

The proposed initiative does not lead to a loss of competence of the Member States. In fact, the proposed initiative should be seen as complementary and reinforcing national and sub-

national initiatives in the same area. Previous quantitative and qualitative assessments of Horizon Europe and Horizon 2020 have shown that the proposed EU-level action do not displace national ones and tend to concentrate on initiatives that would not have been funded by the Member States themselves, or would not have reached the same scale and ambition without EU-level intervention, due to their complexity and trans-national nature.

(e) Will there be improved legal clarity for those having to implement the legislation?

Yes. The proposed initiatives will be implemented in line with the Horizon Europe single set of rules for participation; this will ensure increased clarity and legal certainty for end beneficiaries, other stakeholders and programme administrators. It will also reduce the administrative burden for beneficiaries, and for the Commission services. In addition, the accessibility and attractiveness of the broader Horizon Europe programme, in particular for applicants with limited resources, would be sustained.

- 3. Proportionality: How the EU should act
- 3.1 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the proportionality of the proposal and a statement allowing appraisal of the compliance of the proposal with the principle of proportionality?

The principle of proportionality underpins the entire analysis of the candidate partnerships. Specifically, the analysis included in the accompanying impact assessment is structured along the following logic: 1. Justification of the use of a partnership approach in a given area (including considerations on additionality, directionality, link with strategic priorities) instead of other forms of intervention available under Horizon Europe; 2. If the partnership approach is deemed appropriate, proportionality considerations guide the assessment of which type of partnership intervention (collaborative calls, co-programmed, co-funded or institutionalised partnership) is most effective in achieving the objectives. This will also be reflected in the explanatory memorandum.

3.2 Based on the answers to the questions below and information available from any impact assessment, the explanatory memorandum or other sources, is the proposed action an appropriate way to achieve the intended objectives?

The proposed initiative only focuses on areas where there is a demonstrable advantage in acting at the EU-level due to the scale, speed and scope of the efforts needed for the EU to meet its long-term Treaty objectives and deliver on its strategic policy priorities and commitments. In addition, the present proposal leaves full freedom to the Member States to pursue their own actions in the policy areas concerned. This will also be reflected in the explanatory memorandum.

(a) Is the initiative limited to those aspects that Member States cannot achieve

satisfactorily on their own, and where the Union can do better?

The proposed initiative only focuses on areas where there is a demonstrable advantage in acting at the EU-level due to the scale, speed and scope of the efforts needed for the EU to meet its long-term Treaty objectives and deliver on its strategic policy priorities and commitments.

(b) Is the form of Union action (choice of instrument) justified, as simple as possible, and coherent with the satisfactory achievement of, and ensuring compliance with the objectives pursued (e.g. choice between regulation, (framework) directive, recommendation, or alternative regulatory methods such as co-legislation, etc.)?

For each of the candidate partnerships, the analysis carried out in the accompanying impact assessment has explored several options for implementation. A comparative assessment of the merits of each option also included an analysis of the simplicity of the intervention, its proportionality and effectiveness in achieving the intended objectives. This is reflected in the fact that a tailored approach has been suggested for each candidate partnership, ranging from looser forms of cooperation to more institutionalised ones, depending on the intended policy objectives, specific challenges, and desired outcome identified in each case.

(c) Does the Union action leave as much scope for national decision as possible while achieving satisfactorily the objectives set? (e.g. is it possible to limit the European action to minimum standards or use a less stringent policy instrument or approach?)

The proposed approach leaves full freedom to the Member States to pursue their own actions in the policy areas covered by the present proposal.

(d) Does the initiative create financial or administrative cost for the Union, national governments, regional or local authorities, economic operators or citizens? Are these costs commensurate with the objective to be achieved?

The proposed initiatives do create financial and administrative costs for the Union, national governments and, depending on the chosen mode of implementation, for regional and local authorities. In addition, economic operators and other stakeholders potentially involved in the candidate partnerships will also incur some costs linked to implementation. The financial cost of the proposed initiative is covered under the Horizon Europe programme. Its exact amount is still subject to political decision. As regards the candidate partnerships and the different modes of implementation (co-programmed, co-funded, institutionalised), the relevant costs and benefits are assessed in the individual impact assessments covering each candidate partnership. The additional administrative costs of implementation via partnerships are limited, when compared to the administrative costs of implementation through traditional calls. As indicated by comparable experience with previous initiatives and in feedback provided by a variety of stakeholders, these costs are expected to be fully justified by the benefits expected from the proposed initiative. Where available, additional details on costs are provided in Annex 3 of the impact assessment.

(e) While respecting the Union law, have special circumstances applying in individual Member States been taken into account?

Where relevant, differences between Member States in capacity and stage of advancement of R&I in specific thematic areas have been taken into account in the individual impact assessments.

Annex 6 Additional background information

1. BACKGROUND INFORMATION FOR ALL INITIATIVES

1.1. Selection criteria of European Partnerships

Partnerships based on Article 185 and 187 TFEU shall be implemented only where other parts of the Horizon Europe programme, including other forms of European Partnerships would not achieve the objectives or would not generate the necessary expected impacts, and if justified by a long-term perspective and high degree of integration. At the core of this impact assessment is therefore the need to demonstrate that the impacts generated through a Partnership approach go beyond what could be achieved with traditional calls under the Framework Programme – the Baseline Option. Secondly, it needs to assess if using the Institutionalised form of a Partnership is justified for addressing the priority.

The necessity test for a European Partnership (as set out in the Horizon Europe regulation) has two levels:

- 1. The justification for implementing a priority with a European Partnership to address Horizon Europe and EU priorities. This is linked to demonstrating that a European Partnership can produce added value beyond what can be achieved through other Framework Programme modalities, notably traditional calls in the work programmes (Option 0 Baseline).
- 2. The justification for the use of the form of Institutionalised Partnership: Once it has been demonstrated that a partnerships approach is justified, co-programmed and/or co-funded forms are considered for addressing the priorities as they are administratively lighter, more agile and easier to set-up (Options 1 and/or 2). As Institutionalised Partnerships require setting up a legal framework and the creation of a dedicated implementation structure, they have to justify higher set-up efforts by demonstrating that it will deliver the expected impacts in a more effective and efficient way, and that a long-term perspective and high degree of integration is required (Option 3).

The outcomes of the 'necessity test' is presented together with the preferred option.

Figure 6 Horizon Europe selection criteria for the European Partnerships

Common selection criteria & principles	Specifications
1. More effective (Union added value) clear	Delivering on global challenges and research and innovation objectives
impacts for the EU and its citizens	Securing EU competitiveness
	Securing sustainability
	Contributing to the strengthening of the European Research and Innovation Area
	Where relevant, contributing to international commitments
2. Coherence and	Within the EU research and innovation landscape

Common selection criteria & principles	Specifications
synergies	Coordination and complementarity with Union, local, regional, national and, where relevant, international initiatives or other partnerships and missions
3. Transparency and openness	Identification of priorities and objectives in terms of expected results and impacts
	Involvement of partners and stakeholders from across the entire value chain, from different sectors, backgrounds and disciplines, including international ones when relevant and not interfering with European competitiveness
	Clear modalities for promoting participation of smes and for disseminating and exploiting results, notably by smes, including through intermediary organisations
4. Additionality	Common strategic vision of the purpose of the European Partnership
and directionality	Approaches to ensure flexibility of implementation and to adjust to changing policy, societal and/or market needs, or scientific advances, to increase policy coherence between regional, national and EU level
	Demonstration of expected qualitative and significant quantitative leverage effects, including a method for the measurement of key performance indicators
	Exit-strategy and measures for phasing-out from the Programme
5. Long-term	A minimum share of public and/or private investments
commitment of all the involved parties	In the case of institutionalised European Partnerships, established in accordance with article 185 or 187 TFEU, the financial and/or in-kind, contributions from partners other than the Union, will at least be equal to 50% and may reach up to 75% of the aggregated European Partnership budgetary commitments

1.2. Overview of potential functions for a common back office among Joint Undertakings

Functions	Current situation	Option of joint back- office	Comments
Organising calls for grant and proposal evaluations	Each JU organises this independently.	A central organisation of evaluation, logistics, contracting evaluators, managing the data of the evaluation results Central database of potential evaluators with domain expertise in thematic areas of partnerships	The evaluations would still need to be supervised by the Scientific staff of the individual Joint Undertakings (consensus meetings of expert evaluators etc)
Human Resources related matters	Each JU has own HR policy and resources Quite some resources spent on recruitment in some JUs Some HR facilities are procured from external contractors Some JUs have a Service Level	More generic resources and expertise for HR matters More consistency in HR policy Shared HR investment for specialised expertise	Ensuring consistency with EC HR policies is already in place

	Agreement with COM for HR	(IP and legal)	
Financial management	Each JU conducts own financial contract management; differences between JUs Each JU is audited separately. Auditing at project level more frequent than in other Horizon 2020 parts and outsourced by JUs thus differences ECA: too many audits on JUs	Financial management by one core team of financial staff Would reduce the number of interfaces for audits and simplifies the auditing of the all JUs Harmonisation of project auditing	Simplifies the harmonisation of financial management across JUs in line with Horizon Europe
Communication (internal and external)	Each JU has a separate communication strategies, teams and resources	A common back-office can support activities such as event organisation, dissemination of results, setting up website communication Can help create a more visible Partnership brand	A considerable share of communication activity is partnership specific (addressing particular target groups, synthesising project results) however there are generic communication activities that can be shared Needs to avoid duplication of efforts
Data management on calls, project portfolios, information on project results	Most JUs but not all use e- Corda for project data Overall IT integration of JUs still difficult	Harmonised data management Reduction of IT systems and support that is procured	This will need to happen regardless of the common back office but will likely be more smooth if managed centrally

2. BACKGROUND INFORMATION FOR THIS SPECIFIC INITIATIVE

Table 1: EU28 share of the world production of electronics for downstream industries and mass-market consumer devices — shares in 2018

munici consumo de reces	511011 05 111 2010				
Sector	Semiconductors	Electronic boards	Electronic equipment (embedded and stand- alone)	Downstream industries (auto, aerospace, etc)	Services related to end user equipment
Automotive	22%	22%	27%	20%	22%
Industrial equipment	14%	17%	20%	18%	13%
Aerospace, defence & security	15%	15%	22%	22%	19%
Health and care	20%	20%	19%		20%
Home appliances	4%	8%	17%		
Audio & video	5%	7%	11%		
Computers & data processing	4%	5%	5%		5%
Telecommunications	5%	4%	4%		18%

Source: European Commission. (2019). Study on Emerging technologies in electronic components and systems (ECS) - Opportunities ahead. SMART 2018-0005.

The darker area presents segments where Europe has a strong position with the highest spillover to downstream industries.

Europe risks to be a follower in emerging key digital technologies

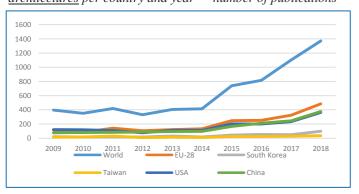
Scientific publications produced per region

Figure 1: Production of publications on microelectronics per country and year — number of publications (2009-2018)



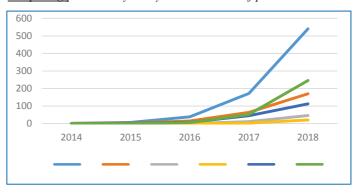
Source: Calculations by Technopolis Group based on Scopus

Figure 3: Growth in production of publications on <u>computer</u> <u>architectures</u> per country and year — number of publications



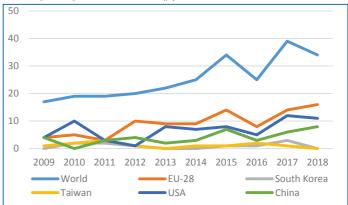
Source: Calculations by Technopolis Group based on Scopus data

Figure 2: Growth in production of publications on <u>edge</u> <u>computing</u> per country and year — number of publications



Source: Calculations by Technopolis Group based on Scopus data

Figure 4: Growth in production of publications on <u>AI</u> per country and year — number of publications



Source: Calculations by Technopolis Group based on Scopus data

The analysis of scientific publications indicate that Europe retains a strong position in microelectronics research³³, producing 31% of publications in the period 2009-2018 (Figure 5). China (25%) comes second followed by the US (24%).

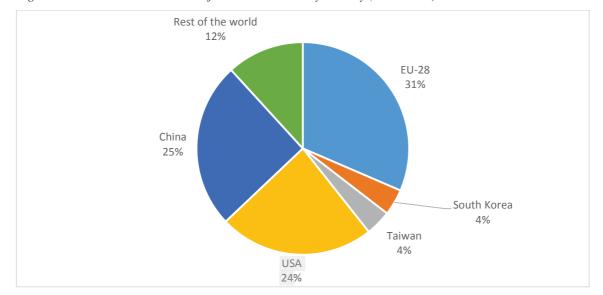


Figure 5: Publications in the area of microelectronics by country (2009-2018)

Source: Calculations by Technopolis Group based on Scopus data.

However, looking at the performance of MS, and comparing their performance against other countries, China is the leader followed by the US (Figure 2). The two top European countries, Germany and France, remain far behind. Comparing the two figures and observing the significant differences in the capacity of individual countries, illustrates the limitations of thinking national, while it also sketches out possibilities and the **added value of pooling together resources at the European level**.

Targeted impacts for the initiative

capabilities on emerging

technologies addressing

energy efficiency and

environmental protection

The initiative is estimated to lead to two key scientific impacts, as illustrated below:



Strengthened research capacity in

RTOs and companies in the area of

novel computing paradigms, Al and related software

Figure 6: Impact pathway leading to scientific impacts

cooperation that strengthen the

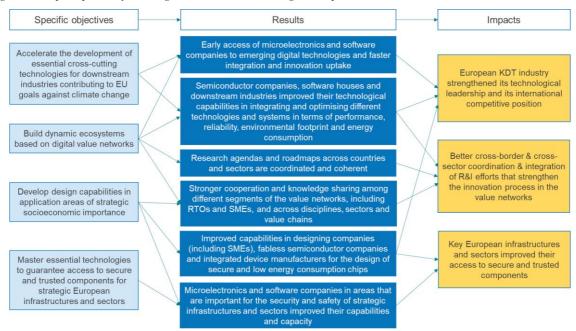
exchange of knowledge within the

value networks

³³ The area of microelectronics was defined by a cloud of keywords suggested by the Expert Panel. The other technological areas included in the analysis were defined in a similar way.

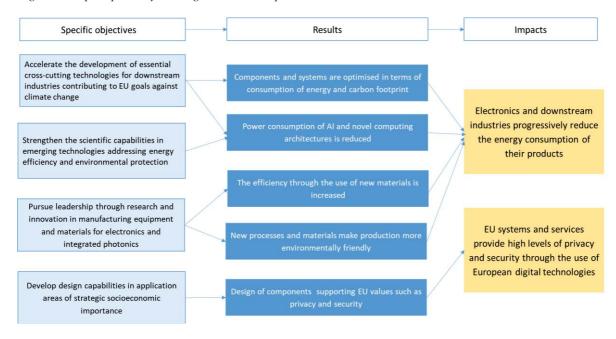
The expected key economic/technological impacts of the initiative are mapped in Figure 7.

Figure 7: Impact pathway leading to economic/technological impacts



The scientific and economic/technological impacts will also support the attainment of societal impacts as shown in Figure 8.

Figure 8: Impact pathway leading to societal impacts



OPTIONS DISCARDED AT AN EARLY STAGE

Option 2 – Co-funded European Partnership

The Co-funded Partnership is based on a *Grant Agreement* between the Commission and the consortium of partners, resulting from a call for a proposal for a programme co-funded action implementing the European Partnerships in the Horizon Europe Work Programme.

Key characteristics of Option 2 – Co-funded European Partnership

	Implications of option
Enabling appropriate profile of participation (actors involved)	 Partners can include any national funding body or governmental research organisation, Possible to include also other type of actors, including foundations. It is not possible to have the KDT industry associations as partners. Requires substantial national R&I programmes (competitive or institutional) in the field and therefore limited the participation to few Member States with existing national KDT programmes. Usually only legal entities from countries that are part of the consortia can apply to calls launched by the partnership, under national rules.
Supporting implementation of R&I agenda (activities)	 Activities may range from R&I, pilot, deployment actions to training and mobility, dissemination and exploitation, but according to national programmes and rules. The decision and implementation are responsibility of the partners through institutional funding KDT programmes, or by "third parties" receiving financial support, following calls for proposals launched by the consortium. The scale and scope of the initiative is limited and depends on the participating programmes. The resulting funded R&I actions are typically smaller in scale than FP projects.
Ensuring alignment with R&I agenda (directionality)	 The strategic R&I agenda/roadmap is agreed between the Member States and EC without the participation of industry. The annual work programme drafted by partners, approved by EC. Objectives and commitments are set in the Grant Agreement. The coherence of the partnership with other actions of the can be ensured by partners and EC. There are strong synergies with national/regional programmes and activities, and they can be ensured by the Member States. Synergies with other European programmes or industrial strategies are limited.
Securing leveraging effects (additionality)	 Low possibilities for leverage of industry contribution as industry does not participate in the decision making.

Option 3a – Institutionalised European Partnership under Art 185 TFEU

Article 185 of the TFEU is a complex and high-effort arrangement and is based on a Decision by the European Parliament and Council and implemented by dedicated structures created for that purpose. It allows the Union to participate in programmes jointly undertaken by Member States and Associated Countries.

Table 3: Key characteristics of Option 3: Institutionalised Partnership Art 185 TFEU

	Implications of option
Enabling appropriate profile of participation (actors involved)	 Partners can include Member States and Associated Countries. Non-associated third countries can only be included as partners if foreseen in the basic act and subjected to conclusion of dedicated international agreements. Good geographical coverage is required with participation of at least 40% of Member States The existence of substantial national R&I programmes (competitive or institutional) in the field is required Substantial differences can be found between legal entities from Participating States and those from other Member or Associated States in the rules for participation and funding.
Supporting implementation of R&I agenda (activities)	 Horizon Europe's standard actions that allow a broad range of coordinated activities from R&I to uptake apply. In case of implementation based on national rules (subject to derogation) the activities follow the national programmes and rules. The option allows the integration of national funding and Union funding into the joint funding of projects
Ensuring alignment with R&I agenda (directionality)	 The strategic R&I agenda/roadmap is agreed between partners and the EC The objectives and commitments are set in the legal base. The annual work programme is drafted by partners and approved by the EC The commitments include the obligation for financial contributions (e.g. to administrative costs, from national R&I programmes).
Securing leveraging effects (additionality)	National R&I activities can be integrated into the programme, which can then be matched from the EU budget to increase scope and promote transnational cooperation.



Brussels, 23.2.2021 SWD(2021) 37 final

PART 8/19

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT REPORT Accompanying the document

Proposal for a COUNCIL REGULATION establishing the Joint Undertakings under Horizon Europe

European Partnership on Smart Networks and Services

{COM(2021) 87 final} - {SEC(2021) 100 final} - {SWD(2021) 38 final}

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Glossary

Term or acronym	Meaning or definition
EIT	European Institute of Innovation & Technology
R&I	Research and Innovation
SDGs	United Nations Sustainable Development Goals
SMEs	Small and Medium-sized Enterprises
TFEU	Treaty on the Functioning of the European Union

PART 1 - COMMON FOR ALL CANDIDATE INSTITUTIONALISED EUROPEAN PARTNERSHIPS

1. BACKGROUND AND CONTEXT TO EUROPEAN PARTNERSHIPS IN HORIZON EUROPE AND FOCUS OF THE IMPACT ASSESSMENT—WHAT IS DECIDED

1.1. Focus and objectives of the impact assessment

This impact assessment accompanies the Commission proposal for Institutionalised European Partnerships to be funded under Horizon Europe, the 2021-2027 Framework Programme for EU Research and Innovation (R&I). It sets out to help decide in a coordinated manner the right form of implementation for specific candidate initiatives based on a common approach and methodology to individual assessments². It also provides an horizontal perspective on the portfolio of candidate European Partnerships to identify further efficiency and coherence gains for more impact.

European Partnerships are initiatives where the Union, together with private and/or public partners (such as industry, public bodies or foundations) commit to support jointly the development and implementation of an integrated programme of R&I activities. The rationale for establishing such initiatives is to achieve the objectives of Horizon Europe more effectively than what can be attained by other activities of the programme.³

Based on the Horizon Europe Regulation, European Partnerships may be set up using **three different forms**: "Co-funded", "Co-programmed" and "Institutionalised". The setting-up of **Institutionalised Partnerships** involves new EU legislation and the establishment of dedicated implementing structures based on Article 185 or 187 of the Treaty on the Functioning of the EU (TFEU). This requires an impact assessment to be performed.

The Horizon Europe Regulation defines **eight priority areas**, scoping the domains in which Institutionalised Partnerships could be proposed⁴. Across these priority areas, **13 initiatives** have been identified **as suitable candidate initiatives** for Institutionalised Partnerships because of their objectives and scope. This impact assessment aims to identify whether 12 of these initiatives⁵ need to be implemented through this form of implementation and would not deliver equally well with traditional calls of Horizon Europe or other lighter forms of European Partnerships under Horizon Europe. This means assessing whether each of these initiatives meets the necessity test set in the **selection criteria** for European Partnerships in the Horizon Europe Regulation, Annex III.

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¹ Horizon Europe Regulation (common understanding), https://data.consilium.europa.eu/doc/document/ST-7942-2019-INIT/en/pdf

² Based on the European Commission Better Regulation framework (SWD (2017) 350) and supported by an external study coordinated by Technopolis Group (to be published in 2020).

³ For further details on these points, see below Section 1.2.2.

⁴ Set out in the Annex Va of the Horizon Europe Regulation (common understanding). https://data.consilium.europa.eu/doc/document/ST-7942-2019-INIT/en/pdf

⁵ Only 12 are subject to this impact assessment, as one initiative on High Performance Computing has already been subject to an impact assessment in 2017 (SEC(2018) 47).

This assessment is done **without any budgetary consideration**, as the overall budget of the Multiannual Financial Framework of the EU – and hence of Horizon Europe – for the next financing period is not known at this stage.⁶

1.2. The political and legal context

1.2.1. Shift in EU priorities and Horizon Europe framework

European priorities have evolved in the last decades, and reflect the social, economic, and environmental challenges for the EU in the face of global developments. In her Political Guidelines for the new European Commission 2019 – 2024⁷, the new Commission President put forward six overarching priorities, which reach well beyond 2024 in scope⁸. Together with the Sustainable Development Goals (SDGs), these priorities will shape future EU policy responses to the challenges Europe faces, and thus also give direction to EU research and innovation.

As part of the Multi-annual Financial Framework (MFF) 2021-27 the new EU Framework Programme for Research and Innovation Horizon Europe will play a pivotal role for Europe to lead the social, economic, and environmental transitions needed to achieve these European policy priorities. It will be more impact driven with a strong focus on delivering European added value, but also be more effective and efficient in its implementation. Horizon Europe finds its rationale in the daunting challenges that the EU is facing, which call for "a radical new approach to developing and deploying new technologies and innovative solutions for citizens and the planet on a scale and at a speed never achieved before, and to adapting our policy and economic framework to turn global threats into new opportunities for our society and economy, citizens and businesses." While Horizon Europe continues the efforts of strengthening the scientific and technological bases of the Union and foster competitiveness, a more strategic and impact-based approach to EU R&I investment is taken. Consequently, the objectives of Horizon Europe highlight the need to deliver on the Union strategic priorities and contribute to the realisation of EU objectives and policies, contribute to tackling global challenges, including the Sustainable Development Goals by following the principles of the Agenda 2030 and the Paris Agreement.

In this context, at least 35 % of the expenditure from actions under the Horizon Europe Programme will have to contribute to climate action. Furthermore, a Strategic Plan is codesigned with stakeholders to identify key strategic orientations for R&I support for 2021-2024 in line with the EU priorities. In the Orientations towards the first Strategic Plan for Horizon Europe, the need to strategically prioritise and "direct a substantial part of the funds towards the areas where we believe they will matter the most" is emphasised. The Orientations

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⁶ EU budget commitments to the European Partnership candidates can only be discussed and decided following the political agreement on the overall Multiannual Financial Framework and Horizon Europe budgetary envelopes. The level of EU contribution for individual partnerships should be determined once there are agreed objectives, and clear commitments from partners. Importantly, there is a ceiling to the partnership budgets in Pillar II of Horizon Europe (the legal proposal specifies that the majority of the budget in pillar II shall be allocated to actions outside of European Partnerships).

https://ec.europa.eu/info/strategy/priorities-2019-2024 en

⁸ 1.A European Green Deal; An economy that works for people; A Europe fit for the Digital Age; Promoting our European way of life; A Stronger Europe in the World; and 6.A New push for European Democracy

⁹ EC (2018) A Modern Budget for a Union that Protects, Empowers and Defends. The Multiannual Financial Framework for 2021-2027. Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, COM(2018) 321 final

¹⁰ Article 3, Common understanding regarding the proposal for Horizon Europe Framework Programme.

specify, that actions under Pillar II of Horizon Europe "Global Challenges and European Industrial Competitiveness" will target only selected themes of especially high impact that significantly contribute to delivering on the political priorities of the Union. Most of the candidate European Partnerships fall under this Pillar.

1.2.2. Key evolutions in the approach to partnerships in Horizon Europe

Since their start in 1984 the successive set of Framework Programmes uses a variety of instruments and approaches to support R&I activities, address global challenges and industrial competitiveness. Collaborative, competition-based and excellence-driven R&I projects funded through Work Programmes are the most traditional and long-standing approach for implementation. Since 2002, available tools also include **partnerships**, whereby the Union together with private and/or public partners commit to jointly support the development and implementation of a R&I programme. These were introduced as part of creating the European Research Area (ERA) to align national strategies and overcome fragmentation of research effort towards an increased scientific, managerial and financial integration of European research and innovation. Interoperable and integrated national research systems would allow for better flows of knowledge, technology and people. Since then, the core activities of the partnerships consist of building critical mass mainly through collaborative projects, jointly developing visions, and setting strategic agendas.

As analysed in the **interim evaluation of Horizon 2020**¹¹, a considerable repertoire of partnership initiatives have been introduced over time, with 8 forms of implementation¹² and close to 120 partnership initiatives running under Horizon 2020 - without clear exit strategies and concerns about their degree of coherence, openness and transparency. Even if it is recognised that these initiatives allow setting long-term agendas, structuring R&I cooperation between otherwise dispersed actors, and leveraging additional investments, the evaluation points to the complexity generated by the proliferation of instruments and initiatives, and their insufficient contribution to policies at EU and national level.

Box 1 Key lessons from the interim evaluation of Horizon 2020 and R&I partnerships

- The **Horizon 2020 Interim Evaluation** concludes that the overall partnership landscape has become overly complex and fragmented. It identifies the need for rationalisation, improve their openness and transparency, and link them with future EU R&I missions and strategic priorities.
- The **Article 185 evaluation** finds that these public-public partnerships have scientific quality, global visibility and networking/structuring effects, but should in the future focus more on the achievement of policy impacts. From a systemic point of view, it found that the EU public-to-public cooperation (P2P) landscape has become crowded, with insufficient coherence.
- The **Article 187 evaluation** points out that Public-Private Partnership (PPP) activities need to be brought more in line with EU, national and regional policies, and calls for a revision of the Key Performance Indicators. As regards the **contractual PPPs (cPPPs)** their reviews identified challenges of coherence among cPPPs and the need to develop collaborations and synergies with other relevant initiatives and programmes at EU, national and regional level.

11 Interim evaluation of Horizon 2020, Commission Staff Working Document, SWD(2017)221 and 222 Interim evaluation of the Joint Undertakings operating under Horizon 2020 (Commission Staff Working)

Interim evaluation of the Joint Undertakings operating under Horizon 2020 (Commission Staff Working Document, SWD(2017) 339); Evaluation of the Participation of the EU in research and development programmes undertaken by several Member States based on Article 185 of the TFEU, Commission Staff Working Document, SWD (2017)340) ¹² E.g. initiatives based on Article 187 (Joint Technology Initiatives), Article 185 TFEU, Contractual Public-Private Partnerships (cPPPs), Knowledge & Innovation Communities of the European Institute of Innovation & Technology (EIT-KICs), ERA-NETs, European Joint Programmes, Joint Programming Initiatives.

Over 80% of respondents to the Open Public Consultation (OPC) indicated that a significant contribution by future European Partnerships is 'fully needed' to achieve climate-related goals, to develop and effectively deploy technology, and for EU global competitiveness in specific sectors/domains. Views converged across all categories of respondents, including citizens, industry and academia.

The impact assessment of Horizon Europe identifies therefore the need to rationalise the EU R&I funding landscape, in particular with respect to partnerships, as well as to re-orient partnerships towards more impact and delivery on EU priorities. To address these concerns and to realise the higher ambition for European investments, Horizon Europe puts forward a major simplification and reform for the Commission's policy on R&I partnerships¹³. Reflecting its pronounced systemic nature aimed at contributing to EU-wide 'transformations' towards the sustainability objectives, Horizon Europe indeed intends to make a more effective use of these partnerships with a more strategic, coherent and impact-driven approach. Key related changes that apply to all forms of European Partnerships encapsulated in Horizon

Box 2 Key features of the revised policy approach to R&I partnerships under Horizon Europe based on its impact assessment

- ✓ **Simpler architecture & toolbox** by streamlining 8 partnership instruments into 3 implementation forms (Co-Funded, Co-Programmed, Institutionalised), under the umbrella 'European Partnerships'
- ✓ More systematic and transparent approach to selecting, implementing, monitoring, evaluating and phasing out all forms of partnerships (criteria for European Partnerships):
 - The selection of Partnerships is embedded in the strategic planning of Horizon Europe, thereby ensuring coherence with the EU priorities. The selection criteria require that partnerships are established with stronger ex-ante commitment and higher ambition.
 - The implementation criteria stipulate that initiatives adopt a systemic approach in achieving impacts, including broad engagement of stakeholders in agenda-setting and synergies with other relevant initiatives to promote the take-up of R&I results.
 - A harmonised monitoring & evaluation system will be implemented, and ensures that progress is analysed in the wider context of achieving Horizon Europe objectives and EU priorities.
 - All partnerships need to develop an exit strategy from Framework Programme funding. This new approach is underpinned by principles of openness, coherence and EU added value.

✓ Reinforced impact orientation:

- Partnerships are established only if there is evidence they support achieving EU policy objectives
 more effectively than other Horizon Europe actions, by demonstrating a clear vision and targets
 (directionality) and corresponding long-term commitments from partners (additionality).
- European Partnerships are expected to provide mechanisms based on a concrete roadmap to join
 up R&I efforts between a broad range of actors towards the development and uptake of innovative
 solutions in line with EU priorities, serving the economy and society, as well as scientific progress.
- They are expected to develop close synergies with national and regional initiatives, acting as dynamic change agents, strengthening linkages within their respective ecosystems and along the value chains, as well as pooling resources and efforts towards the common EU objectives.

Regulation are summarised in the Box below.

Under Horizon Europe, a 'European Partnership' is defined as "an initiative where the Union, prepared with early involvement of Member States and/or Associated Countries, together with private and/or public partners (such as industry, universities, research organisations, bodies with a public service mission at local, regional, national or international level or civil society organisations including foundations and NGOs), commit to jointly support the development and implementation of a programme of research and innovation activities, including those related to market, regulatory or policy uptake."

The Regulation further specifies that European Partnerships shall adhere to the "principles of Union added value, transparency, openness, impact within and for Europe, strong leverage effect on sufficient scale, long-term commitments of all the involved parties, flexibility in

¹⁴ Article 8 and Annex III of the Horizon Europe Regulation (common understanding))

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¹³ Impact assessment of Horizon Europe, Commission Staff Working Document, SWD(2018)307.

implementation, coherence, coordination and complementarity with Union, local, regional, national and, where relevant, international initiatives or other partnerships and missions."

1.3. Why should the EU act

1.3.1. Legal basis

Proposals for Institutionalised European Partnerships are based on:

- 1) Article 185 TFEU which allows the Union to make provision, in agreement with the Member States concerned, for participation in research and development programmes undertaken by several Member States, including participation in the structures created for the execution of those programmes; or
- 2) Article 187 TFEU according to which the Union may set up joint undertakings or any other structure necessary for the efficient execution of Union research, technological development and demonstration programmes.¹⁵

1.3.2. Subsidiarity

The EU should act only in areas where there is demonstrable advantage that the action at EU level is more effective than action taken at national, regional or local level. Research is a shared competence between the EU and its Member States according to the TFEU. Article 4 (3) specifies that in the areas of research, technological development and space, the EU can carry out specific activities, including defining and implementing programmes, without prejudice to the Member States' freedom to act in the same areas. The candidate initiatives focus on areas where there is a demonstrable value added in acting at the EU level due to the scale, speed and scope of the efforts needed for the EU to meet its long-term Treaty objectives and deliver on its strategic policy priorities and commitments. In addition, the proposed initiatives should be seen as complementary and reinforcing national and sub-national activities in the same area. Overall European Partnerships find their **rationale in addressing a set of systemic failures**¹⁶:

- Their primary function is to create a platform for a strengthened **collaboration** and knowledge exchange between various actors in the European R&I system and an enhanced **coordination** of strategic research agendas and/or R&I funding programmes. They aim to address **transformational failures** to better align agendas and policies of public and private funders, pool available resources, create critical mass, avoid unnecessary duplication of efforts, and leverage sufficiently large investments where needed but hardly achievable by single countries.
- The concentration of efforts and pooling of knowledge on common priorities to solve multi-faceted societal and economic challenges is at the core of these initiatives. Specifically, enhanced cross-disciplinary and cross-sectoral collaboration and an improved integration of value chains and ecosystems are among the key objectives of these instruments. In the light of Horizon Europe, the aim is to drive system transitions and transformations towards EU priorities.
- Especially in fast-growing technologies and sectors such as ICT, there is a need to **react** to **emerging opportunities** and address systemic failures such as shortage in skills or

¹⁵ Both Articles are under Title XIX of the TFEU - Research and Technological Development and Space.

¹⁶ The Interim Evaluation of Horizon 2020 and the impact assessment of Horizon Europe provide qualitative and quantitative evidence on these points. Sections 1 and 2 of each impact assessment on candidate European Partnerships include more detail on the necessity to act at EU level in specific thematic areas.

- critical mass or cross-sectoral cooperation along the value chains that would hamper attainment of future European leadership and/or strategic autonomy.
- They also aim to address **market failures** predominantly to enhancing industry investments thanks to the sharing of risks.

2. THE CANDIDATE EUROPEAN PARTNERSHIPS – WHAT NEEDS TO BE DECIDED

2.1. Portfolio of candidates for Institutionalised European Partnerships

The new approach for more objective-driven and impactful European Partnerships is reflected in the way candidate Partnerships have been identified. It involved a co-design exercise aiming to better align these initiatives with societal needs and policy priorities, while broadening the range of actors involved. Taking into account the 8 areas for Institutionalised European Partnerships set out in the Horizon Europe Regulation¹⁷, a co-design exercise as part of the Strategic Planning process of Horizon Europe lead to the identification of **49 candidates for Co-funded, Co-programmed or Institutionalised European Partnerships**¹⁸. Out of these, **13 were identified as suitable candidate Institutionalised Partnerships because of their objectives and scope**¹⁹. Whilst the Co-Funded and Co-Programmed Partnerships are linked to the comitology procedure (including the adoption of the Strategic Plan and the Horizon Europe Work Programmes), Institutionalised Partnerships require the adoption of legislation and are subject to an impact assessment. The Figure 1 below gives an overview of all candidate European Partnerships according to their primary relevance to Commission priorities for 2019-2024.

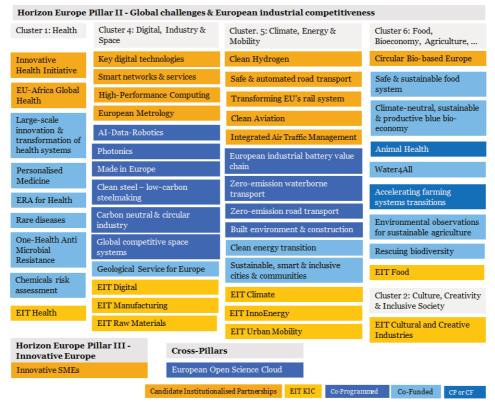
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¹⁷ Horizon Europe Regulation (common understanding), Annex Va.

¹⁸ Shadow configuration of Strategic Programme Committee for Horizon Europe. The list of candidate European Partnerships is described in "Orientations towards the Strategic Plan of Horizon Europe" - Annex 7

¹⁹ Only 12 are subject to this impact assessment, as one initiative on High Performance Computing has already been subject to an impact assessment in 2017 (SEC(2018) 47)

Figure 1 - Overview of the candidates for Co-Funded, Co-Programmed and Institutionalised European Partnerships according to Horizon Europe structure



Source: Technopolis group (2020)

There are only three partnerships for which implementation as an Institutionalised Partnership under Article 185 is an option, i.e. European Metrology, the EU-Africa Global Health partnership, and Innovative SMEs. Ten partnerships are candidates for Institutionalised Partnerships under Article 187. Overall the initiatives can be categorised into 'horizontal' partnerships and 'vertical' partnerships.

The 'horizontal' partnerships have a central position in the overall portfolio, as they are expected to develop methodologies and technologies for application in the other priority areas, ultimately supporting European strategic autonomy in these areas as well as technological sovereignty. These 'horizontal' partnerships are typically proposed as Institutionalised or Coprogrammed Partnerships, in addition to a number of EIT KICs, they cover mainly the digital field in addition to space, creative industries and manufacturing, but also the initiative related to Innovative SMEs. 'Vertical' partnerships are focused on the needs and development of specific application areas, and are primarily expected to support enhanced environmental sustainability thereby addressing Green Deal related objectives. They also deliver on policies for more people centred economy, through improved wellbeing of EU citizen and the economy, like health related candidate European Partnerships.

2.2. Assessing the necessity of a European Partnership and possible options for implementation

Horizon Europe Regulation Article 8 stipulates that Institutionalised European Partnerships based on Article 185 and 187 TFEU shall be implemented only where other parts of the Horizon Europe programme, including other forms of European Partnerships would not achieve the objectives or would not generate the necessary expected impacts, and if justified by a long-term perspective and high degree of integration. At the core of this impact assessment is therefore the

need to demonstrate that the impacts generated through a Partnership approach go beyond what could be achieved with traditional calls under the Framework Programme – the Baseline Option. Secondly, it needs to assess if using the Institutionalised form of a Partnership is justified for addressing the priority.

For all candidate Institutionalised European Partnerships the options considered in this impact assessment are the same, i.e.:

- Option 0 Baseline option Traditional calls under the Framework Programme
- Option 1 Co-programmed European Partnership
- Option 2 Co-funded European Partnership
- Option 3 Institutionalised Partnership
 - o Sub-option 3a Institutionalised Partnerships based on Art 185 TFEU
 - o Sub-option 3b Institutionalised Partnerships based on Art 187 TFEU

2.2.1. *Option 0* - Baseline option – Traditional calls

Under this option, strategic programming for R&I in the priority area will be done through the mainstream channels of Horizon Europe. The related priorities will be implemented through traditional calls of Horizon Europe covering a range of actions, mainly R&I and/or innovation actions but also coordination and support actions, prizes or procurement. Most actions involve consortia of public and/or private actors in ad hoc combinations, while some actions are single actor (mono-beneficiary). There will be no dedicated implementation structure and no support other than what is foreseen in the related Horizon Europe Work Programme. This means that discontinuation costs/benefits of predecessor initiatives should be factored in for capturing the baseline situation when relevant.

Under this option, strategic planning mechanisms in the Framework Programme will allow for a high level of flexibility in the ability of traditional calls to respond to particular needs over time, building upon additional input in co-creation from stakeholders and programme committees involving Member States. The Union contribution to addressing the priority covers the full duration of the initiative, during the lifetime of Horizon Europe. Without a formal EU partnership mechanism, it is less likely that the stakeholders will develop a joint Strategic Research Agenda and commit to its implementation or agree on mutual commitments and contributions outside their participation in funded projects.

2.2.2. European Partnerships

Under this set of options, three different forms of implementation are assessed: Co-funded, Co-Programmed, Institutionalised European Partnerships. These have **commonalities that cannot serve as a distinguishing factor in the impact assessment process**. They are all based on agreed objectives and expected impacts and underpinned by Strategic Research and Innovation Agendas / roadmaps that are shared and committed to by all partners in the partnership. They all have to follow the same set of criteria along their lifecycle, as defined in the Horizon Europe Regulation (Annex III), including ex ante commitment from partners to mobilise and contribute resources and investments. The Union contribution is defined for the full duration of the initiative for all European Partnerships. The Horizon Europe legal act introduces few additional requirements for Institutionalised Partnerships, e.g. the need for long-term perspective, strong integration of R&I agendas, and financial contributions.

Figure 2 - Key differences in preparation and implementation of European Partnerships

Type	Legal form	Implementation		
Co-Programmed	Contractual arrangement / MoU	Division of labour , whereby the Union contribution is implemented through a Framework Programme and partners' contributions under their responsibility.		
Co-Funded	Grant Agreement	Union provides co-funding for an integrated programme with distributed implementation by entities managing and/or funding national research and innovation programmes		
Institutionalised	Basic act (Council regulation,	, Integrated programme with centralised		
based on Article	Decision by European	implementation		
185/187 TFEU	Parliament and Council)			

The main differences between the different forms of European Partnerships are in their preparation and in the way they function, as well as in the overall impact they can trigger. The Co-Programmed form is assessed as the simplest, and the Institutionalised the most complex to prepare and implement. The functionalities of the different form of Partnerships – compared to the baseline option – are presented in Figure 3. They relate to the types of actors Partnerships can involve and their degree of openness, the types of activities they can perform and their degree of flexibility, the degree of commitment of partners and the priority setting system, and their ability to work with their external environment (coherence), etc. These key distinguishing factors will be at the basis of the comparison of each option to determine their overall capacity to deliver what is needed at a minimised cost.

Figure 3 - Overview of the functionalities provided by each form of European Partnerships, compared to the traditional calls of Horizon Europe (baseline)

Baseline: Horizon Europe calls	Option 1: Co- Programmed	Option 2: Co-Funded	Option 3a: Institutio- nalised Art 185	Option 3b: Institutionalised Art 187
Type and composition	of actors (including openn	ess and roles)		
Partners: N.A., no common set of actors that engage in planning and implementation Priority setting: open to all, part of Horizon Europe Strategic planning Participation in R&I activities: fully open in line with Horizon Europe rules	Partners: Suitable for all types: private and/or public partners, foundations Priority setting: Driven by partners, open stakeholder consultation, MS in comitology Participation in R&I activities: fully open in line with Horizon Europe rules	Partners: core of national funding bodies or govern-mental research organisations Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: limited, according to national rules of partner countries	Partners: National funding bodies or governmental research organisation Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: fully open in line with Horizon Europe rules, but possible derogations	Partners: Suitable for all types: private and/or public partners, foundations Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: fully open in line with Horizon Europe rules, but possible derogations
Type and range of acti	vities (including additiona	lity and level of integrat	ion)	
Activities: Horizon Europe standards that allow broad range of individual actions Additionality: no additional activities and investments outside the funded projects Limitations: No systemic approach beyond individual actions	Activities: Horizon Europe standard actions that allow broad range of individual actions, support to market, regulatory or policy/ societal uptake Additionality: Activities/investments of partners, National funding Limitations: Limited	Activities: Broad, according to rules/programmes of participating States, State-aid rules, support to regulatory or policy/societal uptake Additionality: National funding Limitations: Scale & scope depend on participating	Activities: Horizon Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to systemic approach Additionality: National funding	Activities: Horizon Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to systemic approach (portfolios of projects, scaling up of results, synergies with other funds. Additionality:

Baseline: Horizon Europe calls	Option 1: Co- Programmed	Option 2: Co-Funded	Option 3a: Institutio- nalised Art 185	Option 3b: Institutionalised Art 187		
	systemic approach beyond individual actions	programmes, often smaller in scale		Activities/investments of partners/ national funding		
Priority-setting process and directionality						
Priority setting: Strategic Plan and annual work programmes, covering max. 4 years. Limitations: Fully taking into account existing or to be developed SRIA/roadmap	Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Input to FP annual work programme drafted by partners, finalised by EC (comitology) Objectives & commitments set in contractual arrangement	Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Annual work programme drafted by partners, approved by EC Objectives & commitments set in Grant Agreement	Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Annual work programme drafted by partners, approved by EC Objectives & commitments set in legal act	Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Annual work programme drafted by partners, approved by EC (vetoright in governance) Objectives & commitments set in legal act		
Coherence: internal (H strategies)	lorizon Europe) & externa	d (other Union program	nmes, national progran	nmes, industrial		
Internal: Coherence between different parts of the FP Annual Work programme can be ensured by EC External: Limited for other Union programmes, no synergies with national/regional programmes & activities	Internal: Coherence among partnerships & with parts of the FP Annual Work programme can be ensured by partners & EC External: Limited synergies with other Union programmes & industrial strategies. If MS participate, with national/regional programmes & activities	Internal: Coherence among partnerships & with parts of the FP Annual Work programme can be ensured by partners & EC External: Synergies with national/ regional programmes & activities	Internal: Coherence among partnerships & with parts of the FP Annual Work programme can be ensured by partners & EC External: Synergies with national/regional programmes & activities	with parts of the FP Annual Work programme can be ensured by		

Option 1 - Co-programmed European Partnership

This form of European Partnership is **based upon a Memorandum of Understanding or a Contractual Arrangement** signed by the Commission and the private and/or public partners. Private partners are represented by industry associations, which also support the daily management of the partnership. This type of partnership would allow for a large degree of flexibility for the activities, partners and priorities to continuously evolve. The commitments of partners are political efforts described in the contractual arrangement and the contributions from partners are provided in kind more than financially. The priorities for the calls, proposed by the Partnership's members for integration in the Horizon Europe's Work Programmes, are subject to further input from Member States (comitology) and Commission services. The Union contribution is implemented within the executive agency managing Horizon Europe calls for research and innovation projects proposals. The full array of Horizon Europe instruments can be used, ranging from research and innovation (RIA) types of actions to coordination and support actions (CSA) and including grants, prizes, and procurement.

Option 2 – Co-funded European Partnership

The Co-funded European Partnership is **based on a Grant Agreement** between the Commission and a consortium of partners, resulting from a specific call in the Horizon Europe Work Programme. This form of implementation only allows to address public partners at its core.

Typically these provide co-funding to a common programme of activities established and/or implemented by entities managing and/or funding national R&I programmes. The recipients of the EU co-funding implement the initiative under their responsibility, with national funding/resources pooled to implement the programme with co-funding from the Union. The expectation is that these entities would cover most if not all EU Member States. Calls and evaluations would be organised centrally, beneficiaries in selected projects would be funded at national level, following national funding rules.

Option 3 – Institutionalised European Partnership

This type of Partnership is the most complex and high-effort arrangement, and requires meeting additional requirements. Institutionalised European Partnership are based on a Council Regulation (Article 187 TFEU or a Decision by the European Parliament and Council (Article 185 TFEU) and are implemented by dedicated structures created for that purpose. These regulatory needs limit the flexibility for a change in the core objectives, partners, and/or commitments as these would require amending legislation. The basic rationale for this type of partnership is the need for a strong integration of R&I agendas in the private and/or public sectors in the EU in order to address a strategic challenge. It is therefore necessary to demonstrate that other forms of implementation would not achieve the objectives or would not generate the necessary expected impacts, and that a long-term perspective and high degree of integration is needed. For both Article 187 and 185 initiatives, contributions from partners can be in the form of financial and in-kind contributions. Eligibility for participation and funding follows by default the rules of Horizon Europe, unless a derogation is introduced in the basic act.

Option 3a - Institutionalised Partnerships based on Article 185 TFEU

Article 185 of the TFEU allows the Union to participate in programmes jointly undertaken by Member States and limits therefore the scope to **public partners** which are Member States and Associated Third Countries. This type of Institutionalised Partnership aims therefore at reaching the greatest possible impact through the integration of national and EU funding, aligning national strategies in order to optimise the use of public resources and overcome fragmentation of the public research effort. It brings together R&I governance bodies of most if not all EU Member States (legal requirement: at least 40% of Member States) as well as Associated Third Countries that designate a legal entity (Dedicated Implementation Structure) of their choice for the implementation. By default, participation of non-associated Third Countries is not foreseen. Such participation is possible only if it is foreseen in the basic act and subject to conclusion of an international agreement.

Option 3b - Institutionalised Partnerships based on Article 187 TFEU

Article 187 of the TFEU allows the Union to set up joint undertakings or any other structure necessary for the efficient execution of EU research, technological development and demonstration programmes. This type of Institutionalised Partnership brings together a stable set of public and private partners with a strong commitment to taking a more integrated approach and requires the set-up of a dedicated legal entity (Union body, Joint Undertaking (JU)) that carries full responsibility for the management of the Partnership and implementation of the calls. Different configurations are possible:

Partnerships focused on creating strategic industrial partnerships where, most often, the
partner organisations are represented by one or more industry associations, or in some
cases individual private partners;

- Partnerships coordinating national ministries, public funding agencies, and governmental research organisations in the Member States and Associated Countries;
- Or a combination of the two: the so-called tripartite model.

Participation of non-associated Third Countries is only possible if foreseen in the basic act and subject to conclusion of an international agreement.

Overview of the methodology adopted for the impact assessment

The methodology for each impact assessment is based on the Commission Better Regulation Guidelines²⁰ to evaluate and compare options with regards to their efficiency, effectiveness and coherence. This also integrates key selection criteria for European Partnerships.

Box 2 Summary of European Partnerships selection criteria²¹

- *Effectiveness* in achieving the related objectives and impacts of the Programme;
- Coherence and synergies of the European Partnership within the EU R&I landscape;
- Transparency & openness as regards the identification of priorities and objectives and the involvement of partners & stakeholders from the entire value chain, backgrounds & disciplines;
- Ex-ante demonstration of *additionality* and *directionality*;
- Ex-ante demonstration of the partners' *long term commitment*.

2.3.1. Overview of the methodologies employed

In terms of methods and evidence used, the impact assessments draw on an external study covering all candidate Institutionalised European Partnerships in parallel to ensure a high level of coherence and comparability of analysis, in addition to a horizontal analysis.²² For all initiatives, the understanding of the overall context of the candidate institutionalised European Partnerships relied on desk research, including among others the lessons learned from previous partnerships. This was complemented by the analysis of a range of quantitative and qualitative evidence, including evaluations of past and ongoing initiatives; foresight studies; statistical analyses of Framework Programmes application and participation data, and Community Innovation Survey data; analyses of science, technology and innovation indicators; reviews of academic literature; sectoral competitiveness studies and expert hearings. The analyses included a portfolio analysis, a stakeholder and social network analysis in order to profile the actors involved as well as their cooperation patterns, and an assessment of the partnerships' outputs (bibliometrics and patent analysis). A cost modelling exercise was performed in order to feed into the efficiency assessments of the partnership options, as described below. Public consultations (both open and targeted) supported the comparative assessment of the policy options. For each initiative, up to 50 relevant stakeholders were interviewed by the external contractor (policymakers, business including SMEs and business associations, research institutes and universities, and civil organisations, among others). In addition, the analysis was informed by the results of the Open Public Consultation run between September and November 2019, the consultation of Member States through the Strategic Programme Committee and the online feedback received on the Inception Impact Assessments of the set of initiatives.

²⁰ European Commission (2017), Better Regulation Guidelines (SWD (2017) 350)

²¹ For a comprehensive overview of the selection criteria for European Partnerships, see Annex 6.

²² Technopolis Group (2020), Impact Assessment Study for Institutionalised European Partnerships under Horizon Europe, Final Report, Study for the European Commission, DG Research & Innovation

A more detailed description of the methodology and evidence base that were mobilised, completed by thematic specific methodologies, is provided in Annexes 4 and 6.

2.3.2. *Method for identifying the preferred option*

The first step of the assessments consisted in scoping the problems that the initiatives are expected to solve given the overall economic, technological, scientific and social context, including the lessons to be learned from past and ongoing partnerships on what worked well and less well. This supported the identification of the objectives of the initiative in the medium and long term with the underlying intervention logic – showing how to get there.

Given the focus of the impact assessment on comparing different forms of implementation, the Better Regulation framework has then been adapted to introduce "key functionalities needed" making the transition between the definition of the objectives and what would be crucial to achieve them in terms of implementation. The identification of "key functionalities needed" for each initiative as an additional step in the impact assessment is based on the distinguishing factors between the different options (see Section 2.2.1). In practical terms, each option is assessed on the basis of the degree to which it would allow for the key needed functionalities to be covered, as regards e.g. the type and composition of actors that can be involved ('openness'), the range of activities that can be performed (including additionality and level of integration), the level of directionality and integration of R&I strategies; the possibilities offered for coherence and synergies with other components of Horizon Europe, including other Partnerships (internal coherence), and the coherence with the wider policy environments, including with the relevant regulatory and standardisation framework (external coherence). This approach guides the identification of discarded options while allowing at the same time a structured comparison of the options not only as regards their effectiveness, efficiency and coherence, but also against a set of other key selection criteria for European Partnerships (openness, transparency, directionality)²³.

In line with the Better Regulation Framework, the assessment of the effectiveness, efficiency and coherence of each option is made compared to the baseline. Therefore, for each of these aspects the performance of using traditional calls under Horizon Europe is first estimated and scored 0 to serve as a reference point. This includes the discontinuation costs/benefits of existing implementation structures when relevant. The policy options are then scored compared to the baseline with a + and - system with a two-point scale, to show a slightly or highly additional/lower performance compared to the baseline. A scoring of 0 of a policy option means that it would deliver as much as the baseline option.

On the basis of the evidence collected, the intervention logic of each initiative and the key functionalities needed, the impact assessments first evaluate the **effectiveness** of the various policy options to deliver on their objectives. To be in line with the Horizon Europe impact framework, the fulfilment of the specific objectives of the initiative is translated into 'expected impacts' - how success would look like -, differentiating between scientific, economic/technological, and societal (including environmental) impacts. Each impact assessment considers to which extent the different policy options provides the 'key functionalities needed' to achieve the intended objectives. The effectiveness assessment does not use a compound score but shows

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²³ The criterion on the ex-ante demonstration of partners' long term commitment depends on a series of factors that are unknown at this stage, and thus fall outside the scope of the analysis.

how the options would deliver on the different types of expected impacts. This is done to increase transparency and accuracy in the assessment of options²⁴.

A similar approach is followed to evaluate the coherence of options with the overarching objectives of the EU's R&I policy, and distinguishes between internal and external coherence. Specifically, internal coherence covers the consistency of the activities that could be implemented with the rest of Horizon Europe, including European Partnerships (any type). External coherence refers to the potential for synergies and/or complementarities (including risks of overlaps/gaps) of the initiative with its external environment, including with other programmes under the MFF 2021-27, but also the framework conditions at European, national or regional level (incl. regulatory aspects, standardisation).

To compare the expected costs and benefits of each option (efficiency), the thematic impact assessments broadly follow a cost-effectiveness approach²⁵ to establish to which extent the intended objectives can be achieved for a given cost. A preliminary step in this process is to obtain a measure of the expected costs of the policy options, to be used in the thematic assessments. As the options correspond to different implementation modes, relevant cost categories generally include the costs of setting-up and running an initiative. For instance, set-up costs includes items such as the preparation of a European Partnership proposal and the preparation of an implementation structure. The running costs include the annual work programme preparation costs. Where a Partnership already exists, discontinuation costs and costsavings are also taken into account²⁶. The table below provides an overview of the cost categories used in the impact assessment and a qualitative scoring of their intensity when compared to the baseline option (traditional calls). Providing a monetised value for these average static costs would have been misleading, because of the different features and needs of each candidate initiative.²⁷ The table shows the overall administrative, operational and coordination costs of the various options. These costs are then put into context in the impact assessments to reflect the expected co-financing rates and the total budget available for each of the policy options, assuming a common Union contribution (cost-efficiency):

- The costs related to the baseline scenario (traditional calls under Horizon Europe) are predominantly the costs of implementing the respective Union contribution via calls and project, managed by the executive agencies (around 4%, efficiency of 96% for the overall
- For a Co-Programmed partnership the costs of preparation and implementation increase only marginally compared to the baseline (<1%), but lead to an additional R&I investment of at least the same amount than the Union contribution²⁸ (efficiency of 98% for the overall investment).

²⁴ In the thematic impact assessments, scores are justified in a detailed manner to avoid arbitrariness and spurious accuracy. A qualitative or even quantitative explanation is provided of why certain scores were given to specific impacts, and why one option scores better or worse than others.

²⁵ For further details, see Better Regulation Toolbox # 57.

²⁶ Discontinuation costs will bear winding down and social discontinuation costs and vary depending on e.g. the number of full-time-equivalent (FTEs) staff concerned, the type of contract (staff category and duration) and applicable rules on termination (e.g. contracts under Belgian law or other). If buildings are being rented, the cost of rental termination also apply. As rental contracts are normally tied to the expected duration of the current initiatives, these termination costs are likely to be very limited. In parallel, there would also be financial cost-savings related to the closing of the structure, related to operations, staff and coordination costs in particular. This is developed further in the individual efficiency assessments.

²⁷ A complete presentation of the methodology developed to assess costs as well as the sources used is described in the external study supporting this impact assessment (Technopolis Group, 2020).

²⁸ Minimum contributions from partners equal to the Union contribution

- For a Co-Funded partnership the additional R&I investment by Member States accounts for 2.3 times the Union contribution²⁹. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the national programmes, can be estimated at 6% of the Union contribution (efficiency of 98% related to the overall investment).
- For an Article 185 initiative the additional R&I investment by Member States is equal to the Union contribution³⁰. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the dedicated implementation structure, can be estimated at 7% of the Union contribution (efficiency of 96% related to the overall investment).
- For an Article 187 initiative the additional R&I investment by partners is equal to the Union contribution³¹. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the dedicated implementation structure, can be estimated at 9% of the Union contribution (efficiency of 94% related to the overall investment).

Figure 4 - Intensity of additional costs compared with Horizon Europe Calls (for Partners, stakeholders, public and EU)

Cost items	Baseline: traditional calls	Option 1: Co- programmed	Option 2 Co-funded	Option 3a - Art. 185	Option 3b -Art. 187
Preparation and set-up costs					
Preparation of a partnership proposal (partners and EC)	0	$\uparrow \uparrow$			
Set-up of a dedicated implementation structure		0		Existing: ↑ New: ↑↑	Existing: ↑↑ New: ↑↑↑
Preparation of the SRIA / roadmap	0		$\uparrow \uparrow$		
Ex-ante Impact Assessment for partnership	0			$\uparrow \uparrow \uparrow$	
Preparation of EC proposal and negotiation	0			$\uparrow \uparrow \uparrow$	
Running costs (Annual cycle of implementation)					
Annual Work Programme preparation	0				
Call and project implementation	0	0 In case of MS contributions: ↑	\uparrow	\uparrow	↑
Cost to applicants	Comparable, unless there are strong arguments of major differences in oversubscription				
Partners costs not covered by the above	0	\uparrow	0	↑	\uparrow
Additional EC costs (e.g. supervision)	0	1	\uparrow	↑	$\uparrow \uparrow$
Winding down costs					
EC	0				$\uparrow\uparrow\uparrow$
Partners	0	\uparrow	0	↑	↑

Notes: 0: no additional costs, as compared with the baseline; \uparrow : minor additional costs, as compared with the baseline; $\uparrow \uparrow$: medium additional costs, as compared with the baseline; $\uparrow \uparrow \uparrow \uparrow$: higher costs, as compared with the baseline.

The cost categories estimated for the common model are then used to develop a scorecard analysis and further refine the assessment of options for each of the 12 candidate Institutionalised Partnerships. Specifically, the scores related to the set-up and implementation costs are used in

³¹ Based on the minimum requirement in the legal basis that partners contribute at least 50% of the budget.

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²⁹ Based on the default funding rate for programme co-fund actions of 30%, partners contribute with 70% of the total investment.

³⁰ Based on the minimum requirement in the legal basis that partners contribute at least 50% of the budget.

the thematic impact assessments to consider the scale of the expected benefits and thereby allow a simple "value for money" analysis (**cost-effectiveness**)³². In carrying out the scoring of options, the results of fieldwork, desk research and stakeholder consultation undertaken and taken into account.

For the **identification of the preferred option**, the scorecard analysis builds a hierarchy of the options by individual criterion and overall in order to identify a single preferred policy option or in case of an inconclusive comparison of options, a number of 'retained' options or hybrid. This exercise supports the systematic appraisal of alternative options across multiple types of monetary, non-monetary and qualitative dimensions. It also allows for easy visualisation of the pros and cons of each option. Each option is attributed a score of the adjudged performance against each cri

As a last step, the alignment of the preferred option with key criteria for the selection of European Partnerships is described, reflecting the outcomes of the 'necessity test'. The monitoring and evaluation arrangements are concluding the assessment, with an identification of the key indicators to track progress towards the objectives over time.

2.4. Horizontal perspective on candidate Institutionalised European Partnerships

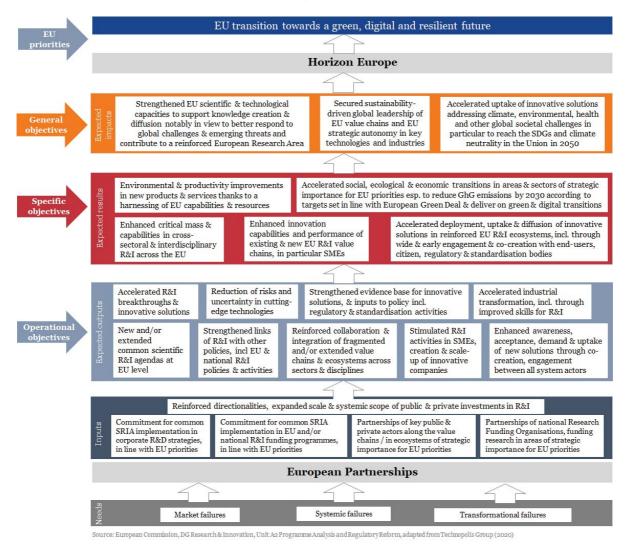
2.4.1. Overall impact orientation, coherence and efficiency needs

The consolidated **intervention logic** for the set of candidate Institutionalised European Partnerships in the Figure below builds upon the objectives as reported in the individual impact assessments.

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³² More details on the methodology can be found in Annex 4.

Figure 5 – Overall intervention logic of the European Partnerships under Horizon Europe



When analysed as a package the 12 candidate Institutionalised European Partnerships are expected to support the achievement of the European policy priorities targeted by Horizon Europe by pursuing the following joint general objectives:

- a) Strengthening and integrating EU scientific and technological capacities to support knowledge creation and diffusion notably in view to better respond to global challenges and emerging threats and contribute to a reinforced European Research Area;
- b) Securing sustainability-driven global leadership of EU value chains and EU strategic autonomy in key technologies and industries; and
- c) Accelerate the uptake of innovative solutions addressing climate, environmental, health and other global societal challenges contributing to Union strategic priorities, in particular to reach the Sustainable Development Goals and climate neutrality in the Union in 2050.

In terms of specific objectives, they jointly aim to:

- a) Enhance the critical mass and scientific capabilities in cross-sectoral and interdisciplinary research and innovation across the Union;
- b) Accelerate the social, ecological and economic transitions in areas and sectors of strategic importance for Union priorities, in particular to reduce greenhouse gas emissions by 2030 according to the targets set in line with the European Green Deal, and deliver on the green and digital transition;

- c) Enhance the innovation capabilities and performance of existing and new European research and innovation value chains, in particular SMEs;
- d) Accelerate the deployment, uptake and diffusion of innovative solutions in reinforced European R&I ecosystems, including through wide and early engagement and co-creation with end-users, citizen and regulatory and standardisation bodies;
- e) Deliver environmental and productivity improvements in new products and services thanks to a harnessing of EU capabilities and resources.

In terms of their operations, taking a horizontal perspective on all initiatives allows for the identification of further possible collective efficiency and coherence gains for more impact:

- Coherence for impact: The extent and speed by which the expected results and impacts will be reached, will depend on the scale of the R&I efforts triggered, the profile of the partners involved, the strength of their commitments, and the scope of the R&I activities funded. To be fully effective it comes out clearly that future partnerships need to operate over their whole life cycle in full coherence with their environment, including potential end users, regulators and standardisation bodies. This relates also to the alignment with relevant EU, national or regional policies and synergies with R&I programmes. This needs to be factored in as of the design stage to ensure a wide take-up and/or deployment of the solutions developed, including their interoperability.
- Collaboration for impact: Effectiveness could also be improved collectively through enhanced cross-disciplinary and cross-sectoral collaboration and an improved integration of value chains and ecosystems. An adequate governance structure appears in particular necessary to ensure cross-fertilisation between all European Partnerships. This applies not only to initiatives where similar R&I topics are covered and/or the same stakeholders involved or targeted, but also to the interconnections needed between the 'thematic' and the 'vertical' Partnerships, as these are expected to develop methodologies and technologies for application in EU priority areas. Already at very early stages of preparing new initiatives, Strategic Research and Innovation Agendas and roadmaps need to be aligned, particularly for partnerships that develop enabling technologies that are needed in other Partnerships. The goal should be to achieve greater impacts jointly in light of common challenges.
- Efficiency for impact: Potential efficiency gains could also be achieved by joining up the operational functions of Joint Undertakings that do not have a strong context dependency and providing them through a common back-office³³. A number of operational activities of the Joint Undertakings are of a technical or administrative nature (e.g. financial management of contracts), or procured from external service providers (e.g. IT, communication activities, recruitment services, auditing) by each Joint Undertaking separately. If better streamlined this could create a win-win situation for all partners leading to better harmonization, economies of scales, and less complexity in supervision and support by the Commission services.
 - 2.4.2. *Analysis of coherence* of the overall portfolio of candidate initiatives at the thematic level

Looking at the coherence of the set of initiatives at the thematic level, the "digital centric" initiatives have a strong focus on supporting the digital competitiveness of the EU ecosystem.

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³³ See Annex 6 for an overview of key functions/roles that could be provided by a common back office.

Their activities are expected to improve alignment and coordination with Member States and industry for the development of world-competitive EU strategic digital technology value chains and associated expertise. Addressing the Key Digital Technologies, the 5G and 6G connectivity needs as part of a Smart Networks and Services initiative and the underlying supercomputing capacities through a European High Performance Computing initiative present potential for synergies that can be addressed through cooperative actions (e.g. joint calls, coordinated support activities, etc.). They may as well profit from and contribute to Partnerships envisaged for Photonics, AI, data, robotics, Global competitive space system and Made in Europe, together with the EIT Digital. Synergies between these initiatives and several programmes (Digital Europe and Connecting Europe as well as cohesion programmes) are needed in areas where EU industry has to develop leadership and competitiveness in the global digital economy. They are expected to impact critical value chains including on sectors where digital is a strong enabler of transformation (health, industrial manufacturing, mobility/transport, etc.).

The **transport** sector face systemic changes linked to decarbonisation and digitalisation. Large scale R&I actions are needed to prepare the transition of these complex sectors to provide clean, safer, digital and economically viable services for citizens and businesses. Past decades have shown that developing and implementing change is difficult in transport due to its systemic nature, many stakeholders involved, long planning cycles and large investments needed. A systemic change of the air traffic network through an Integrated Air Traffic Management initiative should ensure safety and sustainability of aviation, while a Clean Aviation initiative should focus on the competitiveness of tomorrow's clean aircrafts made in Europe. The initiative for Transforming Europe's rail system would comprehensively address the rail sector to make it a cornerstone in tomorrow's clean and efficient door-to-door transport services, affordable for every citizen as well as the most climate-friendly mode of transport for freight. Connected and Automated Mobility is the future of road transport, but Europe is threatened to fall behind other global regions with strong players and large harmonised markets. The initiative Safe and Automated Road Transport would bring stakeholders together, creating joint momentum in digitalising road transport and developing new user-based services. Stronger links and joint actions will be established between initiatives to enable common progress wherever possible. The Clean Hydrogen initiative would be fundamental to that regard. Synergies would also be sought with partnerships driving the digital technological developments.

To deliver a deep decarbonisation of highly emitting industrial sectors such as the steel, transport and chemical industries would require the production, distribution and storage of **hydrogen** at scale. The candidate hydrogen initiative would have a central positioning in terms of providing solutions to the challenges for sustainable mobility and energy, but also is expected to operate in synergies with other industry related initiatives. The initiative would interact in particular with initiatives on the zero emission road and water transport, transforming Europe's railway system, clean aviation, batteries, circular industry, clean steel and built environment partnerships. There are many opportunities for collaboration for the delivery and end-use of hydrogen. However, the Clean Hydrogen initiative would be the only partnership focused on addressing hydrogen production technologies.

Metrology, the science of measurement, is an enabler across all domains of R&I. It supports the monitoring of the Emissions Trading System, smart grids and pollution, but also contributes to meeting demands for measurement techniques from emerging digital technologies and applications. More generally, emerging technologies across a wide range of fields from biotechnologies, new materials, health diagnostics or low carbon technologies are giving rise to demands requiring a world-leading EU metrology system.

The initiative for a **Circular Bio-based Europe** is intended to solve a shortage of industry investments in the development of bio-based products whose markets do not have yet certain long-term prospects. The **Innovative Health Initiative** and **EU-Africa Global Health** address the lack of investments in the development of solutions to specific health challenges. The initiative on **Innovative SMEs** supports innovation-driven SMEs in participating in international, collaborative R&I projects with other innovative firms and research-intensive partners. As a horizontal initiative it is expected to help innovative SMEs to grow and to be successfully embedded in global value chains by developing methodologies and technologies for potential application in the other partnership areas or further development by the instruments of the European Innovation Council.

The description of the interconnections between all initiatives for each Horizon Europe cluster is provided in the policy context of each impact assessment and further assessed in the coherence assessment for each option.

1. Introduction: Political and legal context

1.1. Emerging challenges in the field

Smart Networks and Services (SNS) are the digital infrastructures that provide connectivity-based services to consumers and businesses ranging from mobile and fixed Internet access to professional digital services such as Machine-to-Machine communication or public safety services. They are composed of user devices, communication networks and service computing platforms. SNS will increasingly provide connectivity for industrial 'vertical' sectors such as transport, energy, manufacturing, health care and media. While SNS solutions based on the newest technology standard – 5G - will allow for first such industrial services in the next few years, 6G technology will provide another step change to mainstream such services in this and the next decade enabling the digital and green transition of the economy and society.

Such digital services are increasingly critical. The political guidelines of the new Commission identify related networks as crucial for Europe's technological sovereignty, which is gaining even further significance in light of the COVID-19 pandemic and the need to guarantee security of supply in critical sectors. Europe's capacity to set evolving 5G and later 6G standards will be of paramount importance in this regard. In particular, the role of equipment suppliers, which has been the most strategic issue related to the recent 5G cyber-security toolbox³⁵, needs to be reinforced.

The COVID-19 pandemic is posing enormous challenges to the health of our citizens and to our economic development. It has underlined how critical are communication networks for the functioning of our economy in times of crisis. SNS systems will further improve our capability to guarantee critical and essential digital services, enable remote healthcare and monitoring as well as rapid health crisis responses, e.g. based on big data and artificial intelligence tools that respect Europe's data protection rules. Finally, this initiative, in particular the piloting and deployment part of the partnership (using CEF2, DEP, and InvestEU), will lead to a major infrastructure investment programme, in support of sustainable economic recovery and is expected to provide for major opportunities for SMEs as part of new SNS-based digital ecosystems.

R&I initiatives on 6G are now starting in all leading regions world-wide. SNS systems based on 6G standards are expected to offer a new step change in performance to enable new critical applications such as real-time automation or extended reality as basis for advanced industrial services. There will also be an opportunity for new business models and players through architectures such as Open-RAN³⁶ and software networks, which will be an important basis for a competitive supply market in a multi-vendor environment as targeted in the 5G cyber toolbox. Moreover, the convergence with new technologies in the area of cloud and edge computing, AI, as well as components and devices beyond smartphones offer great opportunities for European players to seize new value chain opportunities. SNS are expected to significantly contribute to Sustainable Development Goals. Radically bringing down the cost of infrastructure with

³⁴ this is a working title which will be adjusted following high-level political guidance in time for the adoption of the Commission proposal

³⁵ COM(2020) 50 final

³⁶ More open and interoperable interfaces in Radio Access Networks (RAN) enabling more competition.

generalised software implementations will decisively contribute to advanced infrastructure availability. Connectivity and IoT will potentially enable distributed energy systems and grid transformation systems, supporting intelligent energy consumption in cities and ensuring optimization of energy production. They will also be able to facilitate precision farming and food monitoring for increased agricultural productivity and reduced need for scarce resources. IoT devices and smart systems will also enhance the efficiency of water usage, quality and the protection of oceans.

In relation to the green deal, SNS systems will be substantial contributor to reducing energy consumption and lower carbon emissions both as enabler for greening industrial sectors (ICT for green) and conceiving new technologies and for deploying greener networks.

1.2. EU positioning in the field

The European **SNS value chain** composed of connected devices, networks and related computing platforms has the following characteristics:

Devices: Europe has the scientific and technology knowledge but is no longer an important player in the smartphone market dominated by three global players (Apple, Samsung, Huawei) with a few additional Chinese ones emerging (Xiaomi, Oppo). Smartphones represent an important global market of €700 billion in 2019 without significant presence of European players. However, Europe maintains strong industrial assets for future generations of connected devices such as cars, drones, robots and agricultural sensors, which will be key for the industrial IoT.

Network services represent about €300 billion of revenues in Europe, about 27% of the global service revenues from service providers. This is a market with little growth at the moment, but new prospects of services to vertical industries may boost growth by 50% in 2026³⁷. Vertical markets are a strong opportunity, also to diversify the European digital dependence to communication services, which represent 50% of digital outputs in Europe against 25-30% in the US or Asia³⁸. In the context of industrial applications, Europe is pioneering with more than 160 major 5G trials running today³⁹.

Network equipment: Europe remains a major player in the network equipment representing about 45% of the mobile infrastructure market, but is increasingly challenged by China, as shown by the Figure 5 below⁴⁰. In some EU countries, Chinese vendors capture more than 40% of the telecom equipment market. Other upcoming challenges relate to the emergence of vendors originating from the IT industry (Cisco, Mavenir, Altiostar..) with potentially highly competitive offers for radio networks. EU industry is part of the Open-RAN initiative and has potential to benefit from these new opportunities.

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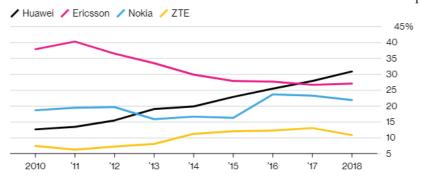
³⁷ A.D. Little: the 5G business potential, 2017

³⁸ Impact Assessment Study for Institutionalised Partnerships under HE for SNS, final report.

³⁹ Source 5GObservatory.eu

⁴⁰https://www.bloomberg.com/news/articles/2019-06-19/huawei-s-troubles-are-a-big-opportunity-for-ericsson-and-nokia

Figure 5: Evolution of mobile infrastructure market shares of the main networks equipment vendors



Cloud/Edge computing: the cloud computing service market in Europe is growing fast with €24 billion revenues in 2017 expected to reach €52 billion after 2020^{41} . This market is though captured mainly by non EU platforms, with only one actor in the field (OVH). The same applies to cloud technology providers. Opportunities reside in edge computing 42 , a new paradigm placing data processing close to the user to minimise latency and optimise user data control. It is expected to become a €13.8 billion market by 2024, with 40% of growth per year 43 . Europe may capture 27% of the market by 2024. Still, this requires solving technological issues, related notably to the security and energy consumption.

Software and IT services importance will grow for SNS. Europe has clear assets: Germany's SAP, France's Capgemini, Atos are all in the global top ten⁴⁴. For IoT and cellular Machine-to-Machine (M2M), the Asia-Pacific and North America regions have now overtaken Europe former lead with large operators developing M2M services. Europe is ahead of North America for IoT in general and behind China. Asia-Pacific is expected to represent 57% of connections in 2030 against 16% for Europe, the second region in the world.⁴⁵

In conclusion, the initiative intends to leverage EU industrial strengths in networking to stimulate industrial opportunities for devices and computing platforms, hence optimising also growth opportunities across the value chain for Europe.

Box 3 Support for the field in the previous Framework Programmes – key strengths & weaknesses identified

What was/is being done with EU research and innovation funding until now

Dedicated R&I activities related to communication networks have been supported since Framework Programmes 3 reflecting the strategic position of this industry for Europe. In recent years this was done mainly through the 5G PPP. This partnership between the European Commission and the 5G Industry Association, received €700 million of EU funding between 2014 and 2020 to deliver technologies and solutions for 5G mobile networks. Details on the way the partnership functions are available in Annex 6.

What has or is being achieved so far

41 https://medium.com/@FIXER.Inc/european-cloud-market-the-hidden-opportunity-6368b5433fbb.

26

⁴² Edge computing corresponds to the optimisation used in cloud computing where data is processed at the edge of the network

⁴³ https://fr.idate.org/produit/edge-computing-report/

Ranking by 2017 turnover except smartphones (market share) - Digital Europe 2030, IDATE Digiworld (2019), based on Forbes

⁴⁵ IDATE Digiworld, World IoT Markets (2018) https://fr.idate.org/produit/iot-markets-4/

The main problem addressed by the 5G-PPP was the need for European industry to create critical mass and to be able to leverage large-scale investment in R&I on 5G technology, focussing mainly on the development of technology building blocks for the global 5G standard and its validation for a range of target use cases. It has allowed European actors to keep 55% of the Standard Essential patents out of the 4 global vendors of network infrastructures, and to be part of the leading regions of the world in this field.

What are the key areas for improvement & challenges not met

The proposed new initiative goes beyond this scope, and needs to respond to new strategic challenges. As SNS become increasingly critical for the functioning of all parts of the economy and society, mastering technologies for SNS and having European players well positioned on a global scale becomes a key issue of public policy. In this perspective, the competitiveness of European industry becomes a strategic challenge to be addressed.

New technological challenges emerging are briefly described in section 2.2.1 to 2.2.4

Furthermore, the initiative needs to address a range of other problems closely linked to the policy priorities of the new Commission, such as technology sovereignty, cybersecurity or low carbon emissions.

Such public policy concerns are not necessarily given the same priority by industry and, certainly, cannot be addressed by industry on their own. Therefore, a loose structure such as the 5G-PPP cannot be expected to deliver on the broad range of policy objectives that are increasingly crucial. Addressing these issues from a holistic and coordinated perspective notably requires a closer partnership with the strategic involvement of Member States.

A more strategic and formal partnership for SNS would be able to tackle these issues with an increased scope of the initiative, an increased set of industrial stakeholders, and the strategic involvement of Member States as part of the governance structure.

For example, the proposed initiative addresses the issue of technological sovereignty and how to stimulate it in a strategic domain, which is a key objective of the new Commission in this particular field and gained further importance in light of COVID-19, in relation of ensuring supply to key sectors. This topic will be addressed by extending the scope from connectivity to the broader strategic value chain including cloud-based service provisioning as well as components and devices. It will also seek to align strategic roadmaps of a wider range of industrial players, including the telecom industry as well as IoT and cloud actors, and to some extent actors from the microelectronics/component domain. The critical role of suppliers identified and addressed in the 5G cybersecurity toolbox will be a key preoccupation for upcoming network technologies such as 6G including the broader strategic value chain.

The initiative will also address energy efficiency and carbon neutrality objectives, as embodied by the Green Deal, which have not been sufficiently addressed by the 5G-PPP, such as reduction of the energy consumption of the connectivity platform itself, and directly supporting the reduction of the carbon footprint of vertical industries enabled by SNS systems.

Finally, the 5G-PPP was not designed to prepare and coordinate deployment programmes. The PPP structure is to not firm enough to align stakeholders towards a deployment agenda and the scaling-up of results that includes a broad range of stakeholders with sometimes diverging interests and that delivers not only for the commercial but also the public interest (e.g. enabling public safety or low-carbon services). In the proposed initiative a coordination mechanism for

CEF2 Digital as well as synergies with DEP and InvestEU are built-in, both as part of the scope and governance of the partnership, which is not possible under a co-programmed partnership. The infrastructure funded by activities in the scope of the partnership is indeed only a smaller part of the overall (private) 5G investment in the EU, focusing on market failure areas with cross-border dimension. However, such programmes are expected to play a major role in shaping cooperation models of 5G deployment and thereby unlocking the overall large-scale investment. This aspect is of particular importance in relation to infrastructure programmes supporting economic recovery post-COVID-19.

1.3. EU policy context beyond 2021

The proposed initiative has to be set in the context of multiple European policies and priorities:

- Availability of advanced smart connectivity infrastructures: The Gigabit Society package (COM(2016)587) adopted by the Commission in 2016 stresses the importance for Europe to benefit from an advanced digital communication infrastructure to move Europe into the Gbit/s era, and sets out deployment targets for 5G in Europe through the 5G Action Plan⁴⁶.

The broadband penetration impact on the per capita GDP is widely recognised⁴⁷. Hence the proposed CEF2 Digital programme, which will be coordinated by the SNS initiative targets 5G deployments into lead markets to support European competitiveness and important societal issues, e.g. enabling reduction of road fatalities and of CO2 emissions by vehicles.

- The Communication of 27 May 2020 on a European recovery post COVID-19⁴⁸ has further emphasized the need to invest in more and better connectivity, with 5G having spill-over effects across the whole digital society and increase Europe's strategic autonomy. It calls for wider efforts to build infrastructure that can handle emerging and future processes and applications, to provide the necessary bandwidth for health, education, transport, logistics and media which are essential for our resilience, competitiveness and economic recovery.
- **Digitisation of the industry.** The Digitising European Industry package⁴⁹ acknowledges the key role of smart 5G communication infrastructures wide availability for the digitalisation and modernisation of sectors like transport, automotive, energy, healthcare and public administration.
- -Technology leadership, sovereignty and competitiveness perspective: the need for Europe to master critical network technologies has been outlined by the European Commission on multiple occasions: the Industrial Policy communication adopted in 2017⁵⁰; the Recommendation on cybersecurity of 5G networks⁵¹ adopted in 2019; the Council conclusions of 3 December 2019⁵², which "WELCOMES the ongoing preparation by the Commission, of a strategic European partnership on Smart Networks and Services", and also the European Political Strategy

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⁴⁶ https://ec.europa.eu/digital-single-market/en/5g-europe-action-plan

⁴⁷ https://www.itu.int/dms_pub/itu-s/opb/pol/S-POL-BROADBAND.19-2018-PDF-E.pdf, WorldBank, OECD

⁴⁸ COM(2020) 456 final, "Europe's moment: Repair and Prepare for the Next Generation"

⁴⁹ https://ec.europa.eu/digital-single-market/en/policies/digitising-european-industry, April 2016

⁵⁰ https://ec.europa.eu/commission/news/new-industrial-policy-strategy-2017-sep-18_en stresses that 5G is the foundation of future business models

⁵¹ https://ec.europa.eu/digital-single-market/en/news/cybersecurity-5g-networks: underlines that Europe should fully master the supply side chain as part of the renewed industrial policy

https://www.consilium.europa.eu/en/press/press-releases/2019/12/03/significance-and-security-risks-of-5g-technology-council-adopts-conclusions/

Centre⁵³ calling for ambitious investments in 5G. The **strategic value chains** identified by the strategic forum put in place by the Commission to define industrial policy priorities for Europe are also relevant (Industrial IoT). The Communication adopted on 29 January 2020 **on the 5G cybersecurity toolbox** is particularly relevant as SNS intends major contributions to its objectives: standards to ensure end-to-end security, maintaining European supply capacities and diversification of actors in the supply chain. The partnership will have an important role to play to establish a dynamic multi-vendor environment and to tap into the potential of Open RAN and software implementations to incentivise existing and new competitive EU players.

- The Communication of 27 May 2020 on a European recovery post COVID-19 has further emphasized the need for a stronger industrial and technological presence in strategic parts of the digital supply chain. In that context, it foresees recovery investment towards strategic digital capacities and capabilities, including 5G and 6G networks
- Climate change and Green Deal⁵⁴: the growth of traffic on communication networks ranges from 50% to 100% per year⁵⁵ with strong impact on energy consumption of SNS platforms, expected to rise by a factor of 10 by 2030 and representing up to 10% of the overall energy demand⁵⁶. SNS has the potential to decrease energy needs in vertical sectors, e.g. automotive or factories between 20 and 30%⁵⁷.

2. PROBLEM DEFINITION

2.1. What are the problems?

Given the scale of the challenges ahead for the transformation of the digital infrastructure, the current scientific, technological and economic positioning of Europe in the field, and the overarching EU policy context, a set of problems have been identified where EU research and innovation and EU deployment policies and programmes in the field of Smart Networks and Services would have a key role to play.

Figure 6: Problem tree for the initiative on Smart Networks and Services

55 https://www.statista.com/statistics/271405/global-mobile-data-traffic-forecast/

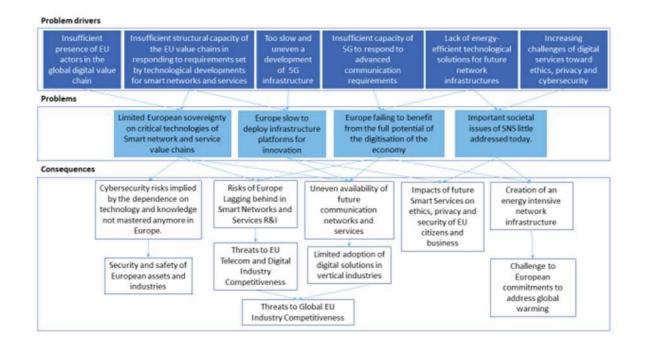
⁵⁷ #SMARTer2030, GeSI report "ICT Solutions for 21st Century Challenges", page 63

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⁵³ https://ec.europa.eu/epsc/publications/strategic-notes/rethinking-strategic-autonomy-digital-age en

https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en

⁵⁶ Anders S. G. Andrae: "On Global Electricity Usage of Communication Technology: Trends to 2030"



Europe's lack of ability to benefit from the full potential of the digitisation of 2.1.1. the economy

The economic potential in the field of SNS is huge. In 2035, they are predicted to enable \$12.3 trillion of global economic output and the global SNS value chain is predicted to generate \$3.6 trillion in economic output and support 22.3 million jobs in 2035⁵⁸. Further estimates predict a global potential economic impact of IoT between €3.5 and €11 trillion per year by 2030 across multiple business domains⁵⁹.

These opportunities, largely represented by the Industrial IoT (IIoT), need SNS as a versatile "connectivity platform" that will become a constituent part of the business process. The Strategic Forum put in place by the Commission⁶⁰ also underlines the need for a better integration of several technological domains, notably cloud computing, connectivity and devices (robots, drones) to reach the full potential of industrial IoT. It also requires performance far beyond the capabilities of the current 5G solutions, e.g. in terms of positioning accuracy, response time, data rates, reliability or automation, which are not available today and will shape the essence of a next generation of mobile and cloud systems towards 6G.

The problem for Europe is hence to put in place the needed critical mass of stakeholders to support a coherent roadmap for SNS, create the needed deployment momentum, and avoid fragmentation. The Open Public Consultation confirmed that stakeholders from different technological horizons and different application and business model perspectives should be involved. It needs to go beyond the current 5G-PPP efforts in this field, as the framework policy constraints surrounding use cases in terms of security, privacy, reliability, deployment and even business models require involvement and steering of public actors in the overall R&I process.

Synergies to avoid fragmentation have to be addressed in particular. The MS consultation led by DG RTD through the SPC (shadow programme committee) has shown that MS are largely

 $^{^{58}\} https://cdn.ihs.com/www/pdf/IHS-Technology-5G-Economic-Impact-Study.pdf$

⁵⁹ McKinsey: The Internet of Things, mapping the value beyond the hype

⁶⁰ Strengthening strategic value chains for a future ready EU industry, 6 Nov 2019.

supportive of the SNS domain (more than 80%) with 70 % having national programme related to SNS issues. Finland is the only MS that has so far labelled an initiative as "6G" but related problems are addressed in several MS, e.g. in Sweden, Germany, France, Spain, even if not as full blown dedicated national programmes. MS have different industrial/academic capabilities regarding SNS. MS with a strong supply side industry are interested from the onset in early R&D. Others are more interested in leveraging the technology to create ecosystems in vertical domains for downstream economic return. In order to motivate the involvement of a large number of MS it is necessary to cover a complete chain, from early R&I to trials and validation with a wide distribution of stakeholders.

2.1.2. Limited European sovereignty as regards critical technologies of smart network and service value chains

SNS technology becomes increasingly contemplated for numerous vertical digital use cases, but Europe has to rely on technologies developed elsewhere, putting European sovereignty at risk.

As outlined in section 1.2, Europe's main technological assets in the SNS value chain is the telecom supply industry, which is challenged both by global competition and by risks of control⁶¹ by non EU actors. Devices and cloud computing are not mastered by Europe, but opportunities exist to develop EU industrial capabilities, through IoT devices and edge computing platforms. New industrial initiatives like Open RAN aiming at providing network functions through cloud based software implementations, a domain where EU industry has less assets today, is also an important area to develop capacities in Europe.

The problem is further aggravated by the trend to design connectivity systems through a vertically integrated perspective from device to service provision, pushed by the very high performance level required in industrial and professional use cases. Non-European actors, who already master vertically integrated value chains, may clearly be at an advantage. The pressure will only increase over time, as the international competition in this domain is fierce, with geopolitical approaches promoted by some of our main competitors, looking for dominance of the full SNS value chain.

2.1.3. Europe slow to deploy infrastructure platforms for innovation

In the wake of early 5G developments, SNS are expected to become platforms for innovation, with a level of openness allowing innovators to develop new applications on top. In spite of technological excellence, the deployment of 5G infrastructure in Europe is not as fast as in other regions, due to fragmented regulation, as well as uncoordinated efforts of both industrial and institutional initiatives. This problem is amplified by the limited investment capabilities of European operators. However, new players in the vertical domains could potentially invest in new 5G infrastructure, but the complexity of integrating such technology with a complete connected ecosystem require significant time to fully validate the solutions in operational conditions.

⁶¹ https://www.justice.gov/opa/speech/attorney-general-william-p-barr-delivers-keynote-address-department-justices-china

2.1.4. Important societal issues of SNS little addressed today

There is a potential conflict between the industrial incentive to develop and deploy SNS, and the concerns of European citizens about the impact of these infrastructures on the environment and on their fundamental rights.

Citizens are increasingly concerned about the use of personal data, by the electro-magnetic field exposure generated by wireless systems and such concerns are already slowing down the adoption of new technologies like 5G. Energy consumption is also an area of concern, as the cloud and network energy consumption may increase by a factor of 10 by 2030, reaching unsustainable levels in the absence of significant technological and operational improvement.

2.2. What are the problem drivers?

2.2.1. Insufficient capacity of 5G to respond to advanced communication requirements

Future digital use cases in professional environments will have very demanding connectivity and service requirements exceeding the most advanced capabilities of 5G roadmaps⁶². These future use cases include:

- Super-immersive multimedia and super-high definition video.
- Holographic telepresence. (up to 100 Gb/s needed, 100 times what 5G offers per user).
- XR Experience: virtual reality (VR), augmented reality (AR) and mixed reality (MR).
- Massive-scale communications (IoT) for anything and anywhere: 6G networks will support extreme massive connectivity.
- Smart City.
- Use cases requiring ultra-high precision 3D positioning, e.g. in factories.

For such a long term perspective, early requirement for future networks and services combining next generation cloud and 6G mobile systems are emerging, with performance improvement factors of at least 10 (positioning, latency) or 50 (capacity, speed) requiring major evolutions beyond the state of the art and across multiple industry sectors.

2.2.2. Insufficient presence of EU actors in the global value chain

The uneven presence of EU actors at each level of the SNS value chain threatens the future European technological sovereignty. This problem is fuelled by several factors:

A fragile position of European actors in the global digital ecosystem: European leadership in 5G R&D depends on a limited number of major 5G infrastructure manufacturers (Ericsson and Nokia) and an associated strong ecosystem of academics and R&I centres. However, reaching out more systematically to vertical industries is necessary to address comprehensive value chains. More collaboration is needed with cloud and device players, as new devices (such as IoT) provide an opportunity for Europe to regain a presence in the device industry as well as the software and cloud domain. This also requires strategic links with the microelectronics industry.

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⁶²See e.g ITU FG2030 White paper: https://www.itu.int/en/ITU-T/focusgroups/net2030/Documents/White Paper.pdf

High risk R&D reinforces the risks for European actors: Connectivity and IT equipment sectors have high research intensity on average around 15% and going up to 30% for some actors63. This is comparable to other R&D intensive sectors such as semiconductors with R&D processes involving significant risks and important upfront investment. The stakeholders' consultation confirms the high risk R&D level of the domain, with particular relevance of public-private risk sharing approaches for long term R&D, as practiced by our main competitors (Asia and USA).

A need for critical mass in standardization: Since its inception end of 2015, the global 5G standardisation in 3GPP64 has generated more than 60,000 industry contributions and thousands of essential patents. European vendors are at the forefront for contributions and patents65 and have been supported by the 5G-PPP programme. However this place remain fragile, and Asia has a strong position on 5G patents and launched 6G programmes. Maintaining European position in global standardisation will require additional European participation, notably more massive involvement of vertical industries.

Stakeholder opinion

A key statement coming up from interviews commonly to all categories deals with the position of Europe lagging behind Asia and US. Indeed almost all interviewees mention the need to keep or regain European leadership in the value chain. Indeed, on network infrastructure, interviewees recognize the leadership of Europe with the presence of two champions. On the rest of the value chain, Europe has lost its position on devices but for most of interviews there could be an opportunity to gain a leadership position on other fields like IoT devices and other emerging technologies like edge computing considered as critical topic. Europe should have the capacity to both support areas where Europe is good at in the value chain and create European alternatives in the whole supply chain.

Also, interviewees from academia categories draw the attention on the necessity to invest more in research in Europe in order to develop its potential, to remain competitive and to avoid shortage of skills and lack of ventures and start-ups.

2.2.3. EU value chains are not integrated to include all actors important for the development of future smart networks and services

The future SNS will be a critical infrastructure to be developed with actors beyond the traditional telecommunication value chain, both from a technological and application perspective:

A future infrastructure relying heavily on multiple advanced digital solutions: The development of an infrastructure able to fit the needs of the future smart services requires cooperation with other field of research beyond pure connectivity infrastructure research (5G-PPP). This implies connection to R&I in IoT, edge computing, artificial intelligence, cybersecurity and cloud, and to address the raising importance of software technologies in networks.

An infrastructure critical for the adoption of digital solutions in many industries: SNS is set to become a critical infrastructure for numerous industries that are transforming themselves by

⁶³ Source: Strategy& PwC, The 2018 Global Innovation 1000 study, analysis of the 1000 largest corporate R&D

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⁶⁴ 3rd Generation Partnership Project, the global standard development organisation for mobile coms. ETSI is member.

⁶⁵ Estimated that out of the 4 main vendors (Nokia, Ericsson, Huawei, ZTE) EU has about 55% of the essential patents

progressively adopting digital technologies. Future research on 5G, beyond 5G and 6G capabilities has to systematically take into account the requirements from the vertical players, beyond initial research on 5G. The integration of the vertical industries into smart networks and services research will need to be strengthened.

An infrastructure that will require structural changes in various value chains: Rapid changes triggered by the deregulation of markets affected the communication industry, increasing competition and technological innovation. As a result, the mobile ecosystem has transformed in a complex network of specific companies involved at different stages in the value chain. The increasing trend towards software implementation and openness of network functions and interfaces opens prospects for new supply side actors, and new business models to emerge.

These changes in the value chain can disrupt existing businesses, and threaten established European actors, but they also provide opportunity for Europe to reposition its industry and to take a larger part in the digital value chain by relying on its strong existing industries.

Stakeholder opinion

According to interviewees with no clear distinction of specific category of stakeholders, the value chain needs to evolve with players emerging from vertical industries. It will give the opportunity to provide new business models such as "Anything as a Service" model allowed by new technologies that provide flexible and open infrastructure.

2.2.4. Too slow and uneven development of 5G infrastructure

Leadership in technology and deployment through lead markets need to go hand in hand to ensure the development of a comprehensive European digital market. Deployment of 5G in Europe is though facing barriers:

Lack of investment in the deployment of the new infrastructure: China is expected to deploy hundreds of thousands of 5G base stations in the coming years. South Korea had already installed more than 90,000 5G base stations by October 2019. Ramp-up is going to be slower in Europe with only hundreds of 5G base stations installed at the same date, what may be due to limited investment capabilities of EU operators. This could be remedied by a new class of investors, like the industry verticals or new value chain actors.

Insufficient synergies between national and European initiatives supporting 5G as well as EU deployment programmes: beyond the European 5G Public Private Partnership (5G-PPP), many European countries have launched national R&D programmes, supporting 5G research and deployments, at national or regional level. They are generally restricted to national participants, and often overlapping with European programs. There is a risk of duplication, and missed opportunities for synergy and coordination. Moreover, deployment programmes such as CEF2 and DEP as well as InvestEU should be coordinated with R&I to achieve a coherent approach. More cooperation at European level would help to optimise the use of resources dedicated to SNS. A consistent strategy with Member States for these two pillars R&I and deployment has been missing to develop an impactful industrial policy in Europe in this field.

A lack of coordination of regulatory approaches, in particular spectrum management: Spectrum assignment remains a national prerogative. There is no formal coordination between EU Member States regarding spectrum assignment conditions. Early 2020, only 16% of the

pioneer bands had been assigned in the EU⁶⁶. This hinders EU wide 5G availability. A common approach to developing a single market environment for large-scale investment in particular spectrum in Europe is beyond the remits of an R&I initiative. However, early technological and business awareness at the Member States level would help to develop a European common approach to spectrum matters and limit the risk for the industry.

Stakeholder opinion

According to the Open Public Consultation, business associations, SMEs and large organizations find very relevant the regulation in the field of radio spectrum allocation.

For several interviewees from different categories, a strong coordination in Europe is required for spectrum harmonization involving the implication of Member States very early in the program. Indeed the spectrum fragmentation in cost and allocation is seen as a key issue.

2.2.5. Increasing challenges of digital services toward ethics, privacy, and cybersecurity

The development of digital services poses several challenges for the EU citizen as to their privacy, data protection, cyber security or ethical concerns. Several fundamental human aspects can be challenged, such as: Identity and Reputation, Relationships, Culture, Motivation and Attention, Responsibility, Fairness, Safety and Privacy. Future integrated connectivity platforms will have to take into account such ethical/societal issues from the start and make them part of the design principle. This in turn requires inclusion of stakeholders with new competence profiles, which are currently not a part of industry initiatives like the 5G-PPP.

2.2.6. Lack of energy efficient technological solutions for future network infrastructures

The systematic inclusion of additional frequency bands to radio sites is expected to double the energy needed per site, a trend further intensified by expected network densification. Coupled with extended computing service platforms, reports indicate a 10 fold increase of network and computing energy consumption, without accounting for the devices. This is exacerbated by a lack of integrated industrial approach towards energy value chains.

2.3. How will the problem evolve?

Limited European sovereignty on critical technologies: in 20 years, the number of European telecom suppliers shrunk from 4 to 2, with increased competition mainly from China and low margins. Also, Europe lost the smartphone industry and failed to create an Internet service industry. Over the coming decade, this trend will be exacerbated. China, Japan, USA, Korea are all planning strategic 6G initiatives. Without a strong EU policy including R&I, European ability to compete is at risk. Market forces may not be sufficient: our main competitors are all considering SNS as a strategic industry and planning financial public support accordingly.

Europe slow to deploy infrastructures for innovation: this issues in the SNS domain is driven by regulatory and financial issues. On regulation, spectrum availability is key to lead deployment, as demonstrated by the aggressive 5G spectrum auction policy in the US. Without an early and coordinated European approach, there is a risk of a patchy "4G like" deployment of future infrastructures. On finances, European operators have lower revenues compared to US operators.

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⁶⁶ 5GObservatory.eu

Investments by vertical industries, as planned in Germany for 5G, would provide new financing sources for deployment. An early involvement of these actors in the R&I process is hence key.

Europe failing to benefit from the full potential of the digitalisation: Reaping the full benefit of digitisation of the industry requires availability of technologies beyond the state of the art to address the most demanding use cases. Deploying such technologies in complex systems takes time and efforts. Should European research on the next step of telecommunication and digital services lag behind, the long term future deployments will be affected, limiting the availability of future infrastructure in Europe with negative impact on the industries requiring it. The development of capabilities of 6G networks and services is also essential to limit the energy need and environmental footprint of the network whilst enabling energy savings in other sectors.

Important societal issues not addressed: citizen concerns like security, trust, privacy, energy footprint or exposure to electromagnetic radiations will be even more exacerbated in the future. Translating these essential requirements into technology will provide a key competitive advantage to leading companies and regions in this field. Failure of European research to address these concerns and to bring them into products and services may leave European policy makers dependent from technological solutions specified elsewhere. Whilst regulation can provide an expost solution, an early involvement of European public actors in the definition of future SNS provides opportunities to visibly address citizen concerns ex ante from a European perspective.

In conclusion, a coordinated EU policy converging visions and objectives across the multiplicity of SNS stakeholders would alleviate the potential negative problem evolution outlined above.

3. WHY SHOULD THE EU ACT?

EU action is based on two Treaty provisions: the EU is empowered to encourage an environment favourable to cooperation between undertakings and fostering better exploitation of the industrial potential of policies of innovation, research and technological development (Art. 173 of the TFEU). Art. 187 TFEU specifies that the EU may set up the structures needed for the efficient execution of EU research, technological development and demonstration programmes.

3.1. Subsidiarity: Necessity of EU action

SNS play a critical role for the competitiveness of the European industries. In Europe, the mobile communication sectors only generates an output of €550 billion (2017 figures) with an employment level of 2.5 million persons. The sector drives the competitiveness of multiple vertical industries (connected cars, smart factories) and has become key for social life.

The challenges faced by the sector are huge: **massive and risky investments** needed to develop new generation of SNS infrastructures, **massive competition** from non-European players in a domain considered strategic, **emergence of new business actors** and new business models, **increased need of public actors** to co-create future systems that will increasingly support areas of public interests (connected healthcare, smart energy grids, connected cars), raising societal concerns of European citizen. These add to the classical issue justifying actions at EU level in the field, such as global consensus on future standards, spectrum and EU wide deployment scenarios.

These issues suggest a rapid and coordinated response of the EU to keep and further improve its competitive position in SNS technologies and related industries. The positive experience from

5G-PPP is not sufficient to mobilise the larger spectrum of required stakeholders whilst avoiding fragmentation and duplications of resources at national level.

3.2. Subsidiarity: Added value of EU action

EU level can clearly drive European actors towards common visions, common technological roadmaps transforming eventually into global standards. This is key to generate economies of scale and economies of scope, limiting if not avoiding EU fragmentation of efforts and national solutions. In the SNS domain, the last 40 years have demonstrated with GSM, 3G, and 4G that a European approach is the only approach that makes sense to cater for citizen obvious requirements, such as interoperability and service portability across multiple providers' domains.

With the move towards industrial domains and vertical use cases, the value of common and standardised technologies translates into cost savings and capex optimisation.

In this domain, which is highly R&I and capex intensive, the European level is the best solution to keep pace with the investments in other regions, notably in Asia. It is also a must if Europe wants to keep a strong industry in this domain, in the context of US efforts to build their own alternative providers⁶⁷.

4. OBJECTIVES: WHAT IS TO BE ACHIEVED?

4.1. General objectives of the initiative

The general objectives address the problems identified in section 2. They take into account the stakeholders' positions expressed in the consultation, the partnership proposal from the industry and research community, from the ETP Networld2020 Strategic Research and Innovation Agenda⁶⁸, and from the Strategic Deployment Agenda (SDA) developed by stakeholders of the connected mobility domain. It has to be noted that even if the core of the initiative is on R&I, deployment aspects cannot be ignored, as industry innovation investments tend to relocate on lead market regions, so it is key to be a lead market in 5G to prepare 6G R&I investments in Europe.

4.1.1. Ensure European technological sovereignty in future smart networks and services

The initiative will address the issue of technological sovereignty and how to stimulate it in a strategic domain, which is a key objective of the new Commission in this particular field and gained further importance in light of COVID-19, in relation of ensuring supply to key sectors. This topic will be addressed by extending the scope from connectivity to the broader strategic value chain including cloud-based service provisioning as well as components and devices. It will also seek to align strategic roadmaps of a wider range of industrial players, including the telecom industry as well as IoT and cloud actors, and to some extent actors from the microelectronics/component domain. The critical role of suppliers identified and addressed in the 5G cybersecurity toolbox will be a key preoccupation for upcoming network technologies such as 6G including the broader strategic value chain.

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https://www.onmsft.com/news/microsoft-and-dell-among-companies-tapped-by-the-white-house-to-build-huawei-5g-network-competitor

⁶⁸ European Technology Platform NetWorld2020: https://www.networld2020.eu/sria-and-whitepapers/

4.1.2. Strengthen the uptake of digital solutions in the European markets

European excellence in SNS supply side requires development of a vertical market for 5G and later 6G infrastructure and services in Europe, preparing for the longer term opportunities of SNS. The automotive market will be targeted with deployment of 5G solutions over cross border corridors in line with the 5G Action Plan targets. A coordination mechanism for CEF2 Digital as well as synergies with DEP and InvestEU are built-in, both as part of the scope and governance of the partnership. The infrastructure funded by activities in the scope of the partnership is indeed only a smaller part of the overall (private) 5G investment in the EU, focussing on market failure areas with cross-border dimension. However, such programmes are expected to play a major role in shaping cooperation models of 5G deployment and thereby unlocking the overall large-scale investment. This aspect is of particular importance in relation to infrastructure programmes supporting economic recovery post-COVID-19. This objective would also contribute to SDG 8, SDG 9 and SDG 11.

4.1.3. Develop digital innovations answering European needs

The aim is to develop the technologies and services required for future SNS platforms. It builds on the most demanding requirements of vertical industries and leverages societal requirements (security, energy efficiency, EMF) as key drivers for competitiveness and differentiation Integration of emerging technologies like Artificial Intelligence to increase performances and entirely new application domains (Internet of senses⁶⁹) is also targeted. It will advance European technological and scientific excellence and support European leadership **to deliver 6G systems by 2030**, and place Europe on par with nations having announced 6G initiatives (China, Korea, Japan, USA, and Taiwan).

4.1.4. Ensure the alignment of future smart networks and services with EU policy and societal needs

The aim is to support the core principles of human centric and sustainable Internet, by addressing ethics, privacy, cybersecurity, electromagnetic fields, and environmental impact from a complete system (data management) and downstream policy perspective. In the Green Deal context, it addresses both radical decrease of energy needs by SNS platforms and SNS contribution to decarbonise vertical sectors through process optimisation. This objective is in line with the political orientations of a "European Green Deal" The initiative will also address green deal objectives, which have not been sufficiently addressed by the 5G-PPP, such as reduction of the energy consumption of the connectivity platform itself, Electromagnetic Fields emissions and support of the reduction of the carbon footprint of vertical industries enabled by SNS systems.

This objective would contribute to SDG 10 (indirectly through lower cost of technology), SDG 12, and SDG 13.

These objectives contribute to the objective of Horizon Europe to deliver scientific, technological, economic and societal impact from the Union's investments in R&I to strengthen the scientific and technological bases of the Union and foster its industrial competitiveness at EU and national levels.

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⁶⁹ Defined as the fusion of environment sensing and communication to provide a context information.

⁷⁰ https://ec.europa.eu/commission/sites/beta-political/files/political-guidelines-next-commission en.pdf

4.2. Specific objectives of the initiative

In order to achieve the general objectives, seven specific objectives are defined. These specific objectives respond to each of the problem drivers discussed in Section 2.2. The list of specific objectives is the following.

- Ensure the development of technologies able to meet advanced communication requirements: the goal is to ensure European excellence for technologies and architectures required for SNS and evolution towards 6G. Typical measurable targets include data rates beyond 100 Gb/s, ultra-low sub millisecond latency, sub centimetre positioning accuracy, ultra-high reliability beyond 99,999%, wide area coverage alleviating digital divide, support of more than 1 million devices per km² for smart city scenario, integrated device to service security. Related objectives include strong European positions on standards, essential patents, and identification of key deployment needs, e.g. spectrum requirements for regulators
- Accelerate the development of energy-efficient network technologies: the goal is to ensure European solutions for architecture and technologies needed to significantly reduce the energy and resource consumption of the whole digital infrastructure from edge cloud services, to the communication network core, the radio access and ultimately to the connected devices. A ten-fold reduction compared to anticipated levels is targeted through reappraisal of integrated architectures networks-clouds and use of low energy technologies such as fibre or new radio spectrum. For SNS support to vertical sectors, a 30% energy decrease of key verticals is targeted.
- Accelerate the development and widespread deployment of 5G and later 6G infrastructure in Europe: the goal is to reach the 5G Action plan objective of 5G deployment along main transport paths by 2025 and 5G introduction in key vertical lead markets. In particular the CEF2 Digital programme is targeting at least 6,000 km of 5G deployment across cross border corridors, as seed initiative targeting places where market forces are not sufficient to ensure deployment. Other deployment programmes under CEF2 as well as DEP and InvestEU will be important to accelerate infrastructure investment and create 5G and later 6G ecosystems.
- Support the transformation of the European value chains: As promoted under the Cybersecurity toolbox, the goal is to stimulate a more diverse supply chain in Europe with more players on the infrastructure side. A related objective is to stimulate emergence of new deployment business models, beyond those of traditional service providers, based either on vertical industry deployment or on neutral host and drawing resources from multiple providers. Target is to have at least one European provider for software based connectivity and pilots for new deployment models, also outlining the related regulatory issues to tackle. This has strong standardisation implication.
- Strengthen the positioning of EU industry in the global digital value chain: the goal is to put in place a critical mass of public and private actors across the SNS value chain, in view of strengthening the EU industries in the global digital value chain, increasing the contribution from software and IoT actors, leveraging national initiatives and supporting the emergence of new actors such as new types of connectivity providers or devices producers. It targets development of commonly shared strategic R&I and deployment roadmaps, coordinated spin offs towards standardisation bodies and strong international

cooperation to stimulate global consensus and visions. Target: at least 30% of new actors expanding the current set of 5G-PPP beneficiaries.

• Ensure alignment with ethical and security requirements: the aim is to include societal and ethical issues as requirements from the onset into the strategic roadmaps with dedicated projects coordinating societal and ethical results developed by SNS as a whole, including at MS level and to map those with existing legislation or to propose new one's as appropriate.

4.3. Intervention logic of the initiative

The relationship between the general and specific objectives of the initiative on Smart Networks and Services is illustrated in Figure 7 below. It outlines a multiplicity of issues to address, including industry competitiveness, industrial policy and repositioning of Europe on strategic value chains and a reinforced EU sovereignty in critical technologies, fostering deployment of advanced infrastructures and addressing societal and challenges from a holistic perspective.

With these challenges in mind, the intervention logic is that the strategic partnership will make a major contribution to several key policies, and that this can not be left entirely to a bottom up industrial approach that leads primarily to a co-ordinated implementation of R&I projects, however excellent this may be from a technological and scientific perspective. The magnitude of the public policies addressed (including deployment in vertical sectors such as healthcare, mobility or energy) suggest a much stronger steering role for the public sector, including at Member State level.

Another dimension of the intervention logic is to engage a wider set of stakeholders from the industrial side, with a compelling roadmap that they can share and agree to, with a view to committing the necessary internal resources. The level of commitment required from the private sector can only be achieved if a long term vision and commitment can be demonstrated from the public side, such that the roadmap can be a mutually shared public-private framework for the full duration of the partnership.

Finally, the partnership needs to join the efforts at Member State level that will further guarantee the success of the initiative. The partnership will not be in a position to resolve fully all the issues at stake, but will place Europe on track to do so. This is particularly important for questions of sovereignty and for the emergence of new industrial players, which will need downstream actions at MS level similar to the IPCEI initiatives in the microelectronics or battery cases. This requires a clear strategic approach across all stakeholders, for which an initiative such as the current 5G PPP was not designed. The requirements and approach will be defined jointly at strategic level in the partnership. However, we recognise that the partnership cannot implement comprehensive reindustrialisation actions nor can it implement general binding legal requirements comparable to the EU legislative process. Whereas the joint approach in the partnership has the advantage of upfront support from a broad range of stakeholders, flanking downstream measures at MS level are still required. Equally, legal measures in the area of spectrum harmonisation, cyber-security or environmental requirements e.g. for networks and data centres, are expected to be a necessary complement. The joint work in the partnership can however prepare the ground for legal proposals and ensure that industrial policy considerations are well addressed.

In practical terms, the mechanism used in the 5G-PPP to achieve ambitious leverage factors for large-scale investment in R&I in the field will be reinforced by a strong prior commitment of financial resources from the public side, and a commitment from industry to co-invest in light of

an R&I and deployment roadmap agreed between a broad range of stakeholders. In particular, stakeholders in the area of cloud computing and Internet-of-Things as well as components and devices will be brought on board of the partnership to address the full range of policy objectives through a comprehensive technology roadmap. Furthermore, public authorities in all Member States as well as technology suppliers and users are being mobilised to support the deployment agenda in view of the CEF2 Digital programme.

As regards public policy objectives, the specific legal basis (in case of an institutionalised partnership) will allow technological sovereignty aspects to be addressed, e.g. by taking into account principles of the 5G cybersecurity toolbox concerning the role of future suppliers, for instance by limiting or excluding non-European headquartered companies from certain calls and activities. In this respect, the initiative will have to balance the stronger role for governments with the continued primacy of European industry in controlling the partnership.

Public policy objectives such as the Green Deal will be emphasised in the R&I and deployment roadmaps as well as in the Work Programmes, e.g. in the form of concrete targets in terms of energy-efficiency or carbon-neutrality of future technologies as well as deployments. This can be achieved by strategic guidance from the Commission and Member States as part of the governance structure.

Figure 7 - Intervention logic for an initiative on Smart Networks and Services

ri S	Limited European sovereignty on critical technologies of Smart network and service		Europe slow to deploy infrastructures platforms for	Europe from the the digi	_	sietal lart ervices
	value chains		innovation	economy	little addressed today	today
Insufficient	Insufficient structural capacity of	ural capacity of	Too slow and	Insufficient capacity of	Lack of energy-	Increasing
actors in the	responding to requirements	quirements set	development	advanced	solutions for future	services toward
global digital value chain	by technological developments for smart networks and services	developments ks and services	of 5G infrastructure	communication reauirements	network infrastructures	ethics, privacy and cybersecurity
				-		
E	Support the	Accelerate the	to the	Enclire the development of	* Δccelerate the	Encure alignment
	transformation	development and	ent and	technologies able to meet	development of energy-	with ethical and
industry in the global	of the European	widespread deployment of	ployment of	advanced communication	efficient network	security
digital value chain	value chain	5G infrastructure in Europe	ire in Europe	requirements	technologies	requirements
rope	Ensure European technological	Strengther	gthen the uptake	Develop digital	Ensure the	Ensure the alignment of future
gnty	sovereignty in future smart	of digital	igital solutions in	innovations answering		smart networks and services with
orks	networks and services	the Europ	the European markets	European needs	EU policy	EU policy and societal needs
	Economic	Economic/Technological		Scientific		Societal

How would success look like?

Should the initiative deliver on its specific objectives, it is expected that it would translate in practice into the following impacts:

Scientific impacts

- ➤ Generation of new knowledge
- > Diffusion of applied knowledge
- > Enhanced positioning of Europe in the S&T field

Should the initiative be successful, the generation of new knowledge in the SNS field would be achieved through the following:

- Enhanced performance requirements for long term connectivity, device and services with creation of new knowledge to meet the most advanced requirement of future digital use cases.
- The development of an energy efficient platform with major scientific breakthrough in the area of energy consumption notably fostering breakthrough all optical networks.
- The integration of new digital services for the industries undergoing a digital transformation will generate system and operational knowledge.
- The acceleration of the deployment of 5G infrastructure and later 6G solutions will create new knowledge.
- Ensuring compliance with European ethics and cybersecurity requirement will also contribute to scientific progress in mathematics, physics and social sciences

The generation of this new knowledge would contribute to European competitiveness in the SNS field through excellence of the European R&I. The initiative would also have important impacts on the diffusion of more operational and applied knowledge through several activities, notably:

- Operational knowledge on deployment and operation of future infrastructures.
- Applied knowledge through adoption of digital applications in various vertical industries.

Economic/technological impacts

- ➤ Enhanced competitiveness of European SNS Industry
- > Increased innovation and research in the field of SNS
- ➤ Adoption of digital technologies in European industries
- > Diminution of regulatory burdens on businesses

The initiative if successful would contribute to an enhanced competitiveness of the European industrial ecosystem, thanks to the large scale coordination and mobilisation of a critical mass of actors across the value chain, in close coordination with member States. The adoption of digital technologies by European industries would be stimulated through support of the development of new smart services, targeting explicitly

the vertical industries and making a large use of advanced digital solutions, by the development of new global standards and the deployment of early services.

Increased innovation and research in the field would be catalysed through bigger direct investment of the European industry in the field and the deployment of the new infrastructure. A leveraging factor of at least 7 is expected with industrial investments and additionally.

Finally the initiative would also have some impacts on the regulatory burden for businesses, through dedicated actions toward the harmonization of regulation and processes around spectrum assignment and usage. The use of untested spectrum beyond 100 GHz as targeted by SNS would be subject to upstream deployment, sharing and co-existence analysis to fuel European regulatory consensus at international levels.

Societal impacts

- > Development of a human-centric internet
- > Equal and safe access to a critical infrastructure
- > Development of employments in field related to SNS
- Mitigate negative environmental impacts

Environmental impacts: Should the initiative be successful two main impacts are envisaged: i) reduction of the planned energy consumption of SNS platform by a factor of 10 compared to the planned evolution by 2030; ii) reduction of the energy footprint of the vertical sectors (factories, vehicles, healthcare, education) by 30% through better process and resource management. Where appropriate, companion legislation would be proposed, needing strong interactions with Member States. Another impact objective is the limitation of Electromagnetic Fields emissions and the coordination with Member States for measurements and public information approaches.

Social impacts: The ability to provide equal access to a critical infrastructure for EU citizens and businesses would be enhanced through higher competition on the supply side and decrease of infrastructure cost due to massive use of software solutions. Ecosystem developments favour job creation and innovative curricula to be developed through industry-academics partnership.

Impacts on fundamental rights: Positive impacts on fundamental rights would be expected from the development of digital services enabling users to fully control their identities and the data they produce or consume.

4.4. What is needed to achieve the objectives – Key functionalities needed

Given the focus of the impact assessment on comparing different forms of implementation, the identification of "key functionalities needed" allows making the transition between the definition of the objectives and what would be crucial to achieve them in terms of implementation. These functionalities relate to the type and composition of actors that have to be involved, the type of range of activities that should be performed, the degree of directionality needed and the linkages needed with the external environment.

4.4.1. Type and composition of the actors to be involved

As initiated by the 5G-PPP and confirmed by the public consultation, SNS need to pool a large critical mass of stakeholders to create an impactful European momentum on Next Generation Mobile and Cloud Systems, 6G.

The core targeted players are the industries and R&I players of the telecommunication value chain complemented with actors representing the Internet of Things, cloud systems, distributed and edge computing, cybersecurity and artificial intelligence. It includes hardware, software and component and equipment manufacturers, and communication service providers.

<u>Vertical industries</u>⁷¹ contribute their advanced requirements, implement validation pilots, and experiments new business models based on alternative connectivity/service providers and data management schemes. Automotive is key for the targeted CEF2 Digital 5G deployment actions.

SME's and start-ups are called upon to benefit from technology transfer, develop and market specific technologies of the entire value chain, from devices to services.

Academics and research centres are key to support research labs of industrial actors and to propose innovative advanced solutions further de-risked by the initiative. In the openness context, academics also mastering social science and societal impacts on technology are called upon to drive ethics/societal related activities and maximise societal acceptability of technology.

International cooperation partners: are not specifically included in SNS but need to be regularly consulted to achieve global vision and standards, especially for what concerns 6G. Reciprocity will be a driver of more operational engagement of such partners.

Member States

The formal and close participation of the Member States as part of the governance structure ensures the possibility to define a top down strategic programming, and to enable synergies with national investments, through a coordinated approach. We foresee a guiding role for Member States in strategic matters that goes beyond the upstream advisory role as in the case of comitology, which is lacking in flexibility when it comes to new and rapidly emerging challenges. This guiding role will be very much needed, considering that for 5G PPP, there were multiple MS initiatives in this field leading to fragmentation and inefficiencies (FI, D, F, ES, S, SL, I, DK, LU, UK..).

The early involvement of MS creates a level of awareness that is key to prepare for deployment in Europe. Deployment of a new generation of connectivity platform requires national involvement in particular in areas of public interest such as 5G along transport paths and 5G cities and communities.

Member States steering is key to the success of the initiative, with upfront strategic guidance, advice on needed regulatory developments, and to support large scale EU wide

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⁷¹ E.g. automotive, factories, media, energy, healthcare, though not limited to those

implementation with access to national relevant facilities⁷² to maximise *directionality*. The participation of members Sates in the governance structure is hence needed

4.4.2. Type and range of activities needed

A comprehensive set of activities reaching beyond the sole R&I is planned to maximise impact and take up whilst fostering *additionally* and leveraging the public investments⁷³:

Roadmap and work programme developments, through large scale consultations and downstream production of Strategic R&I agendas, Strategic deployment and exploitation agendas

R&I activities covering the long term R&I on component, technology and architectural needed to deliver the future 6G standards, the IoT devices operating with 6G and the computing service infrastructure, moving towards cloud native, open and full software implementations running on generic hardware. This is complemented with shorter term R&I on applications covering early deployment and novel usages to initiate the markets and prepare for longer term solutions.

Pilot and deployment actions include lead market development of 5G Corridors as planned under CEF2 Digital, other 5G deployment actions under CEF2, DEP and InvestEU, as well as longer term pilot actions trialling pre-6G technologies in dedicated demanding environments requiring large infrastructures (a factory, a stretch off motorway, an hospital). Such activities are typically supported by private investments beyond the seed public support and require coordination with Member States.

Standardisation and common specifications, coordinated exploitation of project results being submitted to standards through core industry contributions;

International alignment of vision and roadmaps, through dialogue with the main regions having launched similar initiatives targeting 6G;

Development of key regulatory issues notably for what concerns spectrum identification and usages⁷⁴, security standards and certification⁷⁵, energy efficiency and ethical aspects;

Coordination/synergy with relevant European initiatives, through platform of exchanges maximising directionality of the various programmes;

The partnership can realistically achieve the delivery of public policy objectives in its field of activity such as CEF2 Digital deployments or when setting requirements for next-generation technology standards. Since SNS standards such as 5G and later 6G are global standards prepared by the projects of the partnership, the impact of the partnership activities will be significant. There is also the potential that approaches of CEF2 Digital deployment projects defined in the SNS partnership will be a model for other deployment projects in Europe and globally.

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⁷² In the 5G PPP case, at least 10 MS developed 5G pilot facilities independent of EU actions, or only leveraged ad hoc by industry.

⁷³ The 5G PPP level with a leveraging factor of 7 is taken as a baseline objective.

⁷⁴ Target contribution bodies: RSPG, CEPT, ITU

⁷⁵ As contribution to the evolution of the 5G security toolbox released by the EC on 29 January

Such requirements and approaches will be defined jointly at strategic level in the partnership. However, we recognise that the partnership cannot propose general binding legal requirements comparable to the EU legislative process. Whereas the joint approach in the partnership has the advantage of upfront support by a broad range of stakeholders, flanking legal measures in the area of spectrum harmonisation, cyber-security or green deal requirements e.g. for networks and data centres are expected to be a necessary complement. The joint work in the partnership can however prepare the ground for legal proposals and ensure that industrial policy considerations are well addressed.

4.4.3. Priority setting and level of directionality required

Directionality is key and requires a common shared vision to reach the needed ambitious investment to ensure technological sovereignty in the domain⁷⁶. At this stage, multiple fora are already working on such visions: the ITU FG 2030 focus group, the Finish 6G flagship, the IEEE Future Networks initiatives. Similarly, SNS is preparing a similar roadmap. It expands those already mentioned by taking an end to end value chain approach, tackling devices and edge computing. These are instrumental to provide clear investment directions with a 2030 horizon. Development of such visions and roadmaps are classical in this domain and are a must considering the 10 years needed to develop a new generation of connectivity infrastructure. A secured long term budgetary visibility also helps to reconcile two conflicting requirements: the need to have a focused vision and the need to involve a very large variety of stakeholders.

4.4.4. Coherence needed with the external environment

Structured links to external actions are key to the success of SNS. At MS level, establishing links with initiatives like the 6G Flagship of Finland is targeted, and other similar national initiatives will be targeted. Given the wide scope of SNS, clear links have to be established with: the partnership on Key Digital Technologies (KDT) to develop the future generation of components needed for 6G, an issue not well addressed in 5G; the cybersecurity partnership, in view of developing the "landscape aware" security methodology in future systems; the partnership on High Performance Computing (HPC) to develop the enabling technologies for edge processing. SNS will then act as test/validation environment of technologies developed under these initiatives.

5. WHAT ARE THE AVAILABLE POLICY OPTIONS?

This section describes the specific functionalities that could be provided under the baseline scenario of traditional calls and the different options of different types of European partnerships.

5.1. Baseline option – Traditional calls under the Framework Programme

The baseline scenario used in this impact assessment is a situation without a Partnership and only traditional calls of Horizon Europe. Given that there is a predecessor Partnership as well as other funding sources in the area, these will continue generating effects even if there is no new Partnership. In particular it is expected that these already

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⁷⁶ For 5G only, the sole government of South Korea (60 million people, 8 times less than Europe) invested \$ 500 million public support over 6 years. This made possible the emergence of an infrastructure industrial capability (Samsung) that did not exist in 2013 at the start of the programme.

existing initiatives will still create effects on future Smart Networks and Services. This is taken into account in the effectiveness assessment.

In parallel, the baseline situation means that the current implementation structure of the Article 187 would be closed, which bears winding down and social discontinuation costs. There would also be financial cost-savings related to the closing of the structure, related to operations, staff and coordination costs in particular. This is taken into account in the efficiency assessment.

This option cover calls under the Framework Programme and include activities ranging from research action to innovation actions. Coordination and support actions provide a loose ex post coordination framework. Resulting projects run mainly individually. The research agenda is based on a short-term (2 years) perspective through stakeholder consultation.

Table 2: Key characteristics of the baseline situation - Horizon Europe calls

	What is feasible under this option – functionalities of the option
Enabling appropriate profile of participation (actors involved)	 Even if a long term roadmap may be identified, extensive consultations are needed every 2 years to feed the bi annual work programme. Because the long term roadmap would be sliced up into 2 years period (assuming continuity would be granted) early commitment of a wide variety of stakeholders is difficult. In particular users and SME's will be more relevant towards the end of the programme rather than at the beginning when basic technological choices are investigated. Synergies with CEF automotive actors are virtually not possible Mobilisation of national programmes and actors can only be bottom up and ad-hoc
Supporting implementation of R&I agenda (activities)	 Implementation of R&I and demonstration/pilot actions are possible through regular Horizon Europe calls; The needed continuity to deliver on 10 years roadmap is not granted, as it depends from bi annual work programme discussions. The needed financial long term visibility to implement the full R&I cycle is not granted as it depends on bi annual work programme negotiations. Only loose ex post coordination can be implemented, with little possibility to plan for spin off impact like contribution to standards or to spectrum allocation issues.
Ensuring alignment with R&I agenda (directionality)	 Work programmes need to reflect the requirement for R&I activity across TRLs, with input from representatives of all relevant stakeholders. Specification of calls for activity at higher TRLs, particularly demonstration programmes, need substantial input from industry. R&I activity would focus on the short to medium term needs of the industry, it may also include fundamental research, not connected to a long term roadmap Alignment of initiatives across the Union including at MS level very difficult, risks of fragmented and patchy implementations with less interest from MS with little industrial capabilities in the field. Integration with other programmes and synergies with other relevant initiatives (KDT, cyber, HPC) difficult to plan with a programmatic perspective. Each project and activity would function individually without strong coordination.
Securing leveraging effects (additionality)	 Progress of R&I effort depend largely on EU funding, with no expectation of significant leveraging of industry support as actions are not included in a full EU level programme Risks of additional activities being unrelated to actual Horizon Europe R&I.
Key differences compared to the current situation	 The existing 5G PPP is discontinued and its roadmap based piloting and coordination terminated leaving projects without coordination for standardisation, trials and input to regulation The contribution from private side through the 5G Industry Association which coordinates activities has to be replaced by mechanisms to be funded under the Horizon Europe Programme.

5.2. Description of the policy options

Option 1 - Co-programmed European Partnership

This option is based on a memorandum of understanding between the European Commission and a European industry association⁷⁷. The agreement is non-legally binding with "best efforts" KPI's and objectives from the involved stakeholders. The R&I is driven by a long term roadmap primarily defined by the industry and R&I stakeholders and target leveraging effects of at least 5 from the private side.

Table 3: Key characteristics of Option 1 – Co-Programmed European Partnership

	What is feasible under this option – functionalities of the option
Enabling appropriate profile of participation (actors involved)	 Participation of key stakeholders potentially contributing to the specification and delivery of the strategic R&I agenda is possible. Work programme decided biannually impacts the long term visibility of the initiative and may affect commitment of stakeholders. Limited synergies with CEF automotive actors. Mobilisation of national programmes and actors only ad-hoc. The partnership is likely to build upon the existing structure of the 5G-PPP but would have to include new stakeholders to fully cover the scope of the smart networks and services topic. It offer the flexibility to change the profile of participation over time, with new partners joining to support new areas of activity in response to emerging results and changing priorities, but the long term roadmap ensure better participation from the start.
Supporting implementation of R&I agenda (activities)	 Implementation would rely on standard administrative infrastructure underpinning the open calls procedure, drawing on resources of relevant executive agencies and Commission IT systems. Implementation of R&I and demonstration/pilot actions are possible through regular Horizon Europe calls. The needed continuity to deliver on 10 years roadmap is not granted, as it depends from bi annual work programme discussions. The needed financial long term visibility to implement the full R&I cycle is not granted as it depends on bi annual work programme negotiations. Partial programmatic coordination can be implemented for spin off impact like contribution to standards or to spectrum allocation issues. across multiple projects but within the limits of the implemented roadmap actions.
Ensuring alignment with R&I agenda (directionality)	 Work programmes would need to reflect the requirement for R&I activity across TRLs, with input from the various partners to achieve an appropriate balance of activity directed towards different vertical markets (e.g. automotive, manufacturing, transport, health, energy). The partnership would be responsible for ensuring that priorities for calls were specified in line with R&I priorities, including demonstration programmes. Coordination with other initiatives at the European level (CEF, DEP, InvestEU), National and Regional level requires significant efforts. Coordination with the initiatives (KDT, Cyber, HPC) left entirely to industry. R&I activity aligned with the medium-term needs of the industry can be achieved.
Securing leveraging effects (additionality)	 Leveraging target defined and agreed from the onset. Expected in-kind contributions from the private sector identified in the work programme. Agreement to commit extra resources remains "best efforts" from the involved stakeholders.
Key differences	• Extension of the existing industry association of the 5G PPP with new set of stakeholders to

 $^{^{77}}$ The existing 5G Infrastructure Association is considered as the basis for a cPPP

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compared to the current situation

- address of a larger scope of topics to perform 6G R&I as well as to a certain extent deployment actions under CEF2 Digital.
- Additional activities to be planned and reported instead of measuring a mere leveraging factor in H2020.

Option 2 – Institutionalised European Partnership under Article 187 TFEU

This option is based on Article 187 TFEU and requires a Council regulation to implement a Union body, which involve the European Commission, representative from the industry through an industry association Member States and associated countries. The agreement is fixed and legally binding.

The body provides the strategic orientation to work programmes based on a long term research and innovation agenda (5-7 years) following a strategic roadmap to develop 6G networks and services and of providing support for the deployment of 5G infrastructures. It runs the evaluations and decides on the projects to be implemented.

The initiative would benefit from EU funds and seek a leverage effect through the contribution of the industry.

Member States are planned to be strongly involved in the governance of the JU, in particular to provide strategic guidance, advice on specific decisions, and contribute to coherence and synergies with national initiatives. To limit administrative overhead, it is not planned that MS would co-finance the SNS partnership (except possibly in-kind contribution for specific areas).

The institutionalized partnership may also have a dedicated role to define framework deployment conditions namely regulation and legislation (e.g. in the fields of spectrum allocation and use, ethics and cybersecurity of digital services, energy consumption of network infrastructures).

Table 4: Key characteristics of Option 2 – Institutionalised European Partnership (Article 187 TFEU)

	What is feasible under this option – functionalities of the option
Enabling appropriate profile of participation (actors involved)	 Long term visibility provides incentives for mobilisation of large sets of stakeholders at each phase, from definition to implementation and exploitation. The structure enables top down approach to involvement of national initiatives and actors. Industry and MS participation maximise potential involvement of stakeholders.
Supporting implementation of R&I agenda (activities)	 A Joint Undertaking (Union body) would be established to coordinate the specification of R&I activity, manage implementation and report on the results. R&I activities ranging from research action to research and innovation actions (including coordination and support actions) directly conform to industry strategic priorities. Long term budgetary visibility ensures optimised planning of key R&I priorities including additionally aspects. MS involvement maximise exploitation potential of demonstration and validation activities, in addressing regulation and standardization, and support to infrastructure deployment and access to finance.

Ensuring alignment with R&I agenda (directionality)	 The work programme is fully in line with the R&I priorities of the Union and the priorities identified by the industry, combining activity across the TRLs (including pilots) and with application in different vertical industries. Alignment with MS initiatives and other initiatives (KDT, Cybersecurity, HPC) is facilitated with strategic top down approaches. Commission participation in the partnership governance arrangements and approval of the work programme, with MS support, ensure alignment with overarching policy objectives and enable integration with other programmes. Though full openness is the default, restricted calls may be conceived for specific key aspects of the roadmap touching upon sovereignty.
Securing leveraging effects (additionality)	 Legally binding funding requirements would be clearly defined at the outset, with private sector partners expected to provide between 50% and 75% of partnership resources through in-kind and/or financial commitments. A contribution from the Member States in the form of in-kind contribution (such as access to spectrum frequencies and infrastructures) can, be strategically planned top down.
Key differences compared to the current situation	 Extension of the existing industry association of the 5G PPP with new set of stakeholders to address of a larger scope of topics to perform 6G R&I as well as deployment actions under CEF2 Digital. Additional activities to be planned and reported instead of measuring a mere leveraging factor in H2020. Integration of functions for strategic steering for 5G deployment through CEF2 and with MS guidance. Stronger roles for industry and Member States with strategic coordination of EU R&I and policies towards 6G, including input to regulatory processes and societal issues. Stronger long-term commitments of public and private partners allowing for longer term R&I roadmap implementation, including downstream exploitation activities. Inclusion of broader public policy objectives in the roadmap and governance structure with involvement of Member States, which is increasing the wider strategic impact and ambition.

5.3. Options discarded at an early stage

Based on the initial impact assessment and on the analysis of the initiative problem drivers, objectives, and functionalities the option Co-funded European Partnership and Institutionalized Partnership under Article 185 is discarded for following reasons: it does not ensure the required level of industry participation - within the ICT sector, across sectors and across the value chain - to ensure technological sovereignty and rapid market deployment; there is no incentive for private additionality. Whilst the option was supported by 20% of respondents to the public consultation, it turns out that none of the respondent come from the public sector, whilst a very strong commitment is needed for such a public-public partnership. DG RTD consulted the Shadow Programme Committee of Member States mid-2019, and no MS suggested such an option, nor the key industry associations that are behind the SNS industry proposal.

6. HOW DO THE DIFFERENT POLICY OPTIONS COMPARE

Based on the objectives pursued by the initiative and the key functionalities identified to be able to achieve them, each option for implementation is assessed in terms of effectiveness, efficiency and coherence compared to the baseline scenario of traditional calls. The analysis is primarily based on the degree to which the different options would cater for the key needed functionalities. All options are compared to the baseline situation of traditional calls, which is thus consistently scored at 0 to serve as reference point.

6.1. Effectiveness

To be in line with the Horizon Europe impact framework, the fulfilment of the specific objectives of the initiative is translated into 'expected impacts' - how success would look like - differentiating between scientific, economic/technological, and societal (including environmental) impacts. This section considers to which extent the different policy options would allow delivering these expected impacts – confronting what is needed (functionalities) with what each form of implementation can provide in practice. The assessments in this section set the basis for the comprehensive comparative assessment of all retained options against all dimensions in Section 6.4, based on a scoring system⁷⁸.

Scientific impacts

Baseline - Horizon Europe traditional calls

Generation of new knowledge: conventional calls with traditional instruments of the Horizon programme are fully compatible with ambitious research through a competitive process at European scale.

Diffusion of applied knowledge: this option would lack the synergies with larger deployments opportunities, across projects, and large scale connections with vertical industries.

Positioning of Europe in the science and technology field of smart networks and services, this option is adequate as **traditional R&I instruments have demonstrated** their full ability to support high quality research and **open** downstream publications.

Option 1: Co-Programmed European Partnership

Generation of new knowledge, a co-programmed partnership based on the traditional instruments of Horizon programme has a full potential to support ambitious research at European scale. The partnership also bring stronger coordination of the research, critical mass and a better link between the knowledge generated and the industrial needs. It also encourage stronger commitment from the stakeholders. → The potential of the option to generate the expected impact is good (+) compared to the baseline.

Diffusion of applied knowledge, this option allows synergies with larger deployment opportunities, and connections with vertical industries, through formal liaison with other initiatives bring a stronger commitment from industrial players. It potentially reduces academic participation but attracts top academics in strong industry partnership with focused scientific outputs. → The potential of the option to generate the expected impact is good (+) compared to the baseline.

Enhanced positioning of Europe in the science and technology field of smart networks and services: this option is adequate as traditional R&I instrument have demonstrated their full ability to support high quality research and to support downstream open publications. The potential of the option to generate the expected impact is good (+) compared to the baseline, taking into account the quality of the academics attracted by industry.

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⁷⁸ A more in depth and detailed analysis of each policy option is provided in Technopolis Group (2020)

Option 2: Institutionalised European Partnership under Article 187 TFEU

Generation of new knowledge: this option based on the traditional instruments of Horizon Europe has full potential to support ambitious research at the scale of Europe. The partnership also bring a stronger coordination of the research and a better link of the generated knowledge with the industrial needs. It also bring a stronger commitment from the involved stakeholders to the research activities. → The potential of the option to generate the expected impact is good (+) compared to the baseline.

Diffusion of applied knowledge, this option allows critical mass, synergies with larger deployments opportunities, connections with vertical industries, and liaison with other initiatives and a stronger commitment from industrial players. Long term planning visibility reinforces commitment of an institutionalized partnership which may reinforce this impact. → The potential of the option to generate the expected impact is high (++) compared to the baseline.

Enhanced positioning of Europe in the science and technology field of smart networks and services, this option is adequate as traditional R&I instrument have demonstrated their full ability to promote high quality research and to support downstream open publications. → The potential of the option to generate the expected impact is good (+) compared to the baseline.

NB; when moving from FP7 (normal calls) to H2020 with the 5G PPP, industry participation moved from 40% to 60%; with academic participation moving from 50% to 30%. On the other hand, the academic work has been much more focused by industrial requirements which has led to higher usability and relevance of the knowledge generated. When moving from option 1 (cPPP) to option 2 (institutional partnership), it is not expected that academic participation will further decrease, hence the potential generation of new relevant knowledge is similar for the two options, as well as the position of Europe in the S&T field. Usability and diffusion is higher for option 2 due to long term industry involvement.

Table 5: Overview of the options' potential for reaching the scientific impacts

	Option 0: HE calls	Option 1: Co-prog.	Option 2: Institutionalised Art 187
Generation of new knowledge	0	+	+
Diffusion of applied knowledge	0	+	++
Enhanced positioning of Europe in the S&T field	0	+	+

Notes: Score ++ : Option presenting a high potential compared to baseline; Score + : Option presenting a good potential compared to baseline; Score 0: Potential of the baseline

Economic/technological impacts

Baseline – Horizon Europe traditional calls

Competitiveness of European Smart Networks and Services industry: this option is based on loosely coordinated R&I projects and lacks critical mass and directionality. It potentially lacks the stronger commitments of the industry, and the impact of potential synergies with deployment activities, which is due to the lack of long term

visibility deriving from short term (2 years) cycles that are not aligned with long term industrial roadmaps.

Increased innovation and research in SNS: traditional R&I instrument have demonstrated their **ability to promote research and innovation** and a **dedicated initiative** in the field, even only supported by traditional calls is likely to have an effect in that dimension, though on very specific project related topics as deployment is limited

The adoption of digital technologies in European industries: traditional R&I through standalone projects may enable the creation of digital services that can be adopted by vertical industries. However, the research agenda, lacking the commitments of industry is likely to be randomly aligned with the priorities of the industry. The participation of vertical industry stakeholders in calls is likely to be ad-hoc with limited critical mass and both the potential for influencing standards and for adoption of the innovation will remain limited.

Regulatory/standards issues, this option would **lack the strong commitment** and critical mass needed **to influence policy and regulations** as additional activities outside of pure R&I. It is very unlikely that it could contribute to harmonization of regulations and processes around spectrum allocation and usage.

Option 1: Co-Programmed European Partnership

Competitiveness of European smart networks and services industry: a strong commitments of industry is facilitated by a roadmap and SRIA ensuring R&I alignment with the industry needs. Synergies are possible with deployment activities at scale as planned from a comprehensive roadmap which involves from the start a critical mass of stakeholders, with opportunities for new entrants and SMEs to participate in the value chain and contribute to sovereignty. Industry commitment is though not fully secured considering the lack of long term planning capabilities due to unpredictable call cycles (SNS infrastructure developments is an 8 to 10 years process) and content, and implementation trough an Agency process. Also, the ability to establish top down strategic coordination and liaison with related initiatives is limited. → The potential of the option to generate the expected impact is good (+) compared to the baseline.

Increased innovation and research in SNS: the possibility to pool research results across projects through a federated initiative supported by a research roadmap well in line with the industrial needs stimulates the participation of the industry to the partnership and increase the potential research and innovation impact. → The potential of the option to generate the expected impact is good (+) compared to the baseline.

Adoption of digital technologies in European industries: this option could have some impact. The commitment of industry ensure alignment of R&I with the industry needs. The participation of vertical industry stakeholders in calls can be achieved (as shown in last calls of the 5G-PPP) increasing the potential for adoption of the innovation. However, more synergies and coordination with deployment oriented and other initiatives may be constrained. Long term planning lack of visibility due to call cycles and content as well as implementation through an Agency may affect impact industrial long term support and impact. → The potential of the option to generate the expected impact is good (+) compared to the baseline.

Regulatory/standards issues: this option has good standard potential and **commitment** and **ability to influence policy and regulations** due to the involved critical mass of actors and additionality. It may contribute to the necessary harmonization of regulations and processes around spectrum allocation and usage. → The potential of the option to generate the expected impact is good (+) compared to the baseline.

Option 2: Institutionalised European Partnership under Article 187 TFEU

Competitiveness of the European smart networks and services industry: this option maximises industry commitment and impact beyond the establishment of a commonly shared roadmap and SRIA because i) the long term visibility of an Institutional Partnership allows long term planning and industry commitments from the onset across all phases needed for an 8 to 10 years development; ii) industry is directly involved in the project selection, which reinforces directionality; iii) Member States tighter involvement makes top down strategic planning for coordination with MS developments possible; iv) the domain is sensitive for sovereignty and in addition to the default openness of the initiative, the institutional approach allows for calls with restricted participation which is needed to tackle cybersecurity issues in line with the 5G cybersecurity toolbox or to establish strategic links with key initiatives like KDT, HPC, cybersecurity. The potential of the option to generate the expected impact is high (++) compared to the baseline.

Increased innovation and research in SNS: a research strategic roadmap well in line with the industrial needs, the maximised long term industrial commitment, the possible mobilisation of MS initiative, increase the potential research and innovation impact compared to traditional calls. The potential is further increased by the deployment plans promoting higher TRL technologies → The potential of the option to generate the expected impact is high (++) compared to the baseline.

Adoption of digital technologies in European industries: is also maximised through the mobilisation of a critical mass of actors across the complete cycle, owing to the long term visibility provided by the institutional approach and the possibility to influence project selection. Stronger MS involvement is key to quickly diffuse technology at MS level through dedicated pilots in the MS's. Embedded deployment initiative (CEF2, DEP, InvestEU) require MS participation and offer synergy with R&I actions. Optimised participation and commitments also favour additional activities like standardisation, which are needed for deployment and adoption. → The potential of the option to generate the expected impact is high (++) compared to the baseline.

For regulatory/standards **long term commitment** from industry and public actors offer an **ability to influence policy and regulations**, contributing to harmonization of regulations on spectrum allocation and usage. The potential of the option to generate the expected impact is good (+) compared to the baseline.

Table 6: Overview of the options' potential for reaching the likely economic /technological impacts

	Option 0: HE calls	Option 1: Co-prog.	Option 2: Institutionalised Art 187
Enhanced competitiveness of European SNS Industry	0	+	++

Increased innovation and research in the field of SNS	0	+	++
Adoption of digital technologies in European industries	0	+	++
Diminution of regulatory burdens on businesses	0	+	+

Notes: Score ++ : Option presenting a high potential compared to baseline; Score + : Option presenting a good potential compared to baseline; Score 0: Potential of the baseline

Societal impacts

Baseline – Horizon Europe traditional calls

Human-centric internet, taking into account fundamental rights such as ethical, privacy and cybersecurity concerns: standalone projects can develop key technologies in these domains but would lack the additionality required to support downstream legislation for significant impact.

Equal and safe access of European citizens to a communication infrastructure that will prove critical for many digital services: the R&I activities may enable the development of the technology and can support early prototyping. However the scale and scope of these deployments is likely to be limited.

Development of employment in Europe in the SNS domain: the limited critical mass and long term commitment of the scheme entails limited impact on the framework conditions (standards, regulation, tech de-risking, business model validation) mainly covered through additional actions beyond R&I. Those are essential for large scale take up and employment impact.

Mitigation of environmental impacts requires industry wide adoption of technologies and standardised solutions that this option would not support, as elementary projects would lack the needed critical mass.

Option 1: Co-Programmed European Partnership

Human-centric internet, taking into account fundamental rights such as ethical, privacy and cybersecurity concerns may benefit from a roadmap and SRIA including cybersecurity as a priority in the future SNS and the ethical impacts of related use cases. The critical mass mobilised by the scheme favours downstream legislations and regulations to an extent as the lack of long term visibility limits additionality. → The potential of the option to generate the expected impact is good (+) compared to the baseline.

Equal and safe access of European citizens to a critical communication infrastructure for many digital services: this benefits from stronger focus on large scale pilots' activities, involvement of vertical industries and potential liaison with deployment activities to strengthen the access of European citizens and industries to a critical infrastructure. The potential of the option to generate the expected impact is good (+) compared to the baseline.

Development of employment in Europe: it requires take up of the technologies with framework conditions (standards, regulation, and technology de-risking, business model validation) mainly covered through additional actions beyond R&I. The critical mass and

mobilisation of resources of the scheme put in place through common roadmaps and SRIA. It supports the **position of European actors in the value chain**, and the **development of employment in SNS**. The potential of the option to generate the expected impact is good (+) compared to the baseline.

Mitigation of environmental impacts, requires industry wide adoption of technologies and standardised solutions. The critical mass of actors allows to develop the technologies to alleviate energy footprint in both the SNS and the vertical sectors. Full take up require additional take up conditions beyond R&I (standards, certification) and additional activities potentially limited by the lack of long term visibility on the implementation of the R&I roadmap. → The potential of the option to generate the expected impact is good (+) compared to the baseline.

Option 2: Institutionalised European Partnership under Article 187 TFEU

Human-centric internet, taking into account fundamental rights such as ethical, privacy and cybersecurity concerns may benefit from a roadmap and SRIA including cybersecurity as a priority in SNS and including the ethical impacts of future use cases. The additional synergies with Member States initiatives and the long term visibility on the roadmap implementation guarantees the maximum critical mass effect which favours contributions towards needed downstream legislation → The potential of the option to generate the expected impact is high (+++) compared to the baseline.

Equal and safe access of European citizens to a communication infrastructure that will prove critical for many digital services: this benefits from the stronger focus on large scale pilots' activities, involvement of vertical industries. Furthermore the long term visibility on the roadmap implementation maximises the ability of the institutionalized partnership to better coordinate with other deployment oriented initiatives, notably those led at Member States level. → The potential of the option to generate the expected impact is high (++) compared to the baseline.

Development of employment in Europe: it requires take up of the technologies with framework conditions (standards, regulation, and technology de-risking, business model validation) covered through additional actions beyond R&I. The critical mass and mobilisation of resources of the scheme put in place through common roadmaps and SRIA, complemented with synergies with MS initiatives and long term planning of deployment pilot actions provides the framework to multiply R&I activities towards technology take up and favours SNS employment in Europe, through a virtuous circle of "technology push-market pull". → The potential of the option to generate the expected impact is high (++) compared to the baseline.

Mitigation of environmental impacts, requires industry wide adoption of technologies and standardised solutions. The critical mass of actors allows to develop the technologies to alleviate energy footprint in both the SNS and the vertical sectors. Full take up require additional take up conditions beyond R&I (standards, certification) and additional activities favoured by long term visibility on the implementation of the R&I roadmap. This may though be alleviated by the entailed traffic growth on SNS → The potential of the option to generate the expected impact is good (+) compared to the baseline.

Stakeholder opinion

The relevance of this topic has been asked among stakeholders through the Open Public Consultation especially regarding the concerns with using Smart Networks and Services

platforms for ethical, privacy, security, or EMF reasons. For a majority of respondents in several categories including academia, SMEs, large organizations, EU citizen the topic is evaluated as very relevant. For business association and public authority, the topic is seen as relevant but at a lower degree (which can be taken as a hint that this issue is unlikely to resolve only through market dynamics).

Summary

The Table below lists the scores of each of the policy options. The higher potential of option 2 compared to option 1 relates to i) the early MS involvement and strategic steering, that allow for early anticipation of the societal requirements whilst creating early awareness in MS towards the needed deployment policy/regulatory framework to put in place; ii) the integration of deployment actions under option 2, catalysing take up and related societal impact; iii) the industrial commitment to implement a longer term roadmap including deployment, deriving from the long term operational visibility and commitments certainty of the initiative.

Table 7: Overview of the options' potential for reaching the likely societal impacts

	Option 0: HE calls	Option 1: Co-prog.	Option 2: Institutionalised Art 187
Development of a human-centric internet	0	+	++
Equal and safe access to a critical infrastructure	0	+	++
Development of employments in field related to SNS	0	+	++
Mitigate negative environmental impacts	0	+	+

Notes: Score ++ : Option presenting a high potential compared to baseline; Score + : Option presenting a good potential compared to baseline; Score 0: Potential of the baseline

6.2. Efficiency

To compare the policy options in terms of efficiency, a standard cost model was developed for the set of candidate Institutionalised Partnerships. The model and the underlying assumptions and analyses are set out in the Common Part of this impact assessment, Section 2.3.2 and in the Methodology Annex 4. A dedicated Annex 3 also provides more information on who is affected and how by this specific initiative in line with the Better Regulation framework. The scores related to the costs set out in this context allow for a "value for money" analysis (cost-effectiveness) in the final scorecard analysis in Section 6.4.

In addition, for this specific initiative under the baseline scenario of traditional calls, there would be winding down and discontinuation costs for the existing implementation structure of the current 5G PPP initiative. These can be estimated at 6 to 7 FTE which would be transferred from the existing industry association to the Commission of its implementing body (see next section).

The score of the baseline scenario (traditional Horizon Europe calls) is set to 0 to be used as a reference point.

On this basis, the scores in terms of the costs of the different options range from a value of 0, reflecting the fact that the baseline option does not entail any additional costs

compared to the baseline situation, to a score of (-) when an option introduces limited additional costs when compared to the baseline and a score of (-)(-) when substantial additional costs are expected in comparison with the baseline. In case the scores are lower than for the baseline scenario, (+) and (+)(+) are used.

It is considered that while there is a clear gradation in the overall costs of the policy options, the cost differentials are less marked when one takes into account the expected co-financing rates and the total budget available for each of the policy options, assuming a common Union contribution. From this perspective, there are only one or two percentage points that split the most cost-efficient policy options - the baseline (traditional calls) and the Co-Programmed policy options – and the least cost-efficient – the Institutionalised Partnership option. Indeed, in terms of cost-efficiency, the Co-Programmed Partnership (Option 1) is 2 percentage points more efficient than the baseline; and an Article 187 Partnership (Option 2) is 2 percentage points less costefficient than the baseline. A score of + is therefore assigned for **cost-efficiency** to the Co-Programmed options and a score of (-) for the Institutionalised Partnership policy option⁷⁹. However this scoring is based on the simplified assumption that we start from a greenfield site, i.e. there is no pre-existing established initiative. For the final assessment we need to keep in mind that, whereas, there may be an associated cost with discontinuing the 5G-PPP for the baseline, both the Co-Programmed Partnership (Option 1) and the Article 187 Partnership (Option 2) would benefit from existing structures (see next page on 5G-PPP discontinuation).

Table 8: Matrix on 'overall costs' and 'cost-efficiency'

	Option 0: HE calls	Option 1: Co-prog.	Option 2: Institutionalised
Overall cost	0	0	(-)(-)
Cost-efficiency	0	+	(-)

Notes: Score 0 = same costs as for the baseline; score (-) = limited additional costs compared with the baseline; score (-)(-) = substantial additional costs compared with the baseline

Costs of 5G PPP (current partnership) discontinuation.

The assumption behind the assessment of discontinuation of the 5G cPPP is based on the idea that the volume of budget remains similar, but handled through normal calls.

Running the action like a programme.

The currently existing 5G IA, the industry association, has a yearly budget of about 300 k€, financed by its members. This budget is used to organise the programme and all its stages: preparation of calls, mobilisation of stakeholders, organisation of projects around topics of common interests, joint events, publication of PPP level papers and dissemination, organisation of joint trials... In addition, each board member (10 in total) is allowed by his/her mother company to work up to 50% of his/her time for the 5G PPP. Altogether, this represent an overall commitment level that may be estimated to about 6 FTE (Full Time Equivalent). This industrial commitment mirrors the long term commitment of the Commission that announced from the onset an available budget of €700 million for the public side of the PPP.

Should the current structure be disbanded and not replaced by another partnership structure, and assuming that the Commission wishes to reach a similar level of

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⁷⁹ The baseline (traditional calls) is scored 0, as explained above.

stakeholders commitments, coordination and impact, these 6 FTE would be transferred to EC staff.

In addition, implementing the programme as normal calls that are re-discussed every year without a long term visibility will require additional efforts from the Commission to redefine a roadmap every two years, whilst this is fully in the hands of the stakeholders at the moment, with supporting ETP NetWorld that organises the SRIA in partnership with the 5G-IA. This requires organisation of workshops, seminars, discussion between industry and academia. In that case, the efforts of extra constituency building, SRIA definition and follow up may be estimated of about 1 FTE.

For the operational implementation of the calls, the costs will not change if the budgets remain similar. Current level of budget represents in average two to 3 calls per years, fully implemented by Commission staff. If the normal calls without PPP is implemented, similar statutory staff involvement will have to be targeted. So this does not significantly change, also considering that under the current scheme, the retained approach has been to implement a limited amount of projects of large to very large scale which limits the number of projects and the cost of follow up.

In conclusion, it may be roughly assessed that the cost of discontinuing the current PPP implementation model to revert to normal calls renegotiated (from the existence and budget perspectives) could lead to an estimated 6 to 7 extra FTE's to keep the same budget efficiency in terms of coordination and programme impact.

6.3. Coherence

6.3.1. Internal coherence

In this section we assess the extent to which the policy options show the potential of ensuring and maximising coherence with other actions, programmes and initiatives under Horizon Europe, in particular European Partnerships (internal coherence).

Baseline - Horizon Europe traditional calls

This option has a **limited ability to mobilise the broad ecosystem required** by the future development of SNS over a long duration. The participation of **core players from the industry and research communities** is **ensured** (past programmes, e.g FP7 have proven their ability to mobilise such actors) on a work programme basis, but only for the limited time and objectives corresponding to the implementation of specific projects. This also applies to the vertical industries, that may be mobilised ad how through a call but cannot be involved for a long term strategy and planning of the downstream deployment framework.

Similarly, **SMEs** would be involved ad-hoc, on a per call basis.

International cooperation may be envisaged per call, but the lack of long term visibility and predictability does not allow to build a European initiative that would be seen as the counterpart of the visible initiatives launched by China, Japan, and South Korea.

A strong strategic focus could be favoured by a strong cooperation and coordination between the funded projects, which though would lack the long term visibility of a partnership.

This option is the simplest with **governance issue** limited to cross projects coordination at best.

Option 1: Co-Programmed European Partnership

This option has a good ability to mobilise the broad ecosystem required by the future development of SNS on the basis of a shared roadmap and Strategic Research and Innovation Agenda (SRIA). The participation of core players from the industry and research communities may be ensured on a long term basis from the perspective of strategic planning and definition of the needed actions, as shown by the 5G-PPP. The unpredictable implementation cycles discussed every two years may though limit their commitments with engagement of the different communities (ICT tech, verticals, SME's) varying as a function of the planned calls, and limited ability to define a long term strategic plan with MS initiatives. The lack of long term budgetary and planning visibility may limit the impact of downstream additional actions like contribution to standards, spectrum regulation, and business models validation. Whilst these can be planned in advance, they also depend on the implementation of seed R&I actions that cannot be planned with a longer than 2 years cycle.

International cooperation benefits from the **strong positioning and visibility** of a partnership that visibly represents EU R&I in the field of Next Generation Mobile and Cloud Systems.

A strong strategic focus, is enabled by early planning and cooperation and coordination between the funded projects, though subject to short term implementation cycles. It is reinforced by the participation of a dedicated industry association. The participation of a large and active ecosystem of actors to the industry association enable a strong strategic vision, whose implementation is though not secured by a long term approach.

This option benefits from the existing governance and process of previous partnerships (such as the 5G-PPP). Most industrial actors in the field of SNS are already accustomed to the governance and functionalities of a co-programmed partnership. It can be rapidly operational and ensure an efficient governance. However, SNS has a higher ambition than the 5G-PPP (sovereignty across a complete value chain) and requires new actors. The existing industry association of the 5G-PPP has consequently to include a wider set of actors.

Stakeholder opinion

It is to be noted that in the interviews, a large number of actors involved in the 5G-PPP initiative supported this option mostly with regards to the governance aspects.

→Overall, The potential of the option to generate the expected impact is good (+) compared to the baseline.

Option 2: Institutionalised European Partnership under Article 187 TFEU

This option has a good ability to mobilise the broad ecosystem required by the future development of SNS on the basis of a shared roadmap and Strategic Research and Innovation Agenda (SRIA). The participation of core players from the industry and research communities may be ensured on a long term basis from the perspective of strategic planning and definition of the needed actions, as well as at implementation level owing to the long term predictability offered by the scheme. It also maximises matching of implemented actions with the strategic roadmap considering the industry involvement in the selection of the funded actions. It also allows long term strategic planning with the MS initiatives and with other key initiatives like KDT, cybersecurity, and HPC through common calls. Commitment of stakeholders to the **institutionalized partnership structure** may depend on Member States role in the governance. This is seen as a

potential factor to **cause delays** in the gathering of the relevant stakeholders, but not as a factor that would significantly reduce the mid-long term ability of the institutionalized partnership to gather the right stakeholders.

SME participation rely mostly on the traditional Horizon instruments. It is facilitated by SME focused actions of the industrial roadmap and by the presence of SME representatives in the board of the industry association member of the partnership. SME participation in the current 5G PPP is of about 20%. Participation of SME's in the SNS field is very much correlated with the implementation of pilot and trial actions. SME tend to be less present in in depth research phases, but become very active when the technology gets closer to standards and actual implementation. SME participation hence requires a careful planning, with full implementation of a roadmap that ranges from early research to pilot and trials at EU scale. Option 2 is superior in that respect as the long term visibility and commitment towards implementation of a comprehensive roadmap maximises SME participation potential at each stage of the R&D cycle

International cooperation benefit from the **strong positioning and visibility** of a partnership that visibly represents the EU in the SNS domain. At implementation level, the institutional partnership allows to restrict some critical call (sovereignty, security) to specific industrial partners.

A strong strategic focus is enabled by early planning and cooperation between the funded projects. It is reinforced by the participation of a dedicated industry association. The participation of a large and active ecosystem of actors to the industry association enable a strong strategic vision, whose implementation is secured by a long term approach.

This option builds on the 5G-PPP industry association, duly modified to take on board the needed new players, which would eventually represent the industry side of the institutional partnership. It require the set-up of an active and efficient governance. Given the **broad range of stakeholders** to be mobilized and the **need of participation of Member States**, this option will require **dedicated efforts and negotiations** to ensure the **efficiency** of the governance structure. → The potential of the option to generate the expected impact is good (+) compared to the baseline.

6.3.2. External coherence

In this section we assess the extent to which the policy options show the potential of ensuring and maximising coherence with their external environment, including EU-level programmes and initiatives beyond the Framework Programme and/or national and international programmes and initiatives, but as well as with overarching framework conditions, such as regulation, standardisation, etc. (external coherence).

Baseline – Horizon Europe traditional calls

Regarding the ability to **establish liaison with related R&I initiatives** and in neighbouring domains (such as KDT, cybersecurity or HPC research), the initiative relies **solely on coordination and support actions** and on the willingness of the participants to exchange and collaborate, resulting in **a low level of liaison**, without any possibility of long term strategic planning

Furthermore, the initiative using traditional calls would have **no real ability to consistently coordinate** with the **initiatives from Member States** supporting R&I in the field of SNS. The **coordination with deployment oriented initiatives** (such as CEF2, DEP, and InvestEU) would be **very limited**.

Regarding the ability to establish liaison with **initiatives and actors** able to provide **funding and dedicated supports** to **start-ups and innovators**, an initiative under the traditional calls would have a **very limited impact**. The relatively **low visibility of the action**, will leave little space to attract funding and investment in the field.

Regarding the ability to **link and potentially influence** future **regulations** (in spectrum allocation and usage, energy consumption of future networks and services, or ethical and security issues), an initiative using traditional calls would have a **very limited impact**. It would lack the **critical mass of industrial participants** necessary to really have an impact on future legislations and regulations.

Option 1: Co-Programmed European Partnership

Establishing liaison with related R&I initiatives and in neighbouring domains (such as KDT, HPC, or cybersecurity), could rely not only on coordination and support actions but also on potential actions at the level of the respective industry associations. Long term strategic planning is possible but not matched by the short term implementation cycles lacking long term visibility.

The ability to coordinate with the initiatives from Member States supporting R&I in the field is limited as shown by the 5G-PPP. It remains ad-hoc, opportunity driven, without any possibility to establish a long term top down strategic planning. The coordination with deployment-oriented initiatives (such as CEF2, DEP, InvestEU) would also be very limited.

Liaison with initiatives and actors able to provide funding and dedicated supports to start-ups and innovators, the impact is limited and depends on individual actors. The visibility of the partnership, could be exploited to some extent to attract investment. However it would likely lack the ability to set-up dedicated coordination.

Regarding the ability to **link and potentially influence** future **regulations** (in spectrum allocation and usage, energy consumption of future networks and services, or ethical and security issues), moderate good **impact** is possible However the **critical mass and strong commitment of industrial participants** necessary to really have a strong impact on future legislations and regulations requires long term visibility of the roadmap implementation. \rightarrow The potential of the option to generate the expected impact is good (+) compared to the baseline.

Option 2: Institutionalised European Partnership under Article 187 TFEU

Establishing liaison with related R&I initiatives and in neighbouring domains (such as KDT, HPC, or cybersecurity), could rely not only on coordination and support actions but also on potential actions at the level of the respective industry associations. Long term strategic planning is possible making joint calls possible at the level of the institutional partnerships concerned

The coordination with the initiatives from Member States supporting R&I in the field is possible with a top down strategic planning. The coordination with deployment oriented initiatives (such as CEF2, DEP and InvestEU) would also be possible, ensuring liaison with all development and deployment activities of smart networks and services at the local, national and European level.

Establishing links with **initiatives and actors** capable of providing **funding and support** to **start-ups and innovators**, **depends on individual actors**. The **large visibility**, **and political weight of the partnership**, could though be exploited to attract investment (including on an international scale).

Furthermore, the **commitment** (including commitment to funding) of an institutionalized partnership would also **strengthen the leverage effect** as investors and industrials would be **more certain of the long term commitment** of the participants to the initiative.

Regarding the ability to **link and potentially influence** future **regulations** (in spectrum allocation and usage, energy consumption, or ethical and security issues), an initiative using an institutionalized partnership would have a **good impact**, maximised by the large critical mass of actors mobilised, the long term commitment, and the better matching of the roadmap with the implemented R&I actions. \rightarrow The potential of the option to generate the expected impact is high (++) compared to the baseline.

Stakeholder opinion

According to the Open Public Consultation, business associations, SMEs and large organizations find very relevant the regulation in the field of radio spectrum allocation.

For several interviewees from different categories, a strong coordination in Europe is required for spectrum harmonization involving the implication of Member States very early in the program. Indeed the spectrum fragmentation in cost and allocation is seen as a key issue (very irregular depending on the countries).

Summary

Table 10, below, lists the scores of each of the policy options, based on the assessments above, and taking into account the support expressed by the different stakeholders.

Table 9: Overview of the options' potential for ensuring and maximizing coherence

	Option 0: Horizon Europe calls	Option 1: Coprogrammed	Option 2: Institutionalised Art 187
Internal coherence	0	+	+
External coherence	0	+	++

Notes: Score ++ : Option presenting a high potential compared to baseline; Score + : Option presenting a good potential compared to baseline; Score 0: Potential of the baseline

6.4. Tabular comparison of options and identification of preferred option

Building upon the outcomes of the previous sections, this section presents a comparison of the options' 'performance' against the three dimensions of effectiveness, efficiency and coherence. In Section 6.4.1, we first compare the policy options against each other for each criterion in the effectiveness and coherence dimensions, resulting in a scorecard with scores from 1 to 3 where 3 stands for a substantially higher performance. Combined with the results from the comparative assessment for efficiency in Section 6.3, the final scorecard will allow for the identification of the preferred option in Section 6.4.2, taking all dimensions and criteria into account.

Effectiveness

Regarding the **scientific impacts**, the impact of the three considered options would be relatively close, due to the overall good capacity of traditional R&I instruments to ensure the generation of new knowledge and to enhance the positioning of Europe in the S&T field. However, the partnerships options (institutionalized and to some extent, the coprogrammed partnership as well) would be able to achieve more thanks to better capacity to support the diffusion of knowledge through a better critical mass effect and connection with vertical industries. The partnership options (both institutionalized and coprogrammed) would result in a higher impact in term of knowledge creation through a stronger commitment of industrial players to the R&I activities.

Technological and economic impacts: Option 0 ranks significantly lower than the other two options, with limited ability of R&I activities alone to have a strong economic impact beyond a mere increase of R&I in the field. Both partnership options (institutionalized and co-programmed) would be able to achieve more by harnessing a stronger commitment at scale from the industrial actors, including vertical industries. The ability to have a R&I agenda well aligned with industrial needs but also to liaise and support deployment oriented activities further support the partnership options (institutionalized and co-programmed). The institutionalized partnership would provide further impact by ensuring an even stronger longer term commitment of the stakeholders, implementation visibility and by its potential ability to influence R&I projects selection, policy and regulation that could diminish regulatory burdens on businesses. Sovereignty targets are also best addressed through possibilities of restricted actions to strategic EU partners.

Societal impacts: Option 0 (Horizon Europe calls) ranks also significantly lower than the other two options, because of the limited ability of R&I activities to have a strong societal impact without coordination with other actions. The Co-programmed option would provide good societal impact in the 3 considered dimensions. This is directly linked with the fact that the partnership would strengthen the deployment of the infrastructure. Option 2 (institutionalized partnership) would bring additional benefits by enabling an even stronger critical mass, long term visibility and implementation with potentially more coordinated deployment of the infrastructure and by a good ability to influence future regulations (which could be used to foster the development of a human-centric internet).

Coherence

The baseline option can be considered as significantly outranked by the two other options as the initiative would have difficulties to attract the broad range of stakeholders required. Option 1 and Option 2 (co-programmed and institutionalized partnerships) would be comparable in term of internal coherence with a better ability to attract the required stakeholders in the long term for option 2 but a more complex governance scheme.

Regarding the external coherence, the baseline option would have little impact, unable to reach out efficiently to other initiatives. Option 1 would provide some impact by a larger visibility and ability to reach out to other initiatives, but it would lack the benefits brought by the institutionalized partnership (option 2), which benefit from a very high, long term strategic planning and implementation capabilities across institutional partnership, ability to establish strategic synergies with other programmes Including at MS level.

Table 10: Overall scorecard of the policy options for all criteria

	Criteria	Option 0: HE calls	Option 1: Co- programmed	Option 2: Institutionalised	
	Scientific impacts				
ness	Generation of new knowledge	0	+	+	
Effectiveness	Diffusion of applied knowledge	0	+	++	
Eff	Enhanced positioning of Europe in the S&T	0	+	+	

	Criteria	Option 0: HE calls	Option 1: Co- programmed	Option 2: Institutionalised	
	field				
	Economic/technological impacts				
	Enhanced competitiveness of EU SNS Industry	0	+	++	
	Increased innovation and research in the field of SNS	0	+	++	
	Adoption of digital technologies in European industries	0	+	++	
	Diminution of regulatory burdens on businesses		0 +		
	Societal impacts				
	Development of a human-centric internet	0	+	++	
	Equal and safe access to a critical infrastructure	0	+	++	
	Development of employments in field related to SNS	0	+	++	
	Mitigate negative environmental impacts	0	+	+	
er	Internal coherence	0	+	+	
Coher	External coherence	0	+	++	
e e	Overall cost	0	0	(-)(-)	
Efficie ncy	Cost-efficiency	0	+	(-)	

Notes: Score ++ : Option presenting a *high* potential compared to baseline; Score +: Option presenting a *good* potential compared to baseline; Score 0: Potential of the baseline.

The scorecard of policy options shows that the baseline option performs less well against almost all dimensions and criteria compared to the Option 1 and Option 2. Even though it reached a higher score against the cost and cost efficiency criterion, this does not weigh up against its lower performance against the dimensions of effectiveness and coherence.

Stakeholder opinion

Stakeholder opinions from the open consultation and interviews favoured the known model of co-programmed partnership due to the successful implementation of the 5G-PPP, which was found to present significant added value compared to traditional calls.

However, the stakeholders are fully open and understand the advantages of the institutionalised model. For the 37% preferring a co-programmed model, it is to be noted that at least 6 organisations in the 5G PPP, representing a large majority of the Industry and the 5G Industry Association, chose "co-programmed" as preferred option, but with the comment that "this Partnership could be implemented equally as an Institutionalised Partnership". This relativizes the raw statistics and shows support for an institutionalised approach, provided that its complexity and model for financial contributions are reasonable, which is the condition for stakeholders to sign up.

In particular, the main industry players and key associations that are needed to realise the ambitious scope of activities have shown openness to the institutionalised model. They have

understood its strategic character and their responsibility vis-à-vis EU policy objectives such as technological sovereignty and green deal.

The main reason provided by the key stakeholders why they did not express a clear preference in the first instance for the institutionalised options is the fact that concrete implementation conditions including the allocated budget have not been published. However, concrete implementation options for the institutionalised model have been discussed with these key stakeholders as well as Member States, and workable options for the governance structure and co-investment have been identified. We therefore conclude that the flexibility available to set up the institutionalised partnership will minimise the risk of stakeholders not subscribing to the model.

Comparison between the preferred option & the current partnership existing in the area taking into account lessons from past evaluations

What continues	What is different
 The connectivity focus of the 5G PPP (5G) The 5G PPP stakeholders will continue to be highly relevant The roadmap based from early R&I to trials and demos approach The SME objective of the 5G PPP (20%) The standardisation objective The target to open new spectrum frontiers The leveraging factor (7 for 5G PPP industrial players) 	 Much higher level of ambition (scope and policies) Full value chain approach, including capacity building in devices (IoT) and cloud The sovereignty aspect, notably the support of the objectives of the cybersecurity toolbox is integrated to the SNS partnership Societal aspects are integrated, notably SDG's such as "Infrastructure affordability" of SDG 9, Sustainable cities (SDG 11) or Climate actions (SDG 13). The latter is directly coupled with the Green Deal Policy, with two objectives: i) SNS platforms in support of energy efficiency ii) drastic reduction of SNS platforms energy requirements Stakeholders are extended with IoT and cloud systems players Member States are associated, as they are key to develop R&I and test/pilot infrastructures that can be leveraged at EU level, hence improving additionality The JU model imposes a new governance, with a Governing board as specified in an implementing regulation The restriction of the initiative to EU players, in view of sovereignty objectives is planned, the international cooperation is more selective, based on a case by case approach, whilst the 5G PPP had generated several Joint declaration of cooperation with 4 different nations The deployment aspect is also addressed from a systematic perspective, with inclusion of 5G deployment actions (precursor to SNS/6G) along main transport paths, using the CEF2 tools as well as other 5G deployment programmes under CEF2, DEP, and InvestEU. The objective is to go beyond pilots, towards operational deployments Additional activities are factored in from the onset to define the extra investments, e.g. standardisation, specific industry pilots building up on partnership pilots, international regulations (spectrum)

The scorecard also shows that benefits are clearly maximised under the institutionalized partnership option (option 2). In particular, compared with the other options, Option 2 would:

1. Provide greater effectiveness, especially in term of economic, technological and societal impacts by its ability to secure stronger long term commitment of the

- involved stakeholders, to optimise the implementation of the R&I roadmap and to foster regulation and standardization activities.
- 2. Improve the external coherence by a good ability to reach out to other initiative and a strong ability to establish synergies with programmes led at the European, National or Regional level.
- 3. Offer a relatively good overall efficiency despite additional costs.

Summary Assessment

The Institutional Partnership is primarily motivated by the increasingly strategic role of the technology area for European society and economy. Whilst the previous initiative was merely motivated by industry competitiveness in the 5G era, the SNS initiative needs to address a multiplicity of policies encompassing sovereignty across a value chain beyond mere connectivity, sustainable recovery post COVID-19 and Green Deal. This requires a more complex roadmap with several policy dimensions and a larger set of committed stakeholders where Member States have to be fully involved, with an adequate governance model with all parties on equal footing, especially for those aspects dealing with emergence of EU industrial capabilities in domains where the EU is less present. It will enable downstream relay actions at MS level similar to the IPCEI model in other strategic domains like components or batteries. Therefore, long term commitment by a broad set of stakeholders and strategic governance formally involving MS become key differentiators.

From a policy perspective, the two options (1 and 2) hence differ in their capabilities to deliver on the strategic objectives of the SNS initiative. The possibility for a more systemic approach and the ability to ensure synergies with other funds, particularly for deployment, the following are other key elements of differentiation:

Commitment of stakeholders

- A broader set of stakeholders to mobilise which requires the alignment to a common long term roadmap, considering that it takes about 10 years to develop a new generation of connectivity platform (from early R&D to deployment). **This requires long-term investment certainty** that only the institutional partnership may provide (Option 2). Option 1, with workplans discussed every 2 years without any visibility of the investments ex- ante will not provide the long term certainty and predictability needed to secure the right level of industry ownership and commitment;
- Long term visibility is further enhanced by the legislative approach towards a firm budgetary commitment on the public and the private side: a clearly identified contribution from the Union mapped with legally identified commitments from the private side, be it in kind or financial.
- In terms of external coherence, the long-term visibility of option 2 and the increased level of industrial commitment allows to plan consistently over time for key outputs such as contribution to standards, position on spectrum or in other regulatory fora. This is more difficult with option 1, where there is no Council Regulation in place setting the frame and the commitments might be put in question for every new work-programme, e.g. every 2 years with varying priorities and lack of commitment towards a mid to long-term roadmap

Close involvement of Member States

- The formal and close participation of the Member States as part of the governance structure ensures the possibility to define a top down strategic programming, and to enable synergies with national investments, through a coordinated approach. We foresee a guiding role for Member States in strategic matters that goes beyond the upstream advisory role as in the case of comitology, which is lacking in flexibility when it comes to new and rapidly emerging challenges. This guiding role is not formally possible with option 1, but will be very much needed, considering that for 5G PPP, we have noted multiple MS initiatives in this field leading to fragmentation and inefficiencies (UK, FI, D, F, E, S, SL, I, DK, LU..). In particular, European level leveraging of Member State infrastructures would significantly increase additionality.
- In the case of option 2, adherence to an industrial roadmap will be mirrored by an adherence to this roadmap by Member States initiatives. It will build on MS initiatives, as during MS consultations through the Shadow Programme Committee (SPC), 80% of MS have declared having SNS related R&I policies in place. This combined roadmap support (EU, industry, MS) will provide a powerful framework to federate long term commitment from industrial stakeholders whilst enabling MS budget investment efficiently complementing EU investments (additionality). Option one would be limited to provide this long term commitment.
- The early involvement of MS creates a level of awareness that is key to prepare for deployment in Europe. Deployment of a new generation of connectivity platform requires national involvement in particular in areas of public interest such as 5G along transport paths and 5G cities and communities. Option 2 is the option that maximises strategic involvement of MS and preparedness towards deployment of 5G and beyond, in view of maximising Europe wide impact.
- Similarly, the long-term visibility of Option 2 in terms of roadmap implementation allows the partnership to be defined from the outset with links to other relevant key initiatives, notably KDT (components), cybersecurity, EuroHPC. Here again, MS involvement from the outset with Option 2 would also allow a strategic steer of the cross cutting actions between these highly complementary initiatives and stimulate cross cutting investments at MS level in efficient synergy with the cooperating partnerships.

Possibility to derogate from standard rules for participation in R&I activities

As the political debate that developed over the security of 5G network equipment demonstrates, the issue of the cybersecurity of communications networks and services will be increasingly critical as they become central to the working of all facets of the economy and society.

So while this initiative has the vocation to maintain and extend Europe's leadership in the global market for smart networks and services, and to maintain cooperation and collaboration in the development of global standards, it may prove necessary to set rules for participation that are aligned with specific cyber-security principles or other strategic considerations. This would only be considered if necessary to ensure the security of systems being developed but also the technological capability of European industry to produce critical communications equipment and software. An institutionalised partnership with its strategic governance structure is better suited for such requirements. In particular, such strategic decisions would necessarily require the input and advice of Member States in the context of their responsibilities for security, and this would be facilitated by the institutionalised model.

7. THE PREFERRED OPTION

7.1. Description of the preferred option

Based on the above assessment, the preferred option is the institutionalised partnership under Article 187 TFEU. In the Table below, we indicate the alignment of the preferred option with the selection criteria for European Partnerships defined in Annex III of the Horizon Europe Regulation. As the design process of the candidate Institutionalised Partnerships is not yet concluded and several topics are still under discussion (such as governance model, legal act, private industry contribution and Member Sates contribution) at the time of writing, the criteria of additionality/directionality and long-term commitment are covered in terms of *anticipations*.

Table 11: Alignment with the selection criteria for European Partnerships

Criterion	Alignment of the preferred option
Higher level of effectiveness	The analysis presented in section 6 shows that an institutional partnership would have a higher effectiveness than the other options in achieving the objectives defined in section 4 through:
	 A stronger commitment from the whole ecosystem to a long term, sustained 6G strategy whilst leveraging national investments. This is needed considering the potential critical nature of the future network infrastructure and digital services for numerous European industries.
	• The necessary involvement of a broad ecosystem of stakeholders, ranging from incumbent in the field of smart networks and services to vertical industries that will be future adopters of the solutions developed and potential new entrants. This is needed considering the sovereignty objective and the need to cover a comprehensive value chain.
Coherence and synergies	• An institutional partnership allows to establish strategic liaison with other related initiatives and partnerships. The development of smart networks and services has to take into account and use numerous digital technologies (making liaison with the Key Digital Technologies initiative is important) and will serve as the backbone of the digital transformation of numerous industries (Automotive, Health, Transport, Energy, Manufacturing) requiring the set-up of important synergies with other programmes.
	 An institutional partnership allows a stronger top-down strategic liaison and coordination with R&I initiatives supported by national research programmes.
	• An institutional partnership allows a stronger liaison with deployment oriented initiative (at the European, National and Local level) which as presented above in section 3 and 4 cannot be decoupled entirely from R&I perspectives.
	 An institutional partnership allows a stronger ability to foster necessary regulations and legislative adaptation in the field of spectrum allocation and usage, energy consumption or ethics, privacy and cybersecurity.
Transparency and openness	• An institutional partnership allows, for more interdisciplinary research, highly needed for the future of networks and digital services, with coherent roadmap based plans
	• This option also foster the creation of new value chain opportunities (new connectivity providers, new connected device providers), creating higher opportunities for new entrants and SMEs.
Additionality and directionality	• The committed participation of a broad ecosystem of stakeholders developing and using the future SNS infrastructure is required to ensure a strong strategic focus. The institutional partnership optimises directionality with strategic planning with MS actions
	• Additionality is optimised through the long term commitment and visibility offered by the Institutional partnership, which allows strategic planning of long term beyond R&I actions. The 5G-PPP programme has shown a high leverage of industrial investment in R&I activities, (a factor of 10 for larger industries under phase 1 and 2, > 7 in average), which is taken as a basis.

Criterion	Alignment of the preferred option
Long-term commitment	• For an institutional Partnerships, established in accordance with article 187 TFEU, the financial and/or in-kind, contributions from partners other than the Union, will at least be equal to 50% and may reach up to 75% of the aggregated European Partnership budgetary commitments. Long term industry commitment is maximised through long term visibility enabling secure implementation of the strategic roadmap.

7.2. Objectives and corresponding monitoring indicators

7.2.1. *Operational objectives*

Several operational objectives have been identified which would enable the partnership to achieve its specific objectives, as shown in Figure 8 below.

The figure below, lists a range of actions and activities, going also beyond the R&I activities that can be implemented under Horizon Europe (highlighted in yellow). This reflects the definition of European Partnerships in the Horizon Europe regulation as initiatives where the Union and its partners "commit to jointly support the development and implementation of a programme of research and innovation activities, including those related to market, regulatory or policy uptake."

Actions fostering Collaborative Deployment Demonstration and validation Infrastructure and Support Access to research actions and piloting regulation or (RIA or IA) standardisation development Activities synergies between synergies between the efforts toward esearch or regulations research future harmonization on energy regulations research in emergence of new of regulations initiatives efficiency in Smart Networks digital and actors in vertical and processes funding 5G cybersecurity the field of deployments and ethical around application SNS spectrum at the local, ICT allocation and (vertical) national and usage European Operational objectives level Ensure the development of Ensure alignmen positioning of EU technologies able to meet transformation development and development of energy with ethical and dustry in the globa security 5G infrastructure in Europe Specific objectives Ensure European technological Ensure the alignment of future Strengthen the uptake Develop digital smart networks and services with networks and services EU policy and societal needs

Figure 8: Operational objectives of the initiative

General objectives

We introduce here in more details the operational objectives we foresee for the initiative.

Support high risk research in smart networks and services towards 6G: dedicated support for research compensate for the high level of risk and high research intensity of the domain. An average leveraging factor of public investment of at least 7 is targeted.

A strong presence of European actors in standardization is necessary to ensure a critical mass of contributions. This is achieved as a spin-off of collaborative R&I, and demonstration activities, and actions fostering regulation and standardization. It is facilitated by the roadmap based approach of an institutional partnership. A target of 1000 contributions derived from the initiative is targeted, at least 40% of essential patents of future SNS infrastructures with the EU industry.

Promote synergies between network, digital and application domains (vertical) R&I: The value chain approach requires collaborative research across research fields (networking, devices, IT, verticals). This addresses the problem drivers (*An infrastructure relying heavily on advanced digital solutions*) and (*An infrastructure critical for the adoption of digital solutions in many industries*). It leverages strategic links with other initiatives (notably KDT). Target: 40% of the future markets for connectivity infrastructures mastered by EU actors; at least one European supplier at each level of the value chain: devices; networks; edge computing.

Large scale pilots targeting the future application domains of smart networks and services are supported. These should target vertical industries such as: automotive, transportation, manufacturing, healthcare, and energy. It addresses the problem drivers described in section (an infrastructure critical for the adoption of digital solutions in many industries), (an infrastructure that requires structural changes in various value chains), and (a lack of investment in the deployment of the new infrastructure). Target: at least one large scale pilot per vertical with pan European footprint and leveraging trial capabilities developed at MS level. Regarding the automotive domain, at least 6000 km of cross border corridors covered by 5G is targeted.

Support long term research activities: dedicated activities targeting the longer term evolutions of communication networks and digital services, namely 6G capabilities. This would answer to the problem driver described in section (*Insufficient capacity of 5G to respond to advanced communication requirements*). It could be achieved through collaborative research actions.

Support research on energy efficiency in smart networks and services: research in the field of energy efficiency of the future networks, devices and applications is aimed at. This addresses the problem driver described in section. (*Lack of energy efficient technological solutions for future network infrastructures*). It targets an energy reduction factor of at least 10 for SNS platforms and at least 30% energy reduction in key use cases like factories, automotive, energy. At least 30% of the budget is related to Green Deal objectives.

Support research on ethical and secure future digital services: ensure that ethics, privacy and cybersecurity are integrated in the design of future smart networks and digital services. This addresses the problem driver described in section (*Increasing challenges of digital services toward ethics, privacy and cybersecurity*). It supports future standards needed in the context of the 5G security toolbox and support the emergence of alternative value chains. Target: Comprehensive architecture, technologies and standards for an end to end security; full characterisation of risks of data misuse in SNS.In the context of additionality, activities beyond R&I would also:

Promote emergence of new actors in the field: it covers the transformation of the value chain by promoting the emergence of new EU actors in the supply chain and the evolutions of the business models of existing actors (in both the connectivity value chain and vertical industries). This addresses the problem drivers defined in section (an infrastructure that requires structural changes in various value chains). It leverages two trends: the emergence of verticals or neutral hots as suppliers of SNS infrastructures; the softwarisation of SNS infrastructure with lower market entry barriers and potential of new actors to emerge. Targets: availability of European suppliers beyond today actors for the SNS value chain including providers of open solutions like Open RAN or Open Air

Interface cost level of European Radio Access and Core network offers comparable to those of Asian competitors.

Promote efforts toward harmonization of regulations and processes around spectrum allocation and usage: harmonization at the European level of the regulations and processes for spectrum allocation and its usage is sought. This would aim at answering the problem driver defined in section (*A lack of coordination of spectrum policies*). This requires strong contributions towards international bodies. Target: identification of 6G spectrum above 90 GHz, related allocation in ITU, definition of the assignment methods and technical characteristic to be used in licensing process (for licensed bands).

Promote regulations on energy efficiency: fostering regulations that promote energy efficiency and certifications. This would answer the problem driver defined in section (*Lack of energy efficient technological solutions for future network infrastructures*) Target: complement R&I on energy efficiency with specification of an SNS label of energy efficiency and corresponding standards.

Support future regulations on cybersecurity and ethical ICT: To promote a human-centric internet, and mitigate the impact of future digital services on cybersecurity, privacy and other ethical issues, the initiative should aim to foster regulations enforcing an ethical approach. This would answer to the problem driver described in section (*Increasing challenges of digital services toward ethics, privacy and cybersecurity*) Target: label and standards related to ethics and privacy. Compliance with the certification tool put in place in the context of the cybersecurity toolbox.

7.2.2. *Monitoring indicators*

In addition to Key Impact Pathways indicators set centrally in the Regulation of Horizon Europe, additional monitoring indicators have been identified to enable the tracking of progress of the partnership towards meeting its objectives. These are shown in the Table below. A monitoring system to assess the effectiveness of the initiative will particularly be looking at cost benefits and where relevant, the indicators listed below would be used as KPI. Additionally cost, investments levels by the private side should be measured.

One should further divide the KPIs in qualitative and quantitative KPIS or system/performance measurements. The following table present a set of indicators that may be used for SNS.

Table 12: Specific Monitoring indicators for SNS.

Impact Dimension		Short-term (typically as of year 1+)	Medium-term (typically as of year 3+)	Long-term (typically as of year 5+)
	Development of new innovations for smart connectivity value chains.	Number of publications, patents and standard contributions achieved by the partnership on beyond 5G capabilities	Number of publications, patents and standard contributions achieved by the on 6G capabilities	Number of publications, patents and standard contributions achieved by the partnership on 6G capabilities
	consumption devices and infrastructures	Number of publications, patents and standard contributions achieved by the partnership on energy efficiency in connected devices and networked infrastructures	Number of publications, patents and standard contributions achieved by the partnership on energy efficiency in connected devices and networked infrastructures	Energy consumption of integrated smart connectivity platforms, including service and IoT component.
Scientific impact	Use of digital technologies in future smart connectivity	Number and share of projects including cross cutting research mixing network technologies with advanced digital solutions (A.I., Edge, etc.)	Number and share of projects including cross cutting research mixing network technologies with advanced digital solutions (A.I., Edge, etc.)	Uptake of advanced digital solutions and scientific results in future smart connectivity solutions.
	oriented industry	Participation of vertical industry representatives to R&I projects	Participation of vertical industry representatives to R&I projects	Uptake of smart networks and services in vertical industries
	cybersecurity by design	Number of publications, patents and standard contributions achieved by the partnership on Cybersecurity in smart networks and services	Number of publications, patents and standard contributions achieved by the partnership on Cybersecurity in smart networks and services	Number of publications, patents and standard contributions achieved by the partnership on Cybersecurity in smart networks and services

Impact Dimension		Short-term (typically as of year 1+)	Medium-term (typically as of year 3+)	Long-term (typically as of year 5+)
	Ethics by design	Number of publications, patents and standard contributions achieved by the partnership on Ethics and Privacy in smart networks and services	Number of publications, patents and standard contributions achieved by the partnership on Ethics and Privacy in smart networks and services	Number of publications, patents and standard contributions achieved by the partnership on Ethics and Privacy in smart networks and services
	Investment of EU industry in SNS	Leverage effect, investment of EU SNS industry in R&I	Leverage effect, investment of EU SNS industry in R&I	Leverage effect, investment of EU SNS industry in R&I
	Contribution to standardization and patents	Share of EU actors contribution to standards and patents on smart networks and services	Share of EU actors contribution to standards and patents on smart networks and services	Share of EU actors contribution to standards and patents on smart networks and services
	Market share of EU actors	Market Share of EU actors in SNS	Market Share of EU actors in SNS	Market Share of EU actors in SNS
	Vertical oriented applications	Number of large scale pilots targeting vertical industries	Take-up of smart connectivity in vertical industries	Take-up of smart connectivity in vertical industries
Tech. / economic impact	New smart connectivity providers across the value chain.		New businesses in EU as smart connectivity providers across the value chain.	New businesses in EU as smart connectivity providers across the value chain.
	Private investment in infrastructure deployment	CAPEX in network and service infrastructure deployment in Europe	CAPEX in network and service infrastructure deployment in Europe	CAPEX in network and service infrastructure deployment in Europe
	Deployment of 5G	Number of 5G subscription in Europe, Share of global 5G subscription. number of km served across main transport paths	Number of 5G subscription in Europe, Share of global 5G subscription. number of km served across main transport paths	Number of 5G subscription in Europe, Share of global 5G subscription. and number of km served across main transport paths
	Harmonization of regulations on spectrum	Share of 5G spectrum assigned new spectrum identified for 6G	Share of 5G spectrum assigned, new spectrum identified for 6G	Share of 5G spectrum assigned new spectrum identified for 6G

Impact Dimension		Short-term (typically as of year 1+)	Medium-term (typically as of year 3+)	Long-term (typically as of year 5+)
	Burden of spectrum allocation	Delay between identification of new spectrum and assignment of spectrum in Europe	Delay between identification of new spectrum and assignment of spectrum in Europe	Delay between identification of new spectrum and assignment of spectrum in Europe
	Employment	New curricula in the field of smart networks and services	New curricula in the field of smart networks and services	New curricula in the field of smart networks and services
		Take up of digital skills and tools in EU Industries	Take up of digital skills and tools in EU Industries	Take up of digital skills and tools in EU Industries
	Ethics and privacy regulations	Set-up of regulations and legislations regarding ethics, security and privacy in the field of SNS	Set-up of regulations and legislations regarding ethics, security and privacy in the field of SNS	Set-up of regulations and legislations regarding ethics, security and privacy in the field of SNS
Societal impact	Equal Access	Share of the EU population with access to 5G;	Share of the EU population with access to 5G	Share of the EU population with access to 5G
	Impact telecommunicat networks, integral connectivity plant	Energy consumption of telecommunication networks, integrated smart connectivity platforms, including service and IoT component	Energy consumption of telecommunication networks, integrated smart connectivity platforms, including service and IoT component	Energy consumption of telecommunication networks, integrated smart connectivity platforms, including service and IoT component
	Environmental Impact	Lifecycle impact of connected devices	Lifecycle impact of connected devices	Lifecycle impact of connected devices

7.2.3. Evaluation framework

The evaluation of the Partnership will be done in full accordance with the provisions laid out in Horizon Europe Regulation Article 47 and Annex III, with external interim and expost evaluations feeding into the overall Horizon Europe evaluations. As set in the criteria for European Partnerships, the evaluations will include an assessment of the most effective policy intervention mode for any future action; and the positioning of any possible renewal of the Partnership in the overall European Partnerships landscape and its policy priorities. In the absence of renewal, appropriate measures will be developed to ensure phasing-out of Framework Programme funding according to conditions and timeline agreed with the legally committed partners ex-ante.



Brussels, 23.2.2021 SWD(2021) 37 final

PART 9/19

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT REPORT Accompanying the document

Proposal for a COUNCIL REGULATION establishing the Joint Undertakings under Horizon Europe

European Partnership for Smart Networks and Services

{COM(2021) 87 final} - {SEC(2021) 100 final} - {SWD(2021) 38 final}

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Annex 1 Procedural information

1. LEAD DG, DECIDE PLANNING REFERENCES

Co-Lead DG: Directorate-General for Research and Innovation Directorate-General for Communications Networks (CNECT), Directorate General Research and Innovation (RTD)

Decide number: PLAN/2019/5390

2. ORGANISATION AND TIMING

Institutionalised partnerships are foreseen in Articles 185 and 187 of the Treaty on the Functioning of the European Union (TFEU). The preliminary agreement on Horizon Europe contained a list of possible areas for institutionalised partnerships based on Article 185 and 187. For each of these areas the Commission considered 12 potential institutionalised partnerships. Their set up involves new EU legislation and the establishment of dedicated implementing structures and therefore an impact assessment for each of these initiatives.

Following political validation in June 2019, the impact assessment process started with the publication of inception impact assessments for each initiative in August 2019.

An inter-service steering group (ISSG) on research and innovation partnerships under Horizon Europe was set up in May 2019 and held 4 meetings before submission of the Staff Working Document to the Regulatory Scrutiny Board (7 May 2019, 19 June 2019, 5 December 2019, 20 January 2020). The ISSG consisted of representatives of the Secretariat-General, Directorate-General for Budget, Directorate-General for Research and Innovation Directorate-General for Communications Networks, Content and Technology, Directorate-General for Mobility and Transport, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, Directorate-General for Energy, Directorate-General for Environment, Directorate-General for Climate Action, and the Legal Service.

An online public stakeholder consultation was launched between September and November 2019, gathering 1635 replies for all 12 initiatives.

3. CONSULTATION OF THE RSB

Two upstream meetings with the Regulatory Scrutiny Board of were held on 10 July 2019 and 30 September 2019.

In accordance with the feedback received from the Regulatory Scrutiny Board on 15 May 2020 the Staff Working Document has been revised as presented in Figure 1. The impact assessment was endorsed by the Inter Service Steering Group on 20 January 2020.

4. EVIDENCE, SOURCES AND QUALITY

To ensure a high level of coherence and comparability of analysis for all candidate initiatives, an external study was procured to feed into the impact assessments of the 12 candidate

institutionalised partnerships ¹ (Technopolis Group, 2020). It consisted of an horizontal analysis and individual thematic analyses for each of the initiatives under review.

For all initiatives, the evidence used includes desk research partly covering the main impacts and lessons learned from previous partnerships. A range of quantitative and qualitative data sources complement the evidence base, including evaluations; foresight studies; statistical analyses of Framework Programmes application and participation data and Community Innovation Survey data; analyses of science, technology and innovation indicators; reviews of academic literature; sectoral competitiveness studies and expert hearings. The analyses included a portfolio analysis, a stakeholder and social network analysis in order to profile the actors involved as well as their cooperation patterns, and an assessment of the partnerships' outputs (bibliometrics and patent analysis). A cost modelling exercise was performed in order to feed into the efficiency assessments of the partnership options. Public consultations (open and targeted) supported the comparative assessment of the policy options. For each initiative up to 50 relevant stakeholders were interviewed by the external contractor (policymakers, business including SMEs and business associations, research institutes and universities, and civil organisations, among others). In addition the analysis was informed by the results of the Open Public Consultation (Sep – Nov 2019), the consultation of the Member States through the Strategic Programme Committee and the online feedback received on the Inception Impact Assessments of the set of candidate Institutionalised European Partnerships.

A more detailed description of the methodology and evidence base used, completed by thematic specific methodologies, is provided in Annexes 4 and 6.

Figure 1 Modifications to the draft Staff Working Document based on comments received from the Regulatory Scrutiny Board

Comments from the Regulatory Scrutiny Board	Actions taken for the Staff Working Document
(1) The report should put greater focus on assessing and justifying the (change of) partnership choice. It should clarify to what extent the problems addressed by this initiative have developed or differ from those that the current 5G-PPP addresses.	The document has been rewritten to highlight the partnership choice pointing out the limitations of the previous one. It also further clarifies the extension of scope, the new technology challenges, the need to address policy objectives beyond industrial competitiveness such as technological sovereignty, critical role of suppliers, green deal objectives, and deployment programmes. Alongside a number of substantial improvements, Box 3, page 26-27, has been redrafted to clarify the needs for change of partnership.
(2) The report should clarify the intervention logic and the mechanisms through which the partnership would deliver on its objectives (including the environmental and social objectives). It should elaborate on what can	Section 4.3 on intervention logic of the initiative has been rewritten (pages 40 and 41) underlining the sovereignty aspects, the necessary extension of the set of stakeholders, the activities related to deployment, public

¹ Technopolis Group, 2020, forthcoming.

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realistically be achieved via the partnership and to what extent it will need to be complemented by other policy initiatives (regulatory, financial, public and private investments and investments by Member States). The report should clearly outline the roles of the key public and private actors. The report should explain to what extent the initiative intends to integrate the deployment of networks.

policy objectives, what it will deliver and how. The report has been improved to clarify the roles of the key public and private sectors notably in 4.4.1 and 4.4.2

(3) The report should clarify the scoring system applied when assessing the options and explain the relative importance of the different criteria. It should remove the discrepancies between the text and the tables and correct any inconsistencies in terms of expected impacts. On this basis, the report should better describe the main differences in impact between a coprogrammed partnership and a partnership under Article 187 TFEU, and how significant they are. The report should be clearer on the added value of changing from the current coprogrammed partnership to an institutionalized partnership.

The scoring system has been clarified and a few inconsistencies corrected (Tables 5, 6 and 10). Section 6 on how the different policy options compare has been extensively rewritten to highlight the main differences of impacts between a co-programmed and institutionalised partnership, notably on Scientific impacts, social impact, efficiency and coherence. A summary assessment has been added on page 68 underlining the added value of an institutionalised partnership compared to the current model.

(4) The report should explain better how the preferred partnership option would motivate large companies to join, even if this could limit benefiting from size advantages of network industries and opportunities to earn a dominant market position. It should show in more detail how the partnership facilitates a strong prior commitment to public investment.

The report has been revised to better explain how the preferred option will motivate the industry through strategic roadmaps and long-term investment certainty and will also motivate the Member States through formal and close participation as part of the governance structure. These points are now inter alia described on page 68 of the report.

(5) The report should integrate stakeholders' views throughout the assessment. In particular, it should elaborate on stakeholders' positions on the different options and to what extent the preferred partnership form is expected to attract their participation.

In the draft report submitted to the Board, the views of different stakeholders had been reflected in part II, Annex 2 and in part II, Annex 6.4. The main stakeholder views have now been integrated in part I. Details of the results of the Open Public Consultation have been explained beyond the raw statistics, showing the motivation and openness of the stakeholders vis-à-vis the preferred option. These aspects are now presented on page 66 of the IA and in more detail in Annex 2.

Annex 2 Stakeholder Consultation

1. OVERVIEW FOR ALL CANDIDATE INSTITUTIONALISED EUROPEAN PARTNERSHIPS

1.1. Introduction

In line with the Better Regulation Guidelines,² the stakeholders were widely consulted as part of the impact assessment process of the 12 candidates for institutionalised partnerships, including national authorities, the EU research community, industry, EU institutions and bodies, and others. These inputs were collected through different channels:

- A feedback phase on the inception impact assessments of the candidate initiatives in August 2019, gathering 350 replies for all 12 initiatives on the "Have your say" web portal during a period of 3 weeks;
- A structured consultation of Member States performed by the EC services over 2019 through the Shadow Strategic Configuration of the Programme Committee of Horizon Europe (in line with the Article 4a of the Specific Programme of Horizon Europe). This resulted in 44 possible candidates for European Partnerships identified as part of the first draft Orientations Document towards the Strategic Plan for Horizon Europe (2021-2024), taking into account the areas for possible institutionalised partnerships defined in the Regulation.
- An online public stakeholder consultation administered by the EC, based on a structured questionnaire, open between September and November 2019, gathering 1635 replies for all 12 initiatives;
- A targeted consultation run by the external study contractors with a total of 608 interviews performed as part of the thematic studies by the different study teams between August 2019 and January 2020.

1.2. Horizontal results of the Open Public Consultation

The consultation was open to everyone via the EU Survey online system.³ The survey contained two main parts to collect views on general issues related to European partnerships (in Part 1) and specific responses related to one or more of the 12 candidate initiatives (as selected by a participant). The survey was open from 11 September till 12 November 2019. The consultation was available in English, German and French and advertised widely through the European Commission's online channels as well as via various stakeholder organisations.

1.2.1. Profile of respondents

In total, 1635 respondents filled in the questionnaire of the open public consultation. Among them, 272 respondents (16.64%) were identified to have responded to the consultation as part of a campaign (coordinated responses). Based on the Better Regulation Guidelines, the groups of respondents where at least 10 respondents provided coordinated answers were labelled as 'campaigns', segregated and analysed separately and from other responses. In total 11 campaigns were identified, the largest of them includes 57 respondents⁴. In addition, 162 respondents in the

² https://ec.europa.eu/info/files/better-regulation-guidelines-stakeholder-consultation_en

³ https://ec.europa.eu/eusurvey/runner/ConsultationPartnershipsHorizonEurope

The candidate Institutionalised Partnership Clean Hydrogen has the highest number of campaigns, namely 5. A few initiatives, such as Innovative SMEs, Smart Networks and Systems, were not targeted by campaigns. Some campaign respondents decided to provide opinions about several partnerships.

consultation also display similarities in responses but in groups smaller than 10 respondents. Hence, these respondents were not labelled as campaigns and therefore were not excluded from the general analysis.

Table 1: Country of origin of respondents (N=1635)

Country	Number of respondents	Percentage of respondents	
Germany	254	15.54%	
Italy	221	13.52%	
France	175	10.70%	
Spain	173	10.58%	
Belgium	140	8.56%	
The Netherlands	86	5.26%	
Austria; United Kingdom	61	3.73%	
Finland	49	3.00%	
Sweden	48	2.94%	
Poland	45	2.75%	
Portugal	32	1.96%	
Switzerland	28	1.71%	
Czechia	24	1.47%	
Greece	23	1.41%	
Norway; Romania	22	1.35%	
Denmark	20	1.22%	
Turkey	19	1.16%	
Hungary	14	0.86%	
Ireland	12	0.73%	
United States	11	0.67%	
Estonia; Slovakia; Slovenia	10	0.61%	
Bulgaria; Latvia	9	0.55%	
Bosnia and Herzegovina	7	0.43%	
Lithuania	4	0.24%	
Canada; Croatia; Israel	3	0.18%	
China; Ghana; Iceland; Japan; Luxembourg; Morocco	2	0.12%	
Bhutan; Botswana; Cyprus; Iran; Malta; Mexico; Moldova; Mongolia; Palestine; Russia; Serbia; South Africa; Tunisia; Ukraine; Uruguay	1	0.06%	

As shown in Figure 2, the three biggest **categories of respondents** are representatives of companies and business organisations (522 respondents or 31.9%), academic and research institutions (486 respondents or 29.7%) and EU citizens (283 respondents or 17.3%). Among the group of respondents that are part of campaigns, most respondents are provided by the same groups of stakeholders, namely company and business organisations (121 respondents or 44.5%), academic and research institutions (54 respondents or 19.8%) and EU citizens (42 respondents or 15.4%).

283 10% 20% 30% 40% 70% Company/business organisation Academic/research institution ■ EU citizen Business association ■ Public authority Other ■ Non-governmental organisation (NGO) ■ Non-EU citizen ■ Consumer organisation Environmental organisation ■ Trade union

Figure 2 Type of respondents (N=1635) - For all candidate initiatives

Among all consultation respondents, 1303 (79.69%) have been **involved in the on-going research and innovation framework programme** Horizon 2020 or the preceding Framework Programme 7, while 332 respondents (20.31%) were not. In the group of campaign respondents, the share of those who were involved in these programmes is higher (245 respondents out of 272 or 90.07%) than in the group of non-campaign respondents (1058 out of 1363 or 77.62%). When respondents that participated in the Horizon 2020 or in the preceding Framework Programme 7 were asked to indicate in which capacity they were involved in these programmes, the majority stated they were a beneficiary (1033 respondents) or applicant (852 respondents). The main stakeholder categories, e.g. companies/business organisation, academic/research institutions, etc., show a similar distribution across the capacities in which they 'have been involved in Horizon 2020 or in the Framework Programme 7' as the overall population of consultation respondents.

Among those who have been involved in Horizon 2020 or the preceding Framework Programme 7, 1035 respondents (79.43%) are/were **involved in a partnership**. The share of respondents from campaigns that are/were involved in a partnership is higher than for non-campaign respondents, 89.80% versus 77.03% respectively. The list of partnerships under Horizon 2020 or its predecessor Framework Programme 7 together with the numbers, percentages of participants is presented in Table 4, the table also show the key stakeholder categories for each partnership. Most consultation respondents participated in the following partnerships: Fuel Cells and Hydrogen 2 (FCH2) Joint Undertaking, Clean Sky 2 Joint Undertaking, European Metrology Programme for Innovation and Research (EMPIR) and in Bio-Based Industries Joint Undertaking. The comparison between the non-campaign and campaign groups of respondents shows that the overall distribution is quite similar. However, there are some differences. For the campaign group almost a half of respondents is/was involved in the Fuel Cells and Hydrogen 2 (FCH2) Joint Undertaking, a higher share of campaign respondents is/was participating in Clean Sky 2 Joint Undertaking and in Single European Sky Air Traffic Management Research (SESAR) Joint Undertaking.

When respondents were asked in which **role**(s) **they participate(d)** in a **partnership**(s), over 40% indicated that they act(ed) as partner/member/beneficiary in a partnership. The second largest group of respondents stated that they applied for funding under a partnership. The roles selected by non-campaign and campaign respondents are similar.

Table 4: Partnerships in which consultation respondents participated (N=1035)

Name of the partnership	Number and % of respondents from both groups (n=1035)	Number and % of respondents from a non- campaign group (n=815)	Academic/resea rch institutions	Business associations	Company/busin ess	Company/busin ess	EU citizens	NGOs	Public authority
Fuel Cells and Hydrogen 2 (FCH2) Joint Undertaking	354 (33.33%)	247 (30.31%)	97	9	37	43	41	8	5
Clean Sky 2 Joint Undertaking	195 (18.84%)	145 (17.79%)	57	2	10	27	37	1	7
European Metrology Programme for Innovation and Research (EMPIR)	150 (14.49%)	124 (15.21%)	64	0	13	9	14	2	19
Bio-Based Industries Joint Undertaking	142 (13.72%)	122 (14.97%)	39	8	20	27	14	1	6
Shift2Rail Joint Undertaking	124 (11.98%)	101 (12.40%)	31	7	5	31	14	3	7
Electronic Components and Systems for European Leadership (ECSEL) Joint Undertaking	111 (10.72%)	88 (10.80%)	42	2	7	20	12	0	5
Single European Sky Air Traffic Management Research (SESAR) Joint Undertaking	66 (6.38%)	46 (5.64%)	10	3	3	20	3	2	3
5G (5G-PPP)	53 (5.12%)	47 (5.77%)	20	1	6	14	5	0	1
Eurostrars-2 (supporting research- performing small and medium-sized enterprises)	44 (4.25%)	40 (4.91%)	17	0	6	1	7	0	6
Innovative Medicines Initiative 2 (IMI2) Joint Undertaking	37 (3.57%)	35 (4.29%)	18	2	3	3	2	4	3
Partnership for Research and Innovation in the Mediterranean Area (PRIMA)	28 (2.71%)	26 (3.19%)	15	0	3	1	2	0	2
European and Developing Countries Clinical Trials Partnership	25 (2.42%)	24 (2.94%)	12	0	1	2	3	3	2
Ambient Assisted Living (AAL 2)	22 (2.13%)	21 (2.58%)	11	2	1	1	3	0	3
European High-	22 (2.13%)	18 (2.21%)	6	0	2	3	5	0	2

Name of th partnership	Number and % of respondents from both groups (n=1035)	Number and % of respondents from a non- campaign group (n=815)	Academic/resea rch institutions	Business associations	Company/busin ess	Company/busin ess	EU citizens	NGOs	Public authority
Performance Computing Joir Undertaking (EuroHPC)	t								

For the remaining of the consultation respondents could provide their views on each/several of the candidate initiatives. The majority of respondents (31.4%) provided their views on the Clean Hydrogen candidate partnership. More than 45% of respondents from the campaigns selected this partnership. Around 15% provided their views for European Metrology, Clean Aviation and Circular Bio-based Europe. The share of respondents in the campaign group that chose to provide views on the Clean Aviation candidate partnership is of 20%. The smallest number of respondents provided opinions on the candidate initiative 'EU-Africa research partnership on health security to tackle infectious diseases – Global Health'.

Table 5: Candidate Institutionalised Partnerships for which consultation respondents provide responses (N=1613)

Name of the candidate Institutionalised European partnership	Number and % of respondents from both groups (n=1613)	Number and % of respondents from a non-campaign group (n=1341)		
Clean Hydrogen	506 (31.37%)	382 (28.49%)		
European Metrology	265 (16.43%)	225 (16.78%)		
Clean Aviation	246 (15.25%)	191 (14.24%)		
Circular bio-based Europe	242 (15%)	215 (16.03%)		
Transforming Europe's rail system	184 (11.41%)	151 (11.26%)		
Key Digital Technologies	182 (11.28%)	162 (12.08%)		
Innovative SMEs	111 (6.88%)	110 (8.20%)		
Innovative Health Initiative	110 (6.82%)	108 (8.05%)		
Smart Networks and Services	109 (6.76%)	107 (7.98%)		
Safe and Automated Road Transport	108 (6.70%)	102 (7.61%)		
Integrated Air Traffic Management	93 (5.77%)	66 (4.92%)		
EU-Africa research partnership on health security to tackle infectious diseases – Global Health	49 (3.04%)	47 (3.50%)		

1.2.2. Characteristics of future candidate European Partnerships

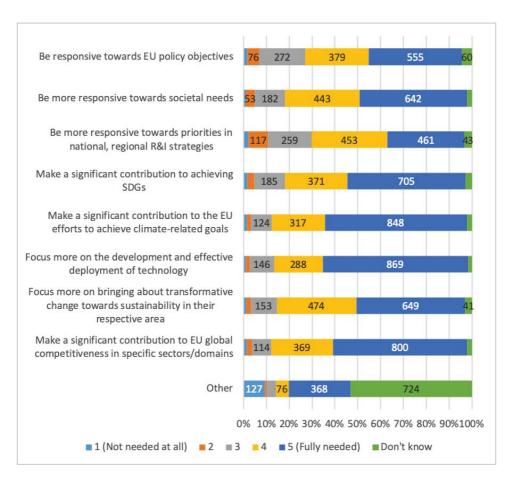
Respondents were asked to assess what areas, objectives, aspects need to be in the **focus of the future European Partnerships** under Horizon Europe and to what extent. According to Figure 6, a great number of respondents consider that a significant contribution by the future European Partnerships is 'fully needed' to achieve climate-related goals, to the development and effective

deployment of technology and to EU global competitiveness in specific sectors/domains. Overall, respondents' views reflect that many aspects require attention of the Partnerships. The least attention should be paid to responding towards priorities of national, regional R&D strategies, including smart specialisation strategies, according to respondents.

Overall, only minor differences can be found between the main stakeholder categories. Academic/research institutions value the responsiveness towards EU policy objectives and focus on development and effective deployment of technology a little less than other respondents. Business associations, however, find that the future European Partnerships under Horizon Europe should focus a little bit more on the development and effective deployment of technology than other respondents. Furthermore, business associations, large companies as well as SMEs value the role of the future European Partnerships for significant contributions to EU global competitiveness in specific sectors domains a little higher than other respondents. Finally, both NGOs and Public authorities put a little more emphasis on the role of the future European Partnerships for significant contributions to achieving the UN SDGs. The views of citizens (249, or 18.3%) do not reflect significant differences with other types of respondents. However, respondents that are/were directly involved in a partnership under Horizon 2020 or its predecessor Framework Programme 7 assign a higher importance of the future European Partnerships to be more responsive towards EU policy objectives and to make a significant contribution to achieving the UN's Sustainable Development Goals.

A qualitative analysis of the "other" answers highlights the importance of collaboration and integration of relevant stakeholders to tackle main societal challenges and to contribute to policy goals against which fragmentation of funding and research efforts across Europe should be avoided. Additionally, several respondents suggested that faster development and testing of technologies, acceleration of industrial innovation projects, science transfer and market uptake are needed. Next to that, many respondents provided answers related to the hydrogen and the energy transition, which corresponds to the high number of respondents that provided answers to the candidate initiative on this topic.

Figure 6: To what extent do you think that the future European Partnerships under Horizon Europe need to (N=1363) (non-campaign replies) For all candidate initiatives



1.2.3. Main advantages and disadvantages of Institutionalised European Partnerships

An open question asked to outline the main advantages and disadvantages of participation in an Institutionalised European Partnership (as a partner) under Horizon Europe (1551 respondents). The advantages mentioned focus on the development of technology, overall collaboration between industry and research institutions, and the long-term commitment. Disadvantages mentioned are mainly administrative burdens. An overview is provided below.

Advantages mentioned: Long term commitment, stability, and visibility in financial, legal, and strategic terms; Participation of wide range of relevant stakeholders in an ecosystem (large/small business, academics, researchers, experts, etc.); Complementarity with other (policy) initiatives at all levels EU, national, regional; Efficient and effective coordination and management; High leverage of (public) funds; Some innovative field require high levels of international coordination/standardisation (at EU/global level); Ability to scale up technology (in terms of TRL) through collaboration; Networking between members; Direct communication with EU and national authorities

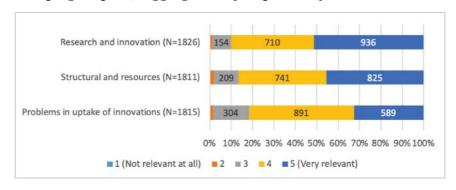
Disadvantages mentioned: Slow processes; System complexity; Continuous openness to new players should be better supported as new participants often bring in new ideas/technologies that are important for innovation; Lower funding percentage compared to regular Horizon Europe projects; Cash contributions; Administrative burdens; Potential for IPR constraints.

1.2.4. Relevance of EU level to address problems in Partnerships' areas

Respondents were asked to rate the relevance of research and innovation efforts at EU level efforts to address specific problems in the area of partnerships. Research and innovation related problems were rated as most relevant across all candidate initiatives, followed by

structural and resources problems and problems in the uptake of innovations. Overall, all three areas were deemed (very) relevant across the partnerships, as more than 80% of respondents found these challenges (very) relevant. Only minor differences were found between stakeholder categories. Research and innovation problems were found slightly more relevant by academic/research institutions, yet slight less relevant by large companies and SMEs. Structural and resource problems were indicated as slightly more relevant by NGOs, but slightly less by academic/research institutions. While both NGOs and public authorities find slightly more relevant to address problems in uptake of innovation than other respondents. The views of citizens are not differing significantly. Respondents that are/were directly involved in a current/preceding partnership find, however, the need to address problems related to the uptake of innovations slightly more relevant than other respondents.

Figure 9: To what extent do you think this is relevant for research and innovation efforts at EU level to address the following problems in relation to the candidate partnership in question? (non-campaign replies) Aggregation of responses of all candidate initiatives



1.2.5. Horizon Europe mode of intervention to address problems

Respondents were asked to indicate how these challenges could be addressed through Horizon Europe intervention. Just over 50% of all respondents indicated that institutionalised partnerships were the best fitting intervention, with relatively strong differences between stakeholder categories. The use of Institutionalised Partnership was indicated more by business associations and large companies, but less by academic/research institutions and SMEs. While academic/research institutions valued traditional calls more often, this was not the case for business associations, large companies and public authorities. Public authorities indicated a coprogrammed intervention more often than other respondents. Citizens indicated slightly less often that institutionalised partnerships were the best fitting intervention. Respondents that are/were directly involved in a current/preceding partnership, selected the institutionalised partnership intervention in far higher numbers (nearly 70%).

Figure 10: In your view, how should the specific challenges described above be addressed through Horizon Europe intervention? (non-campaign replies) For all candidate initiatives



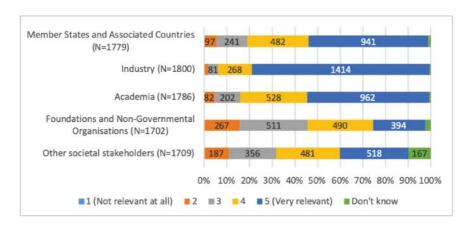
When asked to reflect on their answers, respondents that pointed to the need for using institutionalised partnership mentioned the long-term commitment of collaboration, a common and ambitious R&I strategy as well as the overall collaboration between industry and research institutions. Others shared positive experiences with other modes of interventions:

- Traditional calls, because of their flexibility and integration of a wide range of actors, as long as the evaluation panels do not deviate from the policy premier. This was mentioned by 94 participants, including companies (25), academics (26) and EU citizens (25).
- Co-funded partnership, as a mechanism to ensure that all participants take the effort seriously, while allowing business partnerships to develop. This approach was deemed suitable based on previous experiences with ERANETs. This was raised by 84 participants, 36 of them academic respondents, 18 companies and 16 EU citizens.
- Co-programmed partnerships, to tackle the need to promote and engage more intensively with the private sector. This was mentioned by 97 participants, most of them companies (34), followed by academics (22), business associations (15) and EU citizens (11).
 - 1.2.6. Relevance of a set of elements and activities to ensure that the proposed European Partnership would meet its objectives

Setting joint long-term agendas

Respondents were asked how relevant it is for the proposed European Partnerships to meet their objectives to have a strong involvement of specific stakeholder groups in setting joint long-term agenda. All respondents see stakeholders from industry as the most relevant, followed by academia and governments. The involvement of foundations and NGOs as well as other societal stakeholders were, however, still found to be (very) relevant by more than 50% of the respondents. Most respondents indicated the stakeholder group they belong to themselves or that represent them as relevant to involve.

Figure 11: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives - Setting joint long-term agenda with strong involvement of: (non-campaign replies) For all candidate initiatives

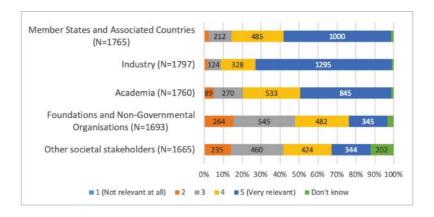


<u>Pooling and leveraging resources through coordination, alignment and integration with stakeholders</u>

Respondents were asked how relevant it is for the proposed European Partnership to meet its objectives to pool and leverage resources (financial, infrastructure, in-kind expertise, etc.)

through coordination, alignment and integration with specific groups of stakeholders. Respondents see stakeholders from industry as the most relevant, followed by academia and governments (Member States and Associated Countries). The involvement of foundations and NGOs as well as other societal stakeholders are also still found to be (very) relevant for more than 50% of the respondents. Similarly as described for the question on setting joint long-term agendas, most stakeholder categories valued their own involvement higher than other respondents – although also here differences between stakeholder categories were minor.

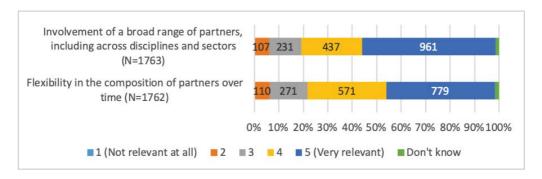
Figure 12: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives — Pooling and leveraging resources (financial, infrastructure, in-kind expertise, etc.) through coordination, alignment and integration with: (non-campaign replies) For all candidate initiatives



Composition of the partnerships

Regarding the composition of the partnership most respondents indicated that for the proposed European Partnership to meet its objectives the composition of partners needs to be flexible over time and that a broad range of partners, including across disciplines and sectors, should be involved (see Figure 13). When comparing stakeholder groups only minor differences were found. Academic/research institutions and public authorities found the involvement of a broad range of partners and flexibility in the composition of partners over time slightly more relevant than other respondents, while large companies found both less relevant. SMEs mainly found the flexibility in the composition of partners over time less relevant than other respondents, while no significant differences were found regarding the involvement of a broad range of partners. Citizens provided a similar response to non-citizens. Respondents that are/were directly involved in a current/preceding partnership, when compared to respondents not involved in a current/preceding partnership, indicated a slightly lower relevance of the involvement of a broad range of partners and flexibility in the composition of partners over time.

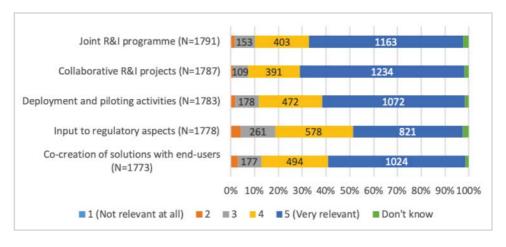
Figure 13: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives – Partnership composition (non-campaign replies) Aggregation of responses of all candidate initiatives



Implementation of activities

Most respondents indicated that implementing activities like a joint R&I programme, collaborative R&I projects, deployment and piloting activities, providing input to regulatory aspects and the co-creation of solutions with end-users are all (very) relevant for the partnerships to be able to meet its objectives. Minor differences were found between the main stakeholder categories, the differences found were in line with their profile. As such, academic/research institutions found joint R&I programme & collaborative R&I projects slightly more relevant and deployment and piloting activities, input to regulatory aspects and co-creation with end-users slightly less relevant than other respondents. For SMEs an opposite pattern is shown. Large companies, however, also found collaborative R&I projects slightly more relevant than other respondents, as well as input to regulatory aspects. The views of citizens are similar to non-citizens. Respondents that are/were directly involved in a current/preceding partnership, when compared to respondents not involved in a current/preceding partnership, show a slightly higher relevance across all activities.

Figure 14: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives – Implementing the following activities (non-campaign replies) For all candidate initiatives

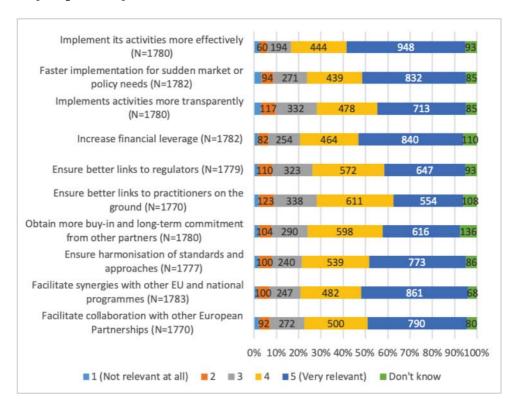


1.2.7. Relevance of setting up a legal structure (funding body) for the candidate European Partnerships to achieve improvements

Respondents were asked to reflect on the relevance of setting up a legal structure (funding body) for achieving a set of improvements, as shown in the Figure below. In general, 70%-80% of respondents find a legal structure (very) relevant for these activities. It was found most relevant

for implementing activities in a more effective way and least relevant for ensuring a better link to practitioners on the ground, however differences are small.

Figure 15: In your view, how relevant is to set up a specific legal structure (funding body) for the candidate European Partnership to achieve the following? (non-campaign replies) Aggregation of responses of all candidate initiatives



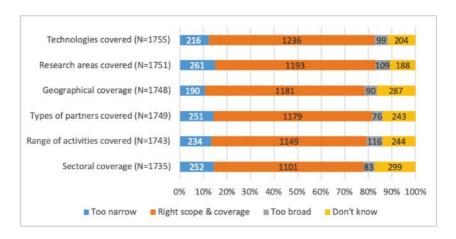
When comparing stakeholder categories there are only minor differences. Academic/research institutions indicated a slightly lower relevance for transparency, better links to regulators as well as obtaining the buy-in and long-term commitment of other partners. SMEs also indicated a lower relevance regarding obtaining the buy-in and long-term commitment of other partners. Large companies showed a slightly higher relevance for implementing activities effectively, ensure better links to regulators, obtaining the buy-in and long-term commitment of other partners, synergies with other EU/MS programmes and collaboration with other EU partnerships. NGOs find it slightly more relevant to implement activities faster for sudden market or policy needs. Public authorities, however, find it slightly less relevant to facilitate collaboration with other European Partnerships than other respondents. The views of citizens show a slightly lower relevance for a legal structure in relation to implementing activities in an effective way. Respondents that are/were directly involved in a current/preceding partnership indicated a higher relevance across all elements presented.

1.2.8. Scope and coverage of the candidate European Partnerships based on their inception impact assessments

Consulted on the scope and coverage for the partnerships, based on their inception impact assessments, the large majority feels like the scope and coverage initially proposed in the inception impact assessments is correct. However, about 11% to 15% of the respondents indicated the scope and coverage to be too narrow. About 11%-17% of respondents answered

"Don't know". Overall, differences between the main stakeholder categories were found to be minor. Academic/research institutions indicated slightly more often that the research area was "too narrow" then other respondents. SMEs on the other hand indicated slightly more often that the research area and the geographical coverage were "too broad". NGOs and public authorities, however, found the geographical coverage slightly more often "too narrow". Large companies found the range of activities slightly more often "too broad" and the sectoral focus slightly more often "too narrow" when compared to other respondents. The views of citizens are the same as for other respondents. Respondents that are/were directly involved in a current/preceding partnership more often indicated that the candidate institutionalised European Partnership have the "right scope & coverage".

Figure 16: What is your view on the scope and coverage proposed for this candidate institutionalised European Partnership, based on its inception impact assessment? (non-campaign replies) Aggregation of responses of all candidate initiatives



1.2.9. Scope for rationalisation and alignment of candidate European Partnerships with other initiatives

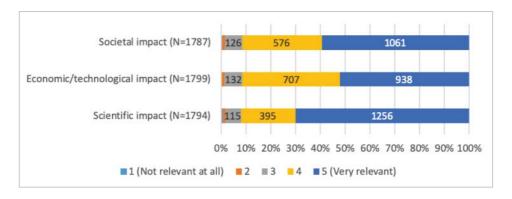
When asked whether it would be possible to rationalise a specific candidate European Institutionalised Partnership and its activities, and/or to better link with other comparable initiatives, nearly two thirds of respondents answered "Yes" (1000, or 62%), while over one third answered "No" (609, or 39%). Nearly no differences were found between stakeholder categories, only large companies and SMEs indicated slightly more often "Yes" in comparison to other respondents. The views of citizens are the same as for other respondents. Respondents that are/were directly involved in a current/preceding partnership, indicated "No" more often, the balance is about 50/50 between "Yes" and "No" for this group.

1.2.10. Relevance of European Partnerships to deliver targeted scientific, economic/technological and societal impacts

Finally, respondents were asked to rate the relevance of partnership specific impacts in three main areas: Societal; Economic/technological; and Scientific impacts. All three areas were deemed (very) relevant across the candidate partnerships. Scientific impact was indicated as the most relevant impact, more than 90% of respondents indicated that this as (very) relevant. Only minor difference between stakeholder groups were found. Academic/research institutions found scientific impacts slightly more relevant, while large companies found economic and

technological impacts slightly more relevant than other respondents. NGOs found societal impact slightly more relevant, while SMEs found this slightly less important. Citizens did not a significantly different view when compared to other respondents. Respondents that are/were directly involved in a current/preceding partnership find all impacts slightly more relevant than other respondents.

Figure 17: In your view, how relevant is it for the candidate European Institutionalised Partnership to deliver on the following impacts? (non-campaign replies) Aggregation of responses of all candidate initiatives



1.3. Stakeholder consultation results for this specific initiative

The consultation strategy aimed to involve potential members of the partnership, currently involved in the 5G Public-Private Partnership (PPP) or in the other domains, together with a broad range of interested stakeholders from the European ICT sector and vertical industries. New actors from complementary technological domains such as artificial intelligence (AI), components and devices, and from vertical sectors, energy, health and transport that were not yet involved were involved as well.

The main stakeholders are the European Technology Platform Networld2020 with more than 1000 members, covering a vast research constituency of academics and industry actors active in the field of telecommunications: network vendors and operators, SMEs, researchers from universities and research centres. A further extension to stakeholders from IoT and cloud has been established to reflect the convergence of these areas of research: the 5G Infrastructure Association (5G-IA) with more than 55 organisations, which comprises the major players of 5G research leading the 5G-PPP R&I, and the Alliance for Internet of Things Innovation (AIOTI), working on the deployment of Internet of Things (IoT) and its applications in Europe and on the development of a future vision for Horizon Europe.

A list of profiles that have been consulted either directly, or through consultation efforts such as an open public consultation, covers the following type of stakeholders:

- The **research community** across the EU, which includes academic/research institutions such as universities, public government-funded organisations, independent organisations or private research centres.
- The **industrial community**, which includes large companies, SMEs and start-ups, network operators and manufacturers.
- Business oriented stakeholders.
- **Public authorities**, which includes ministries, utility companies and national bodies for research.
- **Non-governmental organisations** (NGOs), including non-profit advocacy organisations and scientific medical societies.
- EU citizens responding on their own behalf.
- 'Other' stakeholders, which includes multi-utility companies, independent authorities and platforms (interest representatives).

1.3.1. Feedback to the inception impact assessment on candidate initiatives for Institutionalised Partnerships

The inception impact assessment⁵ of the initiative was published for feedback from 30 July 2019 to 27 August 2019, with the aim to seek initial feedback. Eight feedback reactions were received, notably from industry associations dealing with 5G and IoT, such as for example the 5G Infrastructure Organisation (5G IA) the Alliance for Internet of Things Innovation (AIOTI). There was also a feedback reaction from the German government and from citizens.

⁵ Available at https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2019-4972300 en

In summary, the reactions showed a strong support for the initiative. The AIOTI association promoted larger inclusion of the IoT dimension which is being taken into account the Partnership proposal. The 5G IA considers that a 'Co-programmed partnership' (option 1), including mechanisms to ensure effective communication and coordination with Member States, would be the most suitable instrument to achieve them. Alternatively, the creation of a joint undertaking bringing together the European Commission and private partners without requiring a financial contribution from Member States (option 2a) could also be considered.

1.3.2. Structured consultation of the Member States on European partnerships

The Commission has organised three workshops on the future involvement of Member States in the candidate European Partnerships with industry participation. In parallel, the engagement of Member States was discussed through some bilateral meetings (notably FR, DE) and through the Future Internet Forum. This provided space for Member States to present their ideas and discuss modalities for possible future participation in industry partnerships.

<u>The Future Internet Forum (FIF) consultations</u> - 3 FIF consultation meetings on the proposed SNS partnership took place, followed by a questionnaire on all aspects of the SNS partnership, including R&I. The FIF is a registered group which aims to exchange views on H2020 topics relating to "Future Networks" (5G, cloud, Next-Generation Internet and IoT). The members of this group have been appointed by the respective national authorities of the Member States.

<u>Smart Networks and Services Partnership Members States consultation meeting</u> (Brussels, Belgium) was held on 11 September 2019. Most of the participants considered the two-pillar approach (R&I and deployment) with very ambitious objectives of the proposed partnership to be highly relevant for Europe. They welcomed the idea of developing a body that offers strategic orientation at European level on, among others, support to 5G cross-border corridors. Grouping R&I and deployment in the same partnership was considered very appropriate, as it should facilitate the link between research, testing, validation and deployment. At the same time, several Member States expressed their concerns about the complexity inherent to the implementation of such an approach.

The 'Digital partnerships workshop' with Member States (Brussels, Belgium) took place on 28 November 2019 as part of efforts to ensure early involvement of Member States in the preparation of European Partnerships with the industry. All 'digital-centric' partnerships were considered of high relevance. For SNS, the added value of closer cooperation with the Member States compared to the current Public Private Partnership (PPP) would be the alignment of R&I agendas with for example the following topics: 6G, terabit connectivity, next generation IoT, cloud computing continuum made possible by high-speed connectivity, standardisation for interoperability. In addition, the partnership would enable structured collaboration on key issues related to 5G deployment, such as cross-border corridors for connected and automated mobility, or regulatory issues.

There was broad agreement that joint cooperation must offer clear added value that goes beyond financial leverage and that other motivators must be included. Cooperation was also perceived as important for scaling up technologies, especially in sectoral applications.

1.3.3. Targeted consultation of stakeholders

For the preparation of the research period after 2020, the first actions of the engagement process were taken by the 5G Infrastructure Association and the Networld2020 European Technology

Platform. They jointly organised workshops on 17 and 29 October 2019, with a large audience, including representatives of key stakeholders in the telecommunications and microelectronics sectors (e.g. Ericsson, Nokia, Infineon, LETI, IMEC, Amazon Edge Computing, ADVA and SMEs). The events included discussions related to the preparation of the planned future partnership, particularly with a focus on the various options for links between partnerships, notably Key Digital Technologies (KDT) and SNS. The workshops have also revealed the accrued importance of relatively new drivers including sustainability and security. To complement the previous initiatives the Commission has organised a series of workshops to gather input from a larger number of interested parties through direct interaction.

Workshops dedicated to the SNS partnership with private sector (Industry, Research and Academia)

Several workshops took place, with a focus on key related areas, such as next generation internet of things, next generation cloud, cybersecurity, components and devices, core smart networks technologies and industrial perspectives.

<u>The 6G Wireless Summit</u> (Levi, Finland) took place on 26 March 2019. The Commission presented the current status of preparation of the partnership, the upcoming steps and the possible timetable towards legislative implementation. Among positive feedback, Nokia has confirmed that they are actively investigating the institutionalised partnership scenario, as well as the coprogrammed partnership scenario. The Finnish authorities insisted on the necessity to develop a strong European approach for the deployment of future networks that support the digitisation of the society. They also advocated for a coordinated approach among the Member States, especially with regards to investments.

<u>The European Conferences on Networks and Communications</u> took place in June 2018 (Ljubljana, Slovenia) and June 2019 (Valencia, Spain). The theme for the EuCNC'19 was 'Enabling Smart Connectivity'. The event was thus very useful to gather stakeholders' views on the future of connectivity in the research and innovation domain.

The Smart Networks and Services partnership stakeholder workshop (Brussels, Belgium) with a focus on next generation internet of things (IoT), next generation cloud and cybersecurity. The Commission held the workshop on 4 July 2019, during which participants exchanged their views on challenges associated with the development of future Smart Networks and Services.

The 5G World Forum + SNS Partnership Stakeholder Workshop (Dresden, Germany) took place from 30 September to 2 October 2019. The event gathered industry leaders such as the Huawei CTO, the Nokia CEO for Germany, the Vodafone CTO. The developing ideas for SNS were supported by several speakers: the current trend towards digitisation of industry will continue to be an important driver and push the limits of the KPI's identified for 5G and stimulate collaboration across connectivity, cloud and IoT; the security and energy efficiency are key; societal issues such as climate, sustainable development goals, accessibility are also seen as important design drivers; emerging technologies such as AI, blockchain should be included.

<u>The Panel session 'Partnering for Digital Excellence' at the ICT Proposers Day</u> (Helsinki, Finland) took place on 19 September 2019. The event included a session on the challenges and opportunities offered by future European partnerships. Colin Willcock, Chairman of the 5G-IA, emphasized the necessity and the impact of a European partnership on Smart Networks and

Services, and how such a partnership will boost innovation in vertical industries and public sectors.

The Strategic Deployment Agenda and Stakeholders workshop at Digital Transport Day, (Helsinki, Finland) took place on 7-9 October 2019. The European Commission and key stakeholders discussed 5G deployment for connected and automated mobility. In general, there was agreement that the partnership should contribute to the digital transformation of vertical sectors through deployment of connectivity infrastructure, in parallel to developing the next wave of technologies beyond 5G.

<u>SNS Partnership Stakeholder Vision Workshop,</u> with a focus on core smart networks technologies, 26-27 November 2019 aimed at refining the Strategic Research and Innovation Agenda of the future partnership.

1.3.4. Open Public Consultation

An online public consultation⁶ took place from 11 September 2019 to 12 November 2019, with the aim to seek the views of EU research and innovation stakeholders and citizens on the 12 proposed institutionalised European partnerships under the future Horizon Europe Research and Innovation programme (2021-2027). The consultation was available in English, German and French. It was advertised widely the European Commission's online channels as well as via various stakeholder organisations.

The consultation focused on the overall need for and the planned focus of these potential European partnerships, and had a part with specific questions on the proposed SNS Partnership.

Participants in the consultation

For the Smart Networks and Services Partnership, 107 respondents provided their views. Among them, 21 respondents (20%) are citizens. The group is dominated by respondents from academic and research institutions (34 respondents or 32%), citizens and company/business organisations (29 respondents or 27%).

The majority of respondents (84 or 78%), have been involved in the on-going research and innovation framework programme, while 62 respondents (74%) were directly involved in a partnership under Horizon 2020 or its predecessor Framework Programme 7.

Results on general questions

In order to assess the stakeholders' views on the relevancy of several listed impacts or problems and thus obtain an overall percentage, the 5 ("very relevant") and 4-ratings were combined.

⁶ Available at https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2019-4972300/public-consultation_en

Relevance of efforts of the candidate European Partnership to address problems

At the beginning of the consultation, all 107 of the respondents for this partnership indicated their views of the needs of the future European Partnerships under Horizon Europe. Overall, respondents indicated that many of the options presented were fully needed (score 5) or gave them a score of 4. The needs where most respondents indicated that it was fully needed was related to its contribution to EU global competitiveness in specific sectors and/or domains (68%). Aside from 'other', the needs where the least respondents indicated that improvements were fully needed, was being more responsive towards priorities in national and/or regional R&I strategies (35%) and focusing more on bringing about transformative change towards sustainability in their respective area (36%). However, these options have a large number of respondents who have given the option a 4 out of 5 on the scale. The respondents also had the option to indicate other needs. The results show that respondents have indicated needs around citizen representation and significant healthcare contribution.

Main advantages and disadvantages of participation in the Institutionalised European Partnership

A key-word analysis showed that the respondents viewed collaboration as the main advantage, while also mentioning European leadership and long-term vision.

Results on candidate European Partnership Specific Closed Questions

Relevance of research and innovation efforts at the EU level to address problems in relation to smart networks and services

In the consultation, respondents were asked to provide their view on the relevancy (5-point scale) of research and innovation efforts at EU level to address the following problems:

- Problems in uptake of SNS innovations

With regard to the problems in uptake of SNS innovations, the majority of respondents have picked either a 4 or a 5 on the 5-point relevancy scale. Respondents indicated that insufficient digitalisation (data access and analysis, interoperability) especially for what concerns vertical user sectors is a very relevant problem, with 49 respondents giving this answer (48%). The option that has received the least 5 (very relevant) answers, out of all the problems presented, is regulation in the field of radio spectrum allocation including identification of new innovative spectrum management and sharing technologies (33 respondents or 31%). This lower relevancy could also be related to the higher number of respondents who have indicated that they 'don't know'. 14 respondents have selected this answer (13%), the highest number for any of the options.

Further uptake problems that the initiative would have to address are the 'market fragmentation due to lack of industrial policy favouring harmonised national take up and implementation strategies for new generation of smart connectivity systems', as has been confirmed by 76% of respondents and 'barriers to exploitation due to potential lack of global standards', as confirmed by 76% of respondents. Moreover, efforts are needed to solve 'concerns with use of smart

networks and services platforms for ethical, privacy, security, or EMF reasons", for 74% of respondents.

- Structural and resource problems

The gathered input has also shown that a future initiative on Smart Networks and Services would have to address the 'limited collaboration and pooling of resources between public actors, private actors i.e. network and internet service providers, connectivity vendors, computing and device actors, vertical industries and users, leading research centres and public authorities', as has been indicated by a large majority of respondents (88 respondents or 84% indicated this a relevant or very relevant problem to address).

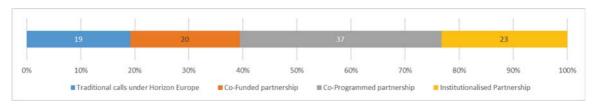
- Research and innovations problems

Respondents have indicated that research and innovation problems are considered the most relevant, as both of the problems presented in this category have received more 5 (very relevant) answers than any of the other problems. The innovation gap in the EU in translating the results of connectivity, cloud and Internet of Things devices research into the development of innovative networks and service platforms is considered the most relevant with 72 respondents (69%) indicating it is a very relevant problem.

Type of partnership to be pursued

Respondents were also asked to indicate how the specific SNS challenges could be addressed through Horizon Europe intervention. As shown in the figure below, just over 20% of the respondents indicated that an institutionalised partnership would be the best fitting intervention.

Figure 1 - Assessment of Horizon Europe intervention



The respondents were asked to briefly explain their answers to the question above. A key-word analysis of respondents that selected an institutionalised partnership as the best fitting intervention revealed 'public private European partnership', 'significant results and specific challenges' as common co-occurring keywords.

Stakeholders favoured the known model of co-programmed partnership due to the successful implementation of the 5G-PPP, which was found to present significant added value compared to traditional calls.

However, the stakeholders are fully open and understand the advantages of the institutionalised model. Even if different stakeholder groups cannot always be properly disaggregated, we found that academics tend slightly to prefer the co-programmed model. The 20% supporting co-funding appears to be a misunderstanding of the instrument since industry is core in the initiative. For the 37% preferring a co-programmed model, it is to be noted that at least 6 organisations in the 5G PPP, representing a large majority of the Industry and the 5G Industry Association, chose "co-programmed" as preferred option with a common line of comments saying "In our view this Partnership could be implemented equally as an Institutionalised Partnership. The choice between Co-Programmed or Institutionalized Partnership is difficult to make today as the details of how such Programs will be implemented have not been published. In our view the area of SNS

has the breadth, multiple stakeholders and ambitious goals to justify an Institutionalised Partnership however we also believe that this could be achieved by an extended form of a current cPPP". Another 5 stakeholders had a very similar text and this relativises the significantly the raw statistics and shows good support for an institutionalised approach, provided that its complexity and model for financial contributions are reasonable, which is the condition for them to sign up.

Involvement of actors in setting a joint long-term agenda

Respondents were asked how relevant the involvement of actors is in setting a joint long-term agenda to ensure that the proposed European Partnership would meet its objectives. A high number of respondents (86 respondents or 84%) indicated that a strong involvement of industry is very relevant for setting a joint long-term agenda. In contrast, a low number of respondents (21 respondents or 22%) stated that a strong involvement of foundations and NGOs is very relevant for this purpose.

A slight statistical difference was found between the views of citizens and other respondents. Citizens found a strong involvement of other stakeholders (like Connectivity vendors, Telecom operators, regulators, user groups) in setting a joint long-term agenda slightly more relevant.

Coordination in pooling and leveraging resources

Most respondents also considered that coordination with the industry, academia and Member States and associated countries is very relevant in pooling and leveraging resources. Industry is considered as the most relevant actor for this purpose, based on views of 91 out of 101 respondents (90%). The relevance of academia and Member States, Associated Countries and other stakeholders is also perceived relatively high for pooling and leveraging resources to reach objectives of the Smart Networks and Services Partnership (respectively 72% and 78% indicated their role as relevant or very relevant). Here again, less support could be found for foundations and non-governmental organisations (54%), but also for other societal stakeholders (57%).

Partnership composition

Respondents were asked about the relevance of certain elements of the Partnership composition, such as flexibility in the composition of partners over time and involvement of a broad range of partners, to reach Partnership objectives. A high share of respondents (67%) consider the involvement of a broad range of partners very relevant for meeting objectives of the SNS Partnership. Respondents also highlighted the importance of flexibility in the composition of partners over time (46% of the respondents indicated this as very relevant).

Implementation of activities

Respondents were asked to provide opinions on the relevance of implementation of several activities for meeting objectives of the Partnership. The following activities were listed – joint R&I programme, collaborative R&I projects, deployment and piloting activities, input to regulatory aspects and co-creation of solutions with end-users.

A high number of respondents view that that joint R&I programme (72 respondents or 70%), collaborative R&I projects (80 respondents or 77%), as well as, co-creation of solutions with endusers (104 respondents or 65%) is very relevant for meeting the objectives. In comparison, only 38 respondents out of 103 (37%) consider that the input to regulatory aspects is very relevant for this purpose, and 54 respondents (52%) view that deployment and piloting activities are very relevant for meeting objectives of this partnership.

Activities where a specific legal structure is relevant

Respondents were asked to assess the relevance of a specific legal structure (funding body) for the candidate European Partnership to achieve several objectives. A greater number of respondents indicated that the legal structure would be helpful/relevant to implement activities more effectively (83 respondents gave a score of 4 and 5, or 81%), to ensure harmonization of standards and approaches (82 respondents or 83%). The least number of respondents suggest that the legal structure would assist in ensuring better links to regulators, as only 34 respondents (34%) indicated that it would be very relevant (a score of 5) for this purpose.

Scope and coverage of the partnership

Respondents were asked to assess the scope and coverage of the proposed Partnership, based on its inception impact assessment. The majority of them consider that the Partnership has a right scope and coverage in all aspects. However, among listed areas, a slightly smaller share of respondents (64 respondents or 65%) indicated that the sectoral coverage is right and has an appropriate scope, and (13 respondents or 13%) suggested that the sectoral coverage is too narrow.

Societal impact

With regard to the possible societal impacts, the 'digital transformation of industries such as health, education, media and transport' was widely considered to be the most important field of action on which the future partnership should deliver, as has been confirmed by 89% of respondents (93 out 105 respondents indicated this as relevant or very relevant). Furthermore, a large majority of participants considered that the partnership should 'drastically reduce energy consumption of future smart network and service platform' (80 respondents or 76%) and deliver on 'providing consumers faster and smarter mobile communications for consumers' (77 respondents or 75%).

Economic/technological impact

Respondents have widely emphasised the importance of 'developing the digital economy of networks, Internet of Things and cloud computing' (91 respondents or 88% indicated this as relevant or very relevant), 'creating new industrial value chains across different sectors such as network equipment and service providers, big data, cloud, software-defined infrastructures and Internet of things technologies and services' (89 respondents or 86%) and 'faster, energy efficient and affordable advanced communication systems' (89%).

Scientific impact

Respondents have widely emphasized the importance of 'creating synergies between networks, cloud and internet of Things to achieve intelligent connectivity as a basis for the next generation Internet services and applications' (92 respondents or 89% indicated this as relevant or very relevant), 'maintaining and reinforcing European world-class research and innovation capabilities in networks and related domains' (90 respondents or 87%) and 'developing the scientific knowledge preparing for the 6th Generation of mobile communication networks' (88 respondents or 85%).

Results on candidate European Partnership Specific Open questions

This part of the questionnaire allowed respondents to personalize their answers.

A future European partnership was generally perceived as a good option to preserve European independence, especially in light of the success of the 5G-PPP. Many have also underlined that they have difficulties choosing between the institutionalised and the co-programmed model, as they find both appropriate.

For some respondents, traditional calls were the preferred option, as they are easy to work with, function well, take into account quick evolving technologies, and ensure better coordination. For others, an institutionalised partnership was the preferred option, as it could reduce complexity, ensure direct involvement of both member states and industrial actors, and thus strategic alignment between European and national authorities as well. Furthermore, it would allow for pulling and deployment of resources in a more coherent way and improve competitiveness. Finally, its inherent stability could justify its adoption, also considering the broad spectrum and wide range of stakeholders of the current initiative. Respondents who viewed the co-programmed partnership as the most suitable model argued that its advantages are its flexibility and speed (quick to set up). Many respondents also wish to extend the current form of CPPP, given the good experience they had with it and create implementation synergies with other domains.

Many respondents agreed with the technical scope and highlighted the need to focus on mobile communications networks but also to include IoT, cloud, edge computing, and devices, AI and smart algorithms in order to enable novel applications. Several stakeholders also stressed the necessity to involve key vertical industries and recommended to take a comprehensive value chain approach. Other (isolated) propositions were to focus on SME's, or to focus less on connected/automated mobility and smart cities, but rather on fresh food or dangerous goods. With regard to prospective activities, some drew attention to climate change and protection of water resources.

INTERVIEWS REPORT FROM THE IA STUDY

30 stakeholders have been interviewed to support the impact assessment study work, with a large part of the interviewees having experience in EU research program. The objectives of the interviews were to better understand the different perspectives of the stakeholders on the problems to be addressed by the initiative, and to identify the desired objectives and features of a future initiative

The distribution of interviews showed a good balance between academia (23%), the telecom industry (34%), SMEs (17%), industry associations, including verticals, (16%) and representatives from Member States (10%).

Figure 2 - Number of interviews per stakeholder category

Stakeholder category	Number	Share (%)
Academics	7	23%
Telecommunication Equipment / Hardware / Software Providers	8	27%
Telecom Operators	2	7%
Networks, Telecommunications and Digital Services SMEs	5	17%
Other Telecom Representatives (Industry Association, Regulators, Think tanks, etc.)	1	3%
Representatives from Vertical Industries (companies and industrial associations)	4	13%
Representatives from Member States	3	10%
TOTAL	30	100%

The interview outcomes confirm the trends from the other consultation activities, including the strong need for a partnership.

With regard to the preferred form of partnership, the co-programmed partnership was clearly the preferred option. This appears to be linked to the existence of the 5G-PPP, which was successful in a form equivalent to a co-programmed partnership.

- Option 0: Traditional calls

Only two interviewees out of the 30 were in favour of traditional calls because of its greater flexibility. For other interviewees – e.g. representatives of vertical industries and representatives of Member States, this **option should be ruled out** because the proposed partnership is required to have an impact on the increasing global competition in the field of SNS. Also, according to the majority of interviewees, this option lacks coordination and engagement capabilities between all stakeholders and thus is not adapted to reach the required objectives.

- *Option 1: Co-programmed partnership*

A co-programmed partnership is **clearly the preferred option among the majority of the interviewees**. This option is especially backed by those already having experience in the 5G-PPP, and comes mainly from the following categories of stakeholders: telecom operators and telecom infrastructure providers. These stakeholders were satisfied with the good achievements of the currently existing 5G-PPP. Although these stakeholders agree on improving the partnership form, they put forward that there is "no reason to change" the structure at the "risk of losing momentum". Other categories of stakeholders – e.g. academia and SMEs, are also in favour of a co-programmed partnership but they are **also open to an institutionalized partnership**.

- Option 2: Institutionalised partnership

The **second preferred option by interviewees** is an institutionalised partnership. The advantages outlined by stakeholders during the interviews include: the ability to have all relevant players involved including Member States, Commission and the industrial partners, thus maximising cooperation and synergies. It is also seen as a reasonable option if Member States are needed", for the ability to engage in a long-term contract that is legally binding which would be a strong commitment for the implementation to reach scale and for the ability to reach higher ambition to face the global competition.

For other interviewees, the drawbacks for this option are related to its **organisation structure**, and can be summarized by the following points: doubts on the rules of governance; fear of being an organisation that is too cumbersome; too much overhead and heavy procedures; lack of agility; presence of the Member States that introduces political issues and delays. However, some interviewees would be in favour of an institutionalised partnership option without the Member States.

1.3.5. Conclusion

In summary, the consultation followed the original strategy leading to results that clearly indicates very good support for the SNS Partnership. Stakeholders have recognized the importance of a partnership approach in contributing to Europe's future connectivity infrastructure ecosystem across all value chains.

Overall, the evidence shows that, with a few exceptions, respondents agree on the (research and innovation, structure and resources, uptake of innovations) problems that a future partnership would need to address. Problems that were widely considered as relevant were:

- the innovation gap in the EU in translating the results of connectivity, cloud and Internet of Things devices research
- the limited collaboration and pooling of resources between public/private actors
- the understanding of or knowledge about next generation converged Digital Infrastructures.

The same conclusion can be drawn about the (societal, economic/technological and scientific) impacts where the prospective partnership should deliver on. Furthermore, the present analysis has also shown that respondents are generally satisfied with the proposed scope of the partnership – especially with regard to the range of activities and technologies covered.

On average, respondents were also in agreement about the partnership composition (=broad range of partners, flexibility over time), the joint long-term agenda and the pooling/ leveraging of resources (i.e. to involve industry, academia, Member states and associated countries).

The analysis did however reveal more differences with regard to the preferred type of partnership by stakeholders. The gathered results indicated a preference for either a co-programmed or an institutionalised partnership but many respondents also stressed that they lack clear knowledge of the administrative and legal implications to make a choice between the two partnership models.

Annex 3 Who is affected and how?

PRACTICAL IMPLICATIONS OF THE INITIATIVE

This annex describes the practical implications of the preferred option identified in the Impact Assessment – the establishment of an institutionalised partnership to implement R&I on Smart Networks and Services and to implement the CEF2 initiative related to deployment of 5G networks in Europe, as two complementary activities.

I. Overview of benefits (total for all provisions) - Preferred Option

Member States

The EU Member States will have at disposal an effective mechanism providing them with opportunities to leverage their national investments into SNS at European level, which will also help them to get return from this initiative. They will have an upstream capability to plan ahead the needed national measures to facilitate EU level deployment of technologies.

The initiative will enable Member States to create better synergies together with the Commission for their national investments in necessary SNS research and deployment at the national and European levels. The initiative will allow Member States to plan for pooling expertise as well as resources for tools and infrastructures which would otherwise be more costly or not affordable for individual Member States. Such approach would allow economies of scale and rationalisation. This planning capability is a major benefit of the preferred option, which could not be achieved through traditional Horizon Europe calls (baseline option).

The return from such investments would be also proportionally higher as the Member States would benefit from the access to upgraded capacities and facilities that may not be achieved through national efforts only.

The increased coherence and synergies between different funding mechanisms (Horizon Europe, CEF2) would also reduce the administrative burden of managing different funding programmes, with a positive impact on the efficiency of the EU budget to which Member State contribute.

The preferred option will also have a positive impact on the Member States' capability to deal with the wide range of issues related to downstream regulatory and deployment related issues. The functionalities of the initiative linked to the EU wide comprehensive R&I on SNS, will complement the efforts of the Member States initiatives by providing appropriate input to regulatory and policy makers. At the same time, the access for researchers to cutting-edge projects will help contain the "brain drain" phenomenon and increase the chances of retaining the best talents in the EU and attracting foreign highly skilled professionals.

Businesses

European firms from the networking, the cloud computing and the IoT sectors, alongside the companies active in vertical sectors (e.g. automotive, healthcare, media and energy), will profit the most from the partnership. This comprehensive supplier-user approach will stimulate cross industry synergies and innovative digital use cases, helping them to ensure that supplied technology actually cover the requirements of the user side. This should also help them cut

research and development costs and speed up the development process, which would further reinforce their competitiveness.

The chosen mechanism will ensure coordination between research and industry and therefore direct the research efforts towards concrete industrial needs. The provision of cutting-edge expertise and tools in SNS will indirectly support economic operators in complying with the future Internet regulatory environment.

In addition one of the key functionalities of the initiative is to support the deployment of European 5G leading-edge products and solutions across the market (transport paths).

SMEs

The European SMEs and micro-enterprises operating in the SNS field will experience direct and indirect economic benefits from the initiative as highlighted above. While the set-up of the SNS partnership does not impose regulatory obligations upon them, it will open up opportunities in terms of costs reduction for the design of new products and it will help them gaining easier access to the investors' community and attract the necessary funding to deploy marketable solutions at EU scale. In the case of SMEs and micro-enterprises the access to publically funded testing and experimentation facilities is even more important as they are lacking resources to either purchase or to travel outside their market (and often outside the EU) to find necessary infrastructure. It is also hoped that this initiative would open up new markets for European SMEs and micro-enterprises active in the field of SNS.

Research Community

Research and development organisations throughout the EU, both on the supply and usage side, will enjoy the benefits deriving from better coordination, resource pooling and increased availability of advanced methodologies and tools (such as testing and experimentation facilities). They will be able to achieve the critical mass to carry out projects of common interest with a longer-time, strategic perspective. In addition, the chosen mechanism will ensure coordination between research and industry and therefore direct the research efforts towards concrete industrial needs helping the process of turning the outcomes of the research into applicable and marketable solutions that could be then used by different industries and public authorities. The European dimension will help them to plan in advance for important exploitation such as standardisation spin off of R&I.

The hosting of several programmes under a common "umbrella", possible under traditional Horizon Europe calls, would also allow the research community to experience cross-fertilisation among the different stakeholder groups related to SNS and increase the visibility of the EU excellence in research on the global scene.

Citizens

Stronger European know-how in SNS should result in an overall higher level of societal impact directly beneficial to citizens in the Digital Single Market, e.g. in Internet of Things domains such as smart energy, medical devices, or connected automated vehicles. The initiative should result in an improved provision of products and services which reflect European values and are directly in line with European policies and regulations. Key citizen impacts like energy efficiency and reduction of carbon footprint of networked infrastructures, reduction in EMF radiations, better support of medical or automotive applications will positively impact citizens.

EU institutions, agencies and bodies

The EU institutions, agencies and bodies will benefit both from the outcome of the research and development and the procurement activities of the initiative, and from the access to state-of -the art methodologies and tools to perform their operations as effectively as possible. Cross links of the initiatives with other domains opens capabilities of synergies with multiple other bodies of EU relevance such as the European Space Agency, the KDT partnership, the cybersecurity partnership. It is also relevant as "one stop EU shop" for policy and regulatory settings such as the RSPG, BEREC, COCOM and the EU for a dealing with digitisation of industry at large.

II. Overview of direct and indirect costs – Preferred option 7							
			Citizens/Consum Businesses ers			Administrations	
		One- off	Recurren t	One- off	Recurrent	One- off	Recurrent
Management/ Administrative costs	Direct costs				€ 800.000 /year		€ 800.000 /year
Administrative costs	Indirect costs						
Personnel costs	Direct costs				€ 1.2 million /year 50% of 19 FTE		€ 1.2 million /year 50% of 19 FTE
	Indirect costs						
Coordination costs (or transaction costs)							
Budget expenditure/ investment costs							

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⁷ Estimation based on the average expenditures of the H2020 Joint Undertaking ECSELand on the estimation from the SNS industry taskforce ("Smart Networks and Services Partnership Proposal" document).

Annex 4 Analytical Methods

The methodology for each impact assessment is based on the Commission Better Regulation Guidelines⁸ to evaluate and compare options with regards to their **efficiency**, **effectiveness and coherence**. This is complemented by integrating the **conditions and selection criteria for European Partnerships**, as well as requirements for setting up Institutionalised Partnerships.⁹

1. OVERVIEW OF THE METHODOLOGIES EMPLOYED

In terms of **methods and evidence used**, the set of impact assessments for all candidate Institutionalised European Partnerships draw on an external study covering all initiatives in parallel to ensure a high level of coherence and comparability of analysis ¹⁰ (Technopolis Group, 2020).

All impact assessment mobilised a mix of qualitative and quantitative data collection and analysis methods. These methods range from desk research and interviews to the analysis of the responses to the Open Consultation, stakeholder analysis and composition/portfolio analysis, bibliometrics/patent analysis and social network analysis, and a cost-effectiveness analysis.

The first step in the impact assessment studies consisted in the definition of the context and the problems that the candidate partnerships are expected to solve in the medium term or long run. The main data source in this respect was desk research. This includes grey and academic literature to identify the main challenges in the scientific and technologic fields and in the economic sectors relevant for the candidate partnerships, as well as the review of official documentations on the policy context for each initiative.

In the assessment of the problems to address, the lessons to be learned from past and ongoing partnerships were taken into account, especially from relevant midterm or ex-post evaluations.

The description of the context of the candidate institutionalised European Partnerships required a good understanding of the corresponding research and innovation systems and their outputs already measured. Data on past and ongoing Horizon 2020 projects, including the ones implemented through Partnerships, served as basis for descriptive statistic of the numbers of projects and their respective levels of funding, the type of organisations participating (e.g. universities, RTOs, large enterprises, SMEs, public administrations, NGOs, etc.) and how the funding was distributed across them. Special attention was given to analysing the participating countries (and groups of countries, such as EU, Associated Countries, EU13 or EU15) and industrial sectors, where relevant. The sectoral analysis required enriching the eCORDA data received from the European Commission services with sector information extracted from ORBIS, using the NACE codification up to level 2. These data enabled the identification of the main and, where possible, emerging actors in the relevant systems, i.e. the organisations, countries and sectors that would need to be involved (further) in a new initiative.

⁹ A pivotal element of the present analysis is the so-called two-step 'necessity test' for European Partnerships, used to establish: step 1) the need for a partnership approach in the first place, followed by step 2) a justification for the form of Institutionalised Partnership. The necessity test is described in Annex 6. This impact assessment focuses on the second step of the test.

⁸ European Commission (2017), Better Regulation Guidelines (SWD (2017) 350)

¹⁰ Technopolis Group (2020), Impact Assessment Study for Institutionalised European Partnerships under Horizon Europe

A Social Network Analysis was performed by the contractors using the same data. It consisted in mapping the collaboration between the participants in the projects funded under the ongoing R&I partnerships. This analysis revealed which actors – broken down per type of stakeholders or per industrial sector – collaborate the most often together, and those that are therefore the most central to the relevant research and innovation systems.

The data provided finally served a bibliometric analysis run by the contractor aimed at measuring the outputs (patents and scientific publications) of the currently EU-funded research and innovation projects. A complementary analysis of the Scopus data enabled to determine the position and excellence of the European Union on the international scene, and identify who its main competitors are, and whether the European research and innovation is leading, following or lagging behind.

A cost modelling exercise was performed in order to feed into the efficiency assessments of the partnership options.

The conclusions drawn from the data analysis were confronted to the views of experts and stakeholders collected via three means:

- The comments to the inception impact assessments of the individual candidate institutionalised European Partnerships;
- The open public consultation organised by the European Commission from September to November 2019;
- The interviews (up to 50) conducted by each impact assessment study team conducted between August 2019 and January 2020 (policymakers, business including SMEs and business associations, research institutes and universities, and civil organisations, among others).

The views of stakeholders (and experts) were particularly important for determining the basic functionalities (see further below) that the future partnerships need to demonstrate to achieve their objectives as well as their most anticipated scientific, economic and technological, and societal impacts. The interviews allowed more flexibility to ask the respondents to reflect about the different types of European Partnerships. Furthermore, as a method for targeted consultation, it was used to get insights from the actors that both the Study Teams and the European Commission were deemed the most relevant. For the comparative assessment of impacts, the external contractors confronted the outcomes of the different stakeholder consultation exercises to each other with a view of increasing the validity of their conclusions, in line with the principles of triangulation.

Annex 2 includes also the main outcomes of the stakeholder consultation exercises.

2. METHOD FOR ASSESSING THE EFFECTIVENESS, EFFICIENCY AND COHERENCE OF EACH OPTION - THE USE OF FUNCTIONALITIES

Given the focus of the impact assessment on comparing different forms of implementation, the Better Regulation framework has been adapted to introduce "**key functionalities needed**" – so as to link the intended objectives of the candidate European Partnerships and what would be crucial

to achieve them *in terms of implementation*. The identification of "key functionalities needed" for each initiative as an additional step in the impact assessment is based on the distinguishing factors between the different options (see Section 2.2.1 in the main body of the impact assessment). In practical terms, each option is assessed on the basis of the degree to which it would allow for the key needed functionalities to be covered, as regards e.g. the type and composition of actors that can be involved ('openness'), the range of activities that can be performed (including additionality and level of integration), the level of directionality and integration of R&I strategies; the possibilities offered for coherence and synergies with other components of Horizon Europe, including other Partnerships (internal coherence), and the coherence with the wider policy environments, including with the relevant regulatory and standardisation framework (external coherence). This approach guides the identification of discarded options. It also allows for a structured comparison of the options as regards their effectiveness, efficiency and coherence, and also against a set of other key selection criteria for European Partnerships (openness, transparency, directionality)¹¹.

Figure 3 Overview of key functionalities of each form of implementation of European Partnerships

Baseline: Horizon Europe calls	Option 1: Co- programmed	Option 2: Co- funded	Option 3.1: Institutionalised Article 185	Option 3.2: Institutionalised Article 187		
Type and compo	sition of actors (inc	luding openness a	nd roles)			
Partners: N.A., no common set of actors that engage in planning and implementation Priority setting: open to all, part of Horizon Europe Strategic planning Participation in R&I activities: fully open in line with standard Horizon Europe	Partners: Suitable for all types: private and/or public partners, foundations Priority setting: Driven by partners, open stakeholder consultation, MS in comitology Participation in R&I activities: fully open in line with standard Horizon Europe rules	Partners: core of national funding bodies or govern-mental research organisations Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: limited, according to national rules of partner countries	Partners: National funding bodies or governmental research organisation Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: fully open in line with standard Horizon Europe rules, but possible derogations	Partners: Suitable for all types: private and/or public partners, foundations Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: fully open in line with standard Horizon Europe rules, but possible		
rules				derogations		
Type and range	Type and range of activities (including additionality and level of integration)					
Activities: Horizon Europe standards that allow broad	Activities: Horizon Europe standard actions that allow broad	Activities: Broad, according to rules/programm	Activities: Horizon Europe standards that allow broad range	Activities: Horizon Europe standards that allow broad		
range of	range of	es of	of individual	range of		

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¹¹ The criterion on the ex-ante demonstration of partners' long term commitment depends on a series of factors that are unknown at this stage, and thus fall outside the scope of the analysis.

Baseline:	Option 1: Co-	Option 2: Co-	Option 3.1:	Option 3.2:
Horizon	programmed	funded	Institutionalised	Institutionalised
Europe calls			Article 185	Article 187
individual	individual	participating	actions, support	individual
actions	actions, support to	States, State-aid	to regulatory or	actions, support
Additionality:	market,	rules, support to	policy/societal	to regulatory or
no additional	regulatory or policy/ societal	regulatory or policy/ societal	uptake, possibility to	policy/societal uptake,
activities and	uptake	uptake	systemic	possibility to
investments	1	1 -	approach	systemic
outside the	Additionality: Activities/investm	Additionality: National	арргоасп	approach
funded projects	ents of partners,	funding	A 1.11.1 11.	(portfolios of
<u>Limitations:</u> No	National funding		Additionality:	projects, scaling
systemic	Limitations:	Limitations:	National funding	up of results,
approach beyond	Limited systemic	Scale and scope depend on the		synergies with
individual	approach beyond	participating		other funds.
actions	individual	programmes,		Additionality:
actions	actions.	often smaller in		Activities/investm
		scale		nts of partners/
				national funding
Directionality				
Priority setting:	Priority setting:	Priority setting:	Priority setting:	Priority setting:
Strategic Plan	Strategic R&I	Strategic R&I	Strategic R&I	Strategic R&I
and annual	agenda/ roadmap	agenda/	agenda/ roadmap	agenda/ roadmap
work	agreed between	roadmap agreed	agreed between	agreed between
programmes,	partners and	between	partners and	partners and
covering max. 4	COM, covering	partners and	COM, covering	COM, covering
years.	usually 7 years,	COM, covering	usually 7 years,	usually 7 years,
<u>Limitations:</u>	including allocation of	usually 7 years, including	including allocation of	including allocation of
Fully taking	Union	allocation of	Union	Union
into account	contribution	Union	contribution	contribution
existing or to be developed	Input to FP	contribution	Annual work	Annual work
SRIA/ roadmap	annual work	Annual work	programme	programme
SKIA/ Toadillap	programme	programme	drafted by	drafted by
	drafted by	drafted by	partners,	partners,
	partners, finalised	partners,	approved by	approved by
	by COM	approved by	COM	COM (veto-right
	(comitology)	COM	Objectives and	in governance)
	Objectives and	Objectives and	commitments are	Objectives and
	commitments are	commitments	set in the legal	commitments are
	set in the	are set in the	base.	set in the legal
	contractual	Grant		base.
	arrangement.	Agreement.		
	rnal (Horizon Europ	pe) and external (o	other Union program	nmes, national
1 0	dustrial strategies)	l x	T	
Internal:	Internal:	Internal:	Internal:	Internal:
Between	Coherence among	Coherence	Coherence among	Coherence

Baseline: Horizon Europe calls	Option 1: Co- programmed	Option 2: Co- funded	Option 3.1: Institutionalised Article 185	Option 3.2: Institutionalised Article 187
different parts of the Annual Work programme can be ensured by COM External: Limited for other Union programmes, no synergies with national/regiona l programmes and activities	partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Limited synergies with other Union programmes and industrial strategies If MS participate, with national/regional programmes and activities	among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Synergies with national/ regional programmes and activities	partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Synergies with national/ regional programmes and activities	among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Synergies with other Union programmes and industrial strategies If MS participate, with national/ regional programmes and activities

In line with the Better Regulation Framework, the assessment of the effectiveness, efficiency and coherence of each option is made in comparison to the baseline. Therefore, for each of the above criteria, the performance of using traditional calls under Horizon Europe is first estimated and scored 0 to serve as a reference point. When relevant, this estimation also includes the costs/benefits of discontinuing existing implementation structures. The policy options are then scored compared to the baseline with a + and – system along a two-point scale, to indicate limited (+ or -) or high (++ or --) additional/lower performance compared to the baseline. When a policy option is scored 0, this means that its impact is expected to be roughly equal to the baseline option.

On the basis of the evidence collected, the intervention logic of each initiative and the key functionalities needed, the impact assessments first evaluate the **effectiveness** of the various policy options to deliver on their objectives. To be in line with the Horizon Europe impact framework, the fulfilment of the specific objectives of the initiative is translated into 'expected impacts' - how success would look like -, differentiating between scientific, economic/technological, and societal (including environmental) impacts. Each impact assessment considers to which extent the different policy options provides the 'key functionalities needed' to achieve the intended objectives. The effectiveness assessment does not use a compound score but shows

how the options would deliver on the different types of expected impacts. This is done to increase transparency and accuracy in the assessment of options¹².

A similar approach is followed to evaluate the coherence of options with the overarching objectives of the EU's R&I policy, and distinguishes between **internal** and **external coherence**. Specifically, internal coherence covers the consistency of the activities that could be implemented with the rest of Horizon Europe, including European Partnerships (any type). External coherence refers to the potential for synergies and/or complementarities (including risks of overlaps/gaps) of the initiative with its external environment, including with other programmes under the MFF 2021-27, but also the framework conditions at European, national or regional level (incl. regulatory aspects, standardisation).

To compare the expected costs and benefits of each option (efficiency), the thematic impact assessments broadly follow a cost-effectiveness approach to establish to which extent the intended objectives can be achieved for a given cost. A preliminary step in this process is to obtain a measure of the expected costs of the policy options, to be used in the thematic assessments. As the options correspond to different implementation modes, relevant cost categories generally include the costs of setting-up and running an initiative. For instance, set-up costs includes items such as the preparation of a European Partnership proposal and the preparation of an implementation structure. The running costs include the annual work programme preparation costs. Where a Partnership already exists, discontinuation costs and costsavings are also taken into account¹⁴. The table below provides an overview of the cost categories used in the impact assessment and a qualitative scoring of their intensity when compared to the baseline option (traditional calls). Providing a monetised value for these average static costs would have been misleading, because of the different features and needs of each candidate initiative. 15 The table shows the overall administrative, operational and coordination costs of the various options. These costs are then put into context in the impact assessments to reflect the expected co-financing rates and the total budget available for each of the policy options, assuming a common Union contribution (cost-efficiency):

- The costs related to the baseline scenario (traditional calls under Horizon Europe) are predominantly the costs of implementing the respective Union contribution via calls and project, managed by the executive agencies (around 4%, efficiency of 96% for the overall investment).
- For a Co-Programmed partnership the costs of preparation and implementation increase only marginally compared to the baseline (<1%), but lead to an additional R&I

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¹² In the thematic impact assessments, scores are justified in a detailed manner to avoid arbitrariness and spurious accuracy. A qualitative or even quantitative explanation is provided of why certain scores were given to specific impacts, and why one option scores better or worse than others.

¹³ For further details, see Better Regulation Toolbox # 57.

¹⁴ Discontinuation costs will bear winding down and social discontinuation costs and vary depending on e.g. the number of full-time-equivalent (FTEs) staff concerned, the type of contract (staff category and duration) and applicable rules on termination (e.g. contracts under Belgian law or other). If buildings are being rented, the cost of rental termination also apply. As rental contracts are normally tied to the expected duration of the current initiatives, these termination costs are likely to be very limited. In parallel, there would also be financial cost-savings related to the closing of the structure, related to operations, staff and coordination costs in particular. This is developed further in the individual efficiency assessments.

¹⁵ A complete presentation of the methodology developed to assess costs as well as the sources used is described in the external study supporting this impact assessment (Technopolis Group, 2020).

¹⁶ Specifically, some additional set-up costs linked for example to the creation of a strategic research and innovation agenda (SRIA) and additional running costs linked with the partners role in the creation of the annual work programmes and the Commission's additional supervisory responsibilities. A CPP will have lower overall costs than each of the other types of European Partnership, as it will function with a smaller governance and implementation

- investment of at least the same amount than the Union contribution ¹⁷ (efficiency of 98% for the overall investment).
- For a Co-Funded partnership the additional R&I investment by Member States accounts for 2,3 times the Union contribution 18. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the national programmes, can be estimated at 6% of the Union contribution (efficiency of 98% related to the overall investment).¹⁹
- For an Article 185 initiative the additional R&I investment by Member States is equal to the Union contribution²⁰. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the dedicated implementation structure, can be estimated at 7% of the Union contribution (efficiency of 96% related to the overall investment).
- For an Article 187 initiative the additional R&I investment by partners is equal to the Union contribution²¹. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the dedicated implementation structure, can be estimated at 9% of the Union contribution (efficiency of 94% related to the overall investment).

Figure 4 - Intensity of additional costs compared with Horizon Europe Calls (for Partners, stakeholders, *public and EU*)

Cost items	Baseline: traditional calls	Option 1: Coprogrammed	Option 2 Co-funded	Option 3a - Art. 185	Option 3b -Art. 187
Preparation and set-up costs					
Preparation of a partnership proposal (partners and EC)	0		$\uparrow \uparrow$		
Set-up of a dedicated implementation structure		0		Existing: ↑ New: ↑↑	Existing: ↑↑ New: ↑↑↑
Preparation of the SRIA / roadmap	0		$\uparrow \uparrow$		
Ex-ante Impact Assessment for partnership		0		↑ ↑	1
Preparation of EC proposal and negotiation		0			1
Running costs (Annual cycle of implementati	on)				
Annual Work Programme preparation	0		↑		
Call and project implementation	0	0 In case of MS contributions: ↑	1	1	↑
Cost to applicants	Comparable, unless there are strong arguments of major differences in oversubscription				fferences in
Partners costs not covered by the above	0	\uparrow	0	↑	\uparrow
Additional EC costs (e.g. supervision)	0	\uparrow \uparrow \uparrow		↑	$\uparrow \uparrow$
Winding down costs					
EC		0			$\uparrow \uparrow \uparrow$

structure than will be required for a Co-Funded Partnership or an Institutionalised Partnership and - related to this its calls will be operated through the existing HEU agencies and RDI infrastructure and systems.

¹⁷ Minimum contributions from partners equal to the Union contribution.

¹⁸ Based on the default funding rate for programme co-fund actions of 30%, partners contribute with 70% of the total

investment.

19 These costs reflect set-up costs and additional running costs for partners, and the Commission, of the distributed, multi-agency implementation model.

²⁰ Based on the minimum requirement in the legal basis that partners contribute at least 50% of the budget.

²¹ Based on the minimum requirement in the legal basis that partners contribute at least 50% of the budget.

Cost items	Baseline: traditional calls	Option 1: Coprogrammed	Option 2 Co-funded	Option 3a - Art. 185	Option 3b -Art. 187
Partners	0	↑	0	↑	\uparrow

Notes: 0: no additional costs, as compared with the baseline; \uparrow : minor additional costs, as compared with the baseline; $\uparrow \uparrow$: medium additional costs, as compared with the baseline; $\uparrow \uparrow \uparrow$: higher costs, as compared with the baseline.

The cost categories estimated for the common model are then used to develop a scorecard analysis and further refine the assessment of options for each of the 12 candidate Institutionalised Partnerships. Specifically, the scores related to the set-up and implementation costs are used in the thematic impact assessments to consider the scale of the expected benefits and thereby allow a simple "value for money" analysis (**cost-effectiveness**). In carrying out the scoring of options, the results of fieldwork, desk research and stakeholder consultation undertaken and taken into account.

3. METHOD FOR IDENTIFYING THE PREFERRED OPTION – THE SCORECARD ANALYSIS

For the **identification of the preferred option**, a scorecard analysis is used to build a hierarchy of the options by individual criterion and overall in order to identify a single preferred policy option or in case of an inconclusive comparison of options, a number of 'retained' options or hybrid. This exercise supports the systematic appraisal of alternative options across multiple types of monetary, non-monetary and qualitative dimensions. It also allows for easy visualisation of the pros and cons of each option. Each option is attributed a score of the adjudged performance against each criterion with the three broad appraisal dimensions of effectiveness, efficiency and coherence.

This scorecard approach also relies on a standard cost model developed for the external study supporting the impact assessment, as illustrated in Figure 5. . Specifically, the scores related to the set-up and implementation costs are used in the thematic impact assessments to consider the scale of the expected benefits and thereby allow a simple "value for money" analysis (cost-effectiveness). In carrying out the scoring of options, the results of fieldwork, desk research and stakeholder consultation undertaken and taken into account.

These costs essentially refer to the administrative, operational and coordination costs of the various options. The figure shows how the scoring of costs range from a value of 0, in case an option does not entail any additional costs compared to the baseline (traditional calls), to a score of (-) for options introducing limited additional costs relative to the baseline and a score of (-) when substantial additional costs are expected in comparison with the baseline. Should the costs of a policy option be lower than those of the baseline, (+) and (++) are used.

It is considered that while there is a clear gradation in the overall costs of the policy options, the cost differentials are less marked when one takes into account the expected co-financing rates and the total budget available for each of the policy options, assuming a common Union contribution. From this perspective, there are only one or two percentage points that split the most cost-efficient policy options – the baseline (traditional calls) and the Co-Programmed policy options – and the least cost-efficient – the Institutionalised Partnership option. A score of + is therefore assigned for **cost-efficiency** to the Co-Programmed and Co-Funded options, a score of 0 to the

Article 185 option and a score of (-) for the Article 187 Institutionalised Partnership policy option²².

Figure 5: Matrix on 'overall costs' and 'adjusted cost scoring'

	Baseline: Horizon Europe calls	Option 1: Co- programmed	Option 2: Co-funded	Option 3a: Institutionalised 185	Option 3b: Institutionalised 187
Administrative, operational and coordination costs	0	(0)	(-)	()	()
Administrative, operational and coordination costs adjusted per expected co- funding (i.e. cost- efficiency)	0	(+)	(+)	(0)	(-)

Notes: Score 0 = same costs as for the baseline; score (-) = limited additional costs compared to baseline; score (- -) = substantial additional costs compared to baseline.; score (+) = lower costs compared to baseline

Figure 5: Matrix on 'overall costs' and 'adjusted cost scoring'

	Baseline: Horizon Europe calls			Option 3: Institutionalised
Administrative, operational and coordination costs	0	(-)	()	()
Administrative, operational and coordination costs adjusted per expected co-funding (i.e. cost-efficiency)	0	0	(-)	(-)

Notes: Score 0 = same costs as for the baseline; score (-) = limited additional costs compared to baseline; score (- -) = substantial additional costs compared to baseline.

The **baseline** (**regular calls**) has the lowest administrative, operational and coordination costs. This is based on two facts: firstly, that Horizon Europe traditional calls will not entail any additional one-off costs to be set up or discontinued at the end, where each of the other policy options will require at least some additional set-up and phasing out costs; and secondly, that Horizon Europe will not require any additional running costs, where each of the other policy options will involve additional efforts by the Commission and partners in the carrying out of necessary additional tasks (e.g. preparing annual work programmes).

A **co-programmed partnership** (Option 1 - CPP) will entail slightly higher overall costs as compared with the baseline. There will be some additional set-up costs linked for example with the creation of a strategic research and innovation agenda (SRIA) and additional running costs linked with the partners role in the creation of the annual work programmes and the Commission's additional supervisory responsibilities. A CPP will have lower overall costs than each of the other types of European Partnership, as it will function with a smaller governance and implementation structure than will be required for a Co-Funded Partnership or an Institutionalised Partnership and – related to this – its calls will be operated through the existing HEU agencies and RDI infrastructure and systems.

²² The baseline (traditional calls) is scored 0, as explained above.

The Co-Funded Partnership (Option 2 – CFP) has been scored (- -) on overall cost. This reflects the additional set-up costs of this policy option and the substantial additional running costs for partners, and the Commission, of the distributed, multi-agency implementation model.

The Institutionalised Partnership (Option 3 - IP) has been scored (- -) on overall cost. This reflects the substantial additional set-up costs of this policy option – and in particular the high costs associated with preparing the Commission proposal and negotiating that through to a legal document – and the substantial additional running costs for the Commission associated with the supervision of this dedicated implementation model.

It is considered that while there is a clear gradation in the overall costs of the policy options, the cost differentials are less marked when one takes into account the expected co-financing rates and the total budget available for each of the policy options, assuming a common Union contribution. From this perspective, there are only one or two percentage points that split the most costefficient policy options – the baseline (traditional calls) and the Co-Programmed policy options – and the least cost-efficient - the Institutionalised Partnership option. A score of 0 is therefore assigned for cost-efficiency to the Co-Programmed option and a score of (-) for the Co-Funded and the Institutionalised Partnership policy options²³.

²³ The baseline (traditional calls) is scored 0, as explained above.

Annex 5 Subsidiarity Grid

1. Can the Union act? What is the legal basis and competence of the Unions' intended action?

1.1 Which article(s) of the Treaty are used to support the legislative proposal or policy initiative?

This proposal is based on (1) Article 185 TFEU which stipulates that in implementing the multiannual framework programme, the Union may make provision, in agreement with the Member States concerned, for participation in research and development programmes undertaken by several Member States, including participation in the structures created for the execution of those programmes; and (2) Article 187 TFEU according to which the Union may set up joint undertakings or any other structure necessary for the efficient execution of Union research, technological development and demonstration programmes (both Articles are under Title XIX of the TFEU - Research and Technological Development and Space).

The proposal aims to implement Article 8 of the Commission proposal for Horizon Europe - the future EU research and innovation (R&I) programme for 2021-2027, according to which, "European Partnerships shall be established for addressing European or global challenges only in cases where they will more effectively achieve objectives of Horizon Europe than the Union alone and when compared to other forms of support of the Framework programme". The Horizon Europe proposal has received the political agreement of the Council and the European Parliament.

1.2 Is the Union competence represented by this Treaty article exclusive, shared or supporting in nature?

Research is a shared competence between the EU and its Member States according to the TFEU. Article 4 (3) specifies that in the areas of research, technological development and space, the European Union can carry out specific activities, including defining and implementing programmes, without prejudice to the Member States' freedom to act in the same areas.

Subsidiarity does not apply for policy areas where the Union has **exclusive** competence as defined in Article 3 TFEU²⁴. It is the specific legal basis which determines whether the proposal falls under the subsidiarity control mechanism. Article 4 TFEU²⁵ sets out the areas where competence is shared between the Union and the Member States. Article 6 TFEU²⁶ sets out the areas for which the Unions has competence only to support the actions of the Member States.

https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12008E006:EN:HTML

https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12008E004&from=EN

2. Subsidiarity Principle: Why should the EU act?

2.1 Does the proposal fulfil the procedural requirements of Protocol No. 2^{27} :

- Has there been a wide consultation before proposing the act?
- Is there a detailed statement with qualitative and, where possible, quantitative indicators allowing an appraisal of whether the action can best be achieved at Union level?

This proposal and the accompanying impact assessment were supported by a wide consultation of stakeholders, both during the preparation of the Horizon Europe proposal and - later on, all the candidates for European Partnerships. Member States were consulted via the Shadow Strategic configuration of the Horizon Europe Programme Committee. On candidates for institutionalised Partnerships based on Article 185/187 of the TFEU, an Open Public Consultation (OPC) was held between 11 September and 6 November 2019. Over 1 600 replies were received. In addition, targeted consultation activities were undertaken to prepare the present impact assessment. In particular, for each of the candidate partnerships, an external consultant interviewed a representative sample of stakeholders. The need for EU action as well as its added value were covered in those interviews.

The explanatory memorandum and the impact assessment (horizontal part, Section 3) contain a dedicated section on the principle of subsidiarity, as explained in question 2.2 below.

2.2 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the conformity with the principle of subsidiarity?

The impact assessment accompanying the proposal features a horizontal part on relevant common elements to all the candidate partnerships, including the conformity of the proposed initiative with the principle of subsidiarity (Section 3). Moreover, the individual assessments of each candidate partnership include additional details on subsidiarity, touching in particular on the specificities of a candidate partnership that could not be adequately reflected in the horizontal part of the impact assessment. This will also be reflected in the explanatory memorandum.

2.3 Based on the answers to the questions below, can the objectives of the proposed action be achieved sufficiently by the Member States acting alone (necessity for EU action)?

National action alone cannot achieve the scale, speed and scope of support to R&I needed for the EU to meet its long-term Treaty objectives, to deliver on the EU's strategic policy priorities (including the climate and energy goals set out in the Paris Agreement, and the European Green Deal), and to contribute to tackling global challenges and meeting the

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²⁷ https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12016E/PRO/02&from=EN

Sustainable Development Goals (SDGs).

(a) Are there significant/appreciable transnational/cross-border aspects to the problems being tackled? Have these been quantified?

The thematic areas covered by the candidate partnerships feature a series of challenges in terms of cross-border/transnational aspects, need to pool resources, need for a critical mass to meet intended policy objectives, need to coordinate different types of actors (e.g. academia, industry, national and regional authorities) across different sectors of the economy and society, which cannot be tackled to the same degree by Member States alone. This is particularly true for the research and innovation (R&I) dimension of the proposed initiative: the importance of a multi-centre and interdisciplinary approach, cross-country data collection and research, and the need to develop and share new knowledge in a timely and coordinated manner to avoid duplication of efforts are key to achieve high quality results and impact. The Interim Evaluation of Horizon 2020 and the impact assessment of Horizon Europe provide extensive qualitative and quantitative evidence on the above points. In addition, Sections 1 and 2 of the individual impact assessments on the candidate partnerships include more detail on the necessity to act at EU-level in specific thematic areas. Finally, it is worth noting that not all Member States have the same capacity or R&I intensity to act on these challenges. As the desired policy objectives can be fully achieved only if the intended benefits are widespread across the Member States, this requires action at the EU-level.

(b) Would national action or the absence of the EU level action conflict with core objectives of the Treaty²⁸ or significantly damage the interests of other Member States?

As per Article 4(3) TFEU, national action does not conflict with core objectives of the Treaty in the area of R&I. The absence of EU level action in this area would however prevent the achievement of core objectives of the Treaty. Indeed, national action alone cannot achieve the scale, speed and scope of support to R&I needed for the EU to meet its long-term Treaty objectives on e.g. competitiveness, to deliver on the EU's strategic policy priorities, and to contribute to tackling global challenges and meet the Sustainable Development Goals (SDGs).

(c) To what extent do Member States have the ability or possibility to enact appropriate measures?

As foreseen by Article 4(3) TFEU, this proposal does not hamper Member States' ability to enact appropriate measures in the field of R&I. However, the scale and complexity of the policy objectives pursued by the present initiative cannot be fully addressed by acting at national level alone.

(d) How does the problem and its causes (e.g. negative externalities, spill-over effects)

²⁸ https://europa.eu/european-union/about-eu/eu-in-brief en

vary across the national, regional and local levels of the EU?

As described in the horizontal part of the impact assessment accompanying the present proposal, several problems (e.g. on competitiveness, global challenges, demographic change) and their underlying causes affect the EU as a whole rather than individual Member States. Where important differences between Member States are present, these are described in Sections 1 and 2 of the individual impact assessments.

(e) Is the problem widespread across the EU or limited to a few Member States?

The problem of coordinating R&I efforts in the thematic areas covered by the candidate partnerships affects all Member States, albeit to different degrees. However, from a general EU perspective, available evidence shows that the EU as a whole needs to step up efforts and investments in thematic areas that are crucial to tackle present and future policy challenges on several fronts, e.g. ageing population, global technological trends, and climate change to name a few. The way these problems affect the EU and its Member States is described in the horizontal part of the impact assessment and in Sections 1 and 2 of the individual impact assessments.

(f) Are Member States overstretched in achieving the objectives of the planned measure?

As indicated in the horizontal part of the impact assessment and in Sections 1 and 2 of the individual assessments, the sheer scale, speed and scope of the needed support to R&I would overstretch national resources, without guaranteeing the achievement of the intended objectives. Acting at EU-level would achieve greater impact in a more effective and efficient manner.

(g) How do the views/preferred courses of action of national, regional and local authorities differ across the EU?

No specific differences between the views of national, regional and local authorities emerged from the stakeholder consultation.

2.4 Based on the answer to the questions below, can the objectives of the proposed action be better achieved at Union level by reason of scale or effects of that action (EU added value)?

EU funded R&I activities, including those covered by the present proposal, produce demonstrable benefits compared to the corresponding national and regional initiatives, due to the scale, speed and scope achievable by acting at the EU level. In addition, the proposed initiatives should be seen as complementary and reinforcing national and sub-national initiatives in the same area.

(a) Are there clear benefits from EU level action?

Quantitative and qualitative evidence of the benefits of EU level action are available in the interim evaluation of Horizon 2020 and in the impact assessment of Horizon Europe, among others. An analysis of the emerging challenges in each thematic areas, of the EU's competitive positioning, as well as feedback gathered from different types of stakeholders for the present impact assessment indicate that EU level action remains appropriate also for the present proposal. In addition, the benefits of acting at EU-level have been illustrated by the success and the impact achieved by the predecessors to the proposed initiative.

(b) Are there economies of scale? Can the objectives be met more efficiently at EU level (larger benefits per unit cost)? Will the functioning of the internal market be improved?

EU funded R&I activities, including those covered by the present proposal, produce demonstrable benefits compared to the corresponding national and regional initiatives, due to the scale, speed and scope achievable by acting at the EU level. This is the case both in terms of effectiveness in achieving intended policy objectives, but also in terms of efficiency. Positive impact is also visible in terms of competitiveness: recent data on EU funded R&I activities indicate that EU-funded teams grow 11.8% faster and are around 40% more likely to be granted patents or produce patents applications than non-EU funded teams. Efficiency gains are also visible in terms of dissemination of results to users beyond national borders, including SMEs and citizens. EU funded R&I is more effective in leveraging private investment. Finally, there are clear additionality benefits (i.e. EU R&I funding does not displace or replace national funding), as the EU focuses on projects that are unlikely to be funded at national or regional level. Overall, this is beneficial to the functioning of the internal market in several respects, including human capital reinforcement through mobility and training, the removal of barriers to cross-border activity for economic players including SMEs, easier access to finance and to relevant knowledge and research, and increased competition in the area of R&I.

(c) What are the benefits in replacing different national policies and rules with a more homogenous policy approach?

A homogeneous policy approach in the various thematic areas covered by the present proposal would reduce fragmentation and increase efficiency and effectiveness in meeting the intended policy objectives. Indeed fragmentation, persisting barriers in the internal market and differences in the resources available to Member States are some of the key problems that stand in the way of fully achieving the intended policy objectives and reaching the required critical mass to obtain tangible results. Specific detail on how these issues differ in each thematic area are illustrated in Sections 1 and 2 of the individual impact assessments, so as to reflect the specificities of each case.

(d) Do the benefits of EU-level action outweigh the loss of competence of the Member States and the local and regional authorities (beyond the costs and benefits of acting at national, regional and local levels)?

The proposed initiative does not lead to a loss of competence of the Member States. In fact, the proposed initiative should be seen as complementary and reinforcing national and subnational initiatives in the same area. Previous quantitative and qualitative assessments of Horizon Europe and Horizon 2020 have shown that the proposed EU-level action do not displace national ones and tend to concentrate on initiatives that would not have been funded by the Member States themselves, or would not have reached the same scale and ambition without EU-level intervention, due to their complexity and trans-national nature.

(e) Will there be improved legal clarity for those having to implement the legislation?

Yes. The proposed initiatives will be implemented in line with the Horizon Europe single set of rules for participation; this will ensure increased clarity and legal certainty for end beneficiaries, other stakeholders and programme administrators. It will also reduce the administrative burden for beneficiaries, and for the Commission services. In addition, the accessibility and attractiveness of the broader Horizon Europe programme, in particular for applicants with limited resources, would be sustained.

3. Proportionality: How the EU should act

3.1 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the proportionality of the proposal and a statement allowing appraisal of the compliance of the proposal with the principle of proportionality?

The principle of proportionality underpins the entire analysis of the candidate partnerships. Specifically, the analysis included in the accompanying impact assessment is structured along the following logic: 1. Justification of the use of a partnership approach in a given area (including considerations on additionality, directionality, link with strategic priorities) instead of other forms of intervention available under Horizon Europe; 2. If the partnership approach is deemed appropriate, proportionality considerations guide the assessment of which type of partnership intervention (collaborative calls, co-programmed, co-funded or institutionalised partnership) is most effective in achieving the objectives. This will also be reflected in the explanatory memorandum.

3.2 Based on the answers to the questions below and information available from any impact assessment, the explanatory memorandum or other sources, is the proposed action an appropriate way to achieve the intended objectives?

The proposed initiative only focuses on areas where there is a demonstrable advantage in acting at the EU-level due to the scale, speed and scope of the efforts needed for the EU to meet its long-term Treaty objectives and deliver on its strategic policy priorities and commitments. In addition, the present proposal leaves full freedom to the Member States to

pursue their own actions in the policy areas concerned. This will also be reflected in the explanatory memorandum.

(a) Is the initiative limited to those aspects that Member States cannot achieve satisfactorily on their own, and where the Union can do better?

The proposed initiative only focuses on areas where there is a demonstrable advantage in acting at the EU-level due to the scale, speed and scope of the efforts needed for the EU to meet its long-term Treaty objectives and deliver on its strategic policy priorities and commitments.

(b) Is the form of Union action (choice of instrument) justified, as simple as possible, and coherent with the satisfactory achievement of, and ensuring compliance with the objectives pursued (e.g. choice between regulation, (framework) directive, recommendation, or alternative regulatory methods such as co-legislation, etc.)?

For each of the candidate partnerships, the analysis carried out in the accompanying impact assessment has explored several options for implementation. A comparative assessment of the merits of each option also included an analysis of the simplicity of the intervention, its proportionality and effectiveness in achieving the intended objectives. This is reflected in the fact that a tailored approach has been suggested for each candidate partnership, ranging from looser forms of cooperation to more institutionalised ones, depending on the intended policy objectives, specific challenges, and desired outcome identified in each case.

(c) Does the Union action leave as much scope for national decision as possible while achieving satisfactorily the objectives set? (e.g. is it possible to limit the European action to minimum standards or use a less stringent policy instrument or approach?)

The proposed approach leaves full freedom to the Member States to pursue their own actions in the policy areas covered by the present proposal.

(d) Does the initiative create financial or administrative cost for the Union, national governments, regional or local authorities, economic operators or citizens? Are these costs commensurate with the objective to be achieved?

The proposed initiatives do create financial and administrative costs for the Union, national governments and, depending on the chosen mode of implementation, for regional and local authorities. In addition, economic operators and other stakeholders potentially involved in the candidate partnerships will also incur some costs linked to implementation. The financial cost of the proposed initiative is covered under the Horizon Europe programme. Its exact amount is still subject to political decision. As regards the candidate partnerships and the different modes of implementation (co-programmed, co-funded, institutionalised), the relevant costs and benefits are assessed in the individual impact assessments covering each candidate partnership. The additional administrative costs of implementation via partnerships are

limited, when compared to the administrative costs of implementation through traditional calls. As indicated by comparable experience with previous initiatives and in feedback provided by a variety of stakeholders, these costs are expected to be fully justified by the benefits expected from the proposed initiative. Where available, additional details on costs are provided in Annex 3 of the impact assessment.

(e) While respecting the Union law, have special circumstances applying in individual Member States been taken into account?

Where relevant, differences between Member States in capacity and stage of advancement of R&I in specific thematic areas have been taken into account in the individual impact assessments.

Annex 6 Additional background information

1. BACKGROUND INFORMATION FOR ALL INITIATIVES

1.1. Selection criteria of European Partnerships

Partnerships based on Article 185 and 187 TFEU shall be implemented only where other parts of the Horizon Europe programme, including other forms of European Partnerships would not achieve the objectives or would not generate the necessary expected impacts, and if justified by a long-term perspective and high degree of integration. At the core of this impact assessment is therefore the need to demonstrate that the impacts generated through a Partnership approach go beyond what could be achieved with traditional calls under the Framework Programme – the Baseline Option. Secondly, it needs to assess if using the Institutionalised form of a Partnership is justified for addressing the priority.

The necessity test for a European Partnership (as set out in the Horizon Europe regulation) has two levels:

- 1. The justification for implementing a priority with a European Partnership to address Horizon Europe and EU priorities. This is linked to demonstrating that a European Partnership can produce added value beyond what can be achieved through other Framework Programme modalities, notably traditional calls in the work programmes (Option 0 Baseline).
- 2. The justification for the use of the form of Institutionalised Partnership: Once it has been demonstrated that a partnerships approach is justified, co-programmed and/or co-funded forms are considered for addressing the priorities as they are administratively lighter, more agile and easier to set-up (Options 1 and/or 2). As Institutionalised Partnerships require setting up a legal framework and the creation of a dedicated implementation structure, they have to justify higher set-up efforts by demonstrating that it will deliver the expected impacts in a more effective and efficient way, and that a long-term perspective and high degree of integration is required (Option 3).

The outcomes of the 'necessity test' is presented together with the preferred option.

Figure 6 Horizon Europe selection criteria for the European Partnerships

Common selection criteria & principles	Specifications
1. More effective	Delivering on global challenges and research and innovation objectives
(Union added value) clea impacts for the EU and its citizens	Securing EU competitiveness
	Securing sustainability
	Contributing to the strengthening of the European Research and Innovation Area
	Where relevant, contributing to international commitments
2. Coherence and	Within the EU research and innovation landscape

Common selection criteria & principles	Specifications
synergies	Coordination and complementarity with Union, local, regional, national and, where relevant, international initiatives or other partnerships and missions
3. Transparency and openness	Identification of priorities and objectives in terms of expected results and impacts
	Involvement of partners and stakeholders from across the entire value chain, from different sectors, backgrounds and disciplines, including international ones when relevant and not interfering with European competitiveness
	Clear modalities for promoting participation of smes and for disseminating and exploiting results, notably by smes, including through intermediary organisations
4. Additionality	Common strategic vision of the purpose of the European Partnership
and directionality	Approaches to ensure flexibility of implementation and to adjust to changing policy, societal and/or market needs, or scientific advances, to increase policy coherence between regional, national and EU level
	Demonstration of expected qualitative and significant quantitative leverage effects, including a method for the measurement of key performance indicators
	Exit-strategy and measures for phasing-out from the Programme
5. Long-term	A minimum share of public and/or private investments
commitment of all the involved parties	In the case of institutionalised European Partnerships, established in accordance with article 185 or 187 TFEU, the financial and/or in-kind, contributions from partners other than the Union, will at least be equal to 50% and may reach up to 75% of the aggregated European Partnership budgetary commitments

1.2. Overview of potential functions for a common back office among Joint Undertakings

Functions	Current situation	Option of joint back- office	Comments
Organising calls for grant and proposal evaluations	Each JU organises this independently.	A central organisation of evaluation, logistics, contracting evaluators, managing the data of the evaluation results Central database of potential evaluators with domain expertise in thematic areas of partnerships	The evaluations would still need to be supervised by the Scientific staff of the individual Joint Undertakings (consensus meetings of expert evaluators etc)
Human Resources related matters	Each JU has own HR policy and resources Quite some resources spent on recruitment in some JUs Some HR facilities are procured	More generic resources and expertise for HR matters More consistency in HR policy Shared HR investment	Ensuring consistency with EC HR policies is already in place

Financial management	from external contractors Some JUs have a Service Level Agreement with COM for HR Each JU conducts own financial contract management; differences between JUs Each JU is audited separately. Auditing at project level more frequent than in other Horizon 2020 parts and outsourced by JUs thus differences ECA: too many audits on JUs	for specialised expertise (IP and legal) Financial management by one core team of financial staff Would reduce the number of interfaces for audits and simplifies the auditing of the all JUs Harmonisation of project auditing	Simplifies the harmonisation of financial management across JUs in line with Horizon Europe
Communication (internal and external)	Each JU has a separate communication strategies, teams and resources	A common back-office can support activities such as event organisation, dissemination of results, setting up website communication Can help create a more visible Partnership brand	A considerable share of communication activity is partnership specific (addressing particular target groups, synthesising project results) however there are generic communication activities that can be shared Needs to avoid duplication of efforts
Data management on calls, project portfolios, information on project results	Most JUs but not all use e- Corda for project data Overall IT integration of JUs still difficult	Harmonised data management Reduction of IT systems and support that is procured	This will need to happen regardless of the common back office but will likely be more smooth if managed centrally

2. ADDITIONAL INFORMATION ON THE STANDARD COST MODEL

Appendix A Standard cost model for the options assessment related to efficiency

Category \ Policy option (in thousands euros)	Horizon Europe	Co-programmed	Co-funded	Article 185	Article 187
BUDGET					
Total contribution from the Union	1000000	1000000	1000000	1000000	1000000
EU funding rate	100%	50%	30%	50%	50%
TOTAL Investment from partners incl. Union (within the partnership)		1000000	2300000	1000000	1000000
TOTAL BUDGET	1000000	2000000	3333333	2000000	2000000
SET-UP COSTS					
Preparation of a partnership proposal (partners and COM)		500	500	500	900
Preparation of the SRIA/roadmap		1500	1500	1500	1500
Impact Assessment				300	300
Preparation of COM proposal, negotiation				13000	13500
Preparation of dedicated implementation structure					1100
TOTAL SET-UP COSTS		2000	2000	15300	17300
RUNNING COSTS					
AWP preparation and comitology	2100	2100	2100	2100	2100
Call and project implementation	40000	80000	160000	100000	136400
Partners' costs not covered by the above		400			400
Additional COM costs	600	600	600		2500
TOTAL RUNNING COSTS	42700	83100	162700	102100	141400
DISCONTINUATION COSTS					
Costs for COM, MS and partners		500	500	800	1900
TOTAL DISCONTINUATION COSTS		500	500	800	1900
TOTAL COSTS AND INVESTMENTS	1042700	2085600	3498533	2118200	2160600
R&I INVESTMENT	1000000	1959600	3213333	1940600	1901300
EFFICIENCY	96%	94%	92%	92%	88%

Appendix B Notes and sources per cost

Category	Notes	Sources
EU funding rate	The EU funding rates used are the co-financing rates for Horizon 2020 regular calls (research and innovation actions) and the minimum co-financing rates required for each of the European Partnership types.	
TOTAL Investment from partners incl. Union (within the partnership)	The partners' contributions are calculated using the 'theoretical' Union contribution and the standard co-financing rate applicable to the specific policy option.	
Total Budget	The total budget is the total investment available and is the sum of the Union's contribution and the partners' contributions.	
Set-up Costs	The set-up costs are the one-off costs involved in the preparation and setting up of each of the four types of European Partnerships. It has been assumed there are no set-up costs associated with the HEU regular calls, as all of the management and supervisory structures exist already.	
Preparation of a partnership proposal (partners and COM)	We assume 7 staff members are needed to prepare a fully costed proposal for a partnership, covering the costs of all partners. CP require 5 staff from private partners and 2 from the COM, CF and A185s require 5 staff from MS and 2 from the COM, and A187s require 5 COM staff and 2 from private partners.	Cost per capita: €128 k for COM staff (SOURCE: JU benchmark data 2018); € 44.5k for MS staff and private partners (SOURCE: Average EU28 personnel costs (per employee) in 2016 (latest available) for NACE Professional, scientific and technical activities, EUROSTAT).
Preparation of the SRIA/roadmap		In 2019, Horizon 2020 approved a community support action to develop a SRIA for Waterborne Transport, with time horizons to 2025, 203 and 2050. The total Union contribution (100% of eligible costs) is \in 1.5m.
Impact Assessment	This is the cost involved in preparing the ex ante impact assessments for the candidate partnerships: 25 COM staff for 9 months (at yearly rate of $\in\!128$ k) plus $\in\!1.8$ M for a contractor to carry out the 13 IA studies. The total number is then divided by 13 to produce an estimate for the IA cost per partnership. It is assumed these costs only apply to the Institutionalised Partnerships as there is no requirement to carry out an IA for the other policy options. In practice, the cost per partnership will be higher, as not all 13 will be approved and the total effort will need to be amortised across a smaller number than 13.	Advice / data provided by DG RTD A4 'partnerships' team (15/11/19).
Preparation of COM proposal, negotiation	This is the cost involved in developing a full-costed proposal for the candidate Institutionalised Partnerships and the resulting costs of refining and	Cost per capita: €128 k for COM staff (SOURCE: JU benchmark data 2018);

Category	Notes	Sources
	negotiating the proposal through Council and into legislation. We assume that this highly involved procedure only applies to the IPs, and we have been advised by DG RTD that this process might typically require 1 year in elapsed time and 25 staff FTEs from the Commission, 15 FTEs from the Council and 5 FTEs from the EP.	We assume the same cost for the Council and Parliament; €44.5 k for MS staff and private partners (SOURCE: Average EU28 personnel costs (per employee) in 2016 (latest available) for NACE Professional, scientific and technical activities, EUROSTAT). Number of required staff members: Advice / data provided by DG RTD A4 'partnerships' team (15/11/19).
Preparation of dedicated implementation structure	This is the cost involved in setting up the governance and implementation structure. We assume that 1 member of staff is needed per each €268M of total budget to set up the new infrastructure in A187s. We assume that in A185s an existing structure in one or several MS is able to be used.	We based this assumption on the estimate made by the shift2rail IA (2013), where for a total budget of €938M, 3.5 members of staff are required for implementing the structure with a cost of €128k per head. This means that setting up the partnership requires about 1 staff member per each €268M. Once we determine the number of staff needed we multiply that by the corresponding staff cost per capita.
Running Costs		
AWP preparation and comitology	We assume 200 staff are needed working 3 days for €500 per day for the whole 7-year programming period (to be re-assessed).	This is an estimate based on a priori knowledge of the costs associated with the development and negotiation of annual work plans. We have not been able to identify any real cost data from past partnerships.
Call and project implementation	This refers to Title 1 and Title 2 expenditures, which represent a given proportion of the budget implemented in calls.	The costs of implementing HEU and CPP calls is estimated to be 4% of the budget, we use a dual figure for CFPcalls (with is 10% applied to 80% of the budget, to reflect typical MS calls, while the remaining 20% is assumed to be expended through regular HEU calls, where a 4% cost rate is used), 6% for A185s and 6.8% for A187s (SOURCE: Advice / data provided by DG RTD A4 'partnerships' team, 15/11/19); We also add an additional cost of €400k in A187s reflecting extra costs of integrating and making systems interoperable for monitoring; the legal obligations to perform interim and ex-post evaluations (Advice provided by DG RTD A2 team, 25/11/19).
Partners' costs not covered by the above	This refers to the intramural costs borne by private partners as a result of their participation in the governance structure and working groups of the partnership (private partners are not involved in the supervision of HEU calls, CFPs or A185s). We used historical data to estimate that these private coordination costs amount to 1 FTE per €242M of total budget.	The estimation is based on the assumption by the shift2rail IA that a half a person-day per project per week is needed for coordination, thus 1 staff per year for 10 projects running. This resulted (in the shift2rail IA) in 3 additional staff members required to coordinate a total budget of €725M, and thereby 1 staff per €242M. Once defined the number of staff needed under each option, we multiply that by the corresponding cost per capita.
Additional COM costs	The additional COM costs refers to the cost of supervising the partnerships. We use auditing expenditures as proxies for supervision costs. HEU regular calls, CPPs and CFPs have low supervision costs, A185s' costs are included in MS's project implementation costs and A187s require higher levels of COM supervision and therefore have higher costs.	We use the max (35) and min (8) number of audits in past JU as reference for high and low level of supervision effort. Then multiply that by €10k —the average cost per audit (SOURCE: JU benchmark data 2018). The inclusion of this cost category was suggested by DG RTD A4 'partnerships' team (15/11/19).
Discontinuation Costs	Discontinuation costs refer to staff expenditures related to winding-down activand the cost of closing the implementation structure when there is one.	rities, including the disposal of any assets

Category	Notes	Sources
Costs for COM, MS and partners	We assume that at least the same number of staff is needed to discontinue the partnership as it was for the preparation of the partnership proposal. Plus, for A187s, we assume that dismantling the dedicated structure has the same cost as its implementation. As for A185s, we assume the same value as for A187s, but adjusted to the staff costs of A185s.	
Total Costs and Investments	This category is the sum of "Total Budget", "Set-up costs", "Running costs" and "Discontinuation costs".	
R&I Investment	We assume that funding for R&I activities equals the total Budget under the HE policy option. For the remaining options, this category is composed of the "Total Budget" after subtracting "Marginal Running costs" –Running costs for each policy option discounted by the Running costs under HE.	
Efficiency	This ratio is the proportion of "Total costs and investments" that is available to be spent on "R&I investment".	

3. ADDITIONAL INFORMATION ON THE POLICY CONTEXT

Support in the field in the previous work programme

Scope and objectives of the 5G-PPP

Through 5G-PPP, the goal of Europe is to put in place the right framework to tackle 5G challenges and bring the appropriate solutions, architectures, technologies and standards to the next generation of communication networks.

The main target objectives of the 5G-PPP are the technological development of 5G and the contribution to growth and jobs. Considered as EU flagship initiative, the **5G-PPP** comprises public and private partners. The latter also agreed on KPIs to leverage the 700 million EUR public investment by a factor of 5 bringing **total funding into 5G-PPP to 4.2 billion EUR**.

5G-PPP is organized in 3 phases, each comprising several call for projects with a variable duration of 24-36 months:

- Phase 1 with 19 projects (2014-2016) focusing on 5G infrastructure, automotive projects and 5G validation trials across multiple vertical industries;
- Phase 2 (2017-2019) with 21 new projects targeting a move towards demonstrations and experimentations in order to establish closer links between 5G community and verticals industries. Many new stakeholders (more than 60% of phase 2 participants) joined the PPP;
- 3rd and last phase ending in 2020 consolidating the results of the previous phases to support implementation and applicability of 5G and will be dedicated to a number of projects in vertical industries use cases.

The global objectives of the 5G programme is to build the next generation of wireless communication network technologies. This new generation is expected to improve the existing (4G) wireless network capabilities (in term of bandwidth, capacity, coverage, and reliability). But beyond this incremental progress, the 5G technologies also aim to provide new capabilities (ultra-low latencies, ability to connect very large numbers of devices, high dependability and quality of service, etc.) that would enable the wireless network to be used in scenarios that are essential for vertical industries.

Indeed, the vision behind 5G is that this new generation of communication network could serve as a critical infrastructure for numerous industries (automotive, transport, manufacturing, etc.)

5G-PPP objectives

increasing wireless capacity
1,000 times

7 Billion
7 Trillion
90%
90%

onnecting
7 trillion "things"

saving 90% energy
perceiving zero downtime

Source: 5G-PPP.

Stakeholder analysis of the 5G-PPP

Stakeholders involved so far in the 5G-PPP (note that the analysis is only based on projects funded from the 5G-PPP during Phase I and Phase II, i.e. projects funded before 2018²⁹) are mainly from the telecom

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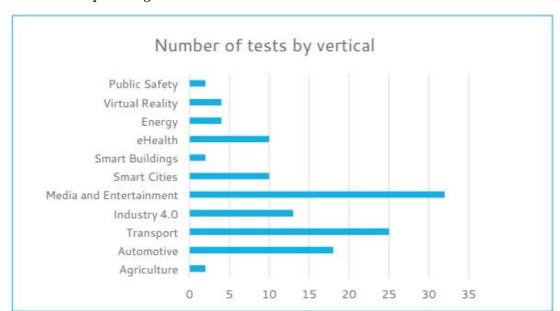
²⁹ Only a part of Phase 3 projects have really started

industry or from the public research centres and universities with a strong background in telecommunications. The majority of funding was directed towards private research (56% of funding), and within that the vast majority for the telecom (operators, OEMs (Original Equipment Manufacturers) and IT industries. The involvement of verticals is still modest but growing. This is globally consistent with the analysis done for just Phase 1 project ³⁰ (65% of private research)

Funding has been essentially allocated to EU 15³¹ Member States (92% of funding, of which 70% for top 5 countries in Phase 1), reflecting also the domination of telcos from bigger EU countries (and their associated partners), which are generally controlling telecom operators from smaller EU countries.

Three main groups of players are mainly involved in the 5G-PPP, as designed by the European Commission and the 5G IA (5G Industry Association):

(1) **Current connectivity providers** (MNOs, MVNOs) are taking the opportunity of these new technologies to try to **diversify their offer and address new market segments** (in specific verticals, including manufacturing) as a way to compensate declining consumer revenues. They have engaged into many projects within the 5G-PPP and trials³² targeting key vertical markets like automotive, healthcare, industry 4.0, energy and media, and additional vertical markets targeted in a second step like public safety and smart city³³. In Europe, Orange, Telefonica, Telecom Italia and BT (plus to a lesser extent Altice, Deutsche Telekom and OTE) have been leading the efforts on 5G.



Trials in Europe testing vertical markets

Source: Euro-5G Annual Journal³⁴

(2) Providers of enabling technologies include software and hardware vendors. **Hardware equipment** manufacturers can also see 5G as an opportunity to diversify their business modelling, by bundling equipment with connectivity service provisioning in, for example, the small cell area. The need for an

Mid-term review of the contractual Public Private Partnerships under Horizon 2020 (2007), Report if the Independent Expert Group https://publications.europa.eu/en/publication-detail/-/publication/6de81abe-a71c-11e7-837e-01aa75ed71a1

³¹ EU 15 being: Germany, Belgium, France, Italy, Luxembourg, Netherlands, Denmark, Ireland, UK, Greece, Spain, Portugal, Austria, Finland and Sweden.

³² Vertical trials may not involve a vertical stakeholder

³³ 5G IA (2019) available at https://5g-ppp.eu/verticals/

³⁴ https://5g-ppp.eu/annual-journal/

upgraded infrastructure, supported by virtualization and allowing for edge computing, is also an opportunity, partly challenged nonetheless by the development of pure software players. Traditional OEMs (especially Nokia and Ericsson, but also Huawei and NEC) and their counterpart software and/or electronics companies (Atos, Samsung, Intel) are well represented within the 5G-PPP projects.

- (a) Fundamental building blocks may also be developed by academic and public research institutes/centres also well represented in the 5G-PPP. Close to 40% of participants in 5G-PPP (and 36% of funding)³⁵ was allocated to either high education and research centres (with a slight bigger proportion for education).
- (3) Some content providers (including OTT players) and industrial solution providers, and potentially manufacturers (a.k.a. vertical stakeholders), will also play a role in the new communication value chains, not only as content and service providers, but also as connectivity providers, and infrastructure providers. This is reinforced by the integration of direct, proximity communications (such as public safety services or V2V (Vehicle to Vehicle communication), V2I (Vehicle to Infrastructure)) in the 5G standards, thereby removing partially or even entirely in some cases the need for a mobile operator in the value chain. Their engagement as participants in projects is still modest (5% overall for Phases 1 and 2) but increasing. Indeed, the NACE code analysis shows the following evolution. Most vertical stakeholders have participated to only 1 project.

Analysis of participants based on NACE codes³⁶

	2014 ³⁷	2016	2017
% of participants from "vertical" NACE codes 38	2%	6.3%	16.4%
% of funding from "vertical" NACE codes	2%	5.4%	16.6%

Source: IDATE Digiworld

Vertical industries were not very active around 5G developments before 2018-2019. Among the active vertical industries, a few already really stand out: the automotive industry (thanks to the creation of the 5G AA (5G Automotive association)) and to a lesser extent manufacturing industries (5G ACIA - 5G Alliance for Connected Industries and Automation) and utilities. These vertical stakeholders are often not involved around business use cases but rather focus on specific technologies development. The question of the business sustainability of the proposed scenario thus often remain open.

The main vertical stakeholders in projects of phases 1 and 2 and in other 5G initiatives involving vertical stakeholders.

Vertical industri	es Vertical stakeholders
Utilities/Energy	ENGIE, ASM Terni, PowerOps, RomGaz, eMOTION, VerticalM2M, EFAFEC, Power Solutions Group, Siemens, World Sensing
Automotive	Volvo, PSA, Bosch, Fiat, ExpertSystems 5GAA (created late 2016) including also AUDI AG, BWM Group, Daimler AG, Ford, Denso, Continental, Honda, Hyundai, Nissan, Mitsubishi, Volkswagen
Public Safety	Thales, ENGIE, WIND-3, RomGaz, ASM Temi Public Safety Communication Europe (PSCE), the European public safety Association, and 5G IA, signed a Cooperation agreement in May 2018 to foster collaboration on 5G development.

³⁵ NACE code analysis

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³⁶ NACE code analysis based on participant portal data made available by the European Commission.

³⁷ No calls for the 5G PPP in 2015

³⁸ Vertical NACE codes excludes all NACE codes related to ICT industry, support actions like marketing or administration and wholesale trade

Vertical industrie	es Vertical stakeholders
Healthcare	Servicio de Asistencia Municipal de Urgencia y Rescate (SAMUR), Irish National Ambulance Services facilitated by CIT; LifeSemantics, Camanio Care AB
Media	RAI, RTVE, BBC, EBU, IRT, Nurogames
Transport	Fiat, COMSA, FGC, Hamburg Port Authority, riaGnoSys GmbH (Zodiac Inflight Innovations), Ferrovial
	(through Seamless Air Alliance, Delta and Airbus)
	Ports of Thessaloniki, Patras and Pireus (in SMI initiative)
	Ahlers in 5G Manifesto ³⁹
Industry	Weidmüller, Airbus, Siemens, Royal Philips in 5G Manifesto
	5G-ACIA created early 2018
Smart Cities	City of Lucca, City of Bristol, City of Barcelona, Alba Iulia City Flash Lighting Services

Source : IDATE Digiworld⁴⁰

This limited participation of actors from the vertical industries to the 5G-PPP can be explained mainly by the natural phasing of the 5G-PPP, with earlier phases dedicated to technology development and later phases to validation, testbeds and trials, especially around platforms. The increase overtime of the vertical stakeholders' presence in project and access to funding shows positive signs of uptake.

This is in addition confirmed by analysis of the Phase 3 projects started or about to start, reaching even at least 22% of vertical participants (some projects like 5G-TOURS and 5G-DRONES are even with more than a third of vertical participants), when excluding platforms. Verticals industries with the most contributors are by far automotive (with a specific call), transport and industry 4.0, with a mix of very large companies and smaller ones.

Analysis of participants based on listing

		15 Phase 3 projects from calls in 2018		Same scope but excluding th CSA and the 3 platforms	ie
% of participants from "vertical industries" (private only)	18.0%	/ ₀	22.4%	/ ₀	

Source: IDATE Digiworld (from 5G-PPP description of projects) 41

Non-exhaustive list of vertical participants in Phase 3 projects

Vertical	
Energy	Enel, EDF, Iren, Mirantis, Admie
Automotive	3MW, PSA, Renault, Bosch, Volvo, Volkswagen, Fiat, Swarco, Daimler, Ford, Dalian, Valeo,

³⁹ 5G Manifesto is an open letter from 17 telcos, equipment vendors and satellite operators that was sent to European Commissioner for Digital Economy and Society Günther Oettinger in July 2016. The 5G Manifesto covers a wide range of verticals. Five non-telecoms companies expressed their interest and willingness to participate in the next phase: Ahlers (logistics and maritime service provider), Airbus Defence & Space (defence and aerospace), Royal Philips (electronics, healthcare, and lighting), Siemens AG (engineering) and Thales Alenia Space (satellites, payloads).

ESA, Techno-Economic impacts of 5G for the European Satellite Industry, (2019), https://artes.esa.int/projects/techno-economic-impact-5g-standards-european-canadian-satellite-industry-ecosystem

⁴¹ https://5g-ppp.eu/5g-ppp-phase-3-projects/

	Alsa
Industry 4,0 (including robotics and drones)	ABB, Bombardier, Marposs, Bosch, Orbis, Cafa, Involi, Unmanned systems, Droneradar, Comau
Transport	Athens Airport, Deutsche Bahn, Vediafi, Sanef, Autostrada del Brennero, Aenl, Siemens Mobility, Trenitalia
Other	Procter&Gamble, City of Torino, City of Egaleo, Polar, Sealab, Epitomical, Nurogames, RAI, LiveU, Philips, CHU Rennes, AMA

Source: IDATE Digiworld

Outcomes and (expected) impacts

It is quite early to measure the outcomes of the 5G-PPP based on previous assessments or evaluations, as the 5G-PPP is still ongoing. Only Phase 1 projects are closed and Phase 2 projects ran until mid 2019 for most of them, while most Phase 3 projects have just started or will start in 2020.

The only evaluation conducted so far relates to the 19 Phase 1 projects⁴² (but is not specific to 5G). The 5G-PPP showed some very good performances in shorter average time to grant than FP7 or Horizon 2020 and higher quality and success rates. This illustrates that the overall structuration has been well thought and organized in advance. Funding was mainly allocated to a limited number of beneficiaries (top 50 getting 65% against only 22% in other Horizon 2020 projects). In Phase 1, 5G-PPP was seen as performing well in general, with some improvements needed around inclusion of SMEs and of EU13 (only 2% of funding for Phase 1) and also in terms of links with other cPPPs (contractual Public Private Partnership).

The contractual arrangement defines 12-13 (depending on documents) specific KPIs (Key Performance Indicators) for the 5G-PPP in addition the common set of KPIs defined by the EC for all cPPPs. These KPIs have been assessed in Euro-5G and To-Euro-5G⁴³.

Scientific and technological results

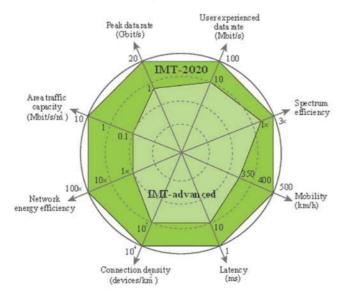
ITU requirements

The targets set for IMT-2020, corresponding to the fifth generation of mobile systems, by ITU are described below. IMT-Advanced corresponds to 3GPP LTE.

Mid-term review of the contractual Public Private Partnerships under Horizon 2020 (2007), Report if the Independent Expert Group https://publications.europa.eu/en/publication-detail/-/publication/6de81abe-a71c-11e7-837e-01aa75ed71a1

⁴³ D4.4 Final report on 5G PPP KPI progression of June 2019, To-Euro 5G

Enhancement of key capabilities from IMT-Advanced to IMT-2020



Source: ITU⁴⁴

5G-PPP KPIs

The following Key Performance Indicators were set by the Public Private Partnership on 5G⁴⁵:

- (4) Providing 1000 times higher wireless area capacity and more varied service capabilities compared to 2010.
- (5) Saving up to 90% of energy per service provided.
- (6) Reducing the average service creation time cycle from 90 hours to 90 minutes.
- (7) Creating a secure, reliable and dependable Internet with a "zero perceived" downtime for services provision.
- (8) Facilitating very dense deployments of wireless communication links to connect over 7 trillion wireless devices serving over 7 billion people.

The 5G Initiative Technology Board produced a document on the definition, assessment and there cannot and will not be one single overall system analysis per Performance KPI across all 5G Infrastructure PPP projects. The running study leads to a summary of clustered projects contributions to the Performance KPIs in a structured programmatic approach. The PPP Performance KPIs definition, at Programme level, are based on the work of a Phase 1 project (Flex5GWare), the approach has been extended to the overall set of PPP Phase 2 Projects.

The PMR (Progress Monitoring Report) Annex consolidates the available KPIs from the different sources of the 5G Infrastructure PPP Programme Working Group activities and projects. It consolidates an agreed definition for each KPI and provides an agreed method of measurement. The PPP Performance KPIs work has also then been further developed on specific Performance KPIs, starting first with Latency and Service Creation Time. This information is included in the PMR Annex. It contains the up-to-date status on these KPIs / Projects contributions. **The work is in progress and the final reports will be released during the second half of 2019.** Potentially, additional White Papers could be developed on Peak Data Rate KPI, Summary of individual Projects Performance KPI and PPP KPIs Cartography development of '5G-PPP Phase II Projects Performance KPIs'.

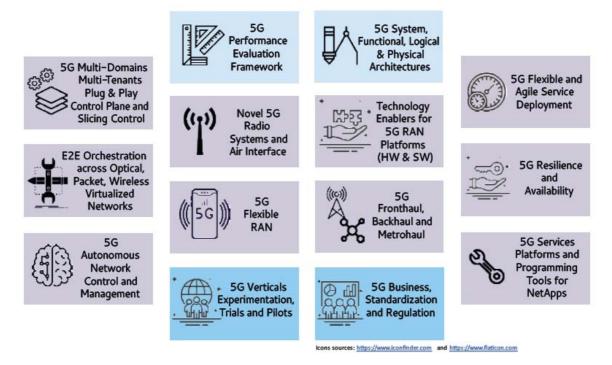
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⁴⁴ ITU, Setting the Scene for 5G: Opportunities and Challenges, 2018. Available at: https://www.itu.int/en/ITU-D/Documents/ITU-5G-REPORT-2018.pdf

⁴⁵ 5G PPP, 5G PPP progress monitoring report, 2017, available at: https://5g-ppp.eu/wp-content/uploads/2018/10/5G-PPP-Progress-Monitoring-Report-2017.pdf

The 5G-PPP Technical Board advanced the approach defined in Phase 1 with the definition of the Programme Golden Nuggets (GNs), elaborated on the basis of the key projects achievements. The PPP GNs Version 2.0 was released in February 2019, allowing all PPP projects to fully understand and match their individual contributions inside the overall programme achievements. **Key achievements from Phase 2 5G-PPP projects include 60 highlighted results categorised under 14 program level achievements as shown in the figure below.**

PPP Key Achievement Phase 2 Projects (Golden Nuggets Version 2.0)



Source: 5G-PPP⁴⁶

Additional Programme-Level KPIs

(9) Patents

At the end of March 2019, Europe had filed for ~22% of standard essential patents (SEP) for 5G communication systems.

(10) Standardisation activities

5G-PPP has had significant influence in building pre-standardization consensus across key actors. Major impact on the 5G architecture ideas has also been achieved through 610 activities leading to standardization (Phase 1: 315; Phase 2: 295). The table below shows a breakdown of the inputs for the development of 5G standardization tracked between June 2018 and June 2019:

Input to 5G standardisation

Number of contributions per category tracked	
Overall architecture: Mostly to 3GPP, with many inputs on the implementation of 5G V2X systems and multimedia broadcast or streaming services.	70
Core and transport architecture: Mostly to 3GPP, with most of the inputs related to terminals.	58
Management and orchestration architecture: Mostly to three ETSI groups, namely, the ZSM ISG, NFV ISG and OSM.	50

EURO 5G – The European 5G Annual Journal, 2019 https://bscw.5g-ppp.eu/pub/bscw.cgi/d302069/Euro%205G%20PPP%20Annual%20Journal%202019-web.pdf

Radio and edge architecture: Mostly to 3GPP, with many inputs on 5G NR enhancements for $V2X$ and multimedia broadcast.	41
Other 3GPP WGs: RAN 3 (new radio); SA1 (service requirements); SA5 (network management, including energy efficiency and architecture); SA4 (codec); SA6 (northbound APIs); SA4-5-6 (media and broadcasting).	21
ETSI Multi-Access Edge Computing (e.g. Instantiating a Network Slice integrating MEC applications, using 3GPP elements).	6
Industry groups (e.g. DVB for media and broadcasting); other standards organisations (e.g. IETF for network virtualisation, fog computing and northbound interfaces); not specified	49
Total	295

Business outcomes and impacts

Three business KPIs were set and have been mostly achieved:

- (11) Leverage effect of EU research and innovation funding in terms of private investment in R&D for 5G systems in the order of 5 to 10 times (B1). The expected KPI has been surpassed, with private investments from large industry and SMEs reaching 10,12 in 2018 (7.24 when taking into account all beneficiaries like education).
- (12) Target SME participation under this initiative commensurate with an allocation of 20% of the total public funding (B2). This KPI has been almost reached over Phase 1 and Phase 2 (19%) and is expected to be reached thanks to the last phase (trials).
- (13) Reach a global market share for 5G equipment & services delivered by European headquartered ICT companies at, or above, the reported 2011 level of 43% global market share in communication infrastructure (B3). With roll-out in progress, it is too early to assess this KPI, but there are some early signs showing the KPI can be reached (such as the good positioning of actors such as Ericsson and Nokia in the standardization and patent activity).

As part of the common set of KPIs, additional outcomes have been calculated or identified

- (14) around 2,000 new jobs are expected from 5G-PPP participants over the period 2014-2018 (i.e. an increase of 5 jobs per participant, of which 2.3 for SMEs)
- (15) an increase of turnover by 10% for SMEs in 2018
- (16) the development of a brochure "European SME expertise in 5G and beyond" (June 2019)

Societal outcomes and impacts

Five business KPIs were set, for which outcomes are not still limited for now (except KPI S3) but are still on track to be achieved for most of them in Phase 3:

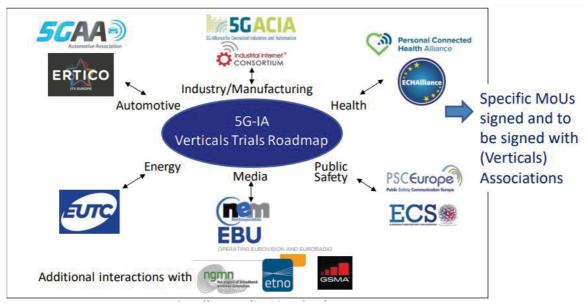
- (17) Enabling advanced user-controlled privacy (S1). Progress has been made around security (especially with MEC and slicing) more than privacy, expected to be tackled around with new projects, in Phase 3 and more likely in the candidate PPP.
- (18) Reduction of energy consumption per service up to 90% (as compared to 2010) (S2). No results yet beyond some initial findings in METIS-II project. Data is indicated to be collected from projects to get better information.
- (19) European availability of a competitive industrial offer for 5G systems and technologies (S3). In addition to B3, progress has been made by progressive integration of verticals during Phase 2 and then Phase3. Current forecasts for the share of patent by European HQ vendors is of 45.6% for 5G RAN, 29.45% for 5G patents at a global level and a 25.32% for 5G declared standard essential patents in the automotive industry⁴⁷.
- (20) Stimulation of new economically-viable services of high societal value like U-HDTV and M2M applications (S4). Initial results are encouraging with the progressive integration of verticals and the definition of candidate pilots for media usage by NEM-Networld 2020 and of various pilots and use cases in other projects (with some live experience for a few of them). MoUs are signed or under negotiation with several stakeholder groups (see image below).

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⁴⁷ To Euro 5G Project - Final Report on 5G PPP KPI progression, July 2019.

(21) Establishment and availability of 5G skills development curricula (in partnership with the EIT) (S5). Around 500 new curricula and educational qualifications among 5G-PPP participants (around 1.25 per participant) were created over the period 2014-2018. 5G IA and EIT are also in discussions.

Highlights from 5G vertical strategy of 5G-PPP



Source: 5G-PPP⁴⁸, Roadmap Version 3.0

⁴⁸ Didier Bourse – 5G IA, 5G Pan-European Trials Roadmap, 7th Global 5G Event in Valencia (June 2019),

4. ADDITIONAL INFORMATION ON THE PROBLEM DRIVERS

Additional evidence on the key problem drivers are further detailed below.

4.1. Insufficient presence of EU actors in the global digital value chain

As presented above in section 1.2.1, the European current digital ecosystem is not in a very strong or favourable position. This threatens the future European technological sovereignty in not only future smart networks and services as the current players, will be under threats of rising, competition but also those industry segments and society at large - "the verticals" that will need to use the Smart Networks Services, will be subject to increasing competition by their correspondents in other regions.

As presented above in section 1.2.1, the European current digital ecosystem is not a very strong or favourable position. This threatens the future European technological sovereignty in future smart networks and services as current players will be under threats of rising competition.

This problem is further reinforced by two factors:

The smart networks and services field is a sector with a strong R&D intensity, illustrating a high-risk research and innovation process. This puts European players at further risk as sustaining a leading position requires important investment in research and innovation.

The smart networks and services field is a sector that relies heavily on standardization, and ensuring a strong presence in Standardization requires a coordinated approach at the European level to ensure a critical mass of European contributions.

4.2. A fragile position of European actors in the global digital ecosystem

Europe cannot be considered as the leader for the 5G R&D (no specific advantage in terms of 5G technology), but is still a contender and stands out regarding some specific initiatives around verticals:

Europe has major and very active 5G infrastructure manufacturers (Ericsson & Nokia), but the rest of the EU ecosystem developing the R&D is more limited: no smartphone manufacturer, some test equipment manufacturers (Rohde & Schwarz), software players and minor activities for chipsets (Sequans).

Collaboration has started with various industries (Automotive, ports...) in Europe through R&D projects and represent a significant potential for 5G B2B services provision. The relatively strong position of European industry (as presented in section 1.2.1.2) present an opportunity for future European digital ecosystem.

New form factors for devices (such as IoT) might provide an opportunity for Europe to regain a presence in the device industry.

Although satellite is likely to have a limited impact on 5G and beyond 5G research as well as business wise, it should also be noted that Europe has two of the world major satellite manufacturers.

Companies outside Europe participating to European R&D programs are mainly equipment vendors that have R&D laboratories in Europe. Countries present in past R&D programs mainly come from the USA (Intel, Interdigital, IBM...), China (Huawei), Japan (NEC, Mitsubishi) and South Korea (Samsung).

Stakeholder opinion

A key statement coming up from interviews commonly to all categories deals with the position of Europe lagging behind Asia and US. Indeed almost all interviewees mention the need to keep or regain European leadership in the value chain. Indeed, on network infrastructure, interviewees recognize the leadership of Europe with the presence of two mastodons – Nokia and Ericsson. On the rest of the value chain, Europe has lost its position on devices but for most of interviews there could be an opportunity to gain a leadership position on other fields like IoT devices and other emerging technologies like edge computing considered as critical topic. Europe should have the capacity to both support areas where Europe is good at in the value chain and create European alternatives in the whole supply chain.

Also, interviewees from academia categories draw the attention on the necessity to invest more in research in Europe in order to develop its potential, to remain competitive and to avoid shortage of skills and lack of ventures and start-ups.

4.3. High risk R&D reinforces the risks for European actors

Telecommunication equipment is among the sectors that have the highest research intensity, with an average value around 15% and going up to 30% for some actors. This level of R&D intensity is comparable to other R&D intensive sectors such as Pharmaceuticals and Semiconductors and is the sign of a R&D process that involve significant risks and require huge investments.

The table below both illustrate this high research intensity and show the limited presence of European actors in the field.

Appendix C R&D Intensity of Telecommunication Equipment providers.

Company	Country	R&D Expens USD billions	· ·	Total Revenue (in USD billions)	R&D Intensity (%)
Huawei	China	12,53	85,54	14,6%	6
Cisco Systems, Inc.	United States	6,06	48,01	12,6%	6
Nokia Corporation	Finland	5,90	27,79	21,29	6
Telefonaktiebolaget LM Ericsson	Sweden	4,63	24,59	18,8%	6
ZTE Corporation	China	1,99	16,72	11,9%	6
ARRIS International plc	United States	0,54	6,61	8,2%	
Motorola Solutions, Inc.	United States	0,57	6,38	8,9%	
Juniper Networks, Inc.	United States	0,98	5,03	19,5%	6
Fiberhome Telecommunication Technologies Co., Ltd.	China	0,30	3,24	9,3%	
Ciena Corporation	United States	0,48	2,80	17,0%	6
F5 Networks, Inc.	United States	0,35	2,09	16,8%	6
Palo Alto Networks, Inc.	United States	0,35	1,76	19,7%	6
Arista Networks, Inc.	United States	0,35	1,65	21,2%	6
Viasat, Inc.	United States	0,20	1,56	12,9%	6
Finisar Corporation	United States	0,24	1,45	16,5%	6
Fujian Star-net Communication Co., Ltd.	China	0,14	1,18	11,9%	6
NetScout Systems, Inc.	United States	0,22	1,16	18,5%	6
Lumentum Holdings Inc.	United States	0,15	0,90	16,4%	6
Viavi Solutions Inc.	United States	0,14	0,81	16,8%	6
Infinera Corporation	United States	0,22	0,74	30,3%	6
Datang Telecom Technology Co., Ltd.	China	0,16	0,67	23,9%	6
ADTRAN, Inc.	United States	0,13	0,67	19,6%	6
ADVA Optical Networking SE	Germany	0,12	0,62	19,1%	6
Calix, Inc.	United States	0,13	0,51	25,0%	6
Ribbon Communications Inc.	United States	0,12	0,33	36,3%	6

Source: Strategy& PwC, The 2018 Global Innovation 1000 study, analysis of the 1000 largest corporate R&D spenders.

The consultations of the stakeholders' further support this view of a risk prone R&D in the sector, and more importantly that R&D efforts need to be sustained overtime at all stage of the innovation process:

from long-term R&D with low Technology Readiness Levels (TRL) (which prepare future generations of communication equipment and investigate very long term technological vision),

- to mid-term R&D (necessary to investigate how identified technology opportunities can transform into potential products),
- to short-term R&D (which investigate deployment issues and the future services enabled by the new infrastructure).

Without long term commitment and sustained R&D efforts at all stages of the innovation process, European industry players would take a significant risk of being, in short or long term relegated to secondary players or even disappear.

A need for critical mass in standardization

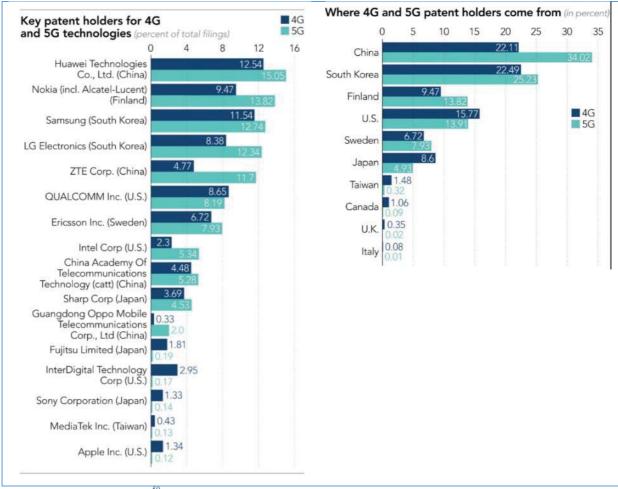
Being in the forefront of standardisation means that those driving standardisation will have a competitive advantage with respect to know how in development but also possibility to file systems and standards blocking (essential) patents and by this being able to position the products and services complying to standards and by this control the market. Generally, those that control the standards arena will have a competitive advantage.

Regarding standardization of 5G: European vendors are at the forefront of contributions to mobile standards. This can be attributed to the dedicated efforts toward standardizations in the 5G-PPP programme. These joint collaborations facilitates submitting standards inputs in a concerted fashion with several partners undersigning and by this creating a European momentum. However, this place remains fragile, and Asia has a strong lead on 5G patents. A lack of future coordinated efforts of European actors in standardization, would lead to lack of the critical mass necessary to sustain the position of Europe.

At the end of March 2019, China had filed for 34% of standard essential patents (SEP) for 5G communication systems, an increase of more than 50% compared with its share of 4G patents, according to IPlytics⁴⁹. South Korea had 25% of key 5G patents, while the share of filings by Japanese and U.S. entities was similar to the one for 4G. As mentioned in Appendix E (analysing KPIs of the 5G-PPP), Europe has around 25% of 5G patents (but more than 50% on RAN), therefore behind China and South Korea.

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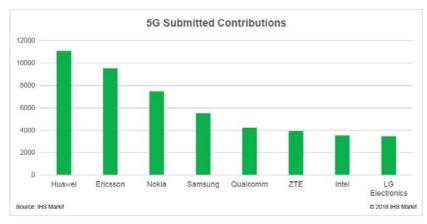
IPLytics, Who is leading the 5G patent race?, July 2019 available at: https://www.iplytics.com/wp-content/uploads/2019/01/Who-Leads-the-5G-Patent-Race 2019.pdf



Source: Nikkei Asian Review⁵⁰

However, the analysis of essential patents is complicated and an analysis taking into account the number of 3GPP contributions shows that **Nokia and Ericsson rank second and third behind Huawei**. These contributions correspond to work item (WI) or study item (SI) level in the 3GPP standardisation work.

Appendix E Figure 21: Number of submitted 5G contributions (3GPP) – 2015 to 2018 H1



⁵⁰ Akito Tanaka, Nikkei Asian Review, *China in pole position for 5G era with a third of key patents*, May 2019, available at: https://asia.nikkei.com/Spotlight/5G-networks/China-in-pole-position-for-5G-era-with-a-third-of-key-patents

In the 3GPP standardisation process between 2015 and the first half of 2018, Nokia and Ericsson had a little bit more than 5000 contributions approved which is more than Chinese vendors Huawei and ZTE.

5G Approved Contributions

3500

3000

2500

2000

1500

Huawei Nokia Ericsson Qualcomm NTT DOCOMO Intel ZTE Samsung
Source: IHS Markit

Appendix F Figure 22: Number of approved 5G contributions (3GPP) – 2015 to 2018 H1

Source: IHS Markit

Stakeholder opinion

According to the Open Public Consultation, the potential lack of global standards has been seen as very relevant as a barrier to exploitation according to the majority of stakeholders in the categories of business association, large organization, EU citizen, NGO and public authority.

4.4. Insufficient structural capacity of the EU value chains in responding to requirements set by technological developments for smart networks and services

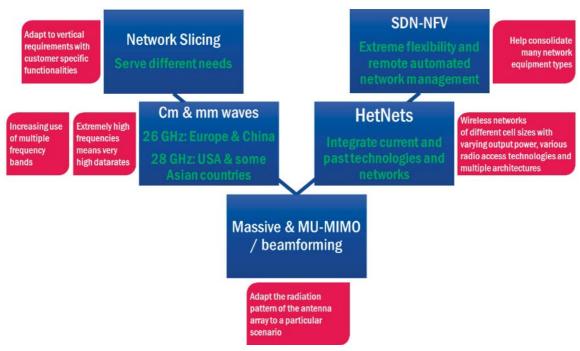
The future smart networks will be an infrastructure relying heavily on advanced digital solutions, that to be developed require the involvement of actors beyond the traditional telecommunication value chain. Furthermore, the services that would be built on top of this infrastructure will have to address the needs of multiple vertical industries (ranging from automotive and manufacturing to transportation, energy, and health). For these industries the future infrastructure and the associated digital services will become critical, which requires their involvement in both defining the requirements and validating its implementation.

4.4.1. A future infrastructure relying heavily on advanced digital solutions

The development of future smart networks and services will require important interactions between the research on future telecommunication networks technologies and other digital technologies. A lack in synergies between these research activities would significantly reduce the potential impact of the initiative.

With 5G, software technologies have taken a critical role in the development of the future generations of telecommunication networks. The development of network slicing and SDN (Software Defined Networks) and NFV (Network Function Virtualization) are key components of the 5G technological stack.

Appendix G Figure 23: Examples of 5G Technology Enabler



Source: IDATE DigiWorld, 5G IoT – Market Opportunities in the Vertical Industries, 2018.

This rising importance of software is impacting the research ecosystem of the telecommunication industry. It requires dedicated investment in software technologies, potentially reaching out of the traditional telecom value chain. A primary example of this need to reach beyond traditional research ecosystem is around the question of cybersecurity. A more important role of software in the network architecture increases the importance of research collaborations between cybersecurity players and telecommunication actors.

Furthermore, the development of an infrastructure able to fit the needs of the future "Smart Services" also requires integration and cooperation with other fields of research that reach beyond pure telecom infrastructure research.

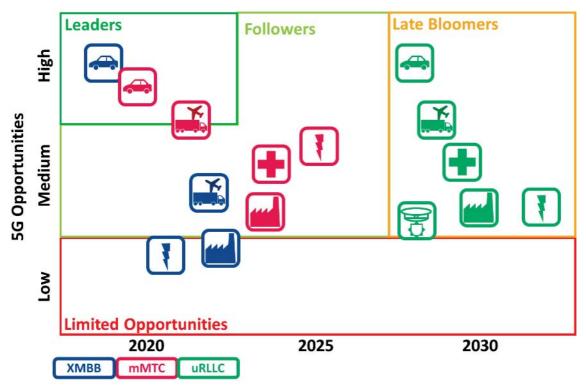
Stakeholder opinion

As such it appears necessary to many stakeholders' interviewed to ensure that future Smart Networks and Services research is sufficiently connected to research in IoT, but also edge computing, artificial intelligence (especially at the edge of the network), cybersecurity and cloud. These technologies will indeed by essential for the development of the future smart services and will also be directly applied to the network infrastructure themselves.

4.4.2. An infrastructure critical for the adoption of digital solutions in many industries

The future network infrastructure is set to become a critical infrastructure for numerous industries that are transforming themselves by progressively adopting digital technologies. The initial research on 5G (as presented above in section 1) has started to mobilise actors beyond the telecommunication industry and dedicated professional associations (such as the 5G AA and 5G ACIA) have been set-up to facilitate the collaboration between the fields.

Appendix H Prospects of adoption of 5G in vertical use cases, by sector (Automotive, Transport, Energy, Health, Manufacturing, Public Services) and technologies (eXtended Mobile Broadband, massive Machine Type Communication, ultra-Reliable Low Latency Communications).



Source: IDATE DigiWorld, 5G IoT – Market Opportunities in the Vertical Industries, 2018.

Future research on 5G, beyond 5G and 6G capabilities will thus have to take into account the requirements from the vertical players. The integration of the players from the vertical industries into Smart Networks and Services research will have to be strengthened. This investment of vertical players is necessary in order to develop both the research on future smart services needed by the various industries to transform themselves and an infrastructure able to meet their requirements.

Stakeholder opinion

The stakeholders interviewed support this vision and insist on the need to have a movement from both the telecommunication industry and the vertical industries to build future smart networks and services and on the necessity of a future programme to encourage such movement. Indeed, vertical industries role is key from the definition of the topics of the research (meeting their requirements) to the evaluation of the technology (applicability) but also in measuring the business approach (value creation) brought by the network technologies.

For the majority of interviewees with no clear distinction of specific category of stakeholders, the involvement of industries is key so that the expansion of the value chain beyond the traditional telecom one is required with notably the integration of vertical players. As a consequence, interviewees insist on the necessity to involve a wide variety of players in the structure of the research program, which is key to understand and to take into account the diversity of verticals' requirements like security, network coverage, energy consumption, ultra-low latency round trip.

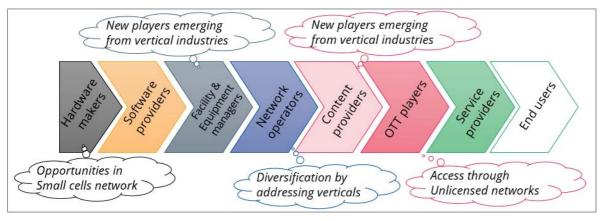
4.4.3. An infrastructure that will require structural changes in various value chains

The telecommunication industry has been characterized by rapid changes triggered by the deregulation of markets, the increased competition and advancing technologies. At the industry level, mobile network operators have traditionally controlled and managed most of the value chain (with the support of OEMs

developing the technologies), but the mobile ecosystem has evolved from a linear relationship into a network of specific companies involved at different stages in the value chain.

The emergence of new modes of communication like 5G is impacting the existing connectivity ecosystem. Indeed, 5G will not only enable new applications and services but also enable more new players to provide connectivity, services and even infrastructure. The virtualisation principle of 5G, for instance, will provide from the end-user perspective a unified network relying on several connectivity providers exploiting various technologies and infrastructures. It can be thus expected that more players will participate in the connectivity value chain.

Appendix I Opportunities of evolution of the value chain



Source: IDATE DigiWorld, 5G IoT, November 2018

Current connectivity providers (MNOs, MVNOs) will take the opportunity of these new technologies to try to diversify their offer and address new market segments (in specific verticals, including manufacturing) as a way to compensate declining consumer revenues.

Hardware equipment manufacturers can also see these new technologies as an opportunity to diversify their business modelling bundling equipment with connectivity service provisioning for example in the small cell area.

Some industrial solution providers, and potentially manufacturers, will also play a role in the new communication value chains, not only as content and service providers, but also as connectivity provider, infrastructure providers. The opening of vertical markets will also open up space for existing actors of the wireless industry to target specific roles for vertical industries. The emergence of new possible roles will offer opportunities for both new and existing players within the vertical value chains.

Appendix J Figure 26: New connectivity business models enabled by 5G

Vertical Specific Vertical technology Vertical actors by providers **Operators** themselves MNOs or MVNOs Actors already present in Integrating connectivity developping vertical vertical value chain as part of their offers specific offers Diversification by integrating Strengthening New vertical specific connected services customer relationships operators appearing Ex: Smart Manufacturing Servicization of Ex: Transport specific providers industry operators

Source: IDATE DigiWorld, 5G IoT, November 2018

This is reinforced by the integration of direct, proximity communications (such as public safety services or V2V, V2I) in the 5G standards, removing partially or even entirely in some case the need for a mobile operator in the value chain.

These evolutions of the value chain have a potential to disrupt existing businesses, and could threaten established European actors. They could also be seen as opportunities for Europe to reposition its industry and take a larger part in the digital value chain by relying on its strong existing industries. This will require dedicated actions to support the evolution of the European industrial ecosystems and support synergies between industries.

Stakeholder opinion

According to interviewees with no clear distinction of specific category of stakeholders, the value chain needs to evolve with players emerging from vertical industries. It will give the opportunity to provide new business models such as "Anything as a Service" model allowed by new technologies that provide flexible and open infrastructure.

4.5. Too slow and uneven a development of 5G infrastructure

It is important to note that, although deployment issues are clearly beyond the scope of research programme, the investment need for the deployment of future network can strongly impact future research on smart networks and services.

Indeed, an insufficient investment in the deployment of 5G network in Europe would result both in delays in future research on networks by European players (no need to research solutions beyond 5G if 5G is not deploying), and in research on the associated smart services (which require a deployed infrastructure).

Addressing deployment issues, and ensuring synergies between deployment and research activities is thus important to support R&I activities in the field, it is also of critical importance to ensure the development the European digital market.

The current deployment of 5G in Europe suffers from several factors that delay it in comparison to other regions of the world:

A lack of investment in the deployment of the new infrastructure Insufficient synergies between national and European initiatives supporting 5G A lack of coordination of spectrum policies

4.5.1. A lack of investment in the deployment of the new infrastructure

The early development of 5G technology shows an increasing competition at the global level on network technologies and deployments of future infrastructure. The current state of play can be seen as a menace for European telecommunication equipment providers.

According to GSMA, a first stage of 5G investments corresponds to early deployments between 2018 and 2020 with \$ 140 billion spent in the USA, South Korea, Japan, and China. It corresponds to two thirds of the global 5G CAPEX. The five largest European countries will contribute for \$30 billion and GCC players will spend roughly \$5 billion.

During the 2021-2023 period, Europe should double its 5G Capex reaching \$ 100 billion as more EU Member States get 5G commercial services. In Asia and in the USA, 5G geographical deployment continue to expand.

After 2024, lagging countries in Latin America, Commonwealth of Independent States Middle East North Africa and other African countries will start to implement 5G infrastructures.

Some mobile operators have already announced their investments in 5G networks for the coming years:

Deutsche Telekom will invest 20 billion EUR in its 5G network for the 2018-2021 period and targets 99% population coverage in 2025.

U.K. operator Three has indicated that it will invest \$2.57 billion in getting ready for 5G.

In South Korea, SKT invested 5 billion USD between 2017 and 2019 to build the first part of its 5G network and KT announced a 5G investment of 20.5 billion USD between 2018 and 2023.

Japanese incumbent, NTT Docomo will spend 8.8 billion USD between 2018 and 2023 on its 5G network. The US mobile operators have awarded multi-year contracts for 5G deployment to Samsung, Ericsson and Nokia. T-Mobile signed two contracts of \$ 3.5 billion each to Nokia and Ericsson.

It is expected that the Radio Access Network (RAN) will represent 80% of the total CAPEX whereas the core network will amount for 20% of the total.

In China, the share of network equipment awarded to foreign vendors is controlled by the government. Huawei and ZTE are expected to get the lion's share of network equipment for 5G networks in China. Consequently, Nokia and Ericsson are likely to get a lower share of the 5G infrastructure market in China compared to 4G.

China is expected to deploy hundreds of thousands of 5G base stations in the coming years whereas South Korea had already installed more than 90,000 5G base stations in October 2019. Ramp-up is going to be much slower in Europe with only hundreds of 5G base stations installed at the same date. This discrepancy in investment timetables might favour Chinese vendors against European ones.

Non-5G capex ■ 5G capex

APAC

NA

EUROPE

LATAM

MENA

SSA

CIS

\$0 \$100 \$200 \$300 \$400 \$500 \$600

Mobile capex (\$ bn, cumulative 2018-2025)

Appendix K Mobile capex by region

Source: GSMA Intelligence

Stakeholder opinion

According to the Open Public Consultation, a very large majority of respondents from the categories of academia, business association, SMEs, large organizations and EU citizen agree on the high relevance to address the innovation gap in the Europe in translating the results of connectivity, cloud and Internet of Things devices research.

This vision is also supported by almost all interviewees in the need from Europe to invest in the development of such technologies but above all to help bringing them to commercialization with trials and development of adapted use cases.

4.5.2. A lack of synergies between national and European initiatives supporting 5G

Past activities around 5G have seen the multiplication of initiatives supporting 5G research as well as 5G deployments in Europe at the European, Member States or Local level. These initiatives often miss opportunities for synergies and coordination.

The European 5G Infrastructure Public Private Partnership (5G-PPP) represents a 3.5 Billion investment in 5G with € 700 million of public investment. Public funding for Phase 1 (2014-2016) was €128 million

and it should be noted that overall EU investments from 2007 to 2013 amount to more than €600m in research on future networks, half of which was allocated to wireless technologies contributing to development of 4G and beyond 4G. Phase 2 of the 5G-PPP represented 149 M€ and Phase 3 the remaining budget (423 M€). Work has already started on beyond 5G as 18M€ have been granted by the European Commission for 6 projects.

Many European countries have launched national R&D programmes which are generally restricted to national participants. As an illustration, the table below shows national 5G research & development programs in Finland, Germany, Spain and in the United Kingdom. Even though the share dedicated to 5G cannot be identified exactly, this amount is quite high already in the UK and in Germany.

Appendix L : National 5G R&D programmes

Country	National 5G R&D programmes
Finland	Business Finland is a publicly funded expert organisation for financing research, development and innovation in Finland with 467 MEUR of funding in 2016 (including 6 MEUR from EU structural funds) for 3,760 projects. Business Finland pushed the 5thGear program with 200 MEUR funding for 2015-2019.
France	Many R&D projects on 5G financed by the national research agency ANR
Germany	100 MEUR from the "Gigabit Germany Initiative for the Future"
	80 MEUR from the "5G Initiative for Germany"
Spain	In March 2019, the Spanish Administration announced it will give €20 million in public funds to two 5G pilot schemes to be carried out by Telefonica and Vodafone
UK	740 MGBP (834 MEUR) to 5G trials and full fibre deployment across the UK by 2020/2021

Source: IDATE DigiWorld

It should be noted that 5G projects financed by national authorities often overlap the research and development thematic covered by European programs.

Even though players involved in national R&D programs and H2020 projects are mainly the same (vendors, universities, operators...), there is a risk of duplication of the financing effort at national and European level. More coordination is needed at European level in order to optimise resources dedicated to 5G research and development.

Stakeholder opinion

According to the Open Public Consultation, the market fragmentation due to lack of industrial policy and implementation strategies is seen as very relevant for R&I efforts at Europe level especially clearly expressed by the majority of SMEs. For the other categories including academics, business association, large organization and EU citizen, the topic remains relevant but at a lesser level.

This vision is in accordance with interviews where they outline the need to make a link between research and deployment, especially requiring a focus on services and supporting use cases very early in the research program. A pragmatic approach is required in order to have the ability to translate innovation in commercialization. Also, many interviewees from different categories of players mentioned how Europe is good at technologies research but should work on business models and value generation. Lastly, interviewees also mention the lack of coordination to target a single market, lack of incentives to take research to commercialization stage and lack of global vision.

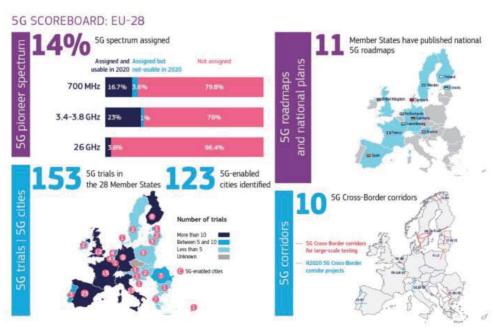
4.5.3. A lack of coordination of spectrum policies

5G pioneer bands identified at EU level are the 700 MHz, the 3.6 GHz (3.4-3.8 GHz) and the 26 GHz (24.25-27.5 GHz) frequencies. Whereas the 700 MHz band has been harmonised through an EC Implementing Decision (EU) 2016(687) of 28 April 2016, a '5G-ready' amendment of the 3.6 GHz

implementing decision has been adopted in January 2019. The European Commission adopted an Implementing Decision to harmonise spectrum in the 26 GHz frequencies in May 2019.

Member States have adopted a common deadline for the effective usability of pioneer spectrum in the European Electronic Communications Code, namely the 3.6 GHz band and at least 1 GHz within the 26 GHz band have to be assigned in all Member States by end of 2020.

Appendix M 5G scoreboard – June 2019



Source: European Commission⁵¹

However, there is no coordination between EU Member States regarding spectrum allocation conditions and at the end of June 2019, only 14.2% of the Pioneer Bands had been assigned in the EU (China is in a similar position). Bands are different in other regions of the world and can therefore not be totally compared. USA has already allocated all its spectrum for low bands, Japan and South Korea have almost allocated all their spectrum for mid and high bands (while Europe is lagging behind).

Lack of coordination of spectrum policies in EU creates uncertainties for the operators. This is already the case for bands as mentioned above. The use of frequency bands above 100 GHz will mean more R&D and more certainty regarding availability timetable for experimentations and future commercial use. A common approach to spectrum allocations is needed in order to limit the risk for the industry, as there is a risk that Member States will use the sales of spectrum as an alternative to general taxation, as has been done in the past.

With combination of verticals, combination of multiple regulatory environments become a challenge, whilst public actors may be called upon to play an increased role considering that many of the targeted verticals (healthcare, automotive/transport..) have a clear public policy dimension, different from broadband which is primarily driven by commercial forces (so regulation is mainly about fair competition, accessibility and consumer protection).

Stakeholder opinion

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According to the Open Public Consultation, business associations, SMEs and large organizations find very relevant the regulation in the field of radio spectrum allocation.

European 5G Observatory, 5G Scoreboard, June 2019 http://5gobservatory.eu/observatory-overview/5g-scoreboards/

For several interviewees from different categories, a strong coordination in Europe is required for spectrum harmonization involving the implication of Member States very early in the program. Indeed the spectrum fragmentation in cost and allocation is seen as a key issue (very irregular depending on the countries).

4.6. Insufficient capacity of 5G to respond to advanced communication requirements

Future digital use cases such as super-immersive multimedia and super-high definition video, massive scale communications (IoT) for anything and anywhere, use cases requiring super-precision 3D positioning, and XR experience (AR+VR+MR) will have very demanding telecommunication requirements that exceed the foreseen capabilities of 5G, even in its most advanced roadmaps.

These future use cases include:

- **Super-immersive multimedia and super-high definition video:** going from 8K to 64 K video, with the integration of sensing, imaging and highly accurate positioning capabilities with mobility to enable the provision of new applications. The development of Five-dimension (5D) services, integrating all human sense information (sight, hearing, touch, smell and taste) is in early development and should be available in about 10 years from now. It will provide a truly immersive experience and new services such as telepresence.
- **Holographic telepresence:** Within a 10 year's timeframe, new forms of interaction will become possible leading to a true immersion into a distant environment. Holographic communications, using multiple-view cameras, will require data rates in the order of Tbps, which are not supported by 5G.
- **XR Experience (AR+VR+MR):** XR reality encompasses virtual reality (VR), augmented reality (AR) and mixed reality (MR). Future devices will include haptic interfaces, earphones, glasses and wearable displays that will replace smartphones and provide a totally new user experience.
- Massive-scale communications (IoT) for anything and anywhere: 6G networks will support extreme massive connectivity, with more than 500 billion connected things are expected worldwide by 2030. 6G will target capacity expansion to offer high throughput and continuous connectivity. Wider coverage is also planned, including bringing connectivity at sea and in the air.
- **Smart City:** The objectives are improvements of life quality, environmental monitoring, traffic control and city management automation. 6G smart city applications will include support for user-centric M2M communication and use low-cost and low-energy consuming sensors that will interact with each other. Autonomous vehicles will combine wireless networks, sensing and distributed AI.
- Use cases requiring super-precision 3D positioning: Many use cases will require super-precision 3D positioning such as commercial UAVs, ground-robotics navigation, lane-level navigation, industrial navigation and tracking, and heavy-machine navigation. 6G will foster the Industry 4.0 revolution and will see new semiconductor and integrated circuit innovations.

Based on this long-term perspective, the early requirement of future communication networks are starting to appear. Some of them can be considered as extensions of 5G requirements, but other are clearly disruptive, requiring major evolutions beyond the state of the art.

Appendix N 5G and 6G technology requirements

KPI	5 G	6G
Traffic capacity	10 Mbps/m²	~1-10 Gbps/m ³
Peak data rate DL	20 Gbps	1 Tbps
Peak data rate UL	10 Gbps	1 Tbps
Uniform user experience	50 Mbps 2D everywhere	10 Gbps 3D everywhere
Latency (radio interface)	1 msec	0.1 msec
Jitter	Not specified	1 micro second
Reliability (frame error rate)	10-5	10-9
Energy/bit	Not specified	1 pJ/bit
Localisation precision	10 cm on 2D	1 cm on 3D

Legend: evolution, disruptive

Source: IDATE DigiWorld based on 6G - The Next Frontier, 2019, Emilio Calvanese Strinati, et al., 6G: So, what happens in 2030?, November 2019

Reaching these future requirements, will require new technological paradigms through the use of spectrum in the THz range (frequencies from 300 GHz to 10THz), innovations in semiconductors, optics and new materials, through a new architecture combining computation and communication resources, and relying heavily on artificial intelligence and machine learning. Energy-efficient communication strategies are also expected to become increasingly important, especially in view of a pervasive deployment of the Internet of Things, with myriads of tiny sensors. Energy harvesting mechanisms and advanced wireless-charging technologies will be developed with a focus on laser-charging techniques (potential of delivery of 2W of power up to a distance of about 10 metres).

Stakeholder opinion

According to respondents from both the Open Public Consultation and interviews, and for a high proportion of SMEs, there is an agreement on the necessity to enlarge the technological scope of the research program beyond 5G. Typically, in order to address critical applications, security should be addressed as well as a wide array of technologies including network intelligence, network automation, network softwarisation, network slicing, edge computing, cybersecurity, machine learning, Artificial Intelligence, IoT, robotics, high performance computing...

4.7. Increasing challenges of digital services toward ethics privacy and cybersecurity

The development of digital services in recent years has seen the rise of several challenges for EU citizen regarding their privacy, data protection, cyber security or more generally ethical concerns.

Several fundamental human principles can be challenged by the development of future smart networks and services, such as:

Identity and Reputation: Several innovative smart services challenges the notions of Identity (relation that one bears to oneself) and of Reputation (relation that others bears to oneself). The limitation of digital technologies to define rationally such notions that are, by human nature, multiple, complex and changing raises several challenges. From the right to be forgotten to the right to have complex and evolving identities that cannot rely on a single online or offline identity. As future smart services are likely to more and more store but also increasingly generate automatically (through profiling and

presentation) identities and reputation, serious challenges can be envisioned on the definition of human identity and reputation. The rise in profiling approach and the rising use of digital profile as a basis for real life services and interactions, and technologies such as Artificial Intelligence can be seen as threatening these human fundamental notions.

Relationships: Digital services based relationships also face the same danger as identity: to try to define rationally, in a Boolean approach the complexity and evolving nature of human relationships. The rise of digitally mediated relationships questions the future of human relationships as physical interactions and non-verbal language, key to human interactions, are for now mostly left out of digital relationships. Concerns can be raised both for those who are left out of the online conversation and for those for which the online conversation replace to a large extent real relationships. Questions of how to consider and handle relationships with purely digital avatars will also have to be handled as such relationships, once considered as farfetched science fiction become closer and closer to our reality.

Culture: The disappearance of traditional boundaries of time and space enabled by smart networks and services is fuelling the definition of ever multiplying alternative cultures as group cutting across traditional boundaries come to define their own set of symbols and values that are coherent and meaningful in their understanding. At the same time the rapid ubiquitous communication mechanisms offered by new digital services enable the rapid spread of cultural elements. The application of evolutionary principles to cultural elements shows that faced to this increased creativity and competition traditional cultural elements could be put to risk. The human impact of putting cultures at risks, with the risk of violent reaction and protective isolative move is a serious challenge.

Motivation and Attention: The collective data and knowledge production, publication, archiving and research capacity has since long far exceeded the human brain ability to process it. This raises serious challenges to both human attention (capacity to freely focus) and human motivation (capacity to freely choose on which information to process).

Responsibility: The rising complexity of digital systems, often based on networks and sometimes decentralized, combined with the multiple roles of stakeholders result in near to impossible attribution of responsibilities in case of failure, error, or denegation of complex digital services. This will have stronger and stronger consequences as such systems get more complex and more intertwined with Physical devices in the vertical industries. Difficulty to attribute responsibility raises the double risk of either putting too much constraint on smart services providers, and therefore impeding innovation capacity, or to the contrary that the risk entirely reposes on end users.

Fairness: The existing risk of "Digital divide" can in a near future be significantly increased both in scale and impact. The differences in access to future network infrastructure and digital services, is being reinforced in a knowledge divide, which create the risk of a 2 speed society with a strong divide between those who master and understand digital technologies and their impact on society and life and those who don't. Additionally, questions of fairness, linked with responsibility, of automated decisions and algorithms will have to be raised. The intentions, and views of the world of the designer are embedded in every creation, therefore the fairness of the decisions can always be questioned even for supposedly neutral and machine automated choices.

Safety and Privacy: Safety concerns are on the rise as digital technologies are having a stronger and stronger impact on everyday lives not only in online world but also increasingly offline. The rise of privacy concerns is also a well-documented risk as personal data collection; archiving, processing, transfer becomes the norm in many digital scenarios. Although these two notions are for now well covered by regulations, past example shows that these regulations were often put into place after the technology development, and that future development could challenge the status quo.

Stakeholder opinion

The relevance of this topic has been asked among stakeholders through the Open Public Consultation especially regarding the concerns with using Smart Networks and Services platforms for ethical, privacy, security, or EMF reasons. For a majority of respondents in several categories including academia, SMEs, large organizations, EU citizen the topic is evaluated as very relevant. For business association and public authority, the topic is seen as relevant but at a lower degree (which can be taken as a hint that this issue is unlikely to resolve only through market dynamics).

4.8. Lack of energy efficient technological solutions for future network infrastructures

The development and deployment of any infrastructure at a European scale will require significant energy consumption, resulting in increased emissions of greenhouse gases. Beyond this simple fact, the current lack of energy efficient technological solutions for future smart networks and services raise a significant threat in term of future energy consumption throughout the lifespan of the infrastructure.

Current feedbacks on the deployment of early 5G networks points toward an increase in energy consumption of the network. Furthermore, the development of new solutions, such as Edge Computing, that are likely to complement rather than replace cloud-based solutions will result in the deployment of additional computing resources, with increased energy consumption.

Current perspective on the electricity consumption of mobile network generation point to several years of steep growth of the energy consumption of new networks while legacy solution decreases slowly as they are rolled back.

140 120 100 80 2G data 60 3G data + 4G data 40 5G data 20 2010 2012 2014 2016 2018 2020 2022 2024 2026 2028 2030 Year

Appendix O Expected electricity usage of wireless networks

Source: Symetry/MDPI⁵²

About 80% of the energy consumption in a network is due to base stations. In a recent whitepaper⁵³, Huawei indicates that "According to the measured data of multiple operators, the power consumption of one band 5G equipment (64T64R, 3.5 GHz Massive MIMO, including one BBU and three AAU/RRUs) is 300% to 350% of 4G with the same configuration. A 5G BBU is about 300 W while an AAU is about 900 W at 30% load rate (peak is about 1200 W to 1400 W)."

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⁵² https://www.mdpi.com/2073-8994/11/3/408/pdf

https://carrier.huawei.com/~/media/CNBGV2/download/products/network-energy/5G-Telecom-Energy-Target-Network-White-Paper.pdf

Appendix P Power consumption of frequency evolution

Peak Power: ~8kW Typical Power: ~6kW	Peak Power: ~14kW Typical Power: ~11kW	Peak Power: ~19kW Typical Power: ~14kW
		MEC
		mmWAVE
	MEC	3.5 GHz (64T64R)
	3.5 GHz (64T64R)	2.6 GHz (64T64R)
	2.6 GHz (4T4R)	2.6 GHz (8T8R)
2.1 GHz (2T2R)	2.1 GHz (4T4R)	2.1 GHz (8T8R)
1.8 GHz (2T2R)	1.8 GHz (4T4R)	1.8 GHz (8T8R)
900 MHz (2T2R)	900 MHz (2T2R)	900 MHz (2T2R)
800 MHz (2T2R)	800 MHz (2T2R)	800 MHz (2T2R)
700 MHz (2T2R)	700 MHz (2T2R)	700 MHz (2T2R)
Now	In 3 years	In 5 years

Source: Huawei.

Furthermore, beyond energy issues, the development and deployment of a new infrastructure, as well as the development of new services requiring new devices (including new forms of devices, such as advanced AR/VR solutions or IoT devices) will require the extraction and transformation of primary resources that is very likely to have negative impacts on local environments.

As such and without a specific attention to mitigate these effects, the development of a future smart networks and services is likely to have major environmental impacts, which may not be compatible with other engagements and policies of the European Union and its Member States.

Stakeholder opinion

Based on interviews, this topic is especially seen as primordial for the category of verticals who mention the importance of energy evoking the need to reduce energy consumption as well as the ability to use renewable energies (with the suggestion of new regulation).

This is a cross-referenced vision with the Open Public Consultation in which drastically reducing energy consumption of future smart network and service platforms is seen as very relevant for a couple of categories including academia, SMEs, large organizations, EU citizen and public authority; only the category of business association finds the issue at a lesser level of relevance.

5. ADDITIONAL INFORMATION ON POLICY OPTIONS

Degree of coverage of the different functionalities by policy option

Type and composition of actors (including openness and roles)

Option 0: Horizon Europe Option 2: Co-funded calls	Option 2: Co-funded	Option 3: Institutionalised Art 185	Option 1: Co-programmed	Option 3: Institutionalised Art 187
What is possible? Any legal entity in a consortia can apply to Horizon Europe calls in ad hoc combinations Calls are open to participation from across Europe and the world (not all entities from third countries are eligible for funding) What is limited?	What is possible? Partners can include any national funding body or governmental research organisation, Possible to include also other type of actors, including foundations. What is limited? Requires substantial national R&I programmes (competitive or institutional) in the field.	What is possible? Partners can include MS and Associated Countries. What is limited? Non-associated third countries can only be included as partners if foreseen in the basic act and subjected to conclusion of dedicated international agreements. Needs good geographical coverage — participation of at least 40% of Member	What is possible? Suitable for all types of parmers: private and/or public parmers, including MS, regions, foundations. By default open to AC/3 rd countries, but subject to policy considerations. Can cover a large and changing community. HE rules apply by default to calls included in the FP Work Programme,	What is possible? Suitable for all types of parmers: private and/or public partners, including MS, foundations. By default open to legal entities from AC/ 3 rd countries, but subject to policy considerations. In case of countries participating: non-associated third countries can only be included as partners if foreseen in the basic act and subjected to conclusion of dedicated international agreements
Systematic/ structured engagement with public authorities, MS, regulators, standard making bodies, foundations and NGOs. What is not possible? To have a joint programme of	Usually only legal entities from countries that are part of the consortia can apply to calls launched by the partnership, under national rules. What is not possible? To have industry/ private sector as	Requires substantial national R&I programmes (competitive or institutional) in the field. While by default the FP rules apply for eligibility for funding/participation, in practice (subject to derogation) often only	so any legal entity can apply to these. What is limited? If MS launch calls under their responsibility, usually only legal entities from countries that are part of the consortia can apply to these, under national rules	HE rules apply by default, so any legal entity can apply to partnership calls. What is limited? Requires a rather stable set of partners (e.g. if a sector has small number of key companies).
R&I activities between the EU and committed partners that is implemented based on a common vision.	parmers.	legal entities from countries that are Participating States can apply to calls launched by the partnership, under national rules. What is not possible? To have industry/ private sector as partners.	What is not possible?	Basic act can foresee exceptions for participation in calls / eligibility for funding. What is not possible?

Type and range of activities (including flexibility and level of integration)

Option 3: Institutionalised Art 187	What is possible? HE standard actions that allow to build a portfolio with broad range of activities from research to market uptake. The back-office allows dedicated staff to implement integrated portfolio of projects, allowing to build a "system" (e.g. hydrogen) via pipeline of support to accelerate and scale up the take-up of results of the partnership, including those related to regulations and standardisation and developing synergies with other funds. E.g. setting up biorefinery plants and promoting their replication by additional investments from MS/ private sector. Procuring/purchasing jointly used equipment (e.g. HPC) Allows integrating national funding and Union funding into the joint funding of projects What is limited? Limited flexibility because objectives, range of activities and partners are defined in the Regulation, and negotiated in the Council (EP).
Option 1: Co-programmed	What is possible? Horizon Europe standard actions that allow a broad range of coordinated activities from R&I to uptake. The association representing private partners allows to continuously build further on the results of previous projects, including activities related to regulations and standardisation and developing synergies with other funds. Union contribution is implemented via calls for proposals published in the Work Programmes of Horizon Europe based on the input from partners (adopted via comitology). Open and flexible form that is simple and easy to manage. What is limited? Limited control over precise call definition, resulting projects and outcomes, as they are implemented by EC agencies.
Option 3: Institutionalised Art 185	What is possible? Horizon Europe standard actions that allow a broad range of coordinated activities from R&I to uptake. In case of implementation based on national rules (subject to derogation) Activities according to national programmes and rules. Allows integrating national funding and Union funding into the joint funding of projects
Option 2: Co-funded	Activities may range from R&I, pilot, deployment actions to training and mobility, dissemination and exploitation, but according to national programmes and rules. Decision and implementation by "beneficiaries" (partners in the cofund grant agreement) e.g. through institutional funding programmes, or by "third parties" receiving financial support, following calls for proposals launched by the consortium. What is limited? Scale and scope of the programme the resulting funded R&I actions and depend on the participating programmes, typically smaller in scale than FP projects
Option 0: Horizon Europe Option 2: Co-funded calls	What is possible? Horizon Europe standard actions that allow broad range of individual activities from R&I to TRL 7 or sometimes higher. Calls for proposals published in the Work Programmes of Horizon Europe (adopted via comitology). What is limited? What is not possible? To design and implement in a systemic approach a portfolio of actions. To leverage additional activities and investments beyond the direct scope of the funded actions

Directionality

Option 0: Horizon Europe calls	Option 2: Co-funded	Option 3: Institutionalised Art Option 1: Co-programmed 185	Option 1: Co-programmed	Option 3: Institutionalised Art 187
What is possible?	What is possible?	What is possible?	What is possible?	What is possible?
Strategic Plan (as implementing act), annual work programmes (via comitology). Possible also to base call	Strategic R&I agenda/roadmap agreed between partners and EC	Strategic R&I agenda/roadmap agreed between partners and EC		Strategic R&I agenda/roadmap agreed between partners and EC
topics on existing or to be developed SRIA/roadmap	Annual work programme drafted by partners, approved by EC	Objectives and commitments are set in the legal base.	Objectives and commitments are set in the contractual arrangement.	Objectives and commitments are set in the legal base.
What is limited?	Objectives and commitments are set in the Grant Agreement.	Annual work programme drafted by partners, approved by EC	Input to FP annual work programme drafted by partners, finalised by EC	Annual work programme drafted by partners, approved
No continuity in support of priorities beyond the coverage of the strategic plan		Commitments include obligation for financial contributions (e.g. to	(comitology)	by EC(veto-right in governance)
(+ years) and oudget (2 years Annual work programme).		administrative costs, from national R&I programmes).	Commitments are political/best effort,	Commitments include obligation for financial
What is not possible?		0	but usually fulfilled	is (e.g.
Coordinated implementation and funding linked to the concrete objectives/roadmap, since part of overall project portfolio managed by agency				administrative costs, from national R&I programmes).

Coherence (internal and external)

Option 0: Horizon Europe Option 2: Co-funded calls	Option 2: Co-funded	Option 3: Institutionalised Art Option 1: Co-programmed 185	Option 1: Co-programmed	Option 3: Institutionalised Art 187
What is possible? Coherence between different parts of the Annual Work programme of the FP ensured by EC What is limited? Synergies with other programmes or industrial strategies What is not possible? Synergies with andustrial strategies	What is possible? Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and EC Synergies with national/regional programmes and activities What is limited? Synergies with other programmes or industrial strategies What is not possible?	What is possible? Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and EC Synergies with national/regional programmes and activities Synergies with other programmes What is limited? Synergies with industrial strategies	What is possible? Coherence among partnerships and with different parts of the Annual Work brogramme of the FP can be ensured by partners and EC Synergies with national/regional organizes with national/regional programmes and activities Synergies with industrial strategies What is not possible? What is not possible? What is not possible?	What is possible? Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and EC Synergies with other programmes or industrial strategies If MS participate: Synergies with national/regional programmes and activities What is limited?

6. ADDITIONAL INFORMATION ON GREEN DEAL ISSUES

This annex provides additional information on the Smart Networks and Services (SNS) initiative in relation to the carbon neutral objectives of Europe, as set out in the Green Deal initiative of the Commission. It suggests the need for an extended stakeholder base to reach these ambitious objectives, in view of the fast growing demand of users and industries for connected ICT services

SNS are expected to directly contribute to two key Sustainable Development Goals directly related to energy efficiency and reduction of carbon footprint: SDG 11 on sustainable cities and communities, and SDG 13 on Climate Actions. The targeted impact of SNS is twofold: i) SNS supports energy efficiency improvements of "vertical industries" using SNS to implement their digital business process; ii) drastic reduction and decarbonisation of the energy used for the operations of SNS platforms;

a) Energy savings enabled by SNS platforms

SNS has the potential to optimise the business processes of multiple industrial sectors through tight integration into their digital processes. It can hence enable energy savings and lowering of carbon footprint in other sectors. Already today, the GSMA and the Carbon Trust calculated that the use of mobile technology enabled a global reduction in emissions of around 2,135 million of tons CO2e in 2018⁵⁴ (global emission level in the order of 55000 millions of tons). These emissions savings were almost ten times greater than the global carbon footprint of the mobile industry itself.

Figure 1 below shows the ICT and connectivity gains that could apply to a number of sectors as analysed by GeSI⁵⁵. It shows a potential gain of 12,100 millions of tons of CO² in 2030, which is the extra emission expected over the period. In that context, SNS would contribute to keep the carbon footprint of these sectors constant, rather than significantly increasing over the period.

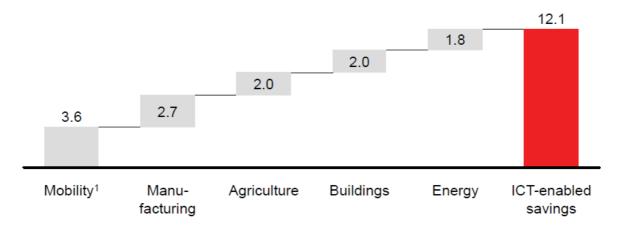


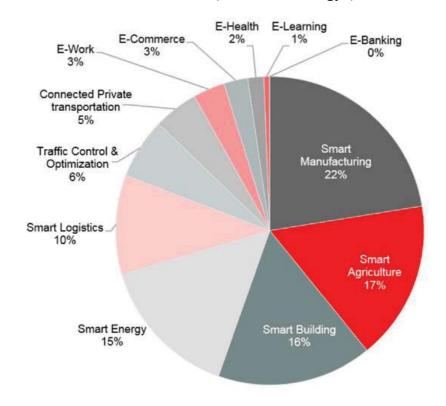
Figure 1, expected CO² abatement potential per sector.

-

https://www.gsma.com/newsroom/press-release/mobile-technologies-enabling-huge-carbon-reductions-in-response-to-climate-emergency/

⁵⁵ Global eSustainabilty Initiative

Figure 2 shows the abatement potential of ICT for a number of use cases as also analysed by GeSI, with a 2030 timeline. These are based on conservative estimate not taking into account the future advanced capabilities of SNS platforms. For this reason, the SNS initiative has set itself an objective of 20 to 30 % energy reduction in at least two key industrial sectors, automotive and factories being identified at this stage. Reaching these objectives will require a clear involvement of the target industries, and the setup of pan European trials with Member States infrastructures in a number of cases (automotive, energy..)



b) Energy efficiency of SNS platforms

The telecommunications sector accounts for roughly 4% of global electricity consumption⁵⁶. As explained in the core text, energy consumption of network platforms are set to increase over the next decade by a factor of about 10 if no specific action is undertaken. Several factors are contributing to such an increase:

- the continued growth of mobile traffic, with typical yearly growth rate between 50% and 100% as data usages get popular and high performance 4G networks get available;
- the densification of networks. This is a long term trend that will shift power consumption patterns from transmission towards computing. Today, the main source of energy consumption of mobile networks is in the radio access transmission, i.e. transporting information from the user device/smartphone to the access radio Base Station. This represents about 70 to 80% of the total energy consumption. Future networks will deploy much denser radio access points, closer to the users, to optimise capacity and reduce network latency. This

⁵⁶ 5G PPP Metro Haul project White Paper: "Optics Research for Future Smart Networks and Services", January 2020, developed by British Telecom, ADVA, Lexdens, University Politecnico de Catalunya, Fraunhofer HHI.

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has two impacts: i) the device being closer to the radio access point, the needed transmitted power decreases; ii) as the device gets connected to many more access points during a mobile session, the computing power increases. As the need to process information closer to the user increases, computing becomes dominant in the energy consumption pattern of both the network and the device⁵⁷.

This evolution is well understood by the community and considered unsustainable in the longer term, and non-compatible with the objectives of the Paris agreement, to cap temperature increase at 1,5° maximum. In that context, the industry has already taken steps to drastically reduce energy consumption and carbon footprint, as exemplified by the release of the science-based pathway to reduce Greenhouse Gas (GHG) emissions across the telecoms sector⁵⁸. This supports the GSMA's commitment to helping the mobile industry achieve Net Zero carbon emissions by 2050.

The new Science-Based Target (SBT) is the result of a collaboration between the International Telecommunication Union (ITU, the telecom agency of the United Nations), the Global eSustainability Initiative (GeSI), the GSM Association (GSMA), and the Science Based Target initiative (SBTi) to develop a sector-specific decarbonisation pathway that allows ICT companies to set targets in line with the latest climate science. It includes emissions reductions trajectories for mobile, fixed and data centre operators to meet the Paris Agreement goal of limiting global warming to 1.5°c, designed to substantially reduce the risks and effects of climate change.

The SBT sets emissions trajectory reductions over the decade (2020-2030) for each ICT subsector. Mobile network operators adopting the SBT are required to reduce emissions by at least 45 per cent over this period. The initiative is based on an extended use of renewables for SNS platforms that will help to reduce carbon footprint. The SNS initiative is designed to support these industry objectives and to extend them further by a reduction of the energy needs of the infrastructure itself, targeted to 1/10 compared to the planned evolution. This later objective would keep energy needs of SNS platforms comparable to those of 2015, an objective considered as possible by GeSI for other industrial sectors supported by SNS. Therefore, SNS sets an objective that is in line with that of other industrial sectors.

Reaching this objective requires a full value chain perspective, as energy consumption is diversely spread over terminals/device, network, and computing platform as described above. Therefore, SNS will develop energy consumption models, technologies and architectures enabling to decrease energy footprint of these platforms in line with the above objectives, as part of its R&I and industrial roadmap.

⁵⁹ A partnership between CDP, UN Global Compact, WRI and WWF.

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⁵⁷ A. Mämmelä and A. Anttonen, "Why will computing power need particular attention in future wireless devices?" IEEE Circuits and Systems Magazine, vol. 17, pp. 12-26, First Quarter 2017, work supported by the EU COHERENT project, http://www.ict-coherent.eu/

⁵⁸ https://www.gsma.com/gsmaeurope/news/sbti/

⁶⁰ GeSI report #SMARTer2030, ICT Solutions for 21st Century Challenges, pages 8, 17.



Brussels, 23.2.2021 SWD(2021) 37 final

PART 10/19

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT REPORT

Accompanying the document

Proposal for a COUNCIL REGULATION establishing the Joint Undertakings under Horizon Europe

European Partnership for Transforming Europe's Rail System

{COM(2021) 87 final} - {SEC(2021) 100 final} - {SWD(2021) 38 final}

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Glossary

Term or acronym	Meaning or definition
АТО	Automatic Train Operation
CEF	Connecting Europe Facility
CF	Cohesion Fund
DEP	Digital Europe Programme
EIT	European Institute of Innovation & Technology
ERA	European Union Agency for Railways
ERDF	European Regional Development Fund
ERRAC	European Rail Research Advisory Council
ERTMS	European Rail Traffic Management System
ETCS	European Train Control System
FP	Framework Programme
GDP	Gross Domestic Product
IM	Infrastructure Manager
IP	Innovation Programme
JU	Joint Undertaking
KIC	Knowledge and Innovation Community
КРІ	Key Performance Indicator
MAAP	Multi Annual Action Plan
MaaS	Mobility as a Service
OEM	Original Equipment Manufacturer
PRM	Person with Reduced Mobility

R&I	Research and Innovation
RSI	Rail Supply Industry
RU	Railway Undertaking
SDGs	United Nations Sustainable Development Goals
SERA	Single European Rail Area
SME	Small and Medium sized Enterprise
SRIA	Strategic Research and Innovation Agenda
S2R	Shift2Rail
TEN-T	Trans-European Transport Network
TRL	Technology Readiness Level
TFEU	Treaty on the Functioning of the European Union
TSI	Technical Specifications for Interoperability
UIC	International Union of Railways (Union Internationale des Chemins de Fer)

PART 1 - COMMON FOR ALL CANDIDATE INSTITUTIONALISED EUROPEAN PARTNERSHIPS

BACKGROUND AND CONTEXT TO EUROPEAN PARTNERSHIPS IN HORIZON EUROPE AND FOCUS OF THE IMPACT ASSESSMENT- WHAT IS DECIDED

Note that the part dedicated to the Partnership on Transforming Europe's rail system starts on page 26.]

1.1. Focus and objectives of the impact assessment

This impact assessment accompanies the Commission proposal for Institutionalised European Partnerships to be funded under Horizon Europe, the 2021-2027 Framework Programme for EU Research and Innovation (R&I). It sets out to help decide in a coordinated manner the right form of implementation for specific candidate initiatives based on a common approach and methodology to individual assessments². It also provides an horizontal perspective on the portfolio of candidate European Partnerships to identify further efficiency and coherence gains for more impact.

European Partnerships are initiatives where the Union, together with private and/or public partners (such as industry, public bodies or foundations) commit to support jointly the development and implementation of an integrated programme of R&I activities. The rationale for establishing such initiatives is to achieve the objectives of Horizon Europe more effectively than what can be attained by other activities of the programme.³

Based on the Horizon Europe Regulation, European Partnerships may be set up using three different forms: "Co-funded", "Co-programmed" and "Institutionalised". The setting-up of Institutionalised Partnerships involves new EU legislation and the establishment of dedicated implementing structures based on Article 185 or 187 of the Treaty on the Functioning of the EU (TFEU). This requires an impact assessment to be performed.

The Horizon Europe Regulation defines eight priority areas, scoping the domains in which Institutionalised Partnerships could be proposed⁴. Across these priority areas, 13 initiatives have been identified as suitable candidate initiatives for Institutionalised Partnerships because of their objectives and scope. This impact assessment aims to identify whether 12 of these initiatives⁵ need to be implemented through this form of implementation and would not deliver equally well with traditional calls of Horizon Europe or other lighter forms of European Partnerships under Horizon Europe. This means assessing whether each of these initiatives meets the necessity test set in the selection criteria for European Partnerships in the Horizon Europe Regulation, Annex III.

Set out in the Annex Va of the Horizon Europe Regulation (common understanding). https://data.consilium.europa.eu/doc/document/ST-7942-2019-INIT/en/pdf

Horizon Europe Regulation (common understanding), https://data.consilium.europa.eu/doc/document/ST-

⁷⁹⁴²⁻²⁰¹⁹⁻INIT/en/pdf

Based on the European Commission Better Regulation framework (SWD (2017) 350) and supported by an external study coordinated by Technopolis Group (to be published in 2020).

³ For further details on these points, see below Section 1.2.2.

⁵ Only 12 are subject to this impact assessment, as one initiative on High Performance Computing has already been subject to an impact assessment in 2017 (SEC(2018) 47).

This assessment is done without any budgetary consideration, as the overall budget of the Multiannual Financial Framework of the EU – and hence of Horizon Europe – for the next financing period is not known at this stage.⁶

1.2. The political and legal context

1.2.1. Shift in EU priorities and Horizon Europe framework

European priorities have evolved in the last decades, and reflect the social, economic, and environmental challenges for the EU in the face of global developments. In her Political Guidelines for the new European Commission 2019 – 2024⁷, the new Commission President put forward six overarching priorities, which reach well beyond 2024 in scope⁸. Together with the Sustainable Development Goals (SDGs), these priorities will shape future EU policy responses to the challenges Europe faces, and thus also give direction to EU research and innovation.

As part of the Multi-annual Financial Framework (MFF) 2021-27 the new EU Framework Programme for Research and Innovation Horizon Europe will play a pivotal role for Europe to lead the social, economic, and environmental transitions needed to achieve these European policy priorities. It will be more impact driven with a strong focus on delivering European added value, but also be more effective and efficient in its implementation. Horizon Europe finds its rationale in the daunting challenges that the EU is facing, which call for "a radical new approach to developing and deploying new technologies and innovative solutions for citizens and the planet on a scale and at a speed never achieved before, and to adapting our policy and economic framework to turn global threats into new opportunities for our society and economy, citizens and businesses." While Horizon Europe continues the efforts of strengthening the scientific and technological bases of the Union and foster competitiveness, a more strategic and impact-based approach to EU R&I investment is taken. Consequently, the objectives of Horizon Europe highlight the need to deliver on the Union strategic priorities and contribute to the realisation of EU objectives and policies, contribute to tackling global challenges, including the Sustainable Development Goals by following the principles of the Agenda 2030 and the Paris Agreement. 10

In this context, at least 35 % of the expenditure from actions under the Horizon Europe Programme will have to contribute to climate action. Furthermore, a Strategic Plan is co-designed with stakeholders to identify key strategic orientations for R&I support for 2021-2024 in line with the EU priorities. In the Orientations towards the first Strategic Plan

⁶ EU budget commitments to the European Partnership candidates can only be discussed and decided following the political agreement on the overall Multiannual Financial Framework and Horizon Europe budgetary envelopes. The level of EU contribution for individual partnerships should be determined once there are agreed objectives, and clear commitments from partners. Importantly, there is a ceiling to the partnership budgets in Pillar II of Horizon Europe (the legal proposal specifies that *the majority of the budget in pillar II shall be allocated to actions outside of European Partnerships*).

⁷ https://ec.europa.eu/info/strategy/priorities-2019-2024_en

⁸ 1.A European Green Deal; An economy that works for people; A Europe fit for the Digital Age; Promoting our European way of life; A Stronger Europe in the World; and 6.A New push for European Democracy

⁹ EC (2018) A Modern Budget for a Union that Protects, Empowers and Defends. The Multiannual Financial Framework for 2021-2027. Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, COM(2018) 321 final

¹⁰ Article 3, Common understanding regarding the proposal for Horizon Europe Framework Programme.

for Horizon Europe, the need to strategically prioritise and "direct a substantial part of the funds towards the areas where we believe they will matter the most" is emphasised. The Orientations specify, that actions under Pillar II of Horizon Europe "Global Challenges and European Industrial Competitiveness" will target only selected themes of especially high impact that significantly contribute to delivering on the political priorities of the Union. Most of the candidate European Partnerships fall under this Pillar.

1.2.2. Key evolutions in the approach to partnerships in Horizon Europe

Since their start in 1984 the successive set of Framework Programmes uses a variety of instruments and approaches to support R&I activities, address global challenges and industrial competitiveness. Collaborative, competition-based and excellence-driven R&I projects funded through Work Programmes are the most traditional and long-standing approach for implementation. Since 2002, available tools also include **partnerships**, whereby the Union together with private and/or public partners commit to jointly support the development and implementation of a R&I programme. These were introduced as part of creating the European Research Area (ERA) to align national strategies and overcome fragmentation of research effort towards an increased scientific, managerial and financial integration of European research and innovation. Interoperable and integrated national research systems would allow for better flows of knowledge, technology and people. Since then, the core activities of the partnerships consist of building critical mass mainly through collaborative projects, jointly developing visions, and setting strategic agendas.

As analysed in the **interim evaluation of Horizon 2020**¹¹, a considerable repertoire of partnership initiatives have been introduced over time, with 8 forms of implementation ¹² and close to 120 partnership initiatives running under Horizon 2020 - without clear exit strategies and concerns about their degree of coherence, openness and transparency. Even if it is recognised that these initiatives allow setting long-term agendas, structuring R&I cooperation between otherwise dispersed actors, and leveraging additional investments, the evaluation points to the complexity generated by the proliferation of instruments and initiatives, and their insufficient contribution to policies at EU and national level.

¹¹ Interim evaluation of Horizon 2020, Commission Staff Working Document, SWD(2017)221 and 222

Interim evaluation of the Joint Undertakings operating under Horizon 2020 (Commission Staff Working Document, SWD(2017) 339); Evaluation of the Participation of the EU in research and development programmes undertaken by several Member States based on Article 185 of the TFEU, Commission Staff Working Document, SWD (2017)340)

¹² E.g. initiatives based on Article 187 (Joint Technology Initiatives), Article 185 TFEU, Contractual Public-Private Partnerships (cPPPs), Knowledge & Innovation Communities of the European Institute of Innovation & Technology (EIT-KICs), ERA-NETs, European Joint Programmes, and Joint Programming Initiatives.

Box 1 Key lessons from the interim evaluation of Horizon 2020 and R&I partnerships

- The **Horizon 2020 Interim Evaluation** concludes that the overall partnership landscape has become overly complex and fragmented. It identifies the need for rationalisation, improve their openness and transparency, and link them with future EU R&I missions and strategic priorities.
- The **Article 185 evaluation** finds that these public-public partnerships have scientific quality, global visibility and networking/structuring effects, but should in the future focus more on the achievement of policy impacts. From a systemic point of view, it found that the EU public-to-public cooperation (P2P) landscape has become crowded, with insufficient coherence.
- The **Article 187 evaluation** points out that Public-Private Partnership (PPP) activities need to be brought more in line with EU, national and regional policies, and calls for a revision of the Key Performance Indicators. As regards the **contractual PPPs** (**cPPPs**) their reviews identified challenges of coherence among cPPPs and the need to develop collaborations and synergies with other relevant initiatives and programmes at EU, national and regional level.

Over 80% of respondents to the Open Public Consultation (OPC) indicated that a significant contribution by future European Partnerships is 'fully needed' to achieve climate-related goals, to develop and effectively deploy technology, and for EU global competitiveness in specific sectors/domains. Views converged across all categories of respondents, including citizens, industry and academia.

The impact assessment of Horizon Europe identifies therefore the need to rationalise the EU R&I funding landscape, in particular with respect to partnerships, as well as to reorient partnerships towards more impact and delivery on EU priorities. To address these concerns and to realise the higher ambition for European investments, Horizon Europe puts forward a major simplification and reform for the Commission's policy on R&I partnerships¹³. Reflecting its pronounced systemic nature aimed at contributing to EU-wide 'transformations' towards the sustainability objectives, Horizon Europe indeed intends to make a more effective use of these partnerships with a more strategic, coherent and impact-driven approach. Key related changes that apply to all forms of European Partnerships encapsulated in Horizon Regulation are summarised in the Box below.

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¹³ Impact assessment of Horizon Europe, Commission Staff Working Document, SWD(2018)307.

Box 2 Key features of the revised policy approach to R&I partnerships under Horizon Europe based on its impact assessment

- ✓ **Simpler architecture & toolbox** by streamlining 8 partnership instruments into 3 implementation forms (Co-Funded, Co-Programmed, Institutionalised), under the umbrella 'European Partnerships'
- ✓ More systematic and transparent approach to selecting, implementing, monitoring, evaluating and phasing out all forms of partnerships (criteria for European Partnerships):
 - The selection of Partnerships is embedded in the strategic planning of Horizon Europe, thereby ensuring coherence with the EU priorities. The selection criteria require that partnerships are established with stronger ex-ante commitment and higher ambition.
 - The implementation criteria stipulate that initiatives adopt a systemic approach in achieving impacts, including broad engagement of stakeholders in agenda-setting and synergies with other relevant initiatives to promote the take-up of R&I results.
 - A harmonised monitoring & evaluation system will be implemented, and ensures that progress is analysed in the wider context of achieving Horizon Europe objectives and EU priorities.
 - All partnerships need to develop an exit strategy from Framework Programme funding. This new approach is underpinned by principles of openness, coherence and EU added value.

✓ Reinforced impact orientation:

- Partnerships are established only if there is evidence they support achieving EU policy objectives
 more effectively than other Horizon Europe actions, by demonstrating a clear vision and targets
 (directionality) and corresponding long-term commitments from partners (additionality).
- European Partnerships are expected to provide mechanisms based on a concrete roadmap to join
 up R&I efforts between a broad range of actors towards the development and uptake of innovative
 solutions in line with EU priorities, serving the economy and society, as well as scientific progress.
- They are expected to develop close synergies with national and regional initiatives, acting as dynamic change agents, strengthening linkages within their respective ecosystems and along the value chains, as well as pooling resources and efforts towards the common EU objectives.

Under Horizon Europe, a 'European Partnership'¹⁴ is defined as "an initiative where the Union, prepared with early involvement of Member States and/or Associated Countries, together with private and/or public partners (such as industry, universities, research organisations, bodies with a public service mission at local, regional, national or international level or civil society organisations including foundations and NGOs), commit to jointly support the development and implementation of a programme of research and innovation activities, including those related to market, regulatory or policy uptake."

The Regulation further specifies that European Partnerships shall adhere to the "principles of Union added value, transparency, openness, impact within and for Europe, strong leverage effect on sufficient scale, long-term commitments of all the involved parties, flexibility in implementation, coherence, coordination and complementarity with Union, local, regional, national and, where relevant, international initiatives or other partnerships and missions."

1.3. Why should the EU act

1.3.1. Legal basis

Proposals for Institutionalised European Partnerships are based on:

1) Article 185 TFEU which allows the Union to make provision, in agreement with the Member States concerned, for participation in research and development

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¹⁴ Article 8 and Annex III of the Horizon Europe Regulation (common understanding)

- programmes undertaken by several Member States, including participation in the structures created for the execution of those programmes; or
- 2) Article 187 TFEU according to which the Union may set up joint undertakings or any other structure necessary for the efficient execution of Union research, technological development and demonstration programmes.¹⁵

1.3.2. Subsidiarity

The EU should act only in areas where there is demonstrable advantage that the action at EU level is more effective than action taken at national, regional or local level. Research is a shared competence between the EU and its Member States according to the TFEU. Article 4 (3) specifies that in the areas of research, technological development and space, the EU can carry out specific activities, including defining and implementing programmes, without prejudice to the Member States' freedom to act in the same areas. The candidate initiatives focus on areas where there is a demonstrable value added in acting at the EU level due to the scale, speed and scope of the efforts needed for the EU to meet its long-term Treaty objectives and deliver on its strategic policy priorities and commitments. In addition, the proposed initiatives should be seen as complementary and reinforcing national and subnational activities in the same area. Overall European Partnerships find their **rationale in addressing a set of systemic failures**¹⁶:

- Their primary function is to create a platform for a strengthened **collaboration** and knowledge exchange between various actors in the European R&I system and an enhanced **coordination** of strategic research agendas and/or R&I funding programmes. They aim to address **transformational failures** to better align agendas and policies of public and private funders, pool available resources, create critical mass, avoid unnecessary duplication of efforts, and leverage sufficiently large investments where needed but hardly achievable by single countries.
- The concentration of efforts and pooling of knowledge on common priorities to solve multi-faceted societal and economic challenges is at the core of these initiatives. Specifically, enhanced cross-disciplinary and cross-sectoral collaboration and an improved integration of value chains and ecosystems are among the key objectives of these instruments. In the light of Horizon Europe, the aim is to **drive system transitions and transformations towards EU priorities**.
- Especially in fast-growing technologies and sectors such as ICT, there is a need to **react to emerging opportunities** and address systemic failures such as shortage in skills or critical mass or cross-sectoral cooperation along the value chains that would hamper attainment of future European leadership and/or strategic autonomy.
- They also aim to address **market failures** predominantly to enhancing industry investments thanks to the sharing of risks.

2. THE CANDIDATE EUROPEAN PARTNERSHIPS – WHAT NEEDS TO BE DECIDED

2.1. Portfolio of candidates for Institutionalised European Partnerships

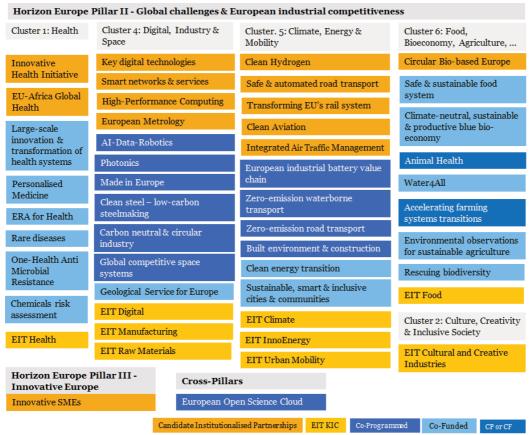
The new approach for more objective-driven and impactful European Partnerships is reflected in the way candidate Partnerships have been identified. It involved a co-design

¹⁵ Both Articles are under Title XIX of the TFEU - Research and Technological Development and Space.

¹⁶ The Interim Evaluation of Horizon 2020 and the impact assessment of Horizon Europe provide qualitative and quantitative evidence on these points. Sections 1 and 2 of each impact assessment on candidate European Partnerships include more detail on the necessity to act at EU level in specific thematic areas.

exercise aiming to better align these initiatives with societal needs and policy priorities, while broadening the range of actors involved. Taking into account the 8 areas for Institutionalised European Partnerships set out in the Horizon Europe Regulation¹⁷, a codesign exercise as part of the Strategic Planning process of Horizon Europe lead to the identification of 49 candidates for Co-funded, Co-programmed or Institutionalised European Partnerships¹⁸. Out of these, 13 were identified as suitable candidate Institutionalised Partnerships because of their objectives and scope¹⁹. Whilst the Co-Funded and Co-Programmed Partnerships are linked to the comitology procedure (including the adoption of the Strategic Plan and the Horizon Europe Work Programmes), Institutionalised Partnerships require the adoption of legislation and are subject to an impact assessment. The Figure below gives an overview of all candidate European Partnerships according to their primary relevance to Commission priorities for 2019-2024.

Figure 1 - Overview of the candidates for Co-Funded, Co-Programmed and Institutionalised European Partnerships according to Horizon Europe structure



Source: Technpolis group (2020)

There are only three partnerships for which implementation as an Institutionalised Partnership under Article 185 is an option, i.e. European Metrology, the EU-Africa Global Health partnership, and Innovative SMEs. Ten partnerships are candidates for

¹⁷ Horizon Europe Regulation (common understanding), Annex Va.

¹⁸ Shadow configuration of Strategic Programme Committee for Horizon Europe. The list of candidate European Partnerships is described in "Orientations towards the Strategic Plan of Horizon Europe" - Annex 7

¹⁹ Only 12 are subject to this impact assessment, as one initiative on High Performance Computing has already been subject to an impact assessment in 2017 (SEC(2018) 47)

Institutionalised Partnerships under Article 187. Overall the initiatives can be categorised into 'horizontal' partnerships and 'vertical' partnerships.

The 'horizontal' partnerships have a central position in the overall portfolio, as they are expected to develop methodologies and technologies for application in the other priority areas, ultimately supporting European strategic autonomy in these areas as well as technological sovereignty. These 'horizontal' partnerships are typically proposed as Institutionalised or Co-programmed Partnerships, in addition to a number of EIT KICs, they cover mainly the digital field in addition to space, creative industries and manufacturing, but also the initiative related to Innovative SMEs. 'Vertical' partnerships are focused on the needs and development of specific application areas, and are primarily expected to support enhanced environmental sustainability thereby addressing Green Deal related objectives. They also deliver on policies for more people centred economy, through improved wellbeing of EU citizen and the economy, like health related candidate European Partnerships.

2.2. Assessing the necessity of a European Partnership and possible options for implementation

Horizon Europe Regulation Article 8 stipulates that Institutionalised European Partnerships based on Article 185 and 187 TFEU shall be implemented only where other parts of the Horizon Europe programme, including other forms of European Partnerships would not achieve the objectives or would not generate the necessary expected impacts, and if justified by a long-term perspective and high degree of integration. At the core of this impact assessment is therefore the need to demonstrate that the impacts generated through a Partnership approach go beyond what could be achieved with traditional calls under the Framework Programme – the Baseline Option. Secondly, it needs to assess if using the Institutionalised form of a Partnership is justified for addressing the priority.

For all candidate Institutionalised European Partnerships the options considered in this impact assessment are the same, i.e.:

- Option 0 Baseline option Traditional calls under the Framework Programme
- Option 1 Co-programmed European Partnership
- Option 2 Co-funded European Partnership
- Option 3 Institutionalised Partnership
 - Sub-option 3a Institutionalised Partnerships based on Art 185 TFEU
 - o Sub-option 3b Institutionalised Partnerships based on Art 187 TFEU

2.2.1. *Option 0 - Baseline option – Traditional calls*

Under this option, strategic programming for R&I in the priority area will be done through the mainstream channels of Horizon Europe. The related priorities will be implemented through **traditional calls** of Horizon Europe covering a range of actions, mainly R&I and/or innovation actions but also coordination and support actions, prizes or procurement. Most actions involve consortia of public and/or private actors in ad hoc combinations, while some actions are single actor (mono-beneficiary). There will be no dedicated implementation structure and no support other than what is foreseen in the related Horizon Europe Work Programme. This means that discontinuation costs/benefits of predecessor initiatives should be factored in for capturing the baseline situation when relevant.

Under this option, strategic planning mechanisms in the Framework Programme will allow for a high level of flexibility in the ability of traditional calls to respond to particular needs over time, building upon additional input in co-creation from stakeholders and programme committees involving Member States. The Union contribution to addressing the priority covers the full duration of the initiative, during the lifetime of Horizon Europe. Without a formal EU partnership mechanism, it is less likely that the stakeholders will develop a joint Strategic Research Agenda and commit to its implementation or agree on mutual commitments and contributions outside their participation in funded projects.

2.2.2. European Partnerships

Under this set of options, three different forms of implementation are assessed: Co-funded, Co-Programmed, Institutionalised European Partnerships. These have **commonalities that cannot serve as a distinguishing factor in the impact assessment process**. They are all based on agreed objectives and expected impacts and underpinned by Strategic Research and Innovation Agendas / roadmaps that are shared and committed to by all partners in the partnership. They all have to follow the same set of criteria along their lifecycle, as defined in the Horizon Europe Regulation (Annex III), including ex ante commitment from partners to mobilise and contribute resources and investments. The Union contribution is defined for the full duration of the initiative for all European Partnerships. The Horizon Europe legal act introduces few additional requirements for Institutionalised Partnerships, e.g. the need for long-term perspective, strong integration of R&I agendas, and financial contributions.

Figure 2 - Key differences in preparation and implementation of European Partnerships

Туре	Legal form	Implementation		
Co-Programmed	Contractual arrangement / MoU	Division of labour , whereby Union contribution is implemented through Framework rogramme and partners' contributions under their responsibility.		
Co-Funded	Grant Agreement	Union provides co-funding for an integrated programme with distributed implementation by entities managing and/or funding national research and innovation programmes		
Institutionalised	Basic act (Council regulation,	Integrated programme with centralised		
based on Article	Decision by European	implementation		
185/187 TFEU	Parliament and Council)			

The main differences between the different forms of European Partnerships are in their preparation and in the way they function, as well as in the overall impact they can trigger. The Co-Programmed form is assessed as the simplest, and the Institutionalised the most complex to prepare and implement. The functionalities of the different form of Partnerships – compared to the baseline option – are presented in Figure 3. They relate to the types of actors Partnerships can involve and their degree of openness, the types of activities they can perform and their degree of flexibility, the degree of commitment of partners and the priority setting system, and their ability to work with their external environment (coherence), etc. These key distinguishing factors will be at the basis of the comparison of each option to determine their overall capacity to deliver what is needed at a minimised cost.

Figure 3 Overview of the functionalities provided by each form of European Partnerships, compared to the traditional calls of Horizon Europe (baseline)

		Option 3b: Institutionalised Art 187					
Europe calls Programmed nalised Art 185 Institutionalised Art 187 Type and composition of actors (including openness and roles)							
Partners: Suitable for all types: private and/or public partners, foundations	Partners: core of national funding bodies or govern-mental research organisations	Partners: National funding bodies or governmental research organisation	Partners: Suitable for all types: private and/or public partners, foundations				
by partners, open stakeholder consultation, MS in comitology Participation in R&I activities: fully open in line with Horizon Europe rules	by partners, open stakeholder consultation Participation in R&I activities: limited, according to national rules of partner countries lity and level of integrat	Driven by partners, open stakeholder consultation Participation in R&I activities: fully open in line with Horizon Europe rules, but possible derogations ion)	Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: fully open in line with Horizon Europe rules, but possible derogations Activities: Horizon				
Europe standard actions that allow broad range of individual actions, support to market, regulatory or policy/societal uptake Additionality: Activities/investments of partners, National funding Limitations: Limited systemic approach beyond individual actions	according to rules/programmes of participating States, State-aid rules, support to regulatory or policy/ societal uptake Additionality: National funding Limitations: Scale & scope depend on participating programmes, often smaller in scale	Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to systemic approach Additionality: National funding	Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to systemic approach (portfolios of projects, scaling up of results, synergies with other funds. Additionality: Activities/investments of partners/ national funding				
and directionality							
Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Input to FP annual work programme drafted by partners, finalised by EC (comitology) Objectives & commitments set in contractual arrangement	Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Annual work programme drafted by partners, approved by EC Objectives & commitments set in Grant Agreement	Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Annual work programme drafted by partners, approved by EC Objectives & commitments set in legal act mes. national program	Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Annual work programme drafted by partners, approved by EC (vetoright in governance) Objectives & commitments set in legal act				
orizon Barope, & externa	n (other Omon program	mes, national program	inics, muustitai				
Internal: Coherence among partnerships & with parts of the FP Annual Work programme can be ensured by partners & EC External: Limited synergies with other Union programmes & industrial strategies. If MS participate, with national/regional	Internal: Coherence among partnerships & with parts of the FP Annual Work programme can be ensured by partners & EC External: Synergies with national/ regional programmes & activities	Internal: Coherence among partnerships & with parts of the FP Annual Work programme can be ensured by partners & EC External: Synergies with national/regional programmes & activities	Internal: Coherence among partnerships & with parts of the FP Annual Work programme can be ensured by partners & EC External: Synergies with other Union programmes and industrial strategies If MS participate, with national/ regional				
	Partners: Suitable for all types: private and/or public partners, foundations Priority setting: Driven by partners, open stakeholder consultation, MS in comitology Participation in R&I activities: fully open in line with Horizon Europe rules vities (including additiona Activities: Horizon Europe standard actions that allow broad range of individual actions, support to market, regulatory or policy/ societal uptake Additionality: Activities/investments of partners, National funding Limitations: Limited systemic approach beyond individual actions s and directionality Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Input to FP annual work programme drafted by partners, finalised by EC (comitology) Objectives & commitments set in contractual arrangement Internal: Coherence among partnerships & with parts of the FP Annual Work programme can be ensured by partners & EC External: Limited synergies with other Union programmes & industrial strategies. If	Partners: Suitable for all types: private and/or public partners, foundations Priority setting: Driven by partners, open stakeholder consultation, MS in comitology Participation in R&I activities: fully open in line with Horizon Europe rules Activities (including additionality and level of integrat Activities: Horizon Europe standard actions that allow broad range of individual actions, support to market, regulatory or policy/societal uptake Additionality: Activities/investments of partners, National funding Limitations: Limited systemic approach beyond individual actions s and directionality Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Input to FP annual work programme drafted by partners, finalised by EC (comitology) Objectives & commitments set in contractual arrangement Internal: Coherence among partnerships & with parts of the FP Annual Work programme can be ensured by partners & EC External: Limited synergies with other Union programmes & industrial strategies. 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Activities: Horizon Europe standard actions that allow broad range of individual actions, support to market, regulatory or policy/societal uptake Additionality: Additionality: Priority setting: Driven by partners, open stakeholder consultation Activities: Horizon Europe standard actions that allow broad range of individual actions, support to market, regulatory or policy/societal uptake Additionality: Additionality: Priority setting: Driven by partners, open stakeholder consultation Activities: Horizon Europe standard actions of unites support to market, regulatory or policy/societal uptake Additionality: Additionality: Priority setting: Driven by partners, open stakeholder consultation Europe standard actions of unites support to regulatory or policy/societal uptake, support to regulatory or policy/societal uptake, possibility to or policy/societal uptake, possibility to pen in line with Horizon Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to pen in line with Horizon Europe standard actions of uniting states, support to regulatory or policy/societal uptake, possibility to pen in line with Horizon Europe standard actions or regulatory or policy/societal uptake, support to regulatory or policy/societal uptake. Additionality: Priority setting: Driven by partners & EC, covering usually 7 years, incl. allocation of Union contribution Annual work programme drafted by partners, approved by EC Covering usually 7 years, incl. allocation of Union c				

Baseline: Horizon Europe calls	Option 1: Co- Programmed	Option 2: Co-Funded	Option 3a: Institutio- nalised Art 185	Option 3b: Institutionalised Art 187	
activities	programmes & activities			programmes & activities	

2.2.2.1. Option 1 - Co-programmed European Partnership

This form of European Partnership is **based upon a Memorandum of Understanding or a Contractual Arrangement** signed by the Commission and the private and/or public partners. Private partners are represented by industry associations, which also support the daily management of the partnership. This type of partnership would allow for a large degree of flexibility for the activities, partners and priorities to continuously evolve. The commitments of partners are political efforts described in the contractual arrangement and the contributions from partners are provided in kind more than financially. The priorities for the calls, proposed by the Partnership's members for integration in the Horizon Europe's Work Programmes, are subject to further input from Member States (comitology) and Commission services. The Union contribution is implemented within the executive agency managing Horizon Europe calls for research and innovation projects proposals. The full array of Horizon Europe instruments can be used, ranging from research and innovation (RIA) types of actions to coordination and support actions (CSA) and including grants, prizes, and procurement.

2.2.2.2. Option 2 – Co-funded European Partnership

The Co-funded European Partnership is **based on a Grant Agreement** between the Commission and a consortium of partners, resulting from a specific call in the Horizon Europe Work Programme. This form of implementation only allows to address public partners at its core. Typically these provide co-funding to a common programme of activities established and/or implemented by entities managing and/or funding national R&I programmes. The recipients of the EU co-funding implement the initiative under their responsibility, with national funding/resources pooled to implement the programme with co-funding from the Union. The expectation is that these entities would cover most if not all EU Member States. Calls and evaluations would be organised centrally, beneficiaries in selected projects would be funded at national level, following national funding rules.

2.2.2.3. Option 3 – Institutionalised European Partnership

This type of Partnership is the most complex and high-effort arrangement, and requires meeting additional requirements. Institutionalised European Partnership are based on a Council Regulation (Article 187 TFEU or a Decision by the European Parliament and Council (Article 185 TFEU) and are implemented by dedicated structures created for that purpose. These regulatory needs limit the flexibility for a change in the core objectives, partners, and/or commitments as these would require amending legislation.

The basic rationale for this type of partnership is the need for a strong integration of R&I agendas in the private and/or public sectors in the EU in order to address a strategic challenge. It is therefore necessary to demonstrate that other forms of implementation would not achieve the objectives or would not generate the necessary expected impacts, and that a long-term perspective and high degree of integration is needed. For both Article 187 and 185 initiatives, contributions from partners can be in the form of financial and in-kind contributions. Eligibility for participation and funding follows by default the rules of Horizon Europe, unless a derogation is introduced in the basic act.

Option 3a - Institutionalised Partnerships based on Article 185 TFEU

Article 185 of the TFEU allows the Union to participate in programmes jointly undertaken by Member States and limits therefore the scope to **public partners** which are Member States and Associated Third Countries. This type of Institutionalised Partnership aims therefore at reaching the greatest possible impact through the integration of national and EU funding, aligning national strategies in order to optimise the use of public resources and overcome fragmentation of the public research effort. It brings together R&I governance bodies of most if not all EU Member States (legal requirement: at least 40% of Member States) as well as Associated Third Countries that designate a legal entity (Dedicated Implementation Structure) of their choice for the implementation. By default, participation of non-associated Third Countries is not foreseen. Such participation is possible only if it is foreseen in the basic act and subject to conclusion of an international agreement.

Option 3b - Institutionalised Partnerships based on Article 187 TFEU

Article 187 of the TFEU allows the Union to set up joint undertakings or any other structure necessary for the efficient execution of EU research, technological development and demonstration programmes. This type of Institutionalised Partnership brings together a stable set of **public and private partners** with a strong commitment to taking a more integrated approach and requires the set-up of a dedicated legal entity (Union body, Joint Undertaking (JU)) that carries full responsibility for the management of the Partnership and implementation of the calls. Different configurations are possible:

- Partnerships focused on creating strategic industrial partnerships where, most often, the partner organisations are represented by one or more industry associations, or in some cases individual private partners;
- Partnerships coordinating national ministries, public funding agencies, and governmental research organisations in the Member States and Associated Countries;
- Or a combination of the two: the so-called tripartite model.

Participation of non-associated Third Countries is only possible if foreseen in the basic act and subject to conclusion of an international agreement.

2.3. Overview of the methodology adopted for the impact assessment

The methodology for each impact assessment is based on the Commission Better Regulation Guidelines²⁰ to evaluate and compare options with regards to their efficiency, effectiveness and coherence. This also integrates key selection criteria for European Partnerships.

Box 2 Summary of European Partnerships selection criteria²¹

- *Effectiveness* in achieving the related objectives and impacts of the Programme;
- Coherence and synergies of the European Partnership within the EU R&I landscape;
- *Transparency* & *openness* as regards the identification of priorities and objectives and the involvement of partners & stakeholders from the entire value chain, backgrounds & disciplines;
- Ex-ante demonstration of *additionality* and *directionality*;
- Ex-ante demonstration of the partners' *long term commitment*.

²¹ For a comprehensive overview of the selection criteria for European Partnerships, see Annex 6.

²⁰ European Commission (2017), Better Regulation Guidelines (SWD (2017) 350)

2.3.1. Overview of the methodologies employed

In terms of methods and evidence used, the impact assessments draw on an external study covering all candidate Institutionalised European Partnerships in parallel to ensure a high level of coherence and comparability of analysis, in addition to an horizontal analysis. 22 For all initiatives, the understanding of the overall context of the candidate institutionalised European Partnerships relied on desk research, including among others the lessons learned from previous partnerships. This was complemented by the analysis of a range of quantitative and qualitative evidence, including evaluations of past and ongoing initiatives; foresight studies; statistical analyses of Framework Programmes application and participation data, and Community Innovation Survey data; analyses of science, technology and innovation indicators; reviews of academic literature; sectoral competitiveness studies and expert hearings. The analyses included a portfolio analysis, a stakeholder and social network analysis in order to profile the actors involved as well as their co-operation patterns, and an assessment of the partnerships' outputs (bibliometrics and patent analysis). A cost modelling exercise was performed in order to feed into the efficiency assessments of the partnership options, as described below. Public consultations (both open and targeted) supported the comparative assessment of the policy options. For each initiative, up to 50 relevant stakeholders were interviewed by the external contractor (policymakers, business including SMEs and business associations, research institutes and universities, and civil organisations, among others). In addition, the analysis was informed by the results of the Open Public Consultation run between September and November 2019, the consultation of Member States through the Strategic Programme Committee and the online feedback received on the Inception Impact Assessments of the set of initiatives.

A more detailed description of the methodology and evidence base that were mobilised, completed by thematic specific methodologies, is provided in Annexes 4 and 6.

2.3.2. Method for identifying the preferred option

The first step of the assessments consisted in scoping the problems that the initiatives are expected to solve given the overall economic, technological, scientific and social context, including the lessons to be learned from past and ongoing partnerships on what worked well and less well. This supported the identification of the objectives of the initiative in the medium and long term with the underlying intervention logic – showing how to get there.

Given the focus of the impact assessment on comparing different forms of implementation, the Better Regulation framework has then been adapted to introduce "key functionalities needed" - making the transition between the definition of the objectives and what would be crucial to achieve them *in terms of implementation*. The identification of "key functionalities needed" for each initiative as an additional step in the impact assessment is based on the distinguishing factors between the different options (see Section 2.2.1). In practical terms, each option is assessed on the basis of the degree to which it would allow for the key needed functionalities to be covered, as regards e.g. the type and composition of actors that can be involved ('openness'), the range of activities that can be performed (including additionality and level of integration), the level of directionality and integration of R&I strategies; the possibilities offered for coherence and synergies with other components of Horizon Europe, including other Partnerships (internal coherence), and the coherence with the wider policy environments, including with the relevant regulatory and standardisation framework

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²² Technopolis Group (2020), Impact Assessment Study for Institutionalised European Partnerships under Horizon Europe, Final Report, Study for the European Commission, DG Research & Innovation

(external coherence). This approach guides the identification of discarded options while allowing at the same time a structured comparison of the options not only as regards their effectiveness, efficiency and coherence, but also against a set of other key selection criteria for European Partnerships (openness, transparency, directionality)²³.

In line with the Better Regulation Framework, the assessment of the effectiveness, efficiency and coherence of each option is made compared to the baseline. Therefore, for each of these aspects the performance of using traditional calls under Horizon Europe is first estimated and scored 0 to serve as a reference point. This includes the discontinuation costs/benefits of existing implementation structures when relevant. The policy options are then scored compared to the baseline with a + and – system with a two-point scale, to show a slightly or highly additional/lower performance compared to the baseline. A scoring of 0 of a policy option means that it would deliver as much as the baseline option.

On the basis of the evidence collected, the intervention logic of each initiative and the key functionalities needed, the impact assessments first evaluate the **effectiveness** of the various policy options to deliver on their objectives. To be in line with the Horizon Europe impact framework, the fulfilment of the specific objectives of the initiative is translated into 'expected impacts' - how success would look like -, differentiating between scientific, economic/ technological, and societal (including environmental) impacts. Each impact assessment considers to which extent the different policy options provides the 'key functionalities needed' to achieve the intended objectives. The effectiveness assessment does not use a compound score but shows how the options would deliver on the different types of expected impacts. This is done to increase transparency and accuracy in the assessment of options²⁴.

A similar approach is followed to evaluate the coherence of options with the overarching objectives of the EU's R&I policy, and distinguishes between **internal** and **external coherence**. Specifically, internal coherence covers the consistency of the activities that could be implemented with the rest of Horizon Europe, including European Partnerships (any type). External coherence refers to the potential for synergies and/or complementarities (including risks of overlaps/gaps) of the initiative with its external environment, including with other programmes under the MFF 2021-27, but also the framework conditions at European, national or regional level (incl. regulatory aspects, standardisation).

To compare the expected costs and benefits of each option (efficiency), the thematic impact assessments broadly follow a cost-effectiveness approach²⁵ to establish to which extent the intended objectives can be achieved for a given cost. A preliminary step in this process is to obtain a measure of the expected costs of the policy options, to be used in the thematic assessments. As the options correspond to different implementation modes, relevant cost categories generally include the costs of setting-up and running an initiative. For instance, set-up costs includes items such as the preparation of a European Partnership proposal and the preparation of an implementation structure. The running costs include the annual work programme preparation costs. Where a Partnership already exists, discontinuation costs and

²³ The criterion on the ex-ante demonstration of partners' long term commitment depends on a series of factors that are unknown at this stage, and thus fall outside the scope of the analysis.

²⁴ In the thematic impact assessments, scores are justified in a detailed manner to avoid arbitrariness and spurious accuracy. A qualitative or even quantitative explanation is provided of why certain scores were given to specific impacts, and why one option scores better or worse than others.

²⁵ For further details, see Better Regulation Toolbox # 57.

cost-savings are also taken into account²⁶. The table below provides an overview of the cost categories used in the impact assessment and a qualitative scoring of their intensity when compared to the baseline option (traditional calls). Providing a monetised value for these average static costs would have been misleading, because of the different features and needs of each candidate initiative.²⁷ The table shows the overall administrative, operational and coordination costs of the various options. These costs are then put into context in the impact assessments to reflect the expected co-financing rates and the total budget available for each of the policy options, assuming a common Union contribution (cost-efficiency):

- The costs related to the baseline scenario (traditional calls under Horizon Europe) are pre-dominantly the costs of implementing the respective Union contribution via calls and project, managed by the executive agencies (around 4%, efficiency of 96% for the overall investment).
- For a Co-Programmed partnership the costs of preparation and implementation increase only marginally compared to the baseline (<1%), but lead to an additional R&I investment of at least the same amount than the Union contribution²⁸ (efficiency of 98% for the overall investment).
- For a Co-Funded partnership the additional R&I investment by Member States accounts for 2,3 times the Union contribution²⁹. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the national programmes, can be estimated at 6% of the Union contribution (efficiency of 98% related to the overall investment).
- For an Article 185 initiative the additional R&I investment by Member States is equal to the Union contribution³⁰. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the dedicated implementation structure, can be estimated at 7% of the Union contribution (efficiency of 96% related to the overall investment).
- For an Article 187 initiative the additional R&I investment by partners is equal to the Union contribution³¹. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the dedicated implementation structure, can be estimated at 9% of the Union contribution (efficiency of 94% related to the overall investment).

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These costs are not monetised. While monetised cost figures are available for existing European Partnerships, they widely differ between each case, thus limiting meaningful comparability. Moreover, they are not readily applicable for new candidate initiatives. Instead, the analysis uses a static, common model of average real costs as a means to show the order of magnitude of efforts and reveal the principal differences between the options. Discontinuation costs will bear winding down and social discontinuation costs and vary depending on e.g. the number of full-time-equivalent (FTEs) staff concerned, the type of contract (staff category and duration) and applicable rules on termination (e.g. contracts under Belgian law or other). If buildings are being rented, the cost of rental termination also apply. As rental contracts are normally tied to the expected duration of the current initiatives, these termination costs are likely to be very limited. In parallel, there would also be financial cost-savings related to the closing of the structure, related to operations, staff and coordination costs in particular. This is developed further in the individual efficiency assessments.

²⁷ A complete presentation of the methodology developed to assess costs as well as the sources used is described in the external study supporting this impact assessment (Technopolis Group, 2020).

²⁸ Minimum contributions from partners equal to the Union contribution

²⁹ Based on the default funding rate for programme co-fund actions of 30%, partners contribute with 70% of the total investment.

³⁰ Based on the minimum requirement in the legal basis that partners contribute at least 50% of the budget.

³¹ Based on the minimum requirement in the legal basis that partners contribute at least 50% of the budget.

Figure 4 - Intensity of additional costs compared with Horizon Europe Calls (for Partners, stakeholders, public and EU)

Cost items	Baseline: traditional calls	Option 1: Coprogrammed	Option 2 Co-funded	Option 3a - Art. 185	Option 3b -Art. 187	
Preparation and set-up costs						
Preparation of a partnership proposal (partners and EC)	0	$\uparrow \uparrow$				
Set-up of a dedicated implementation structure		0		Existing: ↑ New: ↑↑	Existing: ↑↑ New: ↑↑↑	
Preparation of the SRIA / roadmap	0	$\uparrow \uparrow$				
Ex-ante Impact Assessment for partnership		0	$\uparrow \uparrow \uparrow$			
Preparation of EC proposal and negotiation	0			$\uparrow \uparrow \uparrow$		
Running costs (Annual cycle of implementation)						
Annual Work Programme preparation	0	↑				
Call and project implementation	0	0 In case of MS contributions: ↑	↑	1	↑	
Cost to applicants	Comparable, unless there are strong arguments of major differences in oversubscription				fferences in	
Partners costs not covered by the above	0	↑	0	↑	↑	
Additional EC costs (e.g. supervision)	0	\uparrow	↑	↑	$\uparrow \uparrow$	
Winding down costs						
EC	0				$\uparrow \uparrow \uparrow$	
Partners	0	↑	0	↑	↑	

Notes: 0: no additional costs, as compared with the baseline; \uparrow : minor additional costs, as compared with the baseline; $\uparrow \uparrow$: medium additional costs, as compared with the baseline; $\uparrow \uparrow \uparrow$: higher costs, as compared with the baseline.

The cost categories estimated for the common model are then used to develop a scorecard analysis and further refine the assessment of options for each of the 12 candidate Institutionalised Partnerships. Specifically, the scores related to the set-up and implementation costs are used in the thematic impact assessments to consider the scale of the expected benefits and thereby allow a simple "value for money" analysis (cost-effectiveness)³². In carrying out the scoring of options, the results of fieldwork, desk research and stakeholder consultation undertaken and taken into account.

For the **identification of the preferred option**, the scorecard analysis builds a hierarchy of the options by individual criterion and overall in order to identify a single preferred policy option or in case of an inconclusive comparison of options, a number of 'retained' options or hybrid. This exercise supports the systematic appraisal of alternative options across multiple types of monetary, non-monetary and qualitative dimensions. It also allows for easy visualisation of the pros and cons of each option. Each option is attributed a score of the adjudged performance against each criterion with the three broad appraisal dimensions of effectiveness, efficiency and coherence.

As a last step, the alignment of the preferred option with key criteria for the selection of European Partnerships is described, reflecting the outcomes of the 'necessity test'. 33 The

³²³² More details on the methodology can be found in Annex 24.

³³Certain aspects of the selection criteria will be further addressed/ developed at later stages, notably in the context of preparing basic acts (e.g. Openness and Transparency; Coherence and Synergies), in the Strategic Research and Innovation Agendas (e.g. Directionality and Additionality), and by collecting formal commitments (Ex-ante demonstration of partners' long-term commitment).

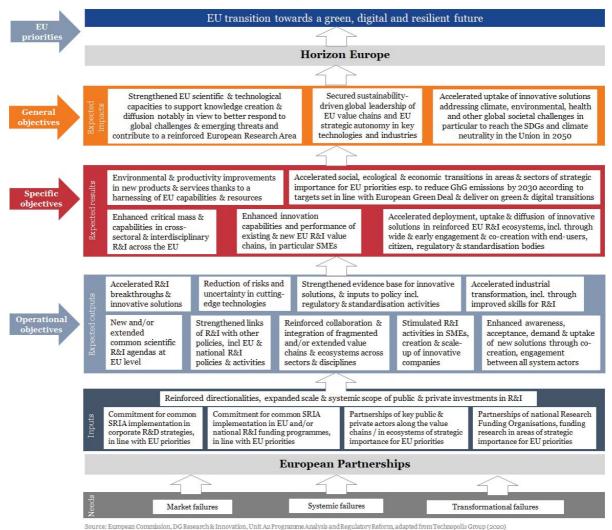
monitoring and evaluation arrangements are concluding the assessment, with an identification of the key indicators to track progress towards the objectives over time.

2.4. Horizontal perspective on candidate Institutionalised European Partnerships

2.4.1. Overall impact orientation, coherence and efficiency needs

The consolidated **intervention logic** for the set of candidate Institutionalised European Partnerships in the Figure below builds upon the objectives as reported in the individual impact assessments.

Figure 5 – Overall intervention logic of the European Partnerships under Horizon Europe



When analysed as a package the 12 candidate Institutionalised European Partnerships are expected to support the achievement of the European policy priorities targeted by Horizon Europe by pursuing the following joint general objectives:

- a) Strengthening and integrating EU scientific and technological capacities to support knowledge creation and diffusion notably in view to better respond to global challenges and emerging threats and contribute to a reinforced European Research Area;
- b) Securing sustainability-driven global leadership of EU value chains and EU strategic autonomy in key technologies and industries; and

c) Accelerate the uptake of innovative solutions addressing climate, environmental, health and other global societal challenges contributing to Union strategic priorities, in particular to reach the Sustainable Development Goals and climate neutrality in the Union in 2050.

In terms of specific objectives, they jointly aim to:

- a) Enhance the critical mass and scientific capabilities in cross-sectoral and interdisciplinary research and innovation across the Union;
- b) Accelerate the social, ecological and economic transitions in areas and sectors of strategic importance for Union priorities, in particular to reduce greenhouse gas emissions by 2030 according to the targets set in line with the European Green Deal, and deliver on the green and digital transition;
- c) Enhance the innovation capabilities and performance of existing and new European research and innovation value chains, in particular SMEs;
- d) Accelerate the deployment, uptake and diffusion of innovative solutions in reinforced European R&I ecosystems, including through wide and early engagement and co-creation with end-users, citizen and regulatory and standardisation bodies;
- e) Deliver environmental and productivity improvements in new products and services thanks to a harnessing of EU capabilities and resources.

In terms of their operations, taking a horizontal perspective on all initiatives allows for the identification of further possible collective efficiency and coherence gains for more impact:

- Coherence for impact: The extent and speed by which the expected results and impacts will be reached, will depend on the scale of the R&I efforts triggered, the profile of the partners involved, the strength of their commitments, and the scope of the R&I activities funded. To be fully effective it comes out clearly that future partnerships need to operate over their whole life cycle in full coherence with their environment, including potential end users, regulators and standardisation bodies. This relates also to the alignment with relevant EU, national or regional policies and synergies with R&I programmes. This needs to be factored in as of the design stage to ensure a wide take-up and/or deployment of the solutions developed, including their interoperability.
- Collaboration for impact: Effectiveness could also be improved collectively through enhanced cross-disciplinary and cross-sectoral collaboration and an improved integration of value chains and ecosystems. An adequate governance structure appears in particular necessary to ensure cross-fertilisation between all European Partnerships. This applies not only to initiatives where similar R&I topics are covered and/or the same stakeholders involved or targeted, but also to the interconnections needed between the 'thematic' and the 'vertical' Partnerships, as these are expected to develop methodologies and technologies for application in EU priority areas. Already at very early stages of preparing new initiatives, Strategic Research and Innovation Agendas and roadmaps need to be aligned, particularly for partnerships that develop enabling technologies that are needed in other Partnerships. The goal should be to achieve greater impacts jointly in light of common challenges.
- Efficiency for impact: Potential efficiency gains could also be achieved by joining up the operational functions of Joint Undertakings that do not have a strong context dependency and providing them through a common back-office³⁴. A number of

³⁴ See Annex 6 for an overview of the key functions/roles that could be provided by a common back office.

operational activities of the Joint Undertakings are of a technical or administrative nature (e.g. financial management of contracts), or procured from external service providers (e.g. IT, communication activities, recruitment services, auditing) by each Joint Undertaking separately. If better streamlined this could create a win-win situation for all partners leading to better harmonization, economies of scales, and less complexity in supervision and support by the Commission services.

2.4.2. Analysis of coherence of the overall portfolio of candidate initiatives at the thematic level

Looking at the coherence of the set of initiatives at the thematic level, the "digital centric" initiatives have a strong focus on supporting the digital competitiveness of the EU ecosystem. Their activities are expected to improve alignment and coordination with Member States and industry for the development of world-competitive EU strategic digital technology value chains and associated expertise. Addressing the Key Digital Technologies, the 5G and 6G connectivity needs as part of a Smart Networks and Services initiative and the underlying supercomputing capacities through a European High Performance Computing initiative present potential for synergies that can be addressed through cooperative actions (e.g. joint calls, coordinated support activities, etc.). They may as well profit from and contribute to Partnerships envisaged for Photonics, AI, data, robotics, Global competitive space system and Made in Europe, together with the EIT Digital. Synergies between these initiatives and several programmes (Digital Europe and Connecting Europe as well as cohesion programmes) are needed in areas where EU industry has to develop leadership and competitiveness in the global digital economy. They are expected to impact critical value chains including on sectors where digital is a strong enabler of transformation (health, industrial manufacturing, mobility/transport, etc.).

The transport sector face systemic changes linked to decarbonisation and digitalisation. Large scale R&I actions are needed to provide cleaner, safer, and economically viable services for citizens and businesses, with digitalisation and automation as enablers. Past decades have shown that developing and implementing change is difficult in transport due to its systemic nature, many stakeholders involved, long planning cycles and large investments needed. A systemic change of the air traffic network through an Integrated Air Traffic Management initiative should ensure safety and sustainability of aviation, while a Clean Aviation initiative should focus on the competitiveness of tomorrow's clean aircrafts made in Europe. The initiative for Transforming Europe's rail system would comprehensively address the rail sector to confirm it as a cornerstone in tomorrow's clean and efficient doorto-door transport services, affordable for every citizen as well as the most climate-friendly mode of transport, and becoming more attractive for passengers and freight. Connected and Automated Mobility is the future of road transport, but Europe is threatened to fall behind other global regions with strong players and large harmonised markets. The initiative Safe and Automated Road Transport would bring stakeholders together, creating joint momentum in digitalising road transport and developing new user-based services. Stronger links and joint actions will be established between initiatives to enable common progress wherever possible. The Clean Hydrogen initiative would be fundamental to that regard. Synergies would also be sought with partnerships driving the digital technological developments.

To deliver a deep decarbonisation of highly emitting industrial sectors such as the steel, transport and chemical industries would require the production, distribution and storage of **hydrogen** at scale. The candidate hydrogen initiative would have a central positioning in terms of providing solutions to the challenges for sustainable mobility and energy, but also is expected to operate in synergies with other industry related initiatives. The initiative

would interact in particular with initiatives on the zero emission road and water transport, transforming Europe's railway system, clean aviation, batteries, circular industry, clean steel and built environment partnerships. There are many opportunities for collaboration for the delivery and end-use of hydrogen. However, the Clean Hydrogen initiative would be the only partnership focused on addressing hydrogen production technologies.

Metrology, the science of measurement, is an enabler across all domains of R&I. It supports the monitoring of the Emissions Trading System, smart grids and pollution, but also contributes to meeting demands for measurement techniques from emerging digital technologies and applications. More generally, emerging technologies across a wide range of fields from biotechnologies, new materials, health diagnostics or low carbon technologies are giving rise to demands requiring a world-leading EU metrology system.

The initiative for a **Circular Bio-based Europe** is intended to solve a shortage of industry investments in the development of bio-based products whose markets do not have yet certain long-term prospects. The **Innovative Health Initiative** and **EU-Africa Global Health** address the lack of investments in the development of solutions to specific health challenges. The initiative on **Innovative SMEs** supports innovation-driven SMEs in participating in international, collaborative R&I projects with other innovative firms and research-intensive partners. As a horizontal initiative it is expected to help innovative SMEs to grow and to be successfully embedded in global value chains by developing methodologies and technologies for potential application in the other partnership areas or further development by the instruments of the European Innovation Council.

The description of the interconnections between all initiatives for each Horizon Europe cluster is provided in the policy context of each impact assessment and further assessed in the coherence assessment for each option.

PART 2 - THE CANDIDATE EUROPEAN PARTNERSHIP ON TRANSFORMING EUROPE'S RAIL SYSTEM

3. Introduction: The political and legal context

Transport is fundamental to Europe's economy and society. It plays a key role in fulfilling citizens' travel needs and distributing the goods which they buy and use. As a result, transport enables economic growth and job creation: in 2019, the transport industry directly employed around 11.7 million people in the EU and accounted for about 5% of Gross Domestic Product (GDP)³⁵ and 7% of European export.

Railways contribute to the Single European Transport Area (SETA) and represent a fundamental element of the EU long term sustainable development strategy policy³⁶. Rail is already a very sustainable mode of transport, with policies such as the European Green Deal addressing the need of shifting to rail from less sustainable modes such as road in order to promote more environmentally friendly modes of transport integrating the logistic value chain as well as journeys for passengers. In terms of economic size, the direct gross value added of the Europe rail sector is \in 69 billion and the indirect value amounted at \in 80 billion³⁷, 1.3 million persons were directly employed in the rail sector and more than one million indirectly.

Rail transport has a series of significant advantages: a very high safety level (only 15 fatalities in 2017³⁸), low land use, high energy efficiency³⁹ and much lower environmental impact than other modes⁴⁰ (being already largely electrified), and the capacity to serve and connect both dense population areas as well as dispersed European areas (e.g. rural). Rail also contributes to decongesting dense urban areas. However, its ability to leverage these advantages and meet the evolving expectations of the European citizens and businesses is hampered by high costs, national operational barriers and limited flexibility, and in some cases poor reliability. These weaknesses have been compounded by divergent national technical standards and operating procedures, and inheritance of legacy systems, limiting the opportunities for extensive capacity use, mass manufacture, standard solutions, and, in addition, hindering cross border passenger and freight flows with the overall consequence of jeopardising the long term capacity of the system to answer the European socio-economic needs.

Over the recent years, it Europe rail sector has experienced increased competition from other non-European countries, especially in Asia, who built upon European know-how to develop rail technologies through subsidised internal markets. Maintaining a high and advanced technological position is key for global competitiveness and European jobs, with innovation being driven by demand and supply.

The introduction of new operational and technological innovative solutions to rail – enabled by digital advancements, robotics and automation to vehicles, European traffic management

³⁵ European Commission (2019): EU Transport in Figures. Statistical Pocketbook 2019.

³⁶ https://ec.europa.eu/transport/sites/transport/files/2019-transport-in-the-eu-current-trends-and-issues.pdf

³⁷ http://cer.be/topics/economic-footprint

³⁸ https://ec.europa.eu/transport/facts-fundings/statistics/pocketbook-2019 en

³⁹ 6 times more energy efficient than road (source CER).

⁴⁰ Rail is 9x less CO2 intensive than road for freight and air travel for passengers (source CER).

system, infrastructure, asset management, and interfaces with passengers and logistic value chain – will allow rail to transform its performance over the years, breaking down barriers.

This document focuses on assessing the most effective, efficient and coherent way of implementing an initiative which would focus on joint European research and innovation activities, covering the full innovation lifecycle for impact, to transform Europe's rail system under Horizon Europe.

3.1. Emerging challenges in the field

Environmental challenges and climate change are issues that are going to shape more and more citizen's everyday life and will affect the transport system too. Transport accounts for some 25% of all GHG emissions. Extreme weather conditions (e.g. flooding, hurricanes and storms) are experienced more and more often and this is increasing the risk of disruptions, damage and failure of critical infrastructure.

Another challenge is the **congestion of infrastructure -and ageing population**. 75% of the world's population (6.1 billion people) currently lives in urban areas, doubling the numbers registered in 1975, while in the EU is estimated to increase from 72% in 2015 to 84% by 2030⁴¹. The ageing of the population affects not only the end-users but also the work force in the rail sector: a large portion of operators and infrastructure managers, in particular, have a staff population with an average age above 50, which means that they will lose large part of their staff within the next decade requiring a substantial shift of skills and competencies.

Rapid technological development, notably digitalisation, automation and robotics, reshape mobility concepts and open new opportunities. The emergence of new technologies (such as 5G, big data, the Internet of Things, automation, artificial intelligence, and blockchain) is considered a powerful driver, increasing efficiency and effectiveness of the solutions and addressing environmental/sustainability challenges delivering resilient, versatile and flexible services for both passengers and freight. However, technological changes carry a significant risk of cyber-attacks that require to consider security mechanisms in the early stages of development of new technological solutions.

Box 1 Possible impact of Covid-19 crisis

The short-term impact of the pandemic on the transport sector, in particular passenger transport, is dramatic and unprecedented on this scale. The long-term effects on transport activity will be related to the length of the pandemic and the depth of the post COVID economic shock.

Mobility patterns and hence the demand are impacted. Sector associations reported an 80-90% reduction in international passenger traffic and increase in ticket reimbursement requests. New entrant operators indicated deep financial distress and may struggle to survive. Rail freight transport was largely exempted from these measures and continues to run smoothly, albeit with much reduced demand overall (some -30%). Still, it saw demand increased on some market segments (combined transport, food products, consumer goods), linked to a shift from road transport to rail.

⁴¹ See United Nations Population Division, World Urbanisation Prospects 2018, available at: https://population.un.org/wup/Download/

According to first estimations⁴², the global rail freight market is expected to decline from \$97.3 billion in 2019 to \$94.9 billion in 2020 at a compound annual growth rate (CAGR) of -2.5%. The decline is mainly due to economic slowdown across countries owing to the COVID-19 outbreak and the measures to contain it. The market is then expected to recover and grow at a CAGR of 7% from 2021 and reach \$114.3 billion in 2023.

Moreover, behavioural changes taking place around the world might carry over beyond the pandemic. It is unclear yet to what extent the restrictions would impact the demand for rail services.

Taken together, these challenges have important implications for both the direction and organisation of rail-related research and innovation in the next programming period.

Stakeholder opinion

There was strong support among stakeholders responding to the Open Public Consultation for aligning the direction of R&I under Horizon Europe with key European policy objectives, in particular decarbonisation of the European economy. A substantial majority of business organisations (both large organisations and SMEs), business associations, academic and research institutions, public authorities and EU citizens considered that any future European Partnership should respond effectively to European policy goals. A majority of these groups also confirmed the importance of meeting societal needs and contributing to Sustainable Development Goals while supporting EU global competitiveness. There was particularly strong

3.2. EU relative positioning in the field

The majority of rail transport is already electric (circa 80% of passenger-km and freight tonne-km⁴³), and more generally rail is very energy efficient. A significant increase of the modal share of rail transport⁴⁴ for passengers and especially for freight would allow rail to make a very substantial contribution to the decarbonisation of the transport system (increasing electrification and fuel efficiency will further reduce emissions per passenger-km and per tonne-km). The Green Deal calls for a significant part of the freight transport currently carried by road to be shifted to rail and inland waterways. Rail freight's modal share has been stagnating over the past years. It is particularly energy efficient, but in order to attract new traffic, rail freight operators have to offer more flexible and reliable services.

The EU has already started to tackle sustainability and cost-efficiency issues but it is only through intensive exploitation of the existing infrastructure, via a substantial transformation of rail systems' concept of operations, in all its segments, that a significant increase of the modal share for passengers and especially for freight could be achieved. Thus addressing the problems preventing rail taking a higher market share is a key deliverable for transport decarbonisation.

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⁴² Rail Freight Global Market Report 2020-30: Covid 19 Impact and Recovery

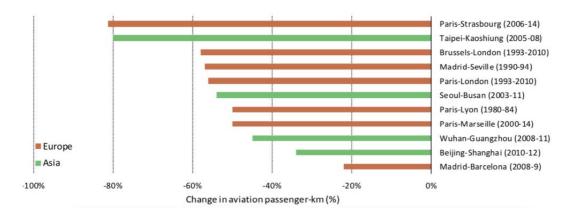
⁴³ https://ec.europa.eu/transport/facts-fundings/statistics/pocketbook-2019 en

⁴⁴ The modal share of rail transport (including heavy rail, tram and metro services) remained stagnant over a period of more than 10 years. However, it has to be noted that heavy freight (coal, steel etc.) in which rail was historically very strong, has greatly declined due to changes in broader industrial structure, and so the fact that overall rail freight market share has remained more or less constant demonstrates that rail *has* managed to increase its share in other sectors.

Similarly, the contribution of rail in addressing the challenges arising from increased urbanisation, including congestion and poor air quality should be higher. This would require further improving the quality of the rail services: 66% of Europeans are satisfied with the frequency of trains, and punctuality and reliability are also well received, with 59% of users satisfied⁴⁵, but further improvements in the quality of rail services would encourage people to travel more by rail. A change in the mobility behaviour is also a result of the increased awareness for sustainability among the population.

High-speed rail provides an important alternative to aviation. According to a report produced by IEA in 2019⁴⁶, high-speed rail lines can reduce aviation transport on the same routes by as much as 80%, see Figure 1.

Figure 1 - Average change in passenger activity on selected air routes after high-speed rail implementation



The integration of rail within the multimodal transport system has proceeded in the past on a piecemeal slow-pace basis, constraining improvements in connectivity.

The European Rail Supply Industry (RSI) has been highly competitive in global markets over many years⁴⁷, and its technological leadership has been strengthened considerably by various EU policy initiatives, notably the European Railway Traffic Management System (ERTMS). The European RSI is a major exporter of rail equipment, for example exporting €4.8 billion of locomotive and rolling stock products in 2017 compared with €2.3 billion exported by China and a similar value by the US.

However, the European rail supply industry's competitive position has been increasingly challenged by suppliers based in Asia, and particularly China, over several years, not least because of their substantial investment in R&I and support provided by their respective national governments⁴⁸. More generally, a perceived imbalance in the openness of Europe's rail market compared to that in other countries has prompted the Commission to explore

⁴⁸ See European Commission (2019b), op. cit.

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⁴⁵ European Commission (2018), Flash Eurobarometer 463: Europeans' satisfaction with passenger rail services, available at: https://data.europa.eu/euodp/en/data/dataset/S2172 ENG

⁴⁶ https://www.iea.org/reports/the-future-of-rail

European Commission (2019), Final report of the expert group on competitiveness of the European rail supply industry, October 2019, available at: https://ec.europa.eu/docsroom/documents/37829

ways of stemming unfair competitive practices and of providing support to European firms struggling to access global markets⁴⁹.

Through joint Rail Research and Innovation, the RSI working with the key stakeholders of the sector - railway undertakings, infrastructure managers, scientific community, etc. through co-creation - from exploring, conception, research, design, testing and demonstrating at large operational scale – could build upon its strengths and a portfolio of solutions – e.g. ERTMS – to maintain its leadership at global level.

A review⁵⁰ conducted in 2015⁵¹ highlighted the significantly higher intensity of R&D effort in competing sectors, notably aviation and automotive, notwithstanding their apparent similarity to rail in terms of both industry structure and the costs and risks of R&D investment. The rail industry still gets relatively small amounts of R&I investments, especially when compared to the automotive industry (40 times smaller)⁵². UNIFE has estimated the level of investment in R&I undertaken by the RSI in 2014 at around 2.7% of the industry's turnover. Moreover, the total amount of European R&I investments in the rail sector is still significantly lower when compared to the US and China⁵³.

Furthermore, the competitiveness of the RSI relies heavily on the ability to maintain knowhow as well as generate and protect intellectual property rights.

The recent study on the competitiveness of the RSI, undertaken for the Commission, found that of the 187,642 patents granted worldwide between 2011 and 2017 under the International Patent Classification 'B61 – Railways', 66% were granted by the relevant Chinese authority.

Hence, Europe's role and contribution to the current research and innovation efforts has implications for the strategic development and competitiveness of the European RSI⁵⁴.

In addition, there is a key role of the railway operating community at large and for the different segments. The market opening requires a shift in the business model relation between infrastructure managers and railway operators, as well as with the supply industry. This new business model, largely unique in the world, requires to innovate railway as an integrated system of systems, ensuring that the interfaces are duly managed and benefits maximized for the European passengers and freight business.

Support for the field in the previous Framework Programmes

⁴⁹ European Political Strategy Centre (2019), EU Industrial Policy after Siemens-Alstom: Finding a new balance between openness and protection, available at:

https://ec.europa.eu/epsc/sites/epsc/files/epsc_industrial-policy.pdf
50 Nash and Smith February (2019), op. cit., based on Wiesenthal et al (2015), Innovation in the European transport sector: A review

⁵¹ Hence before Shift2Rail JU had started operations.

⁵² Wiesenthal T., Condeco-Melhorado A., Leduc G. (2015), Innovation in the European transport sector: A review, Transport Policy, V. 42, pp. 86-93. The study analyses the EC data on railway transport provided in

⁵³ European Commission (2013), Impact Assessment accompanying the document: Proposal for a Council Regulation establishing the Shift2Rail Joint Undertaking, p.13.

⁵⁴ While published research results are, by definition, available to industries around the world, suppliers of rail products and services based close to, and potentially working collaboratively with, leading research organisations in the field are likely to benefit most from the research outputs that they produce.

Box 2 Support for the field in the previous Framework Programmes – key strengths & weaknesses identified

What was/is being done with EU research and innovation funding until now

Dedicated R&I activities related to transport and rail in particular have been supported for many years through the Framework Programmes. This covers traditional (collaborative) projects but also support provided through the Shift2Rail Joint Undertaking (S2R JU) under Horizon 2020.

The S2R JU was established in 2014 to strengthen the role of rail in the European transport system through more effective sponsorship and management of the sector's R&I effort. It manages an extensive programme of R&I activity, aligned with the delivery of a series of major operational and technological innovations set out in its Master Plan and further elaborated in a detailed Multi-Annual Action Plan (MAAP). The Union financial contribution is EUR 450 million that is matched by a similar contribution from the members. Details on how the S2R JU functions are available in Annex 6.

The activity overseen by the JU represents a substantial contribution to the R&I effort of the European RSI. The relatively low intensity of R&I activity in the rail sector observed before Horizon 2020 was an important factor in building the case for establishing the JU.

The founding members of the JU, including the manufacturers Alstom, Ansaldo STS (now Hitachi), Bombardier, CAF, Siemens and Thales and the infrastructure managers Network Rail and Trafikverket, are major contributors to the work programme, as are the associate members Deutsche Bahn and SNCF.

Educational and scientific and research institutions are well represented, although participation is concentrated on a relatively limited number of organisations such as the KTH Royal Institute of Technology, Fraunhofer Gesellschaft and Deutsches Zentrum für Luft und Raumfahrt (DLR).

While the interests of rail operators are clearly represented, including by associate members, representation is distributed in favour of major national passenger operators, freight operators and operators of urban networks are less involved (although organisations such as DB Cargo, Wiener Linien, Metro de Madrid and London Underground have participated in a limited number of projects).

SMEs participate in the Open Calls; for example, 90 SMEs participated in the 2019 Call (i.e. 23% of the applicants) and 40 SMEs were beneficiaries in proposals retained for funding (i.e. 40%). Overall, the SMEs represent 30% of the entities receiving funding from S2R JU.

What has or is being achieved so far

The JU is the first of its kind. It has been successful in building participation from organisations throughout the rail industry value chain, including infrastructure managers, train operators and a wide range of organisations from the RSI as well as research and educational institutions. The profile of participation tends to reflect the allocation of available Union funding, with 40% allocated to founding members, 30% to associated members and their affiliates and 30% to open calls (in accordance with Article 17 of Annex 1 of the Regulation).

According to the Interim Evaluation⁵⁵ the JU had already achieved positive effects by bringing many organisations together to work towards common goals, thereby overcoming industry fragmentation and ensuring greater continuity of research objectives. The report noted widespread support for the JU across the industry, particularly in view of its role in enabling large-scale demonstration projects. Overall, it was judged to be well-placed to achieve the level of trust and partnership characteristic of other transport JUs, providing a catalyst for new ideas and new relationships. Much of the research being undertaken would not have happened if the JU had not existed, and there was wide agreement of the value of the JU when it comes to large-scale demonstration projects.

To date, the JU appears to be making a strong contribution to the development of a more competitive rail transport industry, with its Annual Activity Report for 2019 highlighting significant progress across a range of activities. The Catalogue of Solutions⁵⁶ published by the JU in 2019 illustrates what R&I investments generate as innovative solutions for market uptake. It includes 54 solutions in relation to the whole rail system and hence, covering all IPs. Each solution includes a description and specifies a targeted market, market outlook and estimated date for market uptake.

To give another example, S2R JU developed, in collaboration with industry organisations such as CAF and Wabtec Corporation, competitive automatic coupling solutions to be demonstrated on Trafikverket freight trains in September 2020. It is also seeking the support of its members in preparing a business case for the deployment of the technology, which will require funding of Euro 6 billion over six years with an indicative payback of seven years. This is expected to have a significant impact on the market for freight wagons and on the efficiency of European rail freight services.

Furthermore, the JU helped identify the areas where there is a need to better align the R&I activities with the needs of a competitive sector and confirmed the need of developing a common vision for the future technical evolution. In particular, experience has shown a need to focus in the future on system issues rather than incremental improvements to parts of the complex railway system (hence the focus should be in the future on automation and traffic management) where pan-European standardisation is vital.

What lessons have been learned?

A number of areas for improvement were identified in the interim evaluation of the Joint Undertakings under Horizon 2020⁵⁷ and will have to be better addressed in a new initiative on European rails system. These challenges include:

- With regard to directionality, a more balanced research agenda, taking account of societal and operational issues facing the rail industry and better addressing the needs of freight operators needs to be adopted.
- There is a need for greater emphasis on demonstration projects to improve market takeup of R&I outputs. This requires a move towards more R&I programmes at TRL 7-9, a significant change from the focus on TRL 1-6 under Horizon 2020.
- It is important that both the research outputs and the demonstrators are relevant to a wide range of players and the links with the operational side of both passenger and freight as

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⁵⁵ Commission Staff Working Document - Interim Evaluation of the Joint Undertakings operating under Horizon 2020, {SWD (2017) 339 final}

⁵⁶ https://shift2rail.org/wp-content/uploads/2019/10/Catalogue-of-Solutions-Web.pdf

⁵⁷ Commission Staff Working Document - Interim Evaluation of the Joint Undertakings operating under Horizon 2020, {SWD (2017) 339 final}

well as with urban rail players should be strengthened. There is a need to increase the participation of a greater number of railway undertakings, and the presence of the urban sector and encouraging more Member States and especially SMEs.

- The Programme of S2R JU is structured around five Innovation Programmes (IPs)⁵⁸. This structure is not flexible enough for a strong system approach to deal with all interfaces between the subsystems and between the railway system and the "outside world and bears the risk of working in silos.
- Maximising the impacts of transport research and innovation requires supporting solutions that are closer to the market and bridging the gap to large-scale deployment of innovation. A possible successor of S2R JU should have a stronger deployment agenda.
- There has been insufficient exploitation of synergies between the S2R JU and other JUs, particularly in view of application of key technologies such as digital across the transport sector and more broadly.

It has to be noted that the S2R JU achieved autonomy in May 2016, therefore it was too early for any research results to be included in the evaluation, as no projects had then reached the stage of having concrete outputs.

3.3. EU policy context beyond 2021

At the end of 2019 the Commission presented its new priorities for the upcoming years, including the **European Green Deal**, a new growth strategy that aims to transform the EU into a fair and prosperous society, with a modern, resource-efficient and competitive economy where there are no net emissions of greenhouse gases in 2050 and where economic growth is decoupled from resource use. Priority areas include accelerating the shift to sustainable and smart mobility. Road, rail, aviation, and waterborne transport will all have to contribute to the 90% reduction in transport emissions, which is needed by 2050. As a matter of priority, a substantial part of the 75% of inland freight carried today by road should shift onto rail and inland waterways.

The **New Industrial Strategy for Europe**⁵⁹ (March 2020) underlined that sustainable and smart mobility industries, such as the rail industry, have both the responsibility and the potential to drive the digital and green transition, support Europe's industrial competitiveness and improve connectivity. In this context, the Strategy mentions the need for promoting the technological leadership of EU mobility industries.

In Horizon Europe, the candidate partnership for Transforming Europe's Rail System is part of the R&I activities funded under the **Pillar II Cluster Climate**, **Energy and Mobility** are intended to contribute to the attainment of at least three of the six main ambitions for Europe: 'A European Green Deal', 'A People-centred Economy' and 'A Digital Europe'.

The main objectives of this cluster are to fight climate change, improve the competitiveness of the energy and transport industry as well as the quality of the services that these sectors bring to society. This is supportive of several Sustainable Development Goals (SDG) including affordable and clean energy (SDG7); industry, innovation & infrastructure

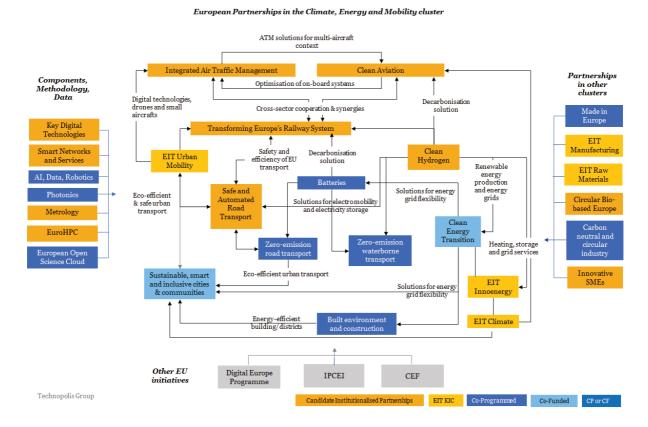
⁵⁸ The five Innovation Programmes (IP) are: Cost-efficient reliable trains, Advanced traffic management, Sustainable and Reliable Infrastructure, IT Solutions and Technologies for Rail Freight. Across all five IPs are overlaid five cross cutting themes and activities (CCAs).

⁵⁹ https://ec.europa.eu/info/strategy/priorities-2019-2024/europe-fit-digital-age/european-industrial-strategy en

(SDG9); sustainable cities & communities (SDG11); sustainable consumption & production (SDG12); and climate action (SDG13). The candidate partnership for Transforming Europe's Rail System also has the potential to support SDG 3 (Good Health and Well-being) -by encouraging greater use of rail services, which in turn will have a positive effect on reduction of greenhouse gas emissions, particulate pollution and noise-, SDG 8 (Decent Work and Economic Growth) and SDG 9 (Industry, Innovation and Infrastructure), by enhancing the competitiveness of rail and especially freight (thereby reducing the volume of freight traffic moving by road) and by addressing many of the challenges such as the increased urbanisation of Europe's population.

A detailed analysis of synergies for the envisaged and candidate Partnerships that are related to this cluster is shown in Figure 2.

Figure 2 - Interconnections between the envisaged partnerships in the Climate, Energy and Mobility cluster



In terms of the **policy goals for the sector**, rail is at a point where substantial transformation is needed. Over the past 25 years, the Commission - and more recently with the European Union Agency for Railways (ERA)-, has developed a single technical framework for rail, with the objective of gradually replacing divergent legacy national approaches developed over the previous 150 years.

The technical pillar of the 4th Railway Package adopted in 2016 but only in force in all Member States from November 2020 is expected to boost the competitiveness of the railway sector by significantly reducing costs and administrative burden for railway undertakings wishing to operate across Europe, starting with ERA issuing vehicle authorizations for

placing on the market and safety certificates for railway undertakings, valid throughout the EU.

This has been accompanied by progressive market liberalisation. The market pillar of the 4th Railway Package adopted in 2016 completes the process of gradual market opening. Competition in rail passenger service markets will encourage railway operators to become more responsive to customer needs, improve the quality of their services and their cost-effectiveness.

Despite the support provided by the current EU legislation to the harmonisation and interoperability of the EU rail market, the large majority of national legacy systems is still far away from integration into the European system⁶⁰. Full realisation of the Single European Rail Area⁶¹ will however require further time due to the very long asset life of rail equipment. For instance, in 2018 there were still some 30 different signalling systems in place which were not interoperable.⁶²

There is now a great opportunity to build the future railway on a common system – which is vital for harnessing the huge potential for digitalisation and automation to reduce rail's costs, increase capacity, and enhance its flexibility and reliability. In the absence of a major system transformation during the next decade to set the basis for a system wide deployment of new technologies and operational solutions, much of the rail potential would not be realised, and undertakings would be lumbered with stranded costs, without a shared European concept of operations and joint effort to deploy it in the market.

Stakeholder opinion

There was strong support among stakeholders responding to the Open Public Consultation for aligning the direction of R&I under Horizon Europe with key European policy objectives, in particular decarbonisation of the European economy. A substantial majority of business organisations (both large organisations and SMEs), business associations, academic and research institutions, public authorities and EU citizens considered that any future European Partnership should respond effectively to European policy goals. A majority of these groups also confirmed the importance of meeting societal needs and contributing to Sustainable Development Goals while supporting EU global competitiveness. There was particularly strong

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⁶⁰ Study on the competitiveness of the Rail Supply Industry – Final Report (2019)

⁶¹ Established by Directive 2012/34/EU.

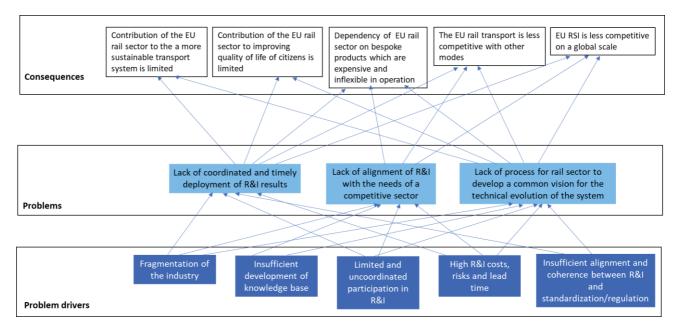
⁶² ERTMS – A guide for stakeholders (2020)

4. PROBLEM DEFINITION

4.1. What is/are the problems?

Given the scale of the challenges ahead for a transition to sustainable mobility, the current scientific, technological and economic positioning of Europe in the field, and the overarching EU policy context, a set of problems have been identified where EU research and innovation in the field of rails systems would have a specific role to play (see Figure 3).

Figure 3 - Problem tree behind an initiative for European research and innovation on Transforming Europe's Rail System



2.1.1 Lack of coordinated and timely deployment of R&I results both between the RUs and IMs and across the network

The current low status of deployment of innovative solutions is explained mainly by the reluctance of many IMs and RUs to invest in the necessary equipment without the assurance that there will be sufficient infrastructure to exploit the investment (where done by an RU) or trains adapted to fully exploit the infrastructure (where the IM invests) – a classic chicken and egg problem. In the absence of an adequate framework, the stakeholders considering the business case do not have confidence in the return for investment.

Previous framework programmes showed that in the absence of a strong coordinated approach at EU level, the market uptake and impact of rail R&I projects is low and slow, and neither technological nor policy-relevant outputs would be as prevalent. For projects selected individually through traditional calls for proposals the consortia are set up ad-hoc according to the specific needs of the project and dismantle afterwards without creating long term value. This hinders the continuous collaborations of partners beyond single projects, resulting in lack of trust, lack of willingness to share information – two essential factors in projects developing outputs with direct commercial value – and strategic decisions on solutions based on the monies invested in the projects instead a shared vision.

2.1.2 Rail research and innovation activities not aligned with the needs of a competitive rail sector

The lack of competitiveness of rail against other modes of transport reflects both the persistence of inefficiency, contributing to relatively high costs and/or excessive calls on public funding, and a lack of innovation.

The impact assessment accompanying the proposal to establish the S2R JU noted that R&I efforts under previous Framework Programmes had not been sufficiently targeted towards the completion of the Single European Rail Area (SERA), notwithstanding that the creation of a large internal market for rail products might have been expected to increase the competitiveness of European rail services. The recent report of the expert group on the competitiveness of Europe's RSI⁶³ noted that the industry faces several major challenges such as embracing new technologies on which both its position in global markets and the R&I activities conducted in a fragmented manner would have a little impact on meeting the needs of the sector as they would unlikely result in the level and scope of R&I activity required to materially improve the competitive position of the rail transport industry.

2.1.3 Lack of process for rail sector to develop a common vision for the technical evolution of the system

The EU rail system was historically characterised by segmentation into national networks with specific technical standards requiring bespoke rolling stock and infrastructure equipment, often supplied by preferred national manufacturers. This resulted in high costs, difficulties in providing international services and a general lack of flexibility. Even where new technologies were developed, these were often applied differently in different Member States, preventing interoperability⁶⁴. Even when a European approach (ERTMS) was developed, customisation to fit existing railway operations was allowed, again limiting the intended interoperability – a problem we are still dealing with.

Successful innovation in the rail sector must deal with these issues and also address the fact that for many developments there will only be a strong business case where wide scale network deployment in a truly interoperable manner can be ensured within a reasonable time scale.

Misalignment of incentives between infrastructure managers and railway undertakings must also be addressed. Finally, in the absence of rapid cross industry agreement on the preferred approach to new technology (including standardisation and/or inclusion of innovations in the EU Technical Standard for Interoperability Regulations) is vital to avoid that divergent solutions are adopted at national level, breaking interoperability and preventing the cost advantages delivered by common EU product specifications. These issues must be addressed with an inclusive governance system at the R&I stage to ensure broad industry acceptance of the finished technology.

⁶³ See European Commission (2019a) Report of the expert group on the RSI's competitiveness

⁶⁴ The classic example is modern train protection systems, where different automated systems were developed in the 1980s and 90s, meaning that trains needing to run in several Member States must have up to 11 different systems – adding hugely to cost and certification difficulty.

Stakeholder opinion

A substantial majority of business organisations, business associations, academic and research institutions, public authorities and EU citizens responding to the Open Public Consultation considered that the need to strengthen the role of rail in the transport system through R&I was very relevant, and support for improving the competitiveness and attractiveness of rail services was also strong among all these groups. Stakeholders also identified the importance of aligning R&I under Horizon Europe with EU societal objectives, in particular climate-related objectives. At the same time, there was strong support for common action to advance key technologies and radically transform rail, particularly from larger business organisations and public authorities.

4.2. What are the problem drivers?

4.2.1. *Fragmentation*

Today's fragmentation is the legacy of a patchwork of national rail systems slowly growing together:

- Infrastructure which is and is likely to remain a national, state-owned, monopoly (with limited exceptions such a few Public-Private-Partnerships). The need for compatibility between infrastructure and rolling stock imposes design constraints on the latter, though these are being progressively eliminated through full application of the Commission's "Technical Standards for Interoperability" (TSI) Regulations.
- Historically close links between national railways and local manufacturers, limiting incentives to develop truly pan-European products.
- Liberalisation is recent and open access for "commercial" services is small compared to services under Public Service Obligations (PSO) which represent about two thirds of the total market for passenger transport. In addition, barriers to entry are high as there is the need for example for bespoke rolling stock and to create economies of scale.
- Limited role of the cross-border traffic as 95% of it is national. Freight is very different after 20 years of EU liberalisation the sector has evolved, with operators operating across the EU; services between Member States represent 60% of freight tonne km.
- Long life of railway assets: 40-50 years for rolling stock, while for infrastructure (including for some signalling components) is much longer.

The high level of product customisation and lack of European standardisation not only prevented the creation of single European railway market, it also resulted in increased production costs and low operational margins. The creation of the Single European Rail Area has addressed these issues by creating a single technical basis – the Technical Specifications for Interoperability (TSI) – for the system. However, it will take many years for the system to fully comply with the TSIs and in the meantime new equipment has to address interface with the legacy systems. For example, the need to manufacture rolling stock to meet specific national track and loading gauge, signalling and other standards inevitably reduces the number of trains that can be produced to a given specification and

increases the unit cost of production⁶⁵. This means that underlying R&I activities need to be properly coordinated and synchronised to ensure the interoperability of solutions.

Furthermore, the problem of fragmentation is compounded by the technical complexity of rail systems, with the risk, that, in the absence of a coordinated approach for R&I at EU level, research projects would mostly focused on just one component of the rail system, rather than on improving the system as a whole. Given the strength of large Original Equipment Manufacturers (OEMs), there is also a limited focus on the development of a system vision or standardised interfaces between components which would allow greater scope for competition between component manufacturers and updating of such components to reflect innovation. This is being addressed in particular in the S2R JU's IPX work stream.

In addition, prior to S2R JU, there was also fragmentation along the innovation life cycle, with research projects focusing on pre-competitive innovation at low TRLs, which frequently came to an end without any plan for follow-up activity leading to market uptake. It was thus difficult to develop ambitious, large-scale and long-term innovation programmes capable of proposing breakthrough solutions that have a real impact on the whole system and that can be deployed EU wide.

Stakeholder opinion

A majority of business organisations (including SMEs), business associations, academic and research institutions, public authorities and EU citizens responding to the Open Public Consultation considered the various aspects of fragmentation discussed above to be relevant or very relevant. They also confirmed the lack of a coordinated approach to programming and funding and the need to bring together the research community, the RSI, train operators and infrastructure managers. A majority of all these groups similarly considered the market take-up of innovations to be slow, either because of deployment issues or as a result of the regulatory framework.

Several of the stakeholders participating in the interviews similarly stressed the difficulties in overcoming the fragmentation of the European rail system, particularly in view of the perceived slow progress in deploying ERTMS and delivering full interoperability. They also highlighted the long-life cycle of railway assets and the costs and risks of R&I investment as major constraints on the speed of innovation. There was a strong consensus that, in the absence of policy intervention, it would not be possible to achieve the long-term strategy and level of stakeholder participation and coordination needed to translate R&I results into higher quality, more efficient rail services. In addition, some stakeholders expressed the view that Horizon Europe represented an important opportunity to substantially improve the competitiveness of rail freight.

The business organisations providing feedback on the inception impact report also confirmed the importance of some of the problem drivers identified above, in particular the sector fragmentation. These and other stakeholders, including EU citizens, also emphasised the importance of ensuring that investment in R&I activity made a difference to the rail industry and its customers through more extensive and rapid take-up of innovation.

https://www2.deloitte.com/content/dam/Deloitte/au/Documents/Economics/deloitte-au-economics-passenger-rolling-stock-procurement-efficiency-opportunities-270913.pdf

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⁶⁵ Firm evidence of the extent of economies of scale in rolling stock manufacture is limited. However, analysis of rolling stock production in Australia by Deloitte Access Economics indicates that a quadrupling of the size of an order from, say, 40 to 160 vehicles can result in a reduction in vehicle unit cost of around 50%. See Deloitte Access Economics (2013), Opportunities for greater passenger rolling stock procurement efficiency, September 2013, available at:

4.2.2. Uncoordinated and limited participation in R&I

Complex technical interactions between subsystems (infrastructure, rolling stock and signalling) and non-coordinated contribution of the railway actors (equipment manufacturers, railway undertakings and infrastructure managers, research community) limit the potential of improving one specific part of the system or the potential of proposing breakthrough solutions that have an impact on the whole system.

Before Horizon 2020, traditional calls for proposals led to formation of ad-hoc consortia and one shot demonstration projects, without all relevant market players with a commitment of implementation. Moreover, consortia frequently failed to include passenger and freight operators, notwithstanding the need to ensure that R&I activity took account of market needs.

The past set-up of EU rail R&I had limited direct leverage of EU funding. The average share of private sector funding for the FP7-Transport was only 34%, and only three projects obtained more than a 40% contribution from private sector participants. In addition, only 28% of rail projects funded under FP7-Transport were coordinated by private companies, while 43% were coordinated by university and other research organisations. This resulted in greater emphasis on projects targeting relatively low TRLs (pre-competitive research at TRL 1-3) rather than development and demonstration projects (TRL 4-7).

S2R JU shows the added value of a better representation of the whole value chain, creating continuous collaboration of partners beyond single projects, resulting in growing confidence among partners and, in many cases, greater market uptake. It runs a R&I Programme of a value of EUR 920 million, which is delivered by the European rail industry at large that contributes with own financial resources, resulting in a net contribution of EUR 470 million. The Union contribution is EUR 450 million. The leverage based on direct costs is 1 Euro funding creating 3 EUR of R&I activities. 666

The results of the consultation activities undertaken as part of this impact assessment confirm the importance of more active participation from a range of stakeholders, bringing different capabilities and a balance of perspectives. While each group has a key contribution to make, they face different incentives and constraints; therefore, operating in isolation, in the absence of a European coordination mechanism, they may be unwilling or unable to contribute in ways that maximise the efficiency and effectiveness of available R&I resources.

4.2.3. *High R&I costs, risks and lead times*

Generic innovation risks are in the rail sector intensified by the need for synchronicity between innovations. Long and diverging product lifecycles and lack of modularity, inhibiting the rapid deployment of new rail technologies; unequal distribution of innovation benefits between stakeholders, reducing incentives to invest in new technologies; lack of synergies and common standards with other industrial sectors, especially in emerging technologies.

In addition, unequal distribution of the benefits of innovation can undermine incentives to invest. Moreover, both infrastructure managers and rail operators become familiar with

⁶⁶ The current S2R JU Members funding rate is 44.44% of their overall total project costs for the indirect action they perform, corresponding to around 33% of the direct costs plus the 25% flat rate for the indirect costs.

application of technologies they have been using for many years such as electric interlocking technology, which is considered reliable and safe, and are therefore reluctant to explore the full potential of digital technology, with its own safety risks. While the prevalence of such an industry mind-set cannot be demonstrated unequivocally, to the extent that it exists it may act to further lower the industry's willingness to invest in R&I.

Furthermore, the interdependency of the different rail sub-systems means that a specific innovation (e.g. Automated Train Operation, signalling) needs to be accompanied by timely innovation in infrastructure or business models, for it to have an impact on the whole system. A Synchronicity between innovations is crucial; an innovation in one sub-system could have negative impacts on other sub-systems if not coordinated properly.

The S2R JU started delivering results breaking down the resistance to change of the rail sector and the rigidity and detachment of the rail-prone standardised/regulatory framework; but major work shall integrate the value chain of innovation to achieve the rapid deployment of innovations.

4.2.4. Insufficient development of the knowledge base

Historically, Europe has made a strong contribution to rail-related research, with universities and research-based institutions generating substantial numbers of publications each year. Between 2010 and 2018 China published substantially more research results than any other country, including all the main countries in which Europe's RSI is based. Moreover, while collectively the European Member States account for more publications than China and the US together, the magnitude of research effort in both these countries is sufficient to suggest that the sustainability of Europe's lead in rail research is at risk.

Before Horizon 2020, traditional calls for proposals led to formation of ad-hoc consortia with dissemination and exploitation of results on a project basis, with no links between projects and continuity. Therefore, a significant part of knowledge generated by stand-alone European R&I projects under and before FP7 never found its way to the market. Since rail-related research undertaken today provides the basis for development and innovation in the rail industry in the future, Europe's contribution to the current research effort has implications for the further development and competitiveness of the European RSI⁶⁷. In particular, the number of registered industrial designs and patents generated by the RSI is partly a function of the level of more fundamental research undertaken in the past to which suppliers have had access, either through formal collaboration with research-based organisations or because of a significant in-house research capability. The extent to which the industry can maintain intellectual property of this kind is an important determinant of its technological lead, and hence its competitiveness, in global markets.

4.2.5. Insufficient alignment and coherence between R&I and standardisation/regulation

With the TSIs, a strong common technical basis for key rail components has been created at EU level. However there are still significant national divergences as regards operating procedures, safety rules, and components not directly impacting interoperability. If these are not addressed and standardised in parallel with R&I development via a coordinated

⁶⁷ While published research results are, by definition, available to industries around the world, suppliers of rail products and services based close to, and potentially working collaboratively with, leading research organisations in the field are likely to benefit most from the research outputs that they produce.

approach at EU level, they will result in the continued customisation of products to national requirements, again creating complexity, cost and generally discouraging rapid innovation (see above the ERTMS example). Standardisation of rail system applications would not be approached in a coherent manner, and would not lead to new solutions that are interoperable by design and – at the same time – accelerating the market-uptake of such solutions.

Overcoming these issues is particularly important given the potential – and need – to develop and deploy new and European standardised solutions for automatic train operation, signalling, traffic management and freight operations.

A common Reference Functional System Architecture that capitalizes on the work of S2R JU can exploit standardisation opportunities. This European integration through a common understanding of the global performance of the mainline rail system and common application of operations across EU is the necessary step to ensure the achievement of SERA. To continue to build on this approach it is not sufficient to standardise once research results and products emerge. The basic system framework must be defined, through a process involving both manufacturers and operators in parallel with the commissioning of R&I work so that the results can be melded into a coherent whole.

Stakeholder opinion

Widespread recognition of the importance of these problem drivers was reflected in the responses to the Open Public Consultation. A majority of business organisations (including SMEs), business associations, academic and research institutions, public authorities and EU citizens considered the various aspects of fragmentation discussed above to be relevant or very relevant. They also confirmed the lack of a coordinated approach to programming and funding and the need to bring together the research community, the RSI, train operators and infrastructure managers. A majority of all these groups similarly considered the market uptake of innovations to be slow, either because of deployment issues or as a result of the regulatory framework.

4.3. How will the problems evolve?

There are indications⁶⁸ that the market uptake of innovative solutions has been substantially higher since the S2R JU was established and it would fall in case of no action. But in the absence of coordinated action at European level, the needs of the sector will not be met in full and the transformation of the system will not be achieved, as isolated investments in R&I done by RUs, IMs or manufacturers alone cannot ensure that. The problems that impacted the sector before the establishment of S2R JU would return.

In the absence of coordinated and higher level investment in R&I, potentially comparable with the levels achieved in the other sectors, the outputs of R&I projects would be limited as well as their market potential. Necessary improvements in the reliability, cost efficiency and capacity of the European rail network would not materialise, hindering the ability of the sector to deliver better and more cost-effective services, hence becoming more competitive and achieving the increase in modal share vital for delivering the Green Deal objectives. Especially for freight, a sector that, as mentioned above, has over the past 10 years seen a

⁶⁸ Foster Rail (on behalf of ERRAC) (2016), Evaluation of finalised projects with clear understanding of the market uptake mechanism, May 2016

stable modal share, in the absence of action at EU level, research on the communication systems, enhancing the interoperability of IT systems, and ensuring that there is enough capacity in all the routes would most probably not be done. This research would be needed to help rail freight to cope with the challenges faced, such as lower priority than for passenger services, underinvestment in infrastructure and agility and technological innovation in road transport.

If outputs already achieved under Horizon 2020 are taken up across the system, then improvements in life cycle costs could be expected by 2030. Synergies between Horizon Europe and Connecting Europe Facility (CEF) will ensure that the latter supports large scale roll-out and deployment of innovative technologies and solutions also in rail⁶⁹. They will therefore need to be combined with the market uptake assumptions to generate an estimate of actual efficiency gains. Some additional efficiency improvements are likely to be generated through additional R&I activity and investment at the national level, but these are difficult to quantify.

Stakeholder opinion

Stakeholders participating in the interviews tended to support the view that the lack of progress in addressing issues such as fragmentation and inadequate coordination of R&I activity observed before Horizon 2020 would be likely to remerge in the absence of significant further policy intervention during Horizon Europe. Similarly, stakeholders providing feedback on the inception impact assessment tended to suggest that the problems identified in the document would be likely to persist in the absence of policy intervention.

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⁶⁹ In June 2018, the European Commission, as part of proposals for the next long-term budget (2021-2027), proposed adapting the CEF programme to support investment in Europe's transport, energy and digital infrastructure networks. A provisional agreement was reached by co-legislators in March 2019.

5. WHY SHOULD THE EU ACT?

5.1. Subsidiarity: Necessity of EU action

In the absence of a rapid cross industry agreement on the preferred approach to new technology (including standardisation and/or inclusion of innovations in the TSIs it is essential to avoid that divergent solutions are adopted at national level, breaking interoperability and preventing the cost advantages delivered by common EU product specifications. An inclusive governance system at the R&I stage is required to ensure the broad industry acceptance of the developed technologies.

R&I funded at the national or organisational level, while potentially contributing to the broader development of the European rail system, is unlikely to enable the rail industry to meet European transport and broader policy objectives, advance the completion of SERA by delivering on an integrated and sustainable rail system, and lead to better and more cost effective services for passengers and businesses, as well as to an increased modal share of rail. The overall result would be a rail system whose performance will be stretched, jeopardising years of investments and action and unable to meet expectations stated in the Green Deal. There can be no Green Deal in terms of Decarbonising transport goes hand in hand with railway taking on more traffic, and for this performance and capacity have to increase more than incrementally.

Similarly, without EU action, the European Rail Supply Industry is unlikely to be able to compete in international rail product markets against suppliers based in China and other third countries actively building their indigenous rail sector capability, including through major R&I programmes.

Stakeholder opinion

Among stakeholders responding to the Open Public Consultation there was widespread recognition of the problem of fragmentation and lack of effective coordination of R&I activity underpinning the case for intervention at the European level. Stakeholders participating in the interviews and providing feedback on the inception impact assessment were also generally fully supportive of EU action to address these and other aspects of the problem.

5.2. Subsidiarity: Added value of EU action

A European integrated and complex network like rail needs a European answer: only through jointly performed rail research and innovation at Union level it will possible to break national silos, converge on operational concepts, introduce digital technologies that will integrate local systems, create a common baseline on which to build new solutions and integrate with other modes of transport, commingle the resources to move away from 150 years old concepts and deliver an ambitious rejuvenation of rail. This should benefit from a joint effort led by Union policy to enable collaboration among actors from across Europe and along the value chain to define an integrated programme mirroring the needs of a complex system designed to address market needs, and enable a fast and targeted delivery on the objectives.

R&I at Union level would bring together the know-how of the sector reducing the overall costs in two important ways. First, it would allow pooling of resources available for R&I, thereby reducing the potential for competing and conflicting projects focusing on the needs of national networks (and tending to reinforce the geographical fragmentation of the sector). Second, it would encourage the RSI to develop products and systems that further enable the development of a fully integrated European rail system, thereby advancing the creation of a single European market for equipment and allowing them to exploit economies of scale in production more effectively.

Another aspect to be considered is that the rail sector in the different Member States, and especially SMS in South-Eastern Europe, have very different needs and are mostly concerned about meeting their basic connectivity needs (upgrading infrastructure) and focus less on R&I than the other Member States. It is important to understand these differences and apply different measures to bring EU rail systems to the same level, some of which would not be within the scope of the proposed initiative (e.g. funding and financing from EIB, CEF, ESIF); all Member States should participate in demonstrations of innovative solutions developed under this initiative.

6. OBJECTIVES: WHAT IS TO BE ACHIEVED?

6.1. General objectives of the initiative

Based on the identified problems, the following general objectives have been defined:

- The first general objective is that rail-related R&I activity under Horizon Europe should enhance rail's contribution to societal development in Europe through:
 - O Support the delivery of the European Green Deal, partly by further reducing the emissions generated by the rail transport industry itself but more importantly by improving the attractiveness of rail services relative to less environmentally friendly modes (such as road and aviation) and thus enhancing air quality;
 - Supporting rail's contribution to improving the quality of life, in particular with a view to increasing connectivity, within and between Member States, by offering efficient, attractive and affordable transport services.
- The second general objective is to advance the completion of the Single European Railway Area by delivering on an integrated rail system. This would be based on a vision shared by the sector towards improved operational reliability, robustness and

efficiency, and secure the sustainability of business models for the European passengers and the freight logistic value chain. It would create a larger market for rail products and reduce costs.

- The third general objective is modernising rail freight so that it increases capability and capacity. Rail freight needs to become digital, for increased efficiency and reliability, and to be fully integrated in the logistic value chain.
- The fourth general objective is to ensure that rail-related R&I activity is better aligned with rail market needs through a user-centric approach. This will mean designing a R&I programme that delivers outputs addressing specific issues identified by rail operators, infrastructure managers and other stakeholders through a whole integrated system of systems approach, thereby delivering better performance in terms of efficiency of rail services and increasing their attractiveness to passengers and freight customers.

These objectives are fully in line with several of the SDGs⁷⁰ supported by the Climate, Energy and Mobility Cluster, including SDG 3 (Good Health and Well-being), SDG 8 (Decent Work and Economic Growth), SDG 9 (Industry, Innovation and Infrastructure), SDG 11 (Sustainable Cities and Communities) and SDG 13 (Climate Action).

Specific objectives 6.2.

In order to achieve the general objectives, five specific objectives are defined. These specific objectives respond to each of the problem drivers discussed in Section 2.2. The list of specific objectives is the following:

Eliminate barriers to interoperability and provide solutions for full integration, covering traffic management, vehicles, infrastructure and services, in order to deliver a high capacity integrated European railway network. By exploiting the huge potential for digitalisation and automation, innovative solutions will be developed to reduce rail's costs, increase capacity, and enhance its flexibility and reliability.

The above should be based upon a solid Reference Functional System Architecture⁷¹ shared by the sector, which main part is currently under development within the S2R JU together with the sector, and in coordination with the European Union Agency for Railways (ERA).

- Increase R&I activities related to rail freight and intermodal transport services, to deliver a competitive green rail freight fully integrated into the logistic value chain. Automation and digitalisation of freight train is the core, but also its operations, yards and intermodal terminals based on real time data are areas which require further R&I.
- Deliver a sustainable and resilient transport system: by developing zero-emission, silent railway system and resilient infrastructure, applying circular economy to the rail sector, and complementarity with the overall transport system.

Establish an ecosystem that facilitates interaction between stakeholders and makes cooperation within and across value chains more efficient. This will ensure that that

⁷⁰ European Commission International Cooperation and Development (2019), The Sustainable Development Goals – available at https://ec.europa.eu/europeaid/policies/sustainable-development-goals en

⁷¹ A shared and guiding Reference Functional System Architecture includes all structural rail subsystems and their functionalities (i.e. control command and signalling, rolling stock, energy, infrastructure, etc.) and identifies the necessary interfaces and interdependencies to ensure the System maximize its performance.

research is translated into market focused innovation through demonstration and deployment.

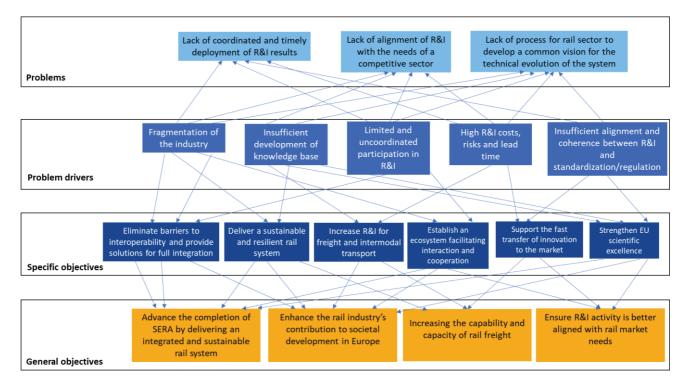
The administration and procedures for participation in the initiative would be simplified to make it accessible and attractive to new organisations. The target is to streamline administrative practices to sensibly reduce the complexity, eliminating any double EU and national intervention at all level of the operations (proposals, projects, audits).

- Launch large-scale projects supporting the fast transfer of innovation to the market. This specific objective would support large scale projects, such as demonstrations that bring together technology suppliers and users. These actions mobilise a high volume of resources and require the combination of public (European and national) and private resources under a common scheme. Large-scale projects bring specific value to the implementation of a long-term strategic planning and, by combining resources, help reducing the risks of R&I investment for organisations within the RSI and the broader rail transport sector seeking to develop and deploy new products and services. Exploiting standardisation and modularity opportunities, and facilitating the interfaces with other modes and systems would open the door to new business opportunities and contributing maintaining the leadership of the European supply industry.
- Strengthen EU scientific excellence and exploit the innovative potential of SMEs and start-ups. This would ensure achieving an advanced scientific knowledge base that could guide the development of required policy measures and technologies essential to catalyse the transition to a climate-neutral emissions economy and society. To stimulate the participation of SMEs and start-ups, efforts to simplify the administrative requirements linked to participation with respect to those of the current partnership will be important.

6.3. Intervention logic of the initiative

The relationship between the general and specific objectives of the potential initiative on Transforming Europe's rail system is shown in Figure 4.

Figure 4 - Intervention logic for the initiative for Transforming Europe's Rail System



How would success look like?

Should the initiative deliver on its specific objectives, it is expected that it would translate in practice into the following impacts:

Scientific impacts

- A strengthened pipeline of potential innovation available to the rail sector
- ➤ Deliver scientific results breaking down the current operating limitations
- Development of the knowledge base
- A new generation of "rail" engineers and scientists coming from different fields
- ➤ Ideas that would challenge current systems and a new thinking

Future rail research and innovation activities delivered through the partnership would contribute to scientific knowledge connecting the European research and scientific rail community with others and through the publication of results. Given the participation of a wide range of stakeholders with complementary skills and capabilities, coupled with appropriate peer review mechanisms, this would enable the development of a strong science base in the field.

Moreover, these activities would provide opportunities for research staff located in both the rail sector and academic and research institutions, and could also contribute to building relationships between universities and research-based institutions and the industry, including formal organisations and informal networks. This would result in an increase in the overall number of high-quality jobs across the European economy.

Further, R&I activity at TRL 1-3 is particularly important in generating new ideas that could have practical applications in the future. The activities covered by the S2R JU's IPX on system architecture indicate some areas that might be investigated further under Horizon Europe. These include for example the use of block chain technology in the management of

remote condition monitoring data. There is a need to move away from the high cost evolutive maintenance of the sector to a virtuous cycle of R&I, where rail becomes permeable to the introduction of new solutions and ideas.

Stakeholder opinion

Among the respondents to the Open Public Consultation a majority of business organisations (both large organisations and SMEs), business associations, academic and research institutions, EU citizens and public authorities considered the creation of new scientific knowledge and capabilities by the candidate institutionalised partnership for the rail sector to be relevant or highly relevant. Most of these groups also expected the partnership to create high quality jobs in the sector, although public authorities were less persuaded of the importance of this impact.

Economic/technological impacts

- An increase in rail's modal share of passenger and freight markets
- ➤ An improvement in the competitiveness of the RSI
- An increase in rail industry direct and indirect employment
- > Creation of new business models and opportunities for the rail stakeholders

Overall, this initiative would lead to a more customer-oriented and market-focused delivery of R&I and to an improvement in the competitive position and market share of rail services in European transport markets, including both passenger and freight markets, and an improvement in the global competitiveness of the RSI.

Should the initiative be successful, the future generation of rail operations and services will create value for the stakeholders as well as for the users of the rail systems. A performance based approach in the revenue apportion should be re-considered and should also result in reducing the public budget envelope invested by Member States annually in each rail system, estimated at EUR 40 billion per year.

It would also encourage greater involvement of SMEs, who have the flexibility to develop innovations and bring them to market relatively rapidly, and of technology-based organisations outside the rail industry, including start-up, who can increase industry awareness of emerging technologies with potential applications in rail.

The initiative would also provide a platform for planning the progression of R&I activity through the TRLs, with the development of internal strategic plans defining the transition from fundamental research, through the development stage, to demonstration and offering to the sector migration plans for future deployment, outside its remit. Finally, it will enable a more effective leveraging of the Union funding, since stakeholders would be more confident of the potential returns from supporting the initiative if their contribution is part of a collaborative effort reflecting differences in capability and expertise.

Societal impacts

- Reductions in the environmental impacts of transport
- > Improvements in the safety, security and health of EU citizens
- Affordable and accessible mobility and connectivity

The initiative would be particularly important in achieving sustainable development goals, since a significant increase in the modal share of rail (especially for freight) would reduce

the demand for less environmentally friendly forms of transport (such as road). In addition, an increase in R&I activity focused on rail freight and intermodal transport is expected to have broader societal impacts, leading to innovations that enhance the attractiveness and accessibility of these services for existing and potential users.

Environmental impacts

Given that rail transport already has a good environmental impact, much of the additional positive environmental impact of R&I would be achieved through making rail more attractive (for both passengers and freight) and thus attracting traffic volume from less sustainable modes of transport.

It is not about rail, whose energy and climate neutrality performance are out of reach for many other modes of transport, it is about making rail more attractive (for both passengers and freight) thus interacting and integrating with other modes of transport to transfer volumes and maximize the overall environmental performance of mobility and transport.

R&I activity focused on various elements (including interfaces of rail with other modes) has the potential to improve the quality of the urban environment in several ways. In particular, the provision of a more integrated transport network including cities across Europe would reduce the need for car travel, reducing congestion and improving air quality while contributing to target reductions in greenhouse gas and other emissions, and noise.

Similarly, greater innovation in the rail freight industry, suitably focused on the needs of the industry's customers, could substantially increase service quality, in such a way that logistics companies and shippers would consider rail as an alternative to road across a much wider range of markets and distances than at present. This effect would be reinforced if innovation also improved the efficiency of freight services and require to include non-rail actors to achieve it. Taken together, these effects could significantly reduce the level of road freight traffic, particularly on inter-urban and inter-regional routes, thereby contributing to a reduction in greenhouse gas and other emissions, and noise.

Social impacts

By putting a greater emphasis on the integration of national, regional and local rail systems with other modes, including through the development of collective transport systems that combine conventional rail with new services such as flexible mobility, the initiative would greatly improve connectivity within and between Member States. This would benefit EU citizens, including persons with reduced mobility (PRMs), by enabling greater freedom of movement, notably for those living in peripheral regions and remote locations whose journey opportunities would otherwise be limited.

Enhancing connectivity would provide access to a wider range of opportunities for employment, education and leisure. It would similarly promote the broader well-being of the citizens, for example by improving air quality. In addition, given the extent that R&I activity is directed towards improving the safety and security of collective transport services, users of such services would benefit from a safer travelling environment and reductions in the level of service disruption. Further, the increase of the efficiency and reduction of costs would make travelling by rail more affordable and accessible to everyone and hence increase its social inclusiveness and attractiveness compared to other modes.

6.4. What is needed to achieve these impacts – Key functionalities needed

Given the focus of the impact assessment on comparing different forms of implementation, the identification of "key functionalities needed" allows making the transition between the definition of the objectives and what would be crucial to achieve them in terms of implementation. These functionalities relate to the type and composition of actors that have to be involved, the type of range of activities that should be performed, the degree of directionality needed and the linkages needed with the external environment.

6.4.1. *Type and composition of the actors to be involved*

Inclusion of the full range of rail stakeholders, and some key actors dealing interfacing with rail, is essential to leverage all relevant expertise and capability, and result in R&I outputs that address a broader set of needs than in the past, for transforming rail's system architecture, increasing emphasis on freight and digitalisation and enhancing focus on deployment of innovative solutions. A comprehensive and balanced representation of the sector (also geographically) would also facilitate the broad acceptance of the solutions developed. The main categories of stakeholders that should be involved are:

- The operating community: European rail infrastructure managers, Rail Undertakings;
- Manufacturers of rail systems or components, contractors and service providers (e.g. maintenance activities) covering the full spectrum of the value chain, from SMEs to large integrators;
- More SMEs and start-ups which can introduce agile innovation within the rail system, including those coming from different domains of activity;
- The Scientific Community;
- Freight forwarders and logistic service providers;
- EU standardisation bodies (e.g. CEN, CENELEC and ETSI) to act on the outcomes of research and innovation activities generated by the partnerships to facilitate the evolution of EU regulation, and to anticipate standardisation activities that can accelerate the market uptake and remove barriers.

There may also be a need to change the profile of stakeholder participation, as well as the geographical diversity, for example by more flexibility in the rules governing participation to ensure that specific gaps in expertise can be filled effectively and efficiently.

The initiative would require the long-term commitment of participating stakeholders to deliver solutions ready to enter industrialisation, operations and deployment. As explained above, a wide range of actors in the rail system, from across the rail supply industry and operational sectors should participate, in order to develop a "system of systems" approach, and that stakeholders familiar with the outputs of, for example, a given development project have a role in the subsequent demonstration programme to achieve a substantial impact during the next decade.

A series of stakeholders, members as well as non-members of the current S2R JU, already expressed their commitment to contribute (also financially) to a future initiative on rail R&I. Further, sectoral association expressed in position papers their support for the initiative.

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While the initiative is industry driven, particular attention will be paid to the cooperation with Member States, which is important not only for the fast implementation of the developed solutions but also for avoiding duplication and create more synergies between activities at national and European level. The participation of state-owned companies will ensure the leverage of some national programmes. Special focus will be put on promoting further participation of stakeholders from EU-13 for example through Large Scale Operational Demonstrations.

6.4.2. *Type and range of activities needed*

The initiative should be a catalyst to address present and future challenges in the transport sector and improve mobility across Europe.

The initiative aims at transforming rail's system architecture, increasing emphasis on freight and digitalisation and enhancing focus on deployment of innovative solutions. Focus on these areas at the level of the partnership is vital since deployment of innovation affecting the *systemic* elements of rail (as opposed to improvements in individual components/vehicles) requires many or all actors in the rail system to make coordinated changes – otherwise trains and track no longer work together, or interoperability between different lines is lost. Such coordinated change is only possible where the industry has collectively agreed on the way forward. As explained above, development of rail freight is a key element of the Green Deal – but the economic performance of the sector is currently poor, so investment in innovation unattractive on a purely commercial basis: hence again the need for EU Partnership intervention.

The following will be particularly important in meeting the identified general and specific objectives:

- Automatic Train Operation (ATO), boosting safety and capacity and resulting in significant (up to 30%) energy savings, deployed in different forms from unmanned vehicles to unmanned self-driving systems;
- New traffic management systems, which maximise performance by allowing trains to run together as effectively as possible through optimising the speed and movements of trains on the network. In particular it should boost the reliability of very long distance trains in particular those running internationally and enhance the ability of networks to recover from disruption;
- Control Command Signalling harmonisation at European level bringing the sector together to develop the operational concepts for passenger and freight services, functions driven by one shared system architecture, and associated specifications and standards, subsuming and replacing previous initiatives;
- Further exploration of the benefits of relevant technologies, for example 5G, digital maintenance, automation, cybersecurity, the realisation of which can be expected to both increase the efficiency and competitiveness of European rail sector and strengthen the technological lead of the European RSI;

The development of technologies supporting a step change in the competitiveness of the rail freight sector, such as management of integrated information to enhance the

customer experience, remote monitoring of the cargo environment, automated loading and unloading and remote monitoring of wagon condition⁷².

The delivery of these activities would require coordination across the TRLs, with work focused on industry and market needs, and focused demonstration activities designed to provide robust evidence of the potential benefits of innovations for users and providers of rail services. It has to be noted that, in the context of the European RSI, SMEs manufacture mostly rail components. A higher TRL would foster the SMEs participation in the initiative, since the results of their research activities would be more likely to be taken up by large manufacturers and system integrators.

It would also be important to establish links with other, related fields of research and associated policy interventions, for example through the specification of joint R&I programmes funded under two or more initiatives with a common focus on a particular field of research or technological application.

6.4.3. Priority setting system and level of directionality required

The initiative should enable or support the following:

- Alignment of the R&I strategy with EU policy objectives: the initiative should support the completion of SERA, in particular through the development of a long-term shared vision of an integrated European railway system: the further development of Europe's railways would need to be based on a whole-system approach to investment, cutting across the various interfaces, which recognises the long-lived nature of railway assets.
- Maximum leverage of available resources: the initiative will also need to ensure that limited resources available for R&I are used as efficiently as possible, and that EU funds are supplemented by financial and/or in-kind resources provided by the RSI, the rail transport industry and technology-based organisations from outside the rail sector.
- An implementation approach with a strong and committed governance led by the Union, and with an inclusive participation. This would also require to define the procedures that would allow an efficient and effective implementation. Transparent decision-making and visibility of outputs: the initiative must be supported by decision-making processes that involve all relevant stakeholders and ensure clear accountability for results. It will also need to be subject to clear rules governing intellectual property, striking a balance between protecting organisations making substantial investment in R&I and ensuring that the outputs of individual projects are sufficiently visible to enable further development and high rates of market take-up.
- Dialogue at the national and international level: the initiative must enable effective dialogue between those engaged in R&I activity and those responsible for rail policy and regulation at the international and national level (including international standards bodies). Efforts should be made to ensure a robust and effective participation of Member States and organisations from EU-13.

⁷² See, for example, Rail Freight Forward, 30 by 2030: Rail Freight Strategy to Boost Modal Shift, available at: https://www.railfreightforward.eu/about-rail-freight-forward, for a discussion of how digital technology, together with other factors, could increase the modal share of rail freight to 30% by 2030.

6.4.4. Coherence needed with the external environment

In order to maximise complementarities and synergies with all concerned sectors, clear and strong collaboration with other initiatives and EU programmes is key in order to reach the expected impacts.

The following provide an illustration of the possible synergies between R&I in rail and other areas:

- Application of digital technology, starting from improving the functionality of ERTMS.
- Exploring complementarity with road, maritime and air transport –exploit the benefits of different modes at different stages of the journey and minimise environmental impacts.
- Exploiting developments in battery and fuel cell technology and other forms of power that has applications in different parts of the transport sector. It is important that the potential benefits for rail of further developments in different sources of power are fully explored. There could be scope for joint programming of R&I activity with the Batteries partnership, recognising the potential for greater use of battery and hydrogen fuel cell technology to reduce the need for investment in electrification of rail infrastructure.
- Synergies with other programmes and initiatives would be needed, in particular: the Digital Europe Programme (DEP) that will focus on reinforcing Europe's capacities in high performance computing, artificial intelligence, cybersecurity and advanced digital skills and ensuring their wide application across the economy and society.
- Synergies with other funding sources and financing mechanisms that would support innovation in particular the Connecting European Facility (CEF) for deployment of the innovative solutions.
- Synergies with the European Regional Development Fund (ERDF) and Cohesion Fund (CF) in order to increase economic and social cohesion and reduce imbalances.
- Global synergies related to new emerging and non-traditional land transport technologies such as hyperloop, hyper-speed maglev, pods' concepts, etc. where experience is shared at global level to accelerate possible future new business models and services that can revolutionize transport and mobility, while maintaining a European know-how competitive edge.

7. WHAT ARE THE AVAILABLE POLICY OPTIONS?

This section describes the specific functionalities that could be provided under the baseline scenario of traditional calls and the different options of different types of European partnerships.

7.1. What is the baseline from which options are assessed?

The baseline scenario used in this impact assessment is a situation without a Partnership and only traditional calls of Horizon Europe. Given that there is a predecessor Partnership as well as other funding sources in the area, these will continue generating effects even if there is no new Partnership. In particular it is expected that these already existing initiatives will still create effects on the ongoing evolution of the rail system, the digitalisation of the sector and the ongoing efforts to meet the EU Green Deal objectives. However, in the absence of a new Partnership, these benefits would be limited in time and their scope is going to be significantly reduced. This is taken into account in the effectiveness assessment.

In parallel, the baseline situation means that the current implementation structure of the Article 187 would be closed, which bears winding down and social discontinuation costs. There would also be financial cost-savings related to the closing of the structure, related to operations, staff and coordination costs in particular. This is taken into account in the efficiency assessment.

Table 2 - Key characteristics of the baseline – Option θ

	What is feasible under this option - Functionalities of option
Enabling appropriate profile of participation (actors involved)	 The Commission would need to prepare or delegate the preparation of the Strategic Research and Innovation Agenda (SRIA) consulting extensively with a wide range of stakeholders to translate the strategic R&I agenda for rail into annual work programmes. There would be no formal and financial commitment from partners to jointly develop and implement the Programme defined in the SRIA. A well-defined process would be needed to ensure that the Programme Committee responsible for mobility was properly informed about R&I priorities, including key demonstration programmes. An evolving profile of participation would be needed, with different consortia forming at different stages to take different types of activity forward, in order to maximise the expected outputs.
Supporting implementation of R&I agenda (activities)	 Implementation would rely on standard infrastructure underpinning the procedure of calls under the work programme, drawing on resources of relevant executive agencies and Commission IT systems. Calls for proposals would be part of the work programmes of Horizon Europe. Transparency and open publication of results would ensure their availability to interested parties. Dissemination of knowledge and share of practice would happen predominantly among partners within the project consortia. Uptake of outcomes into technical specifications for interoperability (TSI) and rail standards would happen sporadically and be heavily dependent on the objectives and quality of results of individual projects. Contribution to the systemic and integrated transformation of the European rail sector would depend on the level of participation in and quality of individual projects.
Ensuring alignment with R&I agenda (directionality)	 The governance structure and the lack of formal commitment from private partners would not fully enable the implementation of the long-term vision defined in the SRIA. Specification of calls for activity at higher TRLs, particularly demonstration programmes, would need substantial input from industry. Calls would need to take into account the results of the S2R JU to ensure continuity where appropriate. R&I activity would focus on the short to medium term needs of the sector in alignment with the EU policy objectives, although it would also include fundamental research. Commission input into specification and oversight of calls would help to ensure alignment with overarching policy objectives but full integration with other programmes would require additional coordination.
Securing effective leveraging of resources (additionality)	 Progress of R&I effort would depend largely on EU funding, with no expectation of significant leveraging of industry support. Given more limited funding than in the past, critical R&I priorities would need to be identified at the outset.
Key differences compared to the current situation	 No formal and financial commitment from private partners to implement the long-term vision defined in the SRIA. Limited participation based on the composition of ad hoc consortia for specific projects. Sporadic translation of projects results into standards and TSIs. Piecemeal approach to R&I (as opposed to the current systemic approach). Lack of long term vision for the transformation of the European rail system. Increased reliance on EU funding as a result of limited leveraging of industry support.

- Limited synergies with other Partnership and EC Programmes (e.g. CEF).
- Sector fragmentation due to the creation of barriers between different rail segments, undermining the overall performance of the network
- Long term phasing out of national barriers undermining the contribution of rail to the Union policies, in particular the Green Deal.
- Increasing operational cost of the rail systems to the detriment of public budget and finances

7.2. Description of the policy options

Option 1 - Co-programmed European Partnership

Table 3 - Key characteristics of Option 1

	What is feasible under this option - Functionalities of option
Enabling appropriate profile of participation (actors involved)	 The option would encourage participation of some key stakeholders committing to jointly support the development and implementation of a R&I programme based on common strategic R&I agenda. It would need to consult with a wide range of stakeholders to ensure that the R&I agenda, and ultimately the work programme, was aligned with industry and market needs. It would offer some degree of flexibility to change the profile of participation) over time, thanks to the possible leading role of sector Associations, with new partners joining in response to emerging results and changing priorities.
Supporting implementation of R&I agenda (activities)	 Implementation of EU funded R&I agenda would rely on standard administrative infrastructure underpinning the calls under the work programme procedure, drawing on resources of relevant executive agencies and Commission IT systems. Calls for proposals would be part of the work programmes of Horizon Europe. Partners would implement their additional activities separately. Sector Associations could provide back-office with relevant functionalities to run the Partnership under Horizon Europe standard implementation would ensure transparency and open publication of results for the interested parties.
Ensuring alignment with R&I agenda (directionality)	 The governance structure and the formal commitment from private partners could enable the implementation of the long-term vision defined in the SRIA, provided that a wide range of partners join the Partnership. Work programmes would need to reflect the requirement for R&I activity across TRLs, with input from the various partners to achieve an appropriate balance of activity directed towards different markets (e.g. freight transport). The partnership would be responsible for ensuring that priorities for calls were specified in line with R&I priorities, including demonstration programmes. R&I activity would be likely to focus on the medium-term needs of the sector combined with EU policy priorities. Programme Committee responsible for mobility or similar configuration would have important role in ensuring alignment with overarching policy objectives and coordination with related programmes. Limited participation from sector's partners could result in limited efficiency to develop outputs that would be rapidly applied across the network.
Securing effective leveraging of resources (additionality)	 Aspirations for partner contributions would be clearly defined at the outset in the contractual arrangement. In-kind commitments from private partners are expected to match Union contribution. Expected in-kind contributions from the private sector would be identified in the work programme.

Key differences compared to the current situation

The Co-Programmed partnership (Option 1) would entail the dismantling of the current S2R JU with the following consequences:

- The implementation of a common vision and ambitious objectives in the area would be less efficient and take longer (if a common vision could be developed at all);
- The basis for R&I cooperation under a stable structure would disappear;
- Large scale R&I actions (pilots, platforms) could not be implemented, affecting the coverage of TRL 5-8 and diminishing the impact of the initiative;
- EU support to the area would move from a shared long-term commitment with the industry to a full financing by the EU, with a much lower volume of resources available;
- Combined European/national public funding of actions would not be possible;
- Winding down and discontinuation costs of the current S2R JU (see rationale at Section 8.2
 Efficiency)

Option 2 – Institutionalised European Partnership under Article 187 TFEU

Table 4 - Key characteristics of Option 2

	What is feasible under this option - Functionalities of option
Enabling appropriate profile of	 The option would enable participation by all key stakeholders to jointly support the development and implementation of a programme of research and innovation activities contributing to the specification and delivery of the SRIA.
participation (actors involved)	• In order to increase the use of results in national contexts, the rail operating community should contribute to the definition of needs, specifications, requirements, and interfaces together with the rail supply industry and research community.
	• This option would enable the development of high-TRL solutions closer to the market, thus fostering SME's participation in the Programme, since the results of their research activities are more likely to be taken up by large manufacturers and system integrators.
	 The governance structure would allow the delivery of sector's needs and EU policy objectives. It creates an interface for consulting stakeholders on R&I priorities and the work programme in a transparent, structured and targeted manner, ensuring that they are aligned with industry, research and market needs and with the agenda of other partnerships and sectoral programmes.
	 Becoming a partner/member would be less flexible than under other options, but it might nevertheless be possible to change the profile of participation over time, with new partners joining to support new areas of activity in response to emerging challenges and evolving priorities.
	 The definition of an integrated R&I Programme looking at internal and external interfaces would attract rail actors of all segments who will find their needs answered. An agile approach should be put in place to address the needs of the beneficiaries to achieve an ambitious programme.
	The definition of the shared vision driven by the Union mobility and transport policy based on a functional system architecture will attract the participation of sector representatives setting the basis for a more delivery oriented R&I Programme.
Supporting implementation of R&I agenda (activities)	• A dedicated administrative structure would be established to coordinate the specification of R&I activity, manage implementation and report on the results (with administrative expenditure subject to rules relating to its level and distribution). This could be mitigated through the use of existing structure under S2R JU and the setting up of a joint back office for a number of JUs.
	• Calls for proposals would be published broadly by the administrative structure allowing efficient coordination among stakeholders.
	 Transparency and open publication of results would ensure their availability to interested parties.
	The creation of a community of stakeholders, with potential diffusion activities managed by the partnership structure would enable the share of knowledge and practices.
	• The interface with national authorities, ERA, European and international standardisation bodies would ensure that results would enter properly the pipeline of regulatory or

standard framework for market uptake and impact.

- An Institutionalised Partnership would make full use of available financial instruments within the limits of the Horizon Europe and of the Partnership Basic Act, building on the experience of the S2R JU (e.g. the use of the lump sum model, prizes, etc.).
- Dissemination and communication activities will be not limited to typical inwards project events, such as in H2020 or future HE programme, but resources would be commingled to leverage a common investment and connect with other sectors and modes.
- The administrative structure would become the single coordinating body to converge the sector together towards a shared vision on concept of operations, ensuring a sector-driven action led by the Union policies towards a major transformation of railway.

Ensuring alignment with R&I agenda (directionality)

- Based on the long-term joint agenda, the partnership would be responsible for defining a work programme fully in line with the R&I priorities identified by the industry, combining activities across the TRLs (including key demonstration programmes) and in different areas (e.g. freight transport).
- In order to achieve a balanced approach between blue-sky and applied research, the Institutionalised Partnership would have the mandate and resources to allow for the completion of the R&I cycle, including industrialisation of innovative solutions.
- The work programme would reflect the medium to long term needs of the sector aligned with EU policy priorities, drawing on the perspectives of different stakeholders.
- The work programme would build on, but not be constrained by, the current programme to ensure continuity where appropriate.
- Commission participation in the partnership governance arrangements and approval of the work programme would help to ensure alignment with overarching policy objectives and enable integration with other programmes.

Securing effective leveraging of resources (additionality)

- Legally binding funding requirements would be clearly defined at the outset, with private sector partners expected to provide a substantial part of the resources through in-kind and/or financial commitments.
- An institutionalised partnership would allow investments for long-term research with the medium or high risk of failure. Also, it would help to recruit and maintain research teams for research activities with a medium or high risk of failure.
- An institutionalised partnership would allow a structure aimed at the deployment of innovation. In particular, strong coordination with the CEF Programme would help filling the qualitative gap to move from TRL 7 to full deployment.
- An institutionalised partnership would allow reducing the overall cost of bringing research and innovation to the market, as it would involve in its processes ERA and standardization bodies.

Key differences compared to the current situation

- The administrative structure of S2R JU would be taken over by the new institutionalised partnership.
- Governance, administrative procedures and practices will be adapted as to ensure that operations are as transparent and efficient as possible.
- The governance structure would reflect the enhanced need for a systemic approach e.g. by including a system pillar steering group.

7.3. Options discarded at an early stage

The co-funded partnership and an institutional partnership created under Article 185 of the TFEU are not considered relevant for the impact assessment of the Transforming Europe's Rail System partnership. This is because of the need to secure the engagement of private sector and other commercial organisations in the co-funding, programming and delivery of R&I, not least because of the key role of such organisations in both the delivery of rail services in Europe and the supply of rail-related products and services in global markets. As the only forms of partnership in which the private sector can participate are the co-programmed partnership and the institutionalised partnerships established under Article 187,

the analysis in the following section is restricted to a comparison of these options with the baseline option of calls under the Work Programmes of Horizon Europe.

8. How do the different policy options compare to achieve the expected impacts?

Based on the objectives pursued by the initiative and the key functionalities identified to be able to achieve them, each option for implementation is assessed in terms of effectiveness, efficiency and coherence compared to the baseline scenario of traditional calls. The analysis is primarily based on the degree to which the different options would cater for the key needed functionalities. All options are compared to the baseline situation of traditional calls, which is thus consistently scored at 0 to serve as reference point.

8.1. Effectiveness

To be in line with the Horizon Europe impact framework, the fulfilment of the specific objectives of the initiative is translated into 'expected impacts' - how success would look like -, differentiating between scientific, economic/ technological, and societal (including environmental) impacts. This section considers to which extent the different policy options would allow delivering these expected impacts – confronting what is needed (functionalities) with what each form of implementation can provide in practice. The assessments in this section set the basis for the comprehensive comparative assessment of all retained options against all dimensions in Section 6.4, based on a scoring system ⁷³.

<u>Scientific impact - Creation and diffusion of high-quality new knowledge, skills, technologies and solutions to global challenges</u>

Under the **baseline option** of traditional calls under Horizon Europe the volume of publications from European universities and research-based organisations is expected to increase at a rate similar to that observed during previous Framework Programmes. Given that this option does not provide a consistent and coordinated ecosystem of stakeholders, it could deliver significant outputs for low and medium TRL, if a clear agenda is set up.

However, the scientific impact under this option would be limited by a number of factors:

- It would be difficult to coordinate the wider participation among stakeholders, since the composition of consortia responding to the calls under Work Programme could not be easily directed and managed according to a common strategy.
- It would not be possible to provide technical solutions and sufficient knowledge to address, since there would be some dislocation between calls launched at different times and no guarantee that the appropriate stakeholders would be involved throughout a given research programme.
- The effective diffusion of any results obtained would be challenging given the fragmentation at project level and the lack of coordination at programme level.

Against this background, Europe's contribution to the knowledge base is expected to develop in a fragmented manner under the baseline option, with China continuing to

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⁷³ A more in depth and detailed analysis of each policy option is provided in Technopolis Group (2020)

strengthen its position in the publication of fundamental research and to dominate the creation of new intellectual property.

Given the higher degree of stability and based on the feedback received in various consultation processes, a greater degree of participation is expected under a European Co-Programmed Partnership than under the baseline option. The scientific impacts under this option would probably be greater than those estimated under the baseline option, with European universities and research-based organisations having easier access to the Programme, thus making a stronger contribution to the volume of publications and the RSI registering marginally more patents and industrial designs as well as possible creation of jobs. Its score would therefore be good compared to the baseline with +.

However, the volume of creation and diffusion of high-level knowledge making a scientific impact would again be constrained by the partial participation of key stakeholders from the rail sector. This option would therefore be subject to many of the same limitations as the baseline. Its score would therefore be similar to the baseline with 0.

An Institutionalised European Partnership established under Article 187 TFEU would be subject to a well-defined legal and financial framework, with a wide range of partners contributing resources in accordance with legally binding requirements relating to the proportion of EU and partner funds, set out in a Council Regulation.

The coordinated involvement of research and industry actors with a long-term commitment, could contribute to the emergence of new applications and to continuous efficiency, quality and reliability improvements in applications and equipment. This impact will be even higher compared to the S2R JU, in light of the stronger system focus of the new Partnership. This would in turn also have an impact in terms of creation of high-quality jobs. The score of Option 2 would therefore be high compared to the baseline with ++.

In addition, creation of networks linking universities and research-based organisations under the coordination of the future Partnership, is expected to strengthen the scientific impact of this option. This, in turn, can encourage interest from organisations that have not participated in the current S2R JU, including SMEs, start-ups and entities from outside the rail sector, resulting in a more dynamic process of exchange and collaboration. The score of Option 2 would therefore be high compared to the baseline with ++. The score for the scientific impact for each option is presented in Table 6.

Table 6 - Overview of the options' effectiveness compared to the baseline -Scientific impacts

	Baseline: Horizon Europe calls	Option 1: Co-programmed	Option 2: Institutionalised Article 187
Increase in number of high-quality jobs	0	+	++
Strengthened pipeline of potential innovation	0	0	++

Notes: Score ++ : Option presenting a *high* potential compared to baseline; Score +: Option presenting a *good* potential compared to baseline; Score 0: Potential of the baseline.

Economic/Technological impacts - Foster all forms of innovation and strengthen market deployment of innovative solutions

The technological and economic impacts under the **baseline option** of traditional calls would be limited by the difficulties of coordinating wider stakeholder participation and

market uptake of innovations and strengthening collaboration in accordance with a long-term strategy.

In addition, lack of participation on the part of some stakeholders would reduce the level of investment in R&I during Horizon Europe as compared with that under Horizon 2020. Progress towards disruptive innovation, for example through delivery of the kind of efficiency, punctuality and capacity targets previously defined for the S2R JU, would therefore be considerably slower.

The market take-up of innovation is not expected to increase substantially under a coprogrammed European Partnership (**Option 1**), although some increase might be expected given a more structured approach to industry participation compared with one based entirely on traditional calls under the Work Programme. The estimated take-up rate between 45% and $60\%^{74}$, represents a significant but not necessarily transformative improvement on the rate achieved before Horizon 2020 and reflecting the degree of uncertainty surrounding the impact of this option ⁷⁵.

The European RSI's technological lead is expected to be eroded under this option, since it would not enable sufficient incremental investment in R&I, over and above that which the industry would anyway undertake, to deliver a step change in the level of both fundamental research and market-focused development. Hence, while the marginal increase in intellectual property could strengthen the industry's position in some countries, for example those where there is potential to deploy ERTMS, this would probably be insufficient to address the challenge from countries such as China and Japan. The score would therefore be good compared to the baseline with +.

Since the stable governance framework of an Institutionalised European Partnership under Article 187 TFEU (Option 2) would ensure a more structured approach in terms of number and composition of actors, coordination of activities and coherence with external environment and other ongoing activities, it could be expected to deliver substantially higher technological and economic impacts, including better leverage of EU funding. In particular, wider, more focused and more structured participation of stakeholders, including key actors within the rail transport industry as well as SMEs and technology-based organisations, combined with better coordination of R&I effort along the value chain, would enable a substantially higher level of demonstration activity. This includes a strong focus on the speed-up of deployment of innovation and market uptake to implement a systemic transformation of rail transport. Moreover, wide and coordinated participation will allow the development of a system of systems and a coordinated approach to transform the rail sector's system architecture, resulting in more tangible economic and technological impacts compared to the S2R JU. The involvement of Member States will be essential in this respect, as they will be in a position to foster the deployment at national level of innovative solutions developed at European level in the Partnership.

The long-term vision and related financial stability provided by an institutionalised partnership would be key to foster stakeholders' involvement, in the aftermath of the Covid-19 breakout and its expected negative economic impacts which could include cuts in the

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⁷⁴ Source: Technopolis Group (2020), Impact Assessment Study for Institutionalised European Partnerships under Horizon Europe, Final Report, Candidate Institutionalised European Partnership on Transforming Europe's Rail System - Study for the European Commission, DG Research & Innovation

⁷⁵ There is no direct experience of a co-programmed partnership in the rail sector and hence no firm evidence on which to base the market take-up assumption.

resources invested in R&I by the sector. Whilst it is too early to say if the Covid-19 crisis will finally lead to major supply chain changes, there are good reasons to assume that ultimately economies of scale will still largely prevail in most sectors. Structural issues such as repatriation of production, questioning of global supply chains and globalisation in general will however all be under review. As a result, digitalisation might be accelerated as opportunity also for the rail sector for new efficiency gains. The score of the option would therefore be high compared to the baseline with ++.

In view of the long term commitment of partners of a JU and the additional resources available to it, such a partnership should target a market take-up rate of between 50% and 100%. The estimate impacts of this option assume a take-up rate of between 50% and 75%⁷⁶ and that the efficiency targets set for the current JU are achieved by 2031. The score would therefore be high compared to the baseline with ++.

These improvements lead to a significant contribution to the increase in the competitiveness of the rail transport industry, with rail's share of passenger traffic rising to 10% or more and its share of rail freight traffic reaching around 20% by 2031, and contributing to the Green Deal objective to shift a substantial part of the 75% of inland freight carried today by road onto rail and inland waterways. The increase in rail industry and other employment under this option is also substantially higher than under those previously discussed. The score would therefore be high compared to the baseline with ++.

Table 7 shows the estimated range of technological and economic impacts of each option. Economic and technological impacts have been estimated using a model developed for a European Commission 'Study on the Cost and Contribution of the Rail Sector'. The model has been adapted to investigate the effect of different combinations of transport cost savings and investment (see Annex 4 for a detailed description of the model). These values do not consider the potential impact and consequences of the Covid-19 pandemic, which are still under assessment.

Table 7 – Technological and economic results and impacts

Range of values in 2031		Option 0	Option 1		Option 2	
		Value	Lower	Upper	Lower	Upper
Results	Reduction in railway costs compared to baseline scenario (€ bn)	0	11.3	15.2	33.2	51.0
Results	Increase in railway investment compared to baseline scenario (€ bn)	0	5.7	7.6	16.6	25.5
Impacts	Increase in passenger traffic compared to baseline scenario (bn passenger-km)	0	23	32	74	123

⁷⁶ Source: Technopolis Group (2020), Impact Assessment Study for Institutionalised European Partnerships under Horizon Europe, Final Report, Candidate Institutionalised European Partnership on Transforming Europe's Rail System - Study for the European Commission, DG Research & Innovation

https://ec.europa.eu/transport/sites/transport/files/modes/rail/studies/doc/2015-09-study-on-the-cost-and-contribution-of-the-rail-sector.pdf

-

Increase in freight traffic compared to baseline scenario (bn tonne-km)	0	23	32	73	122
Increase in total employment compared to baseline scenario by 2031 (thousands of people).	0	201	269	591	904

For each option, the score for the potential to achieve economic/technological impacts is presented in Table 8.

Table 8 - Overview of the options' effectiveness compared to the baseline - Economic/technological impacts

	Baseline: Horizon Europe calls	Option 1: Co-programmed	Option 2: Institutionalised Article 187
Increase in rail's modal share of passenger/ freight markets	0	+	++
Improvements in the competitiveness of RSI	0	+	++
Increase in rail industry and wider employment	0	+	++

Notes: Score ++ : Option presenting a *high* potential compared to baseline; Score +: Option presenting a *good* potential compared to baseline; Score 0: Potential of the baseline.

Stakeholder opinion

The Open Public Consultation responses provide further support for the view that a well-defined legal structure of the kind underpinning an institutional partnership would increase the economic and technological impacts of the initiative. A substantial majority of business organisations of different sizes, business associations, academic institutions, public authorities and EU citizens considered that such a structure was either relevant or very relevant for achieving more effective and faster implementation of the initiative, increased financial leverage, better links to both regulators and practitioners on the ground, more long-term commitment from partners and harmonised standards.

A majority of the interviewees representing train operators, infrastructure managers and the RSI considered that an institutionalised partnership was essential if EU funding of rail-related R&I was to have a transformative economic and technological impact on the sector. In the view of a number of key stakeholders involved in the S2R JU, the legal framework established under this approach, together with the associated commitments in respect of the provision and allocation of funding, was essential if major public sector stakeholders were to obtain internal and external approval for their participation. It followed that, in the absence of such a framework, these stakeholders would substantially reduce their support for, or even disengage from, an initiative to promote rail-related R&I under Horizon Europe.

Most of the organisations providing feedback on the inception impact assessment also strongly supported the implementation of an institutionalised partnership. They considered such a partnership to be significantly more effective in delivering economic and technological impacts, noting that it would be better placed to develop a long-term strategy for R&I investment, coordinate the contributions of different stakeholders and ensure efficient use and better leverage of EU funding.

<u>Societal impacts - supporting and implementing Union policies, and the uptake of innovative solutions in industry and society to global challenges;</u>

Under the **baseline option**, the net reduction in CO₂ emissions in 2031 is estimated to be between 0.4 and 0.5 million tonnes⁷⁸ (after taking account of the impact of increased traffic levels and the transfer of traffic to rail), with a value of Euro 18 - 24 million⁷⁹, reflecting the limited modal shift for both passenger and freight noted above.

Moreover, the option is unlikely to contribute significantly to the better integration of transport systems needed to enhance connectivity for EU citizens and materially improve the quality of life for the growing proportion of the European population living in cities. This will depend on the involvement of national rail operators, infrastructure managers and other transport service providers who can help coordinate the R&I activity needed to identify improvements in the interface between national and local networks. Such participation would be limited in circumstances where support for R&I was restricted to standard calls under the Work Programme.

Under a Co-Programmed European Partnership (**Option 1**), the net reduction in CO₂ emissions is estimated between 1.0 and 1.4 million tonnes in 2031⁸⁰, valued at Euro 50 – 68 million. This is approaching three times the reduction achieved under the baseline but still limited when set against total emissions from transport in a single year. The score would therefore be good compared to the baseline with +. This form of partnership would not allow the development of a system of systems and a coordinated approach to transform the rail sector's system architecture, due to the limited participation of stakeholders. In particular, it would not encourage the level of participation from urban transport operators and other stakeholders needed to transform transport systems and increase quality of transport and life within and between cities. The score would therefore be good compared to the baseline with +.

Thanks to a coordinated and market-oriented sectorial approach and a coordinated effort to deploy innovative solutions, the reduction in CO₂ emissions is likely to be more substantial under an Institutionalised European Partnership under Article 187 TFEU (**Option 2**) as significantly more traffic would be diverted to rail from other, less environmentally friendly, modes. The expected reduction is between 2.5 and 4 million tonnes in 2031⁸¹. This impact could be expected to increase if the competitiveness of rail services continued to improve beyond the period of Horizon Europe, hence making a substantial contribution to the achievement of the Green Deal objectives.

Moreover, thanks to the coordinating role of the Commission and the involvement of Member States, an institutionalised partnership would be more likely to deliver the

⁸⁰ Source: Technopolis Group (2020), Impact Assessment Study for Institutionalised European Partnerships under Horizon Europe, Final Report, Candidate Institutionalised European Partnership on Transforming Europe's Rail System - Study for the European Commission, DG Research & Innovation

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⁷⁸ Source: Technopolis Group (2020), Impact Assessment Study for Institutionalised European Partnerships under Horizon Europe, Final Report, Candidate Institutionalised European Partnership on Transforming Europe's Rail System - Study for the European Commission, DG Research & Innovation

⁷⁹ Carbon is valued at €48 per tonne, based on Handbook of External Costs of Transport 2014.

⁸¹ Source: Technopolis Group (2020), Impact Assessment Study for Institutionalised European Partnerships under Horizon Europe, Final Report, Candidate Institutionalised European Partnership on Transforming Europe's Rail System - Study for the European Commission, DG Research & Innovation

transformational change to national transport systems making the European railways cheaper, more reliable and more flexible, hence more attractive. In addition, it would significantly contribute to improving quality of the environment in European cities. The score would therefore be high compared to the baseline with ++.

Since one of the objectives of the candidate rail partnership is to increase R&I activities related to rail freight, one core element of the transformation to logistic on-demand services is the link between customer demand and logistic service supply. This requires seamless, digitized customer communication linked to the management systems of RU, IM, ports, clients and multimodal service providers which can be achieved by means of a wide coordination under an institutionalised partnership. The score would therefore be high compared to the baseline with ++.

Stakeholder opinion

For the most part, various categories of stakeholders participating in the interview programme and responding to the inception impact assessment considered that an institutionalised partnership would be best-placed to deliver a range of beneficial societal impacts, including a reduction in environmental emissions and better integration of the European transport system in the interest of EU citizens.

In the Open Public Consultation, a majority of respondents indicated that the Partnership would be very relevant for contributing to a cleaner mobility at lower costs, reduced noise, energy consumption and emissions. Both companies and academic institutions highlighted the importance of ensuring the competitiveness of the European rail industry at the global level while focusing on societal objectives (e.g. increasing the use of renewable resources) and demonstrating the practical benefits of rail-related R&I to a wide audience.

For each option, the score for the potential to achieve societal impacts is presented in Table 9.

Table 9 - Overview of the potential for achieving societal impacts

	Baseline: Horizon Europe calls	Option 1: Coprogrammed	Option 2: Institutionalised Article 187
Reduction in environmental impacts of transport	0	+	++
Improvements in safety, security and health of EU citizens	0	+	++

Notes: Score ++ : Option presenting a *high* potential compared to baseline; Score +: Option presenting a *good* potential compared to baseline; Score 0: Potential of the baseline.

Expected impact on simplification and/or administrative burden

An Institutionalised Partnership would be capable to simplify the administration related to the membership participation in the research and innovation activities. A generic approach designed for a multibillion diversified Programme such as Horizon Europe with spread accountability and different funding tools would not match the expectations of a mission oriented programme such as rail Research and Innovation.

Expected impacts on fundamental rights

With a significantly strengthened integration of rail systems with other modes citizens would have greater freedom to pursue career, educational and leisure opportunities of their choice and to travel in a safe, secure and healthy environment. In addition, PRMs will be able to access such opportunities more easily. In addition, regional cohesion would be further enhanced, through collaboration in the Research and Innovation lifecycle as well as through the delivery of a new integrated rail system.

8.2. Administrative Costs/Efficiencies

In order to compare the policy options consistently in terms of their efficiency, a standard cost model was developed for the external study supporting the impact assessment for the set of candidate Institutionalised Partnerships. The model and the underlying assumptions and analyses are set out in the Common Part of this impact assessment, Section 2.3.2 and in the Methodology Annex 4. A dedicated Annex 3 also provides more information on who is affected and how by this specific initiative in line with the Better Regulation framework. The scores related to the costs set out in this context allow for a "value for money" analysis (cost-effectiveness) in the final scorecard analysis in Section 6.4. For the purpose of this analysis, the standard cost model is complemented with information based on the current experience of S2R JU, which contributes to providing a realistic estimate of costs of the future Partnership. Indeed, such analysis should take into due account the fact that initiatives deriving from an existing Partnership, such as Transforming Europe's Rail System, would benefit from an administrative structure already in place and set up costs already borne, hence a significant overall cost reduction. In addition, for this specific initiative under the baseline scenario of traditional calls, there would be winding down and social discontinuation costs for the existing implementation structure of the current Article 187 initiative. These can be estimated at EUR 400.000. There would also be longer term financial cost-savings related to the closing of the structure, related to operations, staff and coordination costs in particular. These can be estimated at EUR 3.5 million (EUR 1.6 million administrative costs, EUR 1.9 million personnel costs) per year of operation. The total running costs of the existing S2R JU cannot exceed EUR 27 million (50% from the EU and 50% from private Members through in cash, in kind and additional contributions). Private members will also contribute 50% to all administrative costs that would account for maximum 5% of operational expenditure. These costs are the baseline of the current S2R JU and should therefore be adapted on the basis of the ambition, programme and budget of the Transforming Europe's Rail System candidate Partnership. In S2R JU, indicatively 30% of the funding is allocated to the operating community, whereas the supply industry and research community get approximately 70% of the available funds. Under the future Partnership, a more balanced approach in terms of funding distribution is envisaged.

Annex 3 provides additional information on costs and benefits of the preferred option. Overall it is estimated that the longer term cost savings from using traditional calls instead of an existing Article 187 initiative would considerably exceed the costs incurred for winding down operations. However, it should be also noted that higher costs of an Institutionalised Partnership result in a way more effective performance in terms of outputs for the benefit of European citizens and industry compared to other options. This overall situation is set as the starting point for the comparison of options. The score of this baseline scenario (traditional Horizon Europe calls) is set to 0 to be used as a reference point.

On this basis, the scores for the costs of the different options range from a value of 0, in case an option does not entail any additional costs compared to the baseline, to a score of (-)(-) when an option introduces limited additional costs when compared to the baseline and a

score of (-)(-) when substantial additional costs are expected in comparison with the baseline. In case the scores are lower than for the baseline scenario, (+) and (+)(+) are used.

It is considered that while there is a clear gradation in the overall costs of the policy options, the cost differentials are less marked when one takes into account the expected co-financing rates and the total budget available for each of the policy options, assuming a common Union contribution. From this perspective, there are only one or two percentage points that split the most cost-efficient policy options – the baseline (traditional calls) and the Co-Programmed policy options – and the least cost-efficient – the Institutionalised Partnership option. Indeed, in terms of cost-efficiency, the Co-Programmed Partnership (Option 1) is 2 percentage points more efficient than the baseline; and an Article 187 Partnership is 2 percentage points less cost-efficient than the baseline. A score of + is therefore assigned for **cost-efficiency** to the Co-Programmed options and a score of (-) for the Institutionalised Partnership policy option.

Table 6: Matrix on 'overall costs' and 'adjusted cost scoring'

	Baseline: Horizon Europe calls	Option 1: Coprogrammed	Option 2: Institutionalised Article 187 TFEU
Administrative, operational and coordination costs	0	0	(-)(-)
Administrative, operational and coordination costs adjusted per expected co-funding (i.e. cost-efficiency)	0	+	(-)

Notes: Score 0 = same costs as for the baseline; score (-) = limited additional costs compared with the baseline; score (-)(-) = substantial additional costs compared with the baseline.

8.3. Coherence

8.3.1. Internal coherence

In this section we assess the extent to which the policy options show the potential of ensuring and maximising coherence with other actions, programmes and initiatives under Horizon Europe, in particular European Partnerships (internal coherence).

While some coordination of the activity could be achieved under the baseline option (Option 0), it would be difficult to ensure an effective progression of activity from fundamental research through development work to demonstration. This is a consequence of the difficulty of ensuring continuity between projects at different TRLs under a standard calls approach, not least because the parties responding to individual calls would typically be consortia formed on an ad hoc basis with limited knowledge of the broader strategic programme of R&I activity.

Similarly, coordination of R&I programmes with other initiatives, including any partnerships formed under the Climate, Energy and Mobility cluster or more generally under Horizon Europe, would be challenging, due to the fragmentation at consortia level. This option would allow a coherent approach through the Work Programme and strategic planning but would not enable a proactive approach in terms of activities which need more coordination (for example demonstration activities) and closer collaboration between research, industry and decision-makers.

While the memorandum of understanding underpinning a Co-Programmed European Partnership (Option 1) would reflect the technical content defined in the strategic research agenda, development and delivery of the work programme would rely on Commission

structures, with Member States approving the Work Programme under comitology procedure. Hence, the partnership would not have much control for the direction of rail-related R&I and it would be difficult for it to work with other partnerships within Horizon Europe to define an integrated work programme leveraging synergies in relevant areas. The score would therefore be good compared to the baseline with +.

An Institutionalised European Partnership under Article 187 TFEU (**Option 2**) would meet the functionality requirements described in *Section 4.4* more effectively and would therefore be better placed to deliver a more coherent long-term strategy for rail-related R&I, with the possibility to adjust its strategy considering the evolution of Union policies and stakeholders' needs. In particular, it would be able to call on dedicated management resources to develop the strategy and plan supporting work programmes in collaboration with other partnerships. This would ensure that the strategy could take account of links with key partnerships, such as ECSEL and 5G for digitalisation and automation, Clean Hydrogen and Batteries as alternatives for diesel trains and for autonomous new freight wagons and other transport partnerships concerning interfaces with other modes and multimodality. Synergies and cooperation with the Knowledge and Innovation Communities (KIC) would be established (e.g. with the urban mobility, energy and climate KICs) to increase demonstrations and facilitate deployment of technologies. Moreover, synergies and cooperation with the Missions could be established, in particular on Climate Change and Smart Cities. The score would therefore be high compared to the baseline with ++.

Stakeholder opinion

Stakeholders participating in the interview programme indicated that a future partnership would be able to cooperate more with other initiatives under Horizon Europe to leverage the benefits of technology that is not specific to the rail sector. One regulatory agency stressed the importance of developing a strategy and work programme that reflected the needs of a fully integrated transport system for Europe.

Responding to the Open Public Consultation, a majority of stakeholders stated that the legal structure underpinning an institutionalised partnership was either relevant or very relevant to the facilitation of collaboration with other partnerships under Horizon Europe. Support for this view was particularly strong among large business organisations and business associations, but it was also held by most SMEs, academic and research institutions, public authorities and EU citizens. A substantial majority in each of the same stakeholder groups confirmed that there would be scope for rationalising the activities of the candidate partnership for rail and to link it with other initiatives under Horizon Europe.

Respondents that are/were involved in a current/preceding partnership found a legal structure more relevant than other respondents when it concerned a faster to response to sudden market or policy needs as well as synergies with other programmes and collaboration with other partnerships.

Large companies showed a slightly higher relevance for implementing activities effectively, ensure better links to regulators, obtaining the buy-in and long-term commitment of other partners, synergies with other EU/MS programmes and collaboration with other EU partnerships than other open consultation respondents. Public authorities find it slightly less relevant to facilitate collaboration with other European Partnerships than other respondents.

8.3.2. External coherence

In this section we assess the extent to which the policy options show the potential of ensuring and maximising coherence with their external environment, including EU-level

programmes and initiatives beyond the Framework Programme and/or national and international programmes and initiatives, but as well as with overarching framework conditions, such as regulation, standardisation, etc. (external coherence).

Under the baseline scenario (**Option 0**), it would be difficult to coordinate the development of a work programme taking account of parallel, related activity under the Digital Europe Programme (DEP), Connecting Europe Facility (CEF), European Regional Development Fund (ERDF) and Cohesion Fund (CF). Despite that under this option, some coordination with other European Commission activities is possible at the level of priorities, coordination at the level of implementation is somewhat limited or even not feasible. Finally, collaboration with national or regional initiatives such as national programmes or the coordination with regional clusters is not feasible under this option.

In a Co-Programmed European Partnership (**Option 1**), the barriers to coordination within Horizon Europe would extend to coordination with other programmes under Digital Europe Programme (DEP), Connecting Europe facility (CEF), European Regional Development Fund (ERDF) and Cohesion Fund (CF). The European Commission can contribute to some extent to the coordination with European initiatives outside Horizon Europe at the level of the strategy. The non-systematic participation of Member States provides the opportunity for coordination with the national programmes and initiatives and the regional clusters. Even if joint programmes could be agreed in principle, there could be no guarantee that work undertaken in response to open calls would be fully aligned with the specification of activity anticipated under other funding initiatives. The score would therefore the same compared to the baseline with 0.

An institutionalised European Partnership under Article 187 TFEU (**Option 2**) has necessary structures and resources to ensure a continuous dialogue among all players, including international, national, regional and local authorities and therefore does provide a clear global framework to mainstream rail efforts into the Green Deal objectives. It would be able to explore opportunities for funding of programmes and projects under DEP, CEF, ERDF and CF and set provisions for systemic synergies between the Partnership and existing funding mechanisms. These synergies have been developed only to a limited and occasional extent in the S2R JU and would therefore be more systematically exploited in the future Partnership. In particular, a novelty compared to the S2R JU would be the setting up of a dedicated deployment manager function to ensure strong coordination and synchronisation with the CEF Programme, filling the qualitative gap to move from TRL 7 to full deployment. Increasing the chances of deployment of innovative solutions would result in increased attractiveness of the future Partnership for potential Members, including SMEs.

Moreover, the partnership would also be able to represent the interests of the rail R&I community in discussions with other relevant European institutions, for example the European Investment Bank. Under this option, the possibilities of coordination and

Stakeholder opinion

A majority of the stakeholders responding to the Open Public Consultation considered that establishing a specific legal structure for the candidate European Partnership was either relevant or very relevant to the facilitation of synergies with other EU and national programmes. This view was particularly strongly held by the larger business organisations and business associations as well as by EU citizens.

Interviewees also expressed the view that a future partnership would be well-placed to develop a dialogue with other EU initiatives, notably CEF, and that it could facilitate opportunities for collaborative funding using sources outside the scope of Horizon Europe. A limited number of the stakeholders providing feedback on the inception impact assessment suggested that an institutionalised partnership would be better able to take account of the activities of other, relevant EU agencies and organisations and to explore the potential for support for R&I from CEF.

exploitation of synergies offered by the Co-Programmed option are expanded by the existence of the central coordination level which can improve and extend the collaboration at the level of projects. More generally, as the partnership would be in a better position to facilitate links with a wider range of EU institutions, agencies and initiatives, the score would be high compared to the baseline with ++.

The scores for internal and external coherence are summarized in Table 12.

Table 12 - Overview of the options' potential for achieving coherence

	Baseline: Horizon Europe calls	Option 1: Co-programmed	Option 3: Institutionalised Article 187
Internal coherence	0	+	++
External coherence	0	0	++

Notes: Score ++ : Option presenting a *high* potential compared to baseline; Score +: Option presenting a *good* potential compared to baseline; Score 0: Potential of the baseline.

8.4. Tabular comparison of options and identification of preferred option

Building upon the outcomes of the analysis, this section presents a comparison of the options' 'performance' against the dimensions of effectiveness, efficiency and coherence.

Table 13 - Ranking of the policy options

	Items	Baseline: Horizon Europe calls	Option 1: Co-programmed	Option 3: Institutionalised Article 187
Effectiveness				
	Scientific impacts – increase in high quality jobs	0	+	++
	Scientific impacts – strengthened pipeline of potential innovation	0	+	++
	Technological/economic impacts – increase in rail's modal share	0	+	++
	Technological/economic impacts – increase in RSI competitiveness	0	+	++
	Technological/economic impacts – increase in total employment	0	+	++
	Societal impacts – reductions in environmental impacts	0	+	++
	Societal impacts – improvements in safety, security and health	0	+	++
Coherence	Internal coherence	0	0	++
	External - coherence	0	0	++
Efficiency	Overall cost	0	0	(-) (-)
	Cost-efficiency	0	+	(-)

Notes: Scores for effectiveness and coherence: Score ++: Option presenting a *high* potential compared to baseline; Score +: Option presenting a *good* potential compared to baseline; Score 0: Potential of the baseline Scores for efficiency: Score 0 = same costs as for the baseline; score (-) = limited additional costs compared with the baseline; score (-)(-) = substantial additional costs compared with the baseline

Overall the institutionalised partnership established under Article 187 of TFEU is the preferred option as it dominates all dimensions apart from efficiency. Moreover, while it has higher overall direct transparent cost (without considering the cost of discontinuation of the current Joint Undertaking, which would impact the two other options), it ensures better capability to meet the objectives than the other options thanks to a sufficiently inclusive governance structure and the possibility to define an integrated cycle of research and innovation up to TRL 9 allowing the delivery of sector's needs and EU policy objectives.

This option best ensures that private and public sectors remain fully engaged in the development and implementation of a long-term strategy for rail R&I, while encouraging participation from key stakeholders with access to significant financial and in-kind resources that they would be willing to commit under a clearly defined and stable legal framework. This is all the more a decisive factor at a time when the sector is struggling to recover from the Covid-19 crisis. The upstream financial commitment and the preparation of the technical content through the Master Plan ensure that both private and public sector remain fully engaged in the development and implementation of a long-term strategy for rail R&I.

An Institutionalised Partnership would be based on a publicly accessible programme providing full transparency regarding planning and activities. Building on the experience and lessons learned in the S2R JU, the R&I Programme will be based on a shared concept of operations, establishing a functional system architecture and working on innovation enablers to meet the identified technical and policy objectives. The Partnership will include a strong nucleus of Members, with a balanced participation of key stakeholder groups, selected in a transparent manner. Based on the current experience of S2R JU, the overall number of partners involved could be estimated at more than 400, representing the rail sector value chain and beyond. Enhanced openness compared to the current Partnership will be achieved by attracting entities that will be ready to commit to a shared programme, contributing with their expertise and breakthrough technologies.

Particular attention will be paid to increasing participation of SMEs and possible involvement and creation of start-ups to ensure that rail related new ideas, projects, and solutions would find an opportunity to connect with the sector and explore the possibilities to scale-up. In particular, the development of high TRL solutions closer to the market is expected to foster SME's participation in the Programme, since the results of their research activities are more likely to be taken up by large manufacturers and system integrators.

This form of partnership would continue to provide a stable framework for encouraging the participation of organisations from all concerned sectors (including those outside the rail industry), securing and allocating resources, managing a wide range of RD&I projects across all TRLs and creating synergies with other partnerships and initiatives within and outside the Climate, Energy and Mobility cluster. It is also considered appropriate to develop a strategy for rail in order to implement European Green Deal transport priorities, and especially the European climate commitment, and with several sustainable development goals.

The transition from the current S2R JU to the future European Partnership will be seamless, given that the overall organisational structure will need only some adaptations, rather than radical changes. In terms of content, the S2R JU will ensure a complete and efficient transfer of activities and results into the new Partnership. This should avoid as much as possible dead ends of ongoing activities.

The impact of the Covid-19 breakout on future EU collaborative research needs to be carefully assessed. The financial stability provided by an institutionalised partnership would be reassuring for the European rail sector stakeholders' and would encourage their participation in the programme, also given that they may be under financial pressure and therefore reconsidering their planned investments in R&I.

A comparison of possible stakeholders' commitment and Member States collaboration is provided in the Table 14 (list not exhaustive), under the assumption of EUR 900 million Union contribution and EUR 1550 million contribution from members other than the Union.

Table 14 – Possible contribution of stakeholders and Member States

	Quantitative contribution (Million Euros)	Qualitative contribution
Rail Supply industries	650	Providing the technological know-how and the human resources needed to perform R&I activities leading to future market solutions, covering the whole spectrum of applied research and demonstration activities.
Infrastructure Managers	350	 Providing the network related know-how, the human resources and the installed facilities to perform the R&I activities. Participating in related and additional deployment activities funded under CEF.
Operators (mainline and urban)	350	 - Providing the operations related know-how, the human resources and the rolling stock or installed facilities to perform the R&I activities. - Participating in related and additional deployment activities funded under CEF.
Other stakeholders (such as research organisations)	200	Providing the basic research know-how needed for lower TRL research and scientific expertise in the applied research work.
Member States		 Providing the Transforming Europe's Rail System JU through the State Representatives Group with information on relevant activities in Members States and contribution to generating synergies with those activities. Providing a coordinated position for the implementation of innovative solutions in the Technical Specification for Interoperability and safety for the realisation of a "future proof" a Single European Railway Area.

Box 3 Comparison between the preferred option & the current partnership existing in the area taking into account lessons from past evaluations

	What continues		What is different					
ĺ	• Art 187 Union Body, with EC as Founding	•	System	of	systems	approach	to	the
	Member.	Programme, overcoming the silo-effect of the						

- Strong link with the Single European Railway Area
- Vision to deliver, through railway research and innovation, the capabilities to bring about the most sustainable, cost-efficient, highperforming, time driven, digital and competitive customer-centred transport mode for Europe.
- Systemic approach to collaborative research.
- Overall partner composition involving all stakeholders active in the rail sector, including users
- Long term financial commitments from a number of core members.

- current structure based on different Innovation Programmes (IPs).
- Increased focus on freight, automation and digitalisation,
- Balanced representation of the rail sector across the EU, resulting in a more agile membership structure.
- A more strategic and less administrative role for the Governing Board
- Definition of new KPIs.
- Structured synergies with other Horizon and national initiatives.
- Setting up of a dedicated deployment manager function to ensure strong coordination and synchronisation with the CEF Programme, filling the qualitative gap to move from TRL 7 to full deployment.
- Set up of dedicated activities to co-create with the sector at large independently from the membership of a shared vision and concept of operations led by Union policies.
- A more agile Programme management implementation approach to ensure to meet the policy expectations while reducing the administrative burden.
- Use of the different instruments made available in the General Financial Regulation to implement the Programme and adapt to the needs of the different activities to be implemented (e.g. grants, tenders etc.).

9. The preferred option - How will actual impacts be monitored and evaluated?

9.1. The preferred option

In the table below, the alignment of the preferred option of Institutionalised European Partnership under Article 187 TFEU with the selection criteria for European Partnerships defined in Annex III of the Horizon Europe Regulation is depicted. Seeing that the design process of the candidate Institutionalised European Partnerships is not yet concluded and several of the related topics are still under discussion, the criteria of additionality/directionality and long-term commitment are covered in terms of expectations rather than ex-ante demonstration.

An institutionalised partnership established under Article 187 of TFEU for Transforming Europe's Rail System would meet the requirements set out in *Section 4.4*particularly effectively by:

- Facilitating the development of a strategy that is fully aligned with the completion of SERA, the Green Deal as well as a number of SDGs and the political priorities identified by the President of the Commission;
- Providing a stable framework for encouraging the participation of organisations from different stakeholder groups, also in the context of the post-Covid-19 recovery;

- Developing a system of systems and a coordinated approach to transform the rail sector's system architecture and thereby rail's performance for society;
- Integration of rail innovations in the overall mobility digital eco-system for all modes of transport.
- Leveraging industry financial and in-kind resources such that the impact of funding provided by the Commission is maximised;
- Providing for the effective management of R&I projects, encouraging a high level of market take-up of outputs;
- Facilitating relationships with other partnerships and initiatives within the Climate, Energy and Mobility cluster and other EU initiatives; and
- Enabling timely deployment of innovations with high EU added value through CEF and possibly other instruments, and
- Enabling effective dialogue with national and international standards bodies, Member States and third countries.

General success criteria would include:

- A high market uptake of innovative solutions,
- Increased competitiveness of the rail industry in particular outside Europe, keeping it at the forefront of innovation.
- Increased rail market share, in particular for freight.
- Increased integration of rail operations with other transport modes.
- Creation of jobs.

A number of issues remain open in the definition of the Transforming Europe's Rail System Partnership, notably:

- The budget of the Partnership and, more specifically, the EU funding which will depend on the adoption of the next Multiannual Financial Framework.
- The detailed governance structure, including different categories of members and advisory groups, which is still under discussion with the sector.
- A programme which will be defined in the upcoming stages of the process.
- A specific set of Key Performance Indicators (KPIs) and their related methodology for assessing the achievement of the Partnership's objectives.

Table 15 - Alignment with the selection criteria for European Partnerships

Criterion	Alignment of the preferred option
Higher level of effectiveness	As demonstrated in Chapter 6, an institutionalised partnership would be considerably more effective in improving the competitiveness of both the rail transport industry and RSI and enabling a transformation of the European rail system, since it would ensure that a substantially higher proportion of R&I outputs would be taken up by the market than under other options. The institutionalised partnership would also be effective in meeting the Green Deal objectives and supporting the competitiveness of the European RSI.

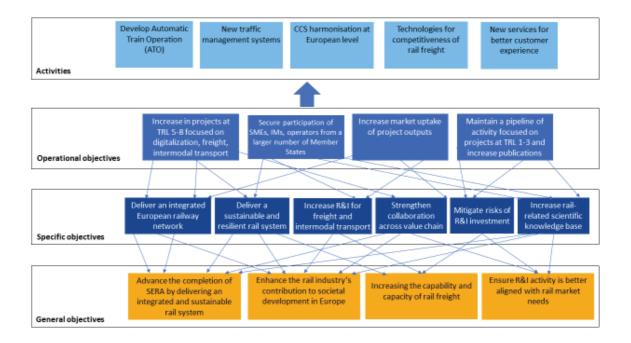
Criterion	Alignment of the preferred option
Coherence and synergies	A dedicated administrative structure responsible for the development of a long-term strategy and supporting work programmes for rail-related R&I would ensure that these were fully integrated with relevant strategies and programmes developed by other partnerships and initiatives. This would enable the better exploitation of synergies from joint programmes and projects, such as ECSEL and 5G for digitalisation and automation, Clean Hydrogen and Batteries as alternative for diesel trains and for autonomous new freight wagon and other transport partnerships concerning interfaces with other modes and multimodality.
	Thanks to a dedicated deployment manager function, strong coordination with the CEF Programme would help filling the qualitative gap to move from TRL 7 to full deployment, thus addressing one of the main issues faced by the S2R JU.
Transparency and openness	An institutionalised partnership would have more impact in identifying priorities and objectives in terms of expected results and impacts, in involving partners and stakeholders from across the entire rail value chain, from different sectors, backgrounds and disciplines, including SMEs.
	An institutionalised partnership would be structured around a common, publicly accessible programme providing full transparency regarding the planned objectives and activities, while ensuring comprehensive and balanced representation of the sector (also geographically) and appropriate protection for intellectual property. The framework governing participation would provide for initial calls for members, attaching conditions relating to the provision of funding and a commitment to supporting EU rail policy objectives.
Additionality and directionality	An institutionalised partnership would develop a long-term strategy for rail-related R&I, in consultation with stakeholders inside and outside the rail industry and establish a set of common objectives governing the direction of R&I activity under Horizon Europe. This would be more focused on industry and market needs as well as on the implementation of EU policy objectives than would be the case under other options as well as under the S2R JU.
	In response to a challenge identified in the interim evaluation of the S2R JU, an institutionalised partnership would be able to set up the appropriate approaches to ensure flexibility of implementation and to adjust to changing policy, societal and/or market needs, or scientific advances, to increase policy coherence between regional, national and EU level.
Long-term commitments	An institutionalised partnership would also encourage long-term commitment of financial and in-kind resources from infrastructure managers, railway undertakings and other stakeholders (such as SMEs) with access to significant levels of internal funding for R&I activity. Hence, the partnership is expected to ensure a significant share of investment from private sector and other commercial stakeholders.

9.2. Objectives and corresponding monitoring indicators

Several operational objectives have been identified which would enable the partnership to achieve its specific objectives, as shown in Figure 5 below.

The figure also lists a broad range of actions and activities, beyond the R&I activities that can be implemented under Horizon Europe. This reflects the definition of European Partnerships in the Horizon Europe Regulation as initiatives for which the Union and its partners "commit to jointly support the development and implementation of a programme of research and innovation activities, including those related to market, regulatory or policy uptake.

Figure 5 - Operational objectives of the initiative



9.2.1. Monitoring indicators

In addition to Key Impact Pathways indicators set centrally in the Regulation of Horizon Europe, additional monitoring indicators have been identified to enable the tracking of progress of the partnership towards meeting its objectives. Data will be collected and processed through a dedicated work stream of the new Partnership, as is currently the case for S2R JU (work on Key Performance Indicators done under Cross Cutting Activities). These are shown in Table 15.

Table 16 - Monitoring indicators in addition to the Horizon Europe key impact pathway indicators

	Short-term (typically as of year 1+)	Medium-term (typically as of year 3+)	Long-term (typically as of year 5+)
Scientific impact – Develop rail-related scientific knowledge base/Deliver scientific results breaking down the current operating limitations/ A strengthened pipeline of potential innovation available to the rail sector	Number of projects resulting in one or more publications	Number of times that publications generated by the partnership are cited in the global literature Number of project outputs taken up in EN standards and TSIs	Number of patents and industrial designs registered by suppliers of railway equipment and systems based in Europe. Project outputs taken up by the market
Scientific impact - A new generation of "rail" engineers and scientists	Number of individuals working on projects initiated by the partnership	Number of occupied and advertised jobs in rail-related R&I	Number of staff transferring between research-based institutions and the rail industry
Technological / economic impact – increase in rail industry direct and indirect	Number of individuals working on projects initiated by the partnership	Level and intensity of rail sector R&I, including new business models	Direct and indirect employment generated by the European rail sector

employment/Creation of new business models and opportunities for the rail stakeholders			
Technological / economic impact – An increase in rail's modal share of passenger and freight markets	Number of programmed projects at TRLs 1 – 3 with a documented strategy for progressing to TRLs 4 - 7	Number of projects considered to have strong market take-up	Rail's modal share of passenger and freight transport markets
Technological / economic impact – Creation of significant additional gross added value for the rail sector compared to 2017/Improvement of competitiveness of RSI	Number of programmed projects involving SMEs	Number of projects considered to have strong market take-up	European RSI's share of global markets
Technological / economic impact – A new rail technological environment	Number of programmed projects developing digital applications	Number of digital projects considered to have strong market take-up	Rail's modal share of passenger and freight transport markets
Environmental / sustainability impact - Reductions in the environmental impacts of transport	Number of programmed projects developing technological applications	Number of projects considered to have strong market take-up	Reduction of CO ₂ emissions generated by passenger and freight transport Reduction of other emissions (NOx, noise, etc.)
Social impact - Improvements in the safety, security and health of EU citizens	Number of programmed projects developing safety/security technological applications	Number of relevant projects considered to have strong market take-up	Increased safety and security performance Positive impact on air quality and safety
Social impact - Affordable and accessible mobility and connectivity	Number of programmed projects developing technologies for increased accessibility	Number of relevant projects considered to have strong market take-up	Increased accessibility of rolling stock and stations

9.2.2. Evaluation framework

The evaluation of the Partnership will be done in full accordance with the provisions laid out in Horizon Europe Regulation Article 47 and Annex III, with external interim and ex-post evaluations feeding into the overall Horizon Europe evaluations. As set in the criteria for European Partnerships, the evaluations will include an assessment of the most effective policy intervention mode for any future action; and the positioning of any possible renewal of the Partnership in the overall European Partnerships landscape and its policy priorities. In the absence of renewal, appropriate measures will be developed to ensure phasing-out of Framework Programme funding according to conditions and timeline agreed with the legally committed partners ex-ante.

CONCLUSION

Based on the lessons learned from the S2R Joint Undertaking, it is clear that joint rail research activities coordinated by the EU contribute to a sustainable, punctual, interoperable, high-capacity rail system, providing a backbone for the whole mobility and transport sector in Europe and contributing to the Single European Railway Area. At the same time, the current S2R experience suggests a number of adaptations to make the future partnership even more successful. These include for example a system of systems approach aiming at

transforming rail's system architecture, a more agile governance structure, an increased emphasis on freight, automation and digitalisation and an enhanced focus on deployment of innovative solutions.

The analysis conducted in this Impact Assessment concludes that an Institutionalised Partnership under Article 187 TFEU is the most suitable policy option to develop rail research at the EU level. The stable financial and regulatory framework provided by an Institutionalised Partnership will ensure accessibility to the programme for a wide range of stakeholders, a clear set of objectives in line with the EU policy priorities and a higher level of effectiveness, resulting in increased market uptake. These elements are all the more important, at a time when the rail sector is expected to face a certain level of economic uncertainty, due to the effects of the Covid-19 breakout. Rail research will be key to address present and future challenges of the transport sector and improve mobility of passengers and goods across Europe. In order to achieve the most tangible impact for society, the focus should be on harnessing rail for digital and sustainable transformation of our economy and society.



Brussels, 23.2.2021 SWD(2021) 37 final

PART 11/19

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT REPORT

Accompanying the document

Proposal for a COUNCIL REGULATION establishing the Joint Undertakings under Horizon Europe

European Partnership for Transforming Europe's Rail System

{COM(2021) 87 final} - {SEC(2021) 100 final} - {SWD(2021) 38 final}

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Annex 1 Procedural information

1. LEAD DG, DECIDE PLANNING REFERENCES

Co-Lead DG: Directorate-General for Mobility and Transport (MOVE), Directorate General Research and Innovation (RTD)

Decide number: PLAN/2019/5398

2. ORGANISATION AND TIMING

Institutionalised partnerships are foreseen in Articles 185 and 187 of the Treaty on the Functioning of the European Union (TFEU). The preliminary agreement on Horizon Europe contained a list of possible areas for institutionalised partnerships based on Article 185 and 187. For each of these areas the Commission considered 12 potential institutionalised partnerships. Their set up involves new EU legislation and the establishment of dedicated implementing structures and therefore an impact assessment for each of these initiatives.

Following political validation in June 2019, the impact assessment process started with the publication of inception impact assessments for each initiative in August 2019.

An inter-service steering group (ISSG) on research and innovation partnerships under Horizon Europe was set up in May 2019 and held 4 meetings before submission of the Staff Working Document to the Regulatory Scrutiny Board (7 May 2019, 19 June 2019, 5 December 2019, 20 January 2020). The ISSG consisted of representatives of the Secretariat-General, Directorate-General for Budget, Directorate-General for Research and Innovation, Directorate-General for Communications Networks, Content and Technology, Directorate-General for Mobility and Transport, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, Directorate-General for Energy, Directorate-General for Environment, Directorate-General for Climate Action, and the Legal Service.

An online public stakeholder consultation was launched between September and November 2019, gathering 1635 replies for all 12 initiatives.

3. CONSULTATION OF THE RSB

Two upstream meetings with the Regulatory Scrutiny Board of were held on 10 July 2019 and 30 September 2019.

In accordance with the feedback received from the Regulatory Scrutiny Board on 12.06.2020, the Staff Working Document has been revised as presented in Figure 1. The impact assessment was endorsed by the Inter Service Steering Group on 20.01.2020.

4. EVIDENCE, SOURCES AND QUALITY

To ensure a high level of coherence and comparability of analysis for all candidate initiatives, an external study was procured to feed into the impact assessments of the 12 candidate

institutionalised partnerships¹. It consisted of an horizontal analysis and individual thematic analyses for each of the initiatives under review.

For all initiatives, the evidence used includes desk research partly covering the main impacts and lessons learned from previous partnerships. A range of quantitative and qualitative data sources complement the evidence base, including evaluations; foresight studies; statistical analyses of Framework Programmes application and participation data and Community Innovation Survey data; analyses of science, technology and innovation indicators; reviews of academic literature; sectoral competitiveness studies and expert hearings. The analyses included a portfolio analysis, a stakeholder and social network analysis in order to profile the actors involved as well as their co-operation patterns, and an assessment of the partnerships' outputs (bibliometrics and patent analysis). A cost modelling exercise was performed in order to feed into the efficiency assessments of the partnership options. Public consultations (open and targeted) supported the comparative assessment of the policy options. For each initiative up to 50 relevant stakeholders were interviewed by the external contractor (policymakers, business including SMEs and business associations, research institutes and universities, and civil organisations, among others). In addition, the analysis was informed by the results of the Open Public Consultation (Sep – Nov 2019), the consultation of the Member States through the Strategic Programme Committee and the online feedback received on the Inception Impact Assessments of the set of candidate Institutionalised European Partnerships.

A more detailed description of the methodology and evidence base used, completed by thematic specific methodologies, is provided in Annexes 4 and 6.

Figure 1 Modifications to the draft Staff Working Document based on comments received from the Regulatory Scrutiny Board

Comments from the Regulatory Scrutiny Board	Actions taken for the Staff Working Document
The report should provide more detail on the current partnership, its objectives and its functioning (membership, financing, research focus). It should include more evidence from the evaluation of the partnership and it should better explain how the new partnership will address the weaknesses identified.	More details on the current partnership and the lessons learned from the interim evaluation of S2R JU have been included in Box 2 (Support for the field in the previous Framework Programmes – key strengths & weaknesses identified) in section 3.2 on EU relative positioning in the field. Moreover, an explanation of the leverage generated by S2R JU has been added to section 4.2.2 on the uncoordinated and limited participation in R&I. The differences between the current and future Partnership have been highlighted in section 7.2 (description of the policy options). Explanations on how the future partnership will address the shortcomings of the current

¹ Technopolis Group, 2020, forthcoming.

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one have been added in section 8 on impacts, coherence and tabular comparison of the options.

The report should analyse stakeholder input on the issues of most relevance to the decision on the future partnership. It should differentiate views of stakeholder groups and explain the views of beneficiaries. It should explain how the new partnership would address stakeholders' concerns. Blue boxes presenting the stakeholder views have been added to sections 4.2.1 (Fragmentation), 4.3 (How the problems will evolve) and 5.1 (5.1. Subsidiarity: Necessity of EU action). Furthermore, the stakeholder views summarised in blue boxes in section 8.1 (Effectiveness) and 8.3 (Coherence) as well as in Annex 1.3 have been revised accordingly, differentiating between various stakeholder groups

The report should better explain the barriers the EU rail sector integration has faced and why the new partnership would be better placed to address these. The report should focus more on how the new partnership would obtain the necessary stakeholder commitment and collaboration from Member States to overcome these barriers. This should include the role and prospects of Member State support for the subsequent uptake of common solutions.

Section 4.2.1 on fragmentation as one of the problem drivers has been thoroughly revised, in order to better present the various aspects related to fragmentation and the related challenges. Moreover, section 6.4.1 on the type and composition of the actors to be involved has been revised accordingly.

The specific objectives of the initiative (section 6.2) have been revised in order to make them more operational, and this is reflected now also in the intervention logic.

A comparison of possible stakeholders' commitment and Member States collaboration has been added in Table 14, section 8.4 (tabular comparison of the options).

The report should better explain the reasons for the changed focus in the research agenda. It should justify the focus on digitalisation, automation and the freight sector. It should explain how the partnership will achieve the necessary changes in membership to serve the changed focus. Overall, the revised governance structure should be more clearly set out and the role of SMEs in the project clarified.

Section 6.4.2 on the types and activities needed has been revised in order to better explain the changed focus in the research agenda. This is also reflected in the section 6.4.1 on the type and composition of the actors to be involved. Further, with regard to freight, the lessons learnt from the interim evaluation have been expanded (Box 2). A paragraph on freight has been added to section 3.2 (EU relative positioning in the field) and the need for R&I to help freight cope with challenges is now reflected in section 4.3 (on how the problem will evolve).

Section 8.4 on the preferred option has been expanded, with additional information,

	referring to more open and transparent processes in the definition of the Programme which will enable wider participation of stakeholders to meet the identified technical and policy objectives. Dedicated paragraphs on the enhanced participation of SMEs and start-ups have been added in section 8.4 on the preferred option and in 6.4.2 on the type and range of activities needed.
The Board notes the estimated costs and benefits of the preferred option in this initiative, as summarised in the attached quantification tables. The table should indicate more clearly who will bear the costs involved.	

Annex 2 Stakeholder Consultation

1. OVERVIEW FOR ALL CANDIDATE INSTITUTIONALISED EUROPEAN PARTNERSHIPS

1.1. Introduction

In line with the Better Regulation Guidelines,² the stakeholders were widely consulted as part of the impact assessment process of the 12 candidates for institutionalised partnerships, including national authorities, the EU research community, industry, EU institutions and bodies, and others. These inputs were collected through different channels:

- A feedback phase on the inception impact assessments of the candidate initiatives in August 2019, gathering 350 replies for all 12 initiatives on the "Have your say" web portal during a period of 3 weeks;
- A structured consultation of Member States performed by the EC services over 2019 through the Shadow Strategic Configuration of the Programme Committee of Horizon Europe (in line with the Article 4a of the Specific Programme of Horizon Europe). This resulted in 44 possible candidates for European Partnerships identified as part of the first draft Orientations Document towards the Strategic Plan for Horizon Europe (2021-2024), taking into account the areas for possible institutionalised partnerships defined in the Regulation.
- An online public stakeholder consultation administered by the EC, based on a structured questionnaire, open between September and November 2019, gathering 1635 replies for all 12 initiatives;
- A targeted consultation run by the external study contractors with a total of 608 interviews performed as part of the thematic studies by the different study teams between August 2019 and January 2020.

1.2. Horizontal results of the Open Public Consultation

The consultation was open to everyone via the EU Survey online system.³ The survey contained two main parts to collect views on general issues related to European partnerships (in Part 1) and specific responses related to one or more of the 12 candidate initiatives (as selected by a participant). The survey was open from 11 September till 12 November 2019. The consultation was available in English, German and French and advertised widely through the European Commission's online channels as well as via various stakeholder organisations.

1.2.1. Profile of respondents

In total, 1635 respondents filled in the questionnaire of the open public consultation. Among them, 272 respondents (16.64%) were identified to have responded to the consultation as part of a campaign (coordinated responses). Based on the Better Regulation Guidelines, the groups of respondents where at least 10 respondents provided coordinated answers were labelled as 'campaigns', segregated and analysed separately and from other responses. In total 11

³ https://ec.europa.eu/eusurvey/runner/ConsultationPartnershipsHorizonEurope

² https://ec.europa.eu/info/files/better-regulation-guidelines-stakeholder-consultation_en

campaigns were identified, the largest of them includes 57 respondents⁴. In addition, 162 respondents in the consultation also display similarities in responses but in groups smaller than 10 respondents. Hence, these respondents were not labelled as campaigns and therefore were not excluded from the general analysis.

Table 1: Country of origin of respondents (N=1635)

Country	Number of	Percentage of		
	respondents	respondents		
Germany	254	15.54%		
Italy	221	13.52%		
France	175	10.70%		
Spain	173	10.58%		
Belgium	140	8.56%		
The Netherlands	86	5.26%		
Austria; United Kingdom	61	3.73%		
Finland	49	3.00%		
Sweden	48	2.94%		
Poland	45	2.75%		
Portugal	32	1.96%		
Switzerland	28	1.71%		
Czechia	24	1.47%		
Greece	23	1.41%		
Norway; Romania	22	1.35%		
Denmark	20	1.22%		
Turkey	19	1.16%		
Hungary	14	0.86%		
Ireland	12	0.73%		
United States	11	0.67%		
Estonia; Slovakia; Slovenia	10	0.61%		
Bulgaria; Latvia	9	0.55%		
Bosnia and Herzegovina	7	0.43%		
Lithuania	4	0.24%		
Canada; Croatia; Israel	3	0.18%		
China; Ghana; Iceland; Japan; Luxembourg; Morocco	2	0.12%		
Bhutan; Botswana; Cyprus; Iran; Malta; Mexico; Moldova; Mongolia; Palestine; Russia; Serbia; South Africa; Tunisia; Ukraine; Uruguay	1	0.06%		

As shown in Figure 2, the three biggest **categories of respondents** are representatives of companies and business organisations (522 respondents or 31.9%), academic and research institutions (486 respondents or 29.7%) and EU citizens (283 respondents or 17.3%). Among the group of respondents that are part of campaigns, most respondents are provided by the same groups of stakeholders, namely company and business organisations (121 respondents or 44.5%), academic and research institutions (54 respondents or 19.8%) and EU citizens (42 respondents or 15.4%).

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⁴⁴ The candidate Institutionalised Partnership Clean Hydrogen has the highest number of campaigns, namely 5. A few initiatives, such as Innovative SMEs, Smart Networks and Systems, were not targeted by campaigns. Some campaign respondents decided to provide opinions about several partnerships.

■ Trade union

Figure 2 Type of respondents (N=1635) - For all candidate initiatives

■ Environmental organisation

Among all consultation respondents, 1303 (79.69%) have been **involved in the on-going research and innovation framework programme** Horizon 2020 or the preceding Framework Programme 7, while 332 respondents (20.31%) were not. In the group of campaign respondents, the share of those who were involved in these programmes is higher (245 respondents out of 272 or 90.07%) than in the group of non-campaign respondents (1058 out of 1363 or 77.62%). When respondents that participated in the Horizon 2020 or in the preceding Framework Programme 7 were asked to indicate in which capacity they were involved in these programmes, the majority stated they were a beneficiary (1033 respondents) or applicant (852 respondents). The main stakeholder categories, e.g. companies/business organisation, academic/research institutions, etc., show a similar distribution across the capacities in which they 'have been involved in Horizon 2020 or in the Framework Programme 7' as the overall population of consultation respondents.

Among those who have been involved in Horizon 2020 or the preceding Framework Programme 7, 1035 respondents (79.43%) are/were involved in a partnership. The share of respondents from campaigns that are/were involved in a partnership is higher than for non-campaign respondents, 89.80% versus 77.03% respectively. The list of partnerships under Horizon 2020 or its predecessor Framework Programme 7 together with the numbers, percentages of participants is presented in Table 4, the table also show the key stakeholder categories for each partnership. Most consultation respondents participated in the following partnerships: Fuel Cells and Hydrogen 2 (FCH2) Joint Undertaking, Clean Sky 2 Joint Undertaking, European Metrology Programme for Innovation and Research (EMPIR) and in Bio-Based Industries Joint Undertaking. The comparison between the non-campaign and campaign groups of respondents shows that the overall distribution is quite similar. However, there are some differences. For the campaign group almost a half of respondents is/was involved in the Fuel Cells and Hydrogen 2 (FCH2) Joint Undertaking, a higher share of campaign respondents is/was participating in Clean Sky 2 Joint Undertaking and in Single European Sky Air Traffic Management Research (SESAR) Joint Undertaking.

When respondents were asked in which **role**(s) **they participate**(d) in a **partnership**(s), over 40% indicated that they act(ed) as partner/member/beneficiary in a partnership. The second largest group of respondents stated that they applied for funding under a partnership. The roles selected by non-campaign and campaign respondents are similar.

Table 4: Partnerships in which consultation respondents participated (N=1035)

Name of the partnership	Number and % of respondents from both groups (n=1035)	Number and % of respondents from a non-campaign group (n=815)	Academic/researc h institutions	Business associations	Company/busines s organisations	Company/busines s organisations	EU citizens	NGOs	Public authority
Fuel Cells and Hydrogen 2 (FCH2) Joint Undertaking	354 (33.33%)	247 (30.31%)	97	9	37	43	41	8	5
Clean Sky 2 Joint Undertaking	195 (18.84%)	145 (17.79%)	57	2	10	27	37	1	7
European Metrology Programme for Innovation and Research (EMPIR)	150 (14.49%)	124 (15.21%)	64	0	13	9	14	2	19
Bio-Based Industries Joint Undertaking	142 (13.72%)	122 (14.97%)	39	8	20	27	14	1	6
Shift2Rail Joint Undertaking	124 (11.98%)	101 (12.40%)	31	7	5	31	14	3	7
Electronic Components and Systems for European Leadership (ECSEL) Joint Undertaking	111 (10.72%)	88 (10.80%)	42	2	7	20	12	0	5
Single European Sky Air Traffic Management Research (SESAR) Joint Undertaking	66 (6.38%)	46 (5.64%)	10	3	3	20	3	2	3
5G (5G PPP)	53 (5.12%)	47 (5.77%)	20	1	6	14	5	0	1
Eurostrars-2 (supporting research-performing small and medium-sized enterprises)	44 (4.25%)	40 (4.91%)	17	0	6	1	7	0	6
Innovative Medicines Initiative 2 (IMI2) Joint Undertaking	37 (3.57%)	35 (4.29%)	18	2	3	3	2	4	3
Partnership for Research and Innovation in the Mediterranean Area (PRIMA)	28 (2.71%)	26 (3.19%)	15	0	3	1	2	0	2
European and Developing Countries Clinical Trials Partnership	25 (2.42%)	24 (2.94%)	12	0	1	2	3	3	2
Ambient Assisted Living (AAL 2)	22 (2.13%)	21 (2.58%)	11	2	1	1	3	0	3
European High- Performance Computing Joint Undertaking (EuroHPC)	22 (2.13%)	18 (2.21%)	6	0	2	3	5	0	2

For the remaining of the consultation, respondents could provide their views on each/several of the candidate initiatives. The majority of respondents (31.4%) provided their views on the Clean Hydrogen candidate partnership. More than 45% of respondents from the campaigns selected this partnership. Around 15% provided their views for European Metrology, Clean Aviation and Circular Bio-based Europe. The share of respondents in the campaign group that chose to provide views on the Clean Aviation candidate partnership is of 20%. The smallest number of respondents provided opinions on the candidate initiative 'EU-Africa research partnership on health security to tackle infectious diseases – Global Health'.

Table 5: Candidate Institutionalised Partnerships for which consultation respondents provide responses (N=1613)

Name of the candidate Institutionalised European partnership	Number and % of respondents from both groups (n=1613)	Number and % of respondents from a non-campaign group (n=1341)	
Clean Hydrogen	506 (31.37%)	382 (28.49%)	
European Metrology	265 (16.43%)	225 (16.78%)	
Clean Aviation	246 (15.25%)	191 (14.24%)	
Circular bio-based Europe	242 (15%)	215 (16.03%)	
Transforming Europe's rail system	184 (11.41%)	151 (11.26%)	
Key Digital Technologies	182 (11.28%)	162 (12.08%)	
Innovative SMEs	111 (6.88%)	110 (8.20%)	
Innovative Health Initiative	110 (6.82%)	108 (8.05%)	
Smart Networks and Services	109 (6.76%)	107 (7.98%)	
Safe and Automated Road Transport	108 (6.70%)	102 (7.61%)	
Integrated Air Traffic Management	93 (5.77%)	66 (4.92%)	
EU-Africa research partnership on health security to tackle infectious diseases – Global Health	49 (3.04%)	47 (3.50%)	

1.2.2. Characteristics of future candidate European Partnerships

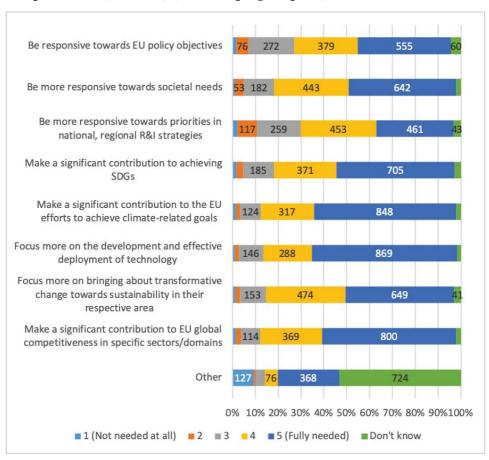
Respondents were asked to assess what areas, objectives, aspects need to be in the **focus of the future European Partnerships** under Horizon Europe and to what extent. According to Figure 6, a great number of respondents consider that a significant contribution by the future European Partnerships is 'fully needed' to achieve climate-related goals, to the development and effective deployment of technology and to EU global competitiveness in specific sectors/domains. Overall, respondents' views reflect that many aspects require attention of the Partnerships. The least attention should be paid to responding towards priorities of national, regional R&D strategies, including smart specialisation strategies, according to respondents.

Overall, only minor differences can be found between the main stakeholder categories. Academic/research institutions value the responsiveness towards EU policy objectives and focus on development and effective deployment of technology a little less than other respondents. Business associations, however, find that the future European Partnerships under Horizon Europe should focus a little bit more on the development and effective deployment of

technology than other respondents. Furthermore, business associations, large companies as well as SMEs value the role of the future European Partnerships for significant contributions to EU global competitiveness in specific sectors domains a little higher than other respondents. Finally, both NGOs and Public authorities put a little more emphasis on the role of the future European Partnerships for significant contributions to achieving the UN SDGs. The views of citizens (249, or 18.3%) do not reflect significant differences with other types of respondents. However, respondents that are/were directly involved in a partnership under Horizon 2020 or its predecessor Framework Programme 7 assign a higher importance of the future European Partnerships to be more responsive towards EU policy objectives and to make a significant contribution to achieving the UN's Sustainable Development Goals.

A qualitative analysis of the "other" answers highlights the importance of collaboration and integration of relevant stakeholders to tackle main societal challenges and to contribute to policy goals against which fragmentation of funding and research efforts across Europe should be avoided. Additionally, several respondents suggested that faster development and testing of technologies, acceleration of industrial innovation projects, science transfer and market uptake are needed. Next to that, many respondents provided answers related to the hydrogen and the energy transition, which corresponds to the high number of respondents that provided answers to the candidate initiative on this topic.

Figure 6: To what extent do you think that the future European Partnerships under Horizon Europe need to (N=1363) (non-campaign replies) For all candidate initiatives



1.2.3. Main advantages and disadvantages of Institutionalised European Partnerships

An open question asked to outline the main advantages and disadvantages of participation in an Institutionalised European Partnership (as a partner) under Horizon Europe (1551 respondents). The advantages mentioned focus on the development of technology, overall collaboration between industry and research institutions, and the long-term commitment. Disadvantages mentioned are mainly administrative burdens. An overview is provided below.

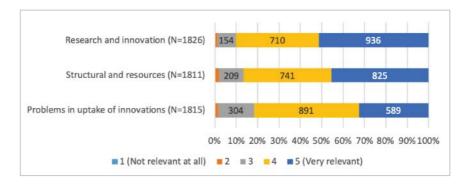
Advantages mentioned: Long term commitment, stability, and visibility in financial, legal, and strategic terms; Participation of wide range of relevant stakeholders in an ecosystem (large/small business, academics, researchers, experts, etc.); Complementarity with other (policy) initiatives at all levels EU, national, regional; Efficient and effective coordination and management; High leverage of (public) funds; Some innovative field require high levels of international coordination/standardisation (at EU/global level); Ability to scale up technology (in terms of TRL) through collaboration; Networking between members; Direct communication with EU and national authorities

Disadvantages mentioned: Slow processes; System complexity; Continuous openness to new players should be better supported as new participants often bring in new ideas/technologies that are important for innovation; Lower funding percentage compared to regular Horizon Europe projects; Cash contributions; Administrative burdens; Potential for IPR constraints.

1.2.4. Relevance of EU level to address problems in Partnerships' areas

Respondents were asked to rate the relevance of research and innovation efforts at EU level efforts to address specific problems in the area of partnerships. Research and innovation related problems were rated as most relevant across all candidate initiatives, followed by structural and resources problems and problems in the uptake of innovations. Overall, all three areas were deemed (very) relevant across the partnerships, as more than 80% of respondents found these challenges (very) relevant. Only minor differences were found between stakeholder categories. Research and innovation problems were found slightly more relevant by academic/research institutions, yet slight less relevant by large companies and SMEs. Structural and resource problems were indicated as slightly more relevant by NGOs, but slightly less by academic/research institutions. While both NGOs and public authorities find slightly more relevant to address problems in uptake of innovation than other respondents. The views of citizens are not differing significantly. Respondents that are/were directly involved in a current/preceding partnership find, however, the need to address problems related to the uptake of innovations slightly more relevant than other respondents.

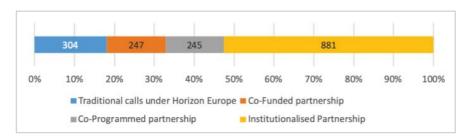
Figure 9: To what extent do you think this is relevant for research and innovation efforts at EU level to address the following problems in relation to the candidate partnership in question? (non-campaign replies) Aggregation of responses of all candidate initiatives



1.2.5. Horizon Europe mode of intervention to address problems

Respondents were asked to indicate how these challenges could be addressed through Horizon Europe intervention. Just over 50% of all respondents indicated that institutionalised partnerships were the best fitting intervention, with relatively strong differences between stakeholder categories. The use of Institutionalised Partnership was indicated more by business associations and large companies, but less by academic/research institutions and SMEs. While academic/research institutions valued traditional calls more often, this was not the case for business associations, large companies and public authorities. Public authorities indicated a co-programmed intervention more often than other respondents. Citizens indicated slightly less often that institutionalised partnerships were the best fitting intervention. Respondents that are/were directly involved in a current/preceding partnership, selected the institutionalised partnership intervention in far higher numbers (nearly 70%).

Figure 10: In your view, how should the specific challenges described above be addressed through Horizon Europe intervention? (non-campaign replies) For all candidate initiatives



When asked to reflect on their answers, respondents that pointed to the need for using institutionalised partnership mentioned the long-term commitment of collaboration, a common and ambitious R&I strategy as well as the overall collaboration between industry and research institutions. Others shared positive experiences with other modes of interventions:

- Traditional calls, because of their flexibility and integration of a wide range of actors, as long as the evaluation panels do not deviate from the policy focus. This was mentioned by 94 participants, including companies (25), academics (26) and EU citizens (25).
- Co-funded partnership, as a mechanism to ensure that all participants take the effort seriously, while allowing business partnerships to develop. This approach was deemed suitable based on previous experiences with ERANETs. This was raised by 84 participants, 36 of them academic respondents, 18 companies and 16 EU citizens.

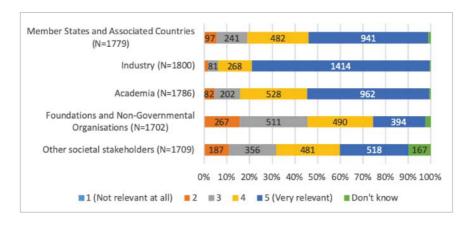
• Co-programmed partnerships, to tackle the need to promote and engage more intensively with the private sector. This was mentioned by 97 participants, most of them companies (34), followed by academics (22), business associations (15) and EU citizens (11).

1.2.6. Relevance of a set of elements and activities to ensure that the proposed European Partnership would meet its objectives

Setting joint long-term agendas

Respondents were asked how relevant it is for the proposed European Partnerships to meet their objectives to have a strong involvement of specific stakeholder groups in setting joint long-term agenda. All respondents see stakeholders from industry as the most relevant, followed by academia and governments. The involvement of foundations and NGOs as well as other societal stakeholders were, however, still found to be (very) relevant by more than 50% of the respondents. Most respondents indicated the stakeholder group they belong to themselves or that represent them as relevant to involve.

Figure 11: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives - Setting joint long-term agenda with strong involvement of: (non-campaign replies) For all candidate initiatives

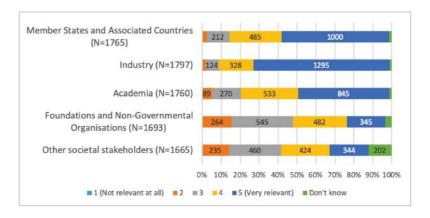


<u>Pooling and leveraging resources through coordination, alignment and integration with stakeholders</u>

Respondents were asked how relevant it is for the proposed European Partnership to meet its objectives to pool and leverage resources (financial, infrastructure, in-kind expertise, etc.) through coordination, alignment and integration with specific groups of stakeholders. Respondents see stakeholders from industry as the most relevant, followed by academia and governments (Member States and Associated Countries). The involvement of foundations and NGOs as well as other societal stakeholders are also still found to be (very) relevant for more than 50% of the respondents. Similarly as described for the question on setting joint long-term agendas, most stakeholder categories valued their own involvement higher than other respondents – although also here differences between stakeholder categories were minor.

Figure 12: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives – Pooling and leveraging

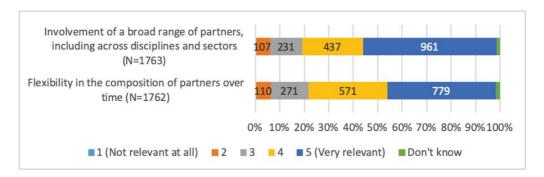
resources (financial, infrastructure, in-kind expertise, etc.) through coordination, alignment and integration with: (non-campaign replies) For all candidate initiatives



Composition of the partnerships

Regarding the composition of the partnership most respondents indicated that for the proposed European Partnership to meet its objectives the composition of partners needs to be flexible over time and that a broad range of partners, including across disciplines and sectors, should be involved (see Figure 13). When comparing stakeholder groups only minor differences were found. Academic/research institutions and public authorities found the involvement of a broad range of partners and flexibility in the composition of partners over time slightly more relevant than other respondents, while large companies found both less relevant. SMEs mainly found the flexibility in the composition of partners over time less relevant than other respondents, while no significant differences were found regarding the involvement of a broad range of partners. Citizens provided a similar response to non-citizens. Respondents that are/were directly involved in a current/preceding partnership, when compared to respondents not involved in a current/preceding partnership, indicated a slightly lower relevance of the involvement of a broad range of partners and flexibility in the composition of partners over time.

Figure 13: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives – Partnership composition (non-campaign replies) Aggregation of responses of all candidate initiatives

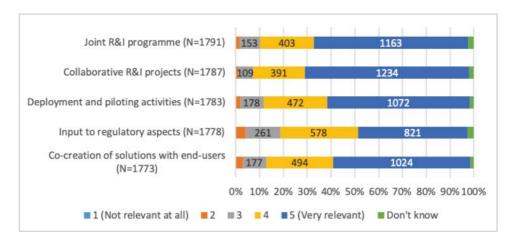


Implementation of activities

Most respondents indicated that implementing activities like a joint R&I programme, collaborative R&I projects, deployment and piloting activities, providing input to regulatory

aspects and the co-creation of solutions with end-users are all (very) relevant for the partnerships to be able to meet its objectives. Minor differences were found between the main stakeholder categories, the differences found were in line with their profile. As such, academic/research institutions found joint R&I programme & collaborative R&I projects slightly more relevant and deployment and piloting activities, input to regulatory aspects and co-creation with end-users slightly less relevant than other respondents. For SMEs an opposite pattern is shown. Large companies, however, also found collaborative R&I projects slightly more relevant than other respondents, as well as input to regulatory aspects. The views of citizens are similar to non-citizens. Respondents that are/were directly involved in a current/preceding partnership, when compared to respondents not involved in a current/preceding partnership, show a slightly higher relevance across all activities.

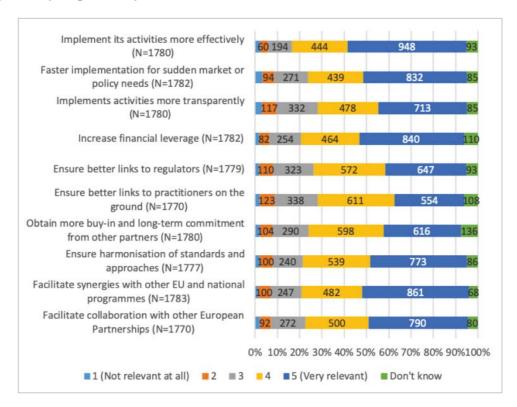
Figure 14: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives – Implementing the following activities (non-campaign replies) For all candidate initiatives



1.2.7. Relevance of setting up a legal structure (funding body) for the candidate European Partnerships to achieve improvements

Respondents were asked to reflect on the relevance of setting up a legal structure (funding body) for achieving a set of improvements, as shown in the Figure below. In general, 70%-80% of respondents find a legal structure (very) relevant for these activities. It was found most relevant for implementing activities in a more effective way and least relevant for ensuring a better link to practitioners on the ground, however differences are small.

Figure 15: In your view, how relevant is to set up a specific legal structure (funding body) for the candidate European Partnership to achieve the following? (non-campaign replies) Aggregation of responses of all candidate initiatives



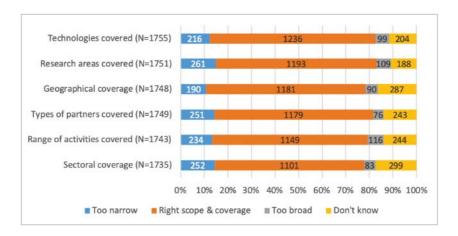
When comparing stakeholder categories there are only minor differences. Academic/research institutions indicated a slightly lower relevance for transparency, better links to regulators as well as obtaining the buy-in and long-term commitment of other partners. SMEs also indicated a lower relevance regarding obtaining the buy-in and long-term commitment of other partners. Large companies showed a slightly higher relevance for implementing activities effectively, ensure better links to regulators, obtaining the buy-in and long-term commitment of other partners, synergies with other EU/MS programmes and collaboration with other EU partnerships. NGOs find it slightly more relevant to implement activities faster for sudden market or policy needs. Public authorities, however, find it slightly less relevant to facilitate collaboration with other European Partnerships than other respondents. The views of citizens show a slightly lower relevance for a legal structure in relation to implementing activities in an effective way. Respondents that are/were directly involved in a current/preceding partnership indicated a higher relevance across all elements presented.

1.2.8. Scope and coverage of the candidate European Partnerships based on their inception impact assessments

Consulted on the scope and coverage for the partnerships, based on their inception impact assessments, the large majority feels like the scope and coverage initially proposed in the inception impact assessments is correct. However, about 11% to 15% of the respondents indicated the scope and coverage to be too narrow. About 11%-17% of respondents answered "Don't know". Overall, differences between the main stakeholder categories were found to be minor. Academic/research institutions indicated slightly more often that the research area was

"too narrow" then other respondents. SMEs on the other hand indicated slightly more often that the research area and the geographical coverage were "too broad". NGOs and public authorities, however, found the geographical coverage slightly more often "too narrow". Large companies found the range of activities slightly more often "too broad" and the sectoral focus slightly more often "too narrow" when compared to other respondents. The views of citizens are the same as for other respondents. Respondents that are/were directly involved in a current/preceding partnership more often indicated that the candidate institutionalised European Partnership have the "right scope & coverage".

Figure 16: What is your view on the scope and coverage proposed for this candidate institutionalised European Partnership, based on its inception impact assessment? (non-campaign replies) Aggregation of responses of all candidate initiatives



1.2.9. Scope for rationalisation and alignment of candidate European Partnerships with other initiatives

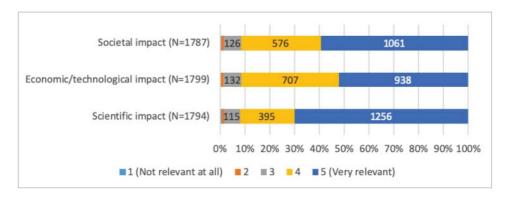
When asked whether it would be possible to rationalise a specific candidate European Institutionalised Partnership and its activities, and/or to better link with other comparable initiatives, nearly two thirds of respondents answered "Yes" (1000, or 62%), while over one third answered "No" (609, or 39%). Nearly no differences were found between stakeholder categories, only large companies and SMEs indicated slightly more often "Yes" in comparison to other respondents. The views of citizens are the same as for other respondents. Respondents that are/were directly involved in a current/preceding partnership, indicated "No" more often, the balance is about 50/50 between "Yes" and "No" for this group.

1.2.10. Relevance of European Partnerships to deliver targeted scientific, economic/technological and societal impacts

Finally, respondents were asked to rate the relevance of partnership specific impacts in three main areas: Societal; Economic/technological; and Scientific impacts. All three areas were deemed (very) relevant across the candidate partnerships. Scientific impact was indicated as the most relevant impact, more than 90% of respondents indicated that this as (very) relevant. Only minor difference between stakeholder groups were found. Academic/research institutions found scientific impacts slightly more relevant, while large companies found economic and technological impacts slightly more relevant than other respondents. NGOs found societal impact slightly more relevant, while SMEs found this slightly less important.

Citizens did not a significantly different view when compared to other respondents. Respondents that are/were directly involved in a current/preceding partnership find all impacts slightly more relevant than other respondents.

Figure 17: In your view, how relevant is it for the candidate European Institutionalised Partnership to deliver on the following impacts? (non-campaign replies) Aggregation of responses of all candidate initiatives



1.3. Stakeholder consultation results for this specific initiative

1.3.1. Scope of the consultation

Transforming Europe's Rail System (TERS) have been identified as one of the Commission's research and innovation initiatives under the Horizon Europe 'Climate, Energy and Mobility' cluster (Pillar II-Cluster 5).

The Commission conducted a series of stakeholder consultations with various stakeholder groups of different levels (e.g. Member States, R&I funding beneficiaries, industry associations, citizens, etc.) to seek views on EU Research and Innovation (R&I), and on the proposed TERS Partnership. In particular, the consultation activities focused on the need for, the scope and coverage, the type and the planned focus of this partnership.

1.3.2. Whom has the Commission consulted

The Commission consulted a wide range of stakeholders (e.g. public authorities, companies, business organisations, academia, research organisations and end-users) to anticipate a broad involvement of interested participants in the partnership. The consultation activities included but were not limited to those which applied for and/or received funding from the current S2R JU. These targeted stakeholders were complemented by the identification of additional relevant stakeholders to be consulted, based on an external study undertaken to feed into the impact assessment for each of the potential institutionalised European Partnerships.

In summary, the following type of stakeholders have been consulted:

- The industrial community, which includes large companies, SMEs and Start-ups, material suppliers and equipment manufacturers;
- The operating community, including railway undertakings and infrastructure managers;
- The research community, consisting of academic/research institutions such as universities, public government-funded organisations, independent organisations or private research centres.
- Public authorities, such as ministries and national bodies for research, EU institutions and bodies.
- EU citizens responding on their own behalf.
- Interested independent authorities and platforms.

1.3.3. How has the Commission consulted?

The Commission launched a structured consultation of Member States through the Shadow Strategic Configuration of the Programme Committee Horizon Europe, which provided early input⁵ into the preparatory work and resulted in 44 possible candidates for European Partnerships, taking into account the identified areas for possible institutionalised partnerships.

⁵ European Partnerships under Horizon Europe: results of the structured consultation of Member States (Report)

In addition, an open public consultation that covered all 12 potential institutionalised partnerships based on Articles 185 and 187 TFEU was launched. This consultation collected input from a broad range of stakeholders, across Europe and associated countries, on both the overall approach and the individual candidates for institutionalised partnerships.

Furthermore, a combination of written consultation tools and direct interactions with stakeholders were put in place, seeking input, views, ideas and experiences. The identified option in the impact assessment largely builds on the outcome of these consultations with stakeholders.

1.3.4. Feedback to the inception impact assessment on candidate initiatives for Institutionalised Partnerships

Following the publication of the inception impact assessment in July 2019, for the initiative "Transforming Europe's Rail System" 46 individual feedbacks were collected, mainly from companies and business organisations from a significant number of EU Member States. Among the elements mentioned were:

- The importance of R&I in enhancing the role of rail in an integrated and sustainable European transport system, and the potential for rail to be more competitive through easier planning of multimodal journeys, better management of service disruption and higher quality on-board service;
- The need to reinforce Europe's technological leadership in rail (an issue highlighted by both business and academic/research organisations);
- The need for EU action to address industry fragmentation currently limiting the level of R&I in the rail sector and the critical need to increase market take-up of new products and services:
- The key role of the rail sector in supporting EU societal objectives, in particular action to limit the impact of climate change;
- Strong endorsement of rail's potential contribution to broader scientific, technological and economic development across Europe;
- Strong support for an institutionalised partnership capable of developing a long-term strategy for both fundamental research and market-focused innovation in the rail sector.

1.3.5. Structured consultation of the Member States on European partnership

A structured consultation of Member States through the Shadow Strategic Configuration of the Programme Committee Horizon Europe in May/June 2019 provided early input into the preparatory work for the candidate initiatives.

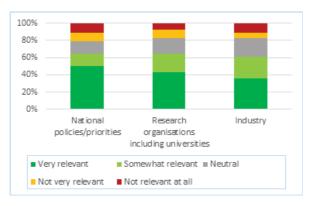
For the initiative "Transforming Europe's Rail System", the feedback from countries suggests that the proposed Partnership is to a large extent relevant, with 64% considering it relevant for their national policies and priorities and for their research organisations, including

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⁶ Feedback on inception impact assessment to be found on https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2019-4980251/feedback en?p id=5722806

universities, and slightly less (61%) consider it very relevant or somewhat relevant for their industry.

Figure 1: Relevance of the European Partnership for Transforming Europe's rail system in the national context



18 countries reported to have relevant national or regional R&I strategies, plans or programmes in place in support of the proposed Partnership. National economic, sectoral strategies and/or plan with a strong emphasis on research and/or innovation (57%) and R&I strategies or plans (54%) were identified most frequently. Countries reported to a lesser extent to having dedicated R&I funding programmes or instruments (32%) and regional R&I and/or smart specialisation strategies (25%). 5 countries reported other policies/ programmes.

Countries from Central and Eastern Europe stressed the need to focus more on deployment and piloting to transform the results of the partnership into real world solutions, and in this context also to ensure synergies with related policies, and investments at national and EU level (e.g. CEF, Cohesion Funds). Other comments suggested the need to adjust the scope of the proposed partnership and focus more on integrating alternative energy solutions (hydrogen, batteries), digitalisation of the existing system, robotisation for maintenance, ensuring a holistic approach to the railways system including infrastructure and maintenance, and developing user-centred innovations.

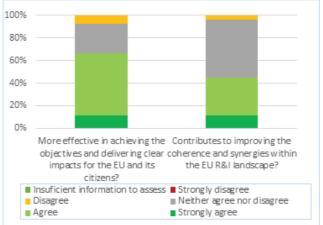
The majority of countries (57%) were undecided concerning their interest to participate as partner. 8 countries expressed an interest to join as a partner, and 3 countries expressed no national interest to participate.

The majority of the countries (86%) expressed interest in having access to results produced in the context of the partnership.

Feedback on objectives and impacts

There was good agreement (60%) on the use of partnership approach for Transforming Europe's Rail System, whilst quarter of respondents remained neutral. The majority of delegations (65%) agreed that the partnership would be effective in achieving the objectives and delivering clear impacts for the EU and its citizens, but to a lesser degree (43%) that it would contribute to improving the coherence and synergies within the EU R&I landscape.

Figure 2: Agreement on arguments for a Partnership for Transforming Europe's rail system in delivering impacts, improving coherence and synergies



Views on partners, contributions and implementation

Slightly more than half (54%) of the responses agreed on the type and composition of partners, whilst 25% remained neutral and 2 countries disagreed. Additional comments suggest several countries wish to see an increased role of Member States, as well as openness towards new and smaller partners.

Most countries (64%) would need more information on the contributions and level of commitments expected from partners. Additional comments highlight the need to ensure synergies with Cohesion Funds and CEF for exploitation and uptake of innovation.

46% of countries wished for more details to make an informed decision on the proposal to implement the proposed partnership based on the Article 187 TFEU, 36% agree and 18% disagree. It was thus, suggested to analyse whether the objectives of this proposal could be reached with alternative implementation modes, notably the co-programmed model; if not, then countries wish to see a considerable reform in the set-up of the JU. The feedback stressed the need to allocate Union funding through open calls for proposals (subject to comitology).

In addition to the structured consultation, on 25 November 2019, DG MOVE organised a dedicated workshop to discuss mobility partnerships with Member States. During the workshop, Member States expressed the view that additional benefit for countries in participating in partnerships is that it provides access to an extensive network of key research actors and industrial players in the mobility sector to either create or make use of emerging technologies. Moreover, they highlighted the need to ensure better information exchange between partnerships roadmaps and relevant Member State programmes and enable synergies with other EU and national programmes, notably with Cohesion Funds for innovation development and demonstration, and CEF for deployment and market uptake.

1.3.6. Targeted consultation of stakeholders

A targeted consultations with businesses, research organisations and other partners addressed different aspects of the Partnership on Transforming Europe's rail system.

Table 1: Number of interviews per stakeholder category

Stakeholder category	Number	Share (%)
Associations	9	18%
European body – regulatory agency	1	2%
Freight operators/supply chain	4	8%
Infrastructure manager	5	10%
Member States' transport authorities	4	8%
Passenger operators	7	14%
Research and technologies organisations	5	10%
Research and technology organisation (non-rail)	1	2%
Third party industry suppliers	7	14%
Universities/academic bodies	5	10%
Urban passenger operators	2	4%
TOTAL	50	100%

Key results from the targeted consultation

Objectives

Stakeholders generally indicated that they agree on the S2R JU objectives. There is a consensus that the current objectives remain valid for the future.

Several stakeholders noted the need for stronger deployment efforts, and focus on users. In particular, several interviewees highlighted that inter-modality and door-to-door mobility are key objectives for rail development, and this calls for innovations which are attractive to rail users.

Additional objectives that stakeholders proposed to be included more prominently are:

- Supporting the European rail industry competitiveness in global markets;
- Accelerating innovation deployment; and
- Reducing innovation time to market.

Moreover, some stakeholders (both members and non-members of the S2R JU) proposed a stronger focus on specific themes, in particular:

- Urban rail transport;
- Rail freight transport;
- Rail service level;
- Energy consumption.

Most stakeholders (especially members of S2R JU) indicated that the Joint Undertaking instrument allows better achievement of objectives; the main reasons they reported are:

- Creating an over-reaching picture in rail research, which would not be possible with the Horizon Europe Programme alone and by single research projects;
- Fostering cooperation in the rail sector;
- The legal certainty that the Joint Undertaking brings to members and innovation investors, as a condition for industry players to invest;
- Facilitating technology and operational harmonisation across Europe;
- Accelerating the sector transformation, also to compete on global markets;
- Allowing longer term cooperation among research stakeholders to move to higher TRL levels;
- Being an independent party for business players.

Some stakeholders also highlighted that moving from the current Joint Undertaking cooperation instrument to a co-programmed partnership (or to the Horizon Programme alone) would delay rail research, slow down innovation processes and have negative impacts on the rail industry.

Membership and openness

Generally, members and non-members of S2R JU consider that more flexibility is needed to engage stakeholders based on research needs' development. Several stakeholders proposed the development of mega-projects in which members and non-members cooperate, and which could have flexibility in engaging partners as the projects develop. On the other hand, two stakeholders indicated that bigger projects increase management workload and do not necessarily deliver improved impacts.

Some stakeholders noted that the funding also needs to cover prototypes and industrial projects, and this justifies that more budget needs to be available. Some stakeholders (especially members of S2R JU) noted the geographical imbalance of membership, but also that this reflects the current rail industry geographic balance and the related dominant position of some Member States. They indicated that open calls can enhance more geographical balance. Several interviewees commented that the urban sector is poorly represented in the current member composition, although they noted that it may be constrained by funding from participating into a Joint Undertaking.

Specific stakeholders' proposals on types of members to include, or to include more prominently, are:

- Verification and certification bodies (to ensure that innovations are usable on national rail networks and compatible with interoperability standards);
- National authorities in order to understand the technologies employed locally;
- Infrastructure managers and railway undertakings, to allow more focus on rail operational and service aspects, and to improve the balance of membership between suppliers and users;
- Rail freight nodes (including ports and terminals), which are users of innovation and an important component of logistics chains.

Both members and non-members of S2R JU noted that the rail Partnership should be more open and flexible and that it is difficult for non-members to join through open calls.

With specific reference to the involvement of universities, stakeholders generally indicated that they have an important role in supporting industrial innovation in bringing a long-term perspective to research activities.

A common point for almost all stakeholders, other than rail providers and manufacturers, was the balance between "blue sky research" and research focused on members' priorities. In particular, research stakeholders noted that business players tend to consider innovation in the shorter term, while universities look at innovation on a longer timescale.

Concerning openness, several stakeholders (in particular most of the S2R Ju members or other stakeholders engaged in S2R JU activities) indicated that in Shift2Rail, research activities in open call projects are not aligned with the research priority of members. Generally, stakeholders noted that a closer cooperation between members and non-members is needed in the future.

Concerning the partnership dimension, the main suggestion was to increase the number of core members to 15-20 and to engage additional stakeholders on a project or research basis.

Leverage effect

Generally, stakeholders indicated that Shift2Rail has the capacity to leverage private investments and to allow the coordination of investments in risky fields, thanks to the Join Undertaking contractual obligations. Shift2Rail members wished a push to higher TRL and more deployment and market up-take of rail innovations. They also indicated that an important component of this would be that research is accompanied by solid business cases to roll out innovation.

Key Performance Indicators (KPI)

Stakeholders indicted that KPIs refer to the Shift2Rail objectives and are still valid for the future. Suggestions for KPI improvements concerned:

- Defining the baseline values;
- Defining KPI assumptions and framework;
- Defining KPI more specifically;

- Including KPI on:
 - o bringing R&I results to the market;
 - o regulatory harmonisation issues (e.g. cross-border services with different standards);
 - o rail freight transport;
 - o rail hubs;
 - o data sharing;
 - o rail attractiveness to passengers, with reference to satisfaction, experience and comfort; and
 - o noise and energy topics.
- Including more focus on coordination with other transport modes and transport decarbonisation.

Costs and benefits

Interviewees indicated the following benefits of the Joint Undertaking cooperation instrument compared to an EU Research & Innovation programme alone or a co-programme partnership:

- More focused calls compared to FP7 and Horizon 2020;
- Long-term vision;
- More visibility compared to other cooperation instruments;
- Legal certainty;
- Reduced fragmentation in research investments/results, avoiding duplication of effort;
- Joint EU approach to solving the rail industry technical problems;
- Wider scale demonstrators and higher TRL;
- Management transparency (compared to projects funded under general Horizon 2020 calls).

On the other hand, interviewees also indicated the following areas of improvement in relation to the current Shift2Rail Joint Undertaking:

- The budget should be higher, and as a consequence many projects have low TRL;
- There could be more flexibility to allocate funding to "blue sky research;
- The multiannual action plan should be flexible and suited to changes.
- Innovation Programmes should be more connected.
- More visibility of activities and research results across IPs is needed.
- A higher level of cooperation between the EC and Members States is needed.

Critical elements raised by stakeholders concerned:

• The usability of results in the national contexts;

- Confidentiality of project results, which limit their diffusion;
- Limited contribution from some partners of open call projects;
- Implementation of R&I outputs;
- A high degree of bureaucratisation, with complicated rules of cooperation;
- Communication and presentation of research results;

One stakeholder involved in S2 JU activities and projects indicated that project implementation would be better in a co-programmed partnership because member and non-member projects are insufficiently coordinated.

Need for a rail EU partnership

There is a general agreement that an EU partnership for rail is needed in the future. Most stakeholders suggested follow-up of Shift2Rail to complement, continue and deploy previous and ongoing activities and to complete the transformation of the rail sector. Stakeholders mentioned the following advantages of the Shift2Rail Joint Undertaking:

- Shift2Rail brought more clarity than single projects and brought together research and business players.
- European support under Horizon Europe alone would not address the issue of industry fragmentation;
- In the JU, all sector representatives are around the table (EC, Member States, Infrastructure Managers, rail operators, rail suppliers, etc.).
- Other types of partnerships can contribute to generating "silos" in research and isolated groups of stakeholders.
- The JU cooperation instrument is essential to public sector entities, which have specific investment rules requiring a demonstration of investment returns and legal certainty.
- It brings competing companies into R&I cooperation and innovation investment risk sharing.
- The Shift2Rail brand helps selling EU rail R&I results internationally.

Several stakeholders also suggested changes and improvements to the current partnership with reference mainly to openness, membership composition; and integration between call for members and call for non-members.

Research needs

Stakeholders proposed the following priority topics in rail research:

- Digitalisation and digital transformation of the sector;
- IT/augmented reality/digitalisation in signalling and remote control;
- Multimodality and rail last mile integration,;
- Artificial intelligence and robotics for maintenance;

- 5G, data (including Internet of Things), data management and cybersecurity;
- Rail freight terminals, including automatic coupling and single wagon development, supply chain data exchange;
- Automation on mainlines and computer-based controls; Automatic Train Operations;
- Decarbonisation and low carbon technologies;
- Rail capacity improvement;
- New materials (e.g. carbon fibre);
- New methods of maintenance/asset management;
- Noise;
- Safety and security.

Some stakeholders indicated that a stronger partnership between ERRAC and JU is needed. On the other hand, some indicated that the future cooperation instrument could be a light partnership (not a JU) working with ERRAC.

Contribution to EU policies

Stakeholders indicated that the future partnership could focus on:

- Increasing rail efficiency and attractiveness to users to achieve modal shift;
- Promoting the rail sector to policy makers and in particular informing European policies by bringing the industry knowledge, technical evidence and expertise; and
- Projects delivering competitive deployment of products and services.

Governance/organisation

Concerning governance, JU members identified the following main areas of improvement:

- The Governing Board should have more focus on strategic topics.
- The Governing Board is very broad, and the number of members could be reduced.
- The Scientific Committee could be more involved and have more influence, also involving representatives of the industry.

Concerning organisation, different non-members of S2R JU highlighted that a stronger national presence is needed (either in terms of communication or contact points) and that this would allow promoting and marketing research results. Better coordination with Member States was also suggested.

EU added-value

All the stakeholders called for EU action in rail research and innovation. Moreover, some stakeholders indicated that JU is an instrument to support the EU rail industry's competitiveness at global level.

Further benefits of the EU actions that stakeholders indicated were:

• Making funds available;

- Tackling topics (e.g. interoperability, ERTMS) which have an EU dimension and cannot only be tackled at national level;
- Sustaining rail as the greenest transport mode and helping rail to innovate;
- Coordinating rail research to avoid research developing in parallel by single stakeholders or groups of stakeholders (e.g. EU as a catalyst to efficiently deliver rail research), and
- Bringing together competitors in rail innovation (especially in a fragmented sector like rail).

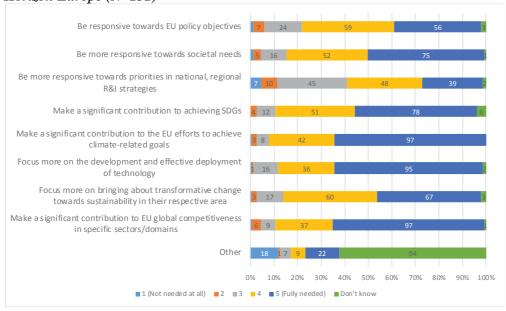
1.3.7. Open Public Consultation

Profile of respondents

151 respondents answered the consultation for the Transforming Europe's rail system Partnership or part of it. Of these respondents, 32 (21.19%) were citizens. The largest group of respondents were businesses with 62 (41.06%) respondents. There were 29 respondents from academic and research institutions (19.21%) and 14 from business associations (9.27%). 7 respondents were from public authorities (4.64%). The remaining respondents were from NGO's (2, 1.32%), consumer organisations (1, 0.66%) and other (4, 2.65%). Over two-thirds of respondents, namely 106 (70.20%), have been involved in the on-going research and innovation framework programme, of which 85 respondents (80.19%) were directly involved in a partnership under Horizon 2020 or its predecessor Framework Programme 7.

Needs of future candidate European Partnerships

Figure 3: Views of the respondents in regard to the needs of future European Partnerships under Horizon Europe (N=151)



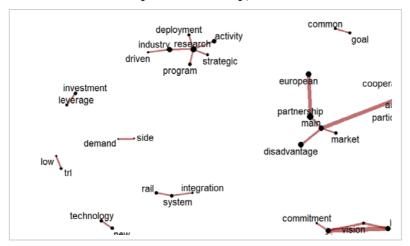
The majority of respondents indicated the need of the future Partnership to make a significant contribution to the EU efforts to achieve climate-related goals (97, 64.24%) and focus more

on the development and effective deployment of technology (95, 62.91%). Both companies and academic institutions highlighted the importance of ensuring the competitiveness of the European rail industry at the global level while focusing on societal objectives and demonstrating the practical benefits of rail-related R&I to a wide audience.

EU citizens identified a range of other needs, including encouraging joint ventures and the participation of SMEs and communicating the key role of the EU in implementing the partnership.

Main advantages and disadvantages of Institutionalised European Partnerships

Figure 4: Assessment of open answers with advantages and disadvantages of participation in an Institutionalised European Partnership, 30 most common co-occurring keywords (N=129)



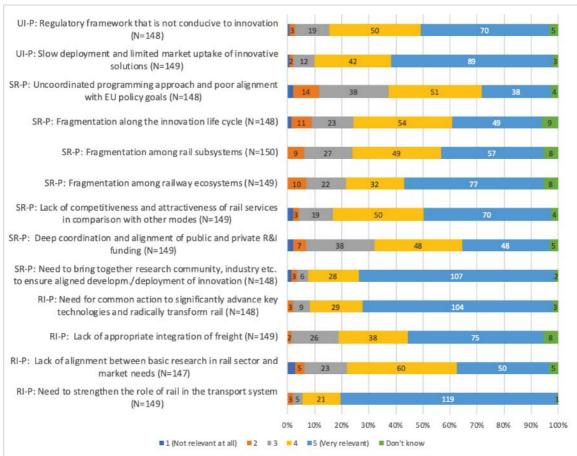
Companies of all sizes emphasised the advantages of collaboration, including between organisations that compete with one another, and effective coordination of R&I activity. They also identified optimal management of projects, the ability to develop a long-term vision and continuity, stability and visibility of projects as important benefits of participation in an institutionalised partnership.

Academic institutions noted the benefits of building relationships with the rail industry and of pursuing research with practical application to the sector. However, they also noted that some research activities are best conducted in collaboration with a single partner rather than a large number of organisations.

EU citizens highlighted a number of advantages of an institutionalised partnership, including collaborative working to develop a standardised platform for innovation, dedicated funding and the ability to develop a long-term strategy. At the same time, they noted some disadvantages, including the risk of establishing an industry-driven 'closed shop' and undue focus on projects with high technology readiness levels (and the associated neglect of more fundamental research).

Relevance of EU level efforts to address problems in relation to the Transforming Europe's Rail System initiative

Figure 5: Views of respondents on relevance of research and innovation efforts at the EU level to address problems in relation to rail systems

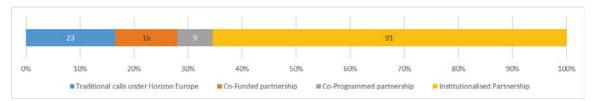


With regard to the uptake in innovation problems, 89 respondents indicated that they view research and innovation efforts at EU level to address the slow deployment and limited market uptake of innovative solutions as very relevant (59.73%). The problem that was viewed as most relevant to be addressed at EU level, was the need to bring together rail research community, supply industry and operators/infrastructure managers, to ensure aligned development and development of innovation.

No statistical differences were found between the views of citizens and other respondents for most problems. Citizens, however, found the research and innovations problem related to the need to strengthen the role of rail in the transport system more relevant and the structural and resource problem related to the fragmentation along the innovation life cycle less.

Horizon Europe mode of intervention to address problems

Figure 6: Assessment of Horizon Europe intervention



Just over 65% of respondents indicated that institutionalised partnerships were the best fitting intervention to address rail challenges and transform the European rail system. People who stated that an institutionalised partnership was the best fitting answer, mentioned the entire product development cycle, long term commitment and market uptake. Respondents who did not select institutionalised partnership as their preferred intervention (N=43) mentioned traditional calls, rail innovation, public and private rail sector and bound funding.

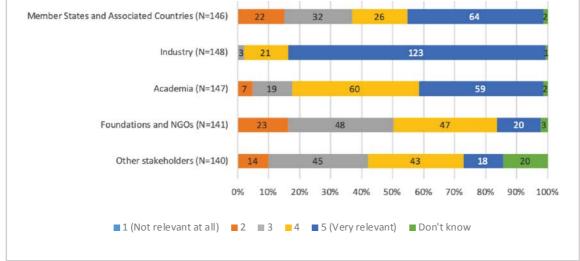
In their open responses, stakeholders gave a number of reasons for supporting an institutionalised partnership as the most effective way of addressing the challenges posed by R&I in the rail sector:

- A number of respondents, including companies, business associations and public authorities, noted that, based on recent experience, only an institutionalised partnership could ensure the level of coordination needed to enable collaboration across a wide range of partner organisations, and that such a partnership would provide the governance and funding framework required to secure their participation.
- EU citizens highlighted the potential for an institutionalised partnership to support the decarbonisation agenda through engagement with national governments and with other EU initiatives focused on exploitation of clean forms of energy.
- However, there was some support for co-financing from at least one academic institution because it would encourage R&I activities focused on the interests of rail users.

Relevance of a set of elements and activities to ensure that the proposed European Partnership would meet its objectives

Member States and Associated Countries (N=146) Industry (N=148)

Figure 7: Views of respondents on relevance of actors in setting a joint long-term agenda



The highest amount of respondents indicated that the involvement of industry is very relevant (123 respondents or 83.11%).

Citizens, as compared to other respondents, found government (Member States and Associated Countries) and foundations and NGOs slightly more relevant. Respondents that are/were involved in a current/preceding partnership (Horizon 2020 or Framework Programme 7) found industry more relevant.

Relevance of elements and activities in pooling and leveraging resources

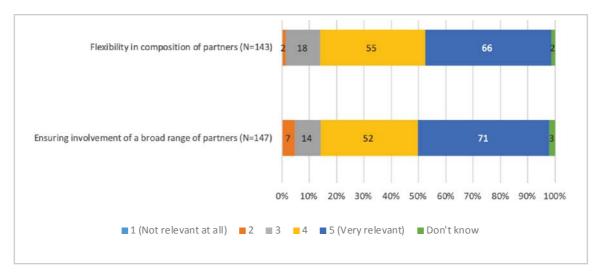
Member States and Associated Countries (N=145) Industry (N=147) 113 Academia (N=147) Foundations and NGOs (N=141) Other stakeholders (N=134) 10% 20% 30% 40% 50% 60% 70% 80% 90% 100% ■1 (Not relevant at all) ■2 **3** ■ 4 ■ 5 (Very relevant) ■ Don't know

Figure 8: Views of respondents on relevance of actors for pooling and leveraging resources

With respect to the relevance of actors in pooling and leveraging resources (such as financial, infrastructure, in-kind expertise etc.), to meet Partnership objectives, 113 respondents (76.87%) indicated that industry was very relevant, which is much larger than for any of the other stakeholders. No respondents indicated that any of the categories was not relevant at all. Citizens, as compared to other respondents, found foundations and NGOs slightly more relevant.

Relevance of elements and activities for the partnership composition

Figure 9: Views of respondents on relevance of partnership composition elements

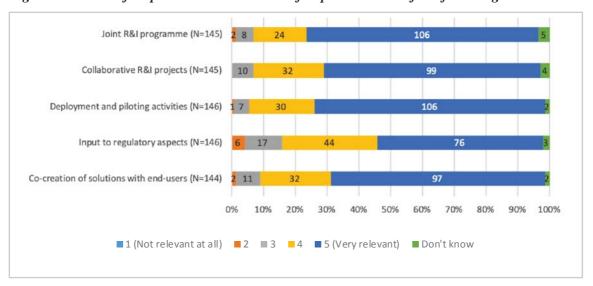


Ensuring involvement of a broad range of partners has slightly more 'very relevant' answers (71, 48.30%) than the flexibility in the composition of partners (66, 46.15%). Interestingly 84.62% of respondents have given flexibility either a score of 4 or 5 (very relevant) which is slightly higher than the 83.67% who have given the broad range of partners a score of 4 or 5 (very relevant).

No statistical differences were found between the views of citizens and other respondents.

Relevance of implementation of activities

Figure 10: Views of respondents on relevance of implementation of the following activities



Out of 145 respondents, 106 (73.10%) indicated that deployment and piloting activities and a Joint R&I programme are very relevant to ensure that the Partnership would meet its objectives. For all the other options, the majority (over 50%) of all respondents have indicated that these are very relevant.

No statistical differences were found between the views of citizens and other respondents.

Relevance of setting up a legal structure (funding body) for the candidate European Partnerships to achieve improvements

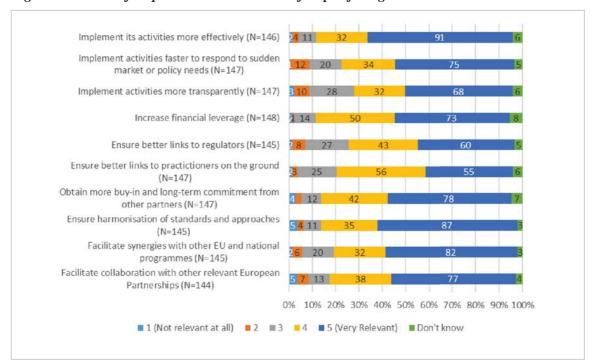


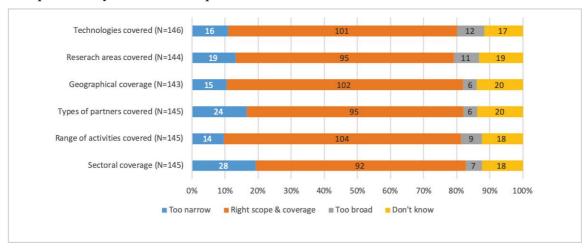
Figure 11: Views of respondents on relevance of a specific legal structure

Respondents indicated that it was very relevant to set up a specific legal structure for the partnership to achieve a more effective implementation of activities (91, 62.33%) and to ensure harmonisation of standards and approaches (87, 60.00%).

Respondents involved in a current or preceding partnership found a legal structure more relevant than other respondents when it concerned a faster to response to sudden market or policy needs as well as synergies with other programmes and collaboration with other partnerships.

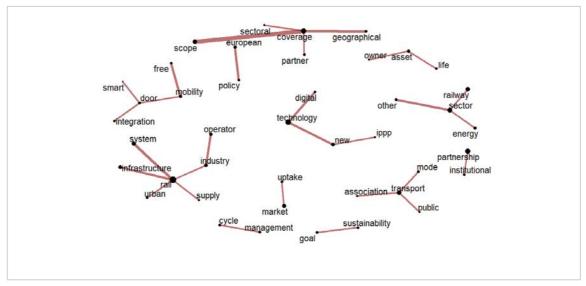
Scope and coverage of the candidate European Partnerships based on their inception impact assessments

Figure 12: Views of respondents on the scope and coverage proposed for the Transforming Europe's Rail System Partnership



The clear majority of the respondents have indicated that the partnership has the right scope and coverage across all areas. The respondents who have indicated that the scope and coverage are not right, have indicated that it was too narrow more often than they viewed it as too broad.

Figure 13: Assessment of open answers with regard to the proposed scope and coverage for this candidate Institutionalised Partnership, 30 most common co-occurring keywords (N=62)



Scope for rationalisation and alignment of candidate European Partnerships with other initiatives

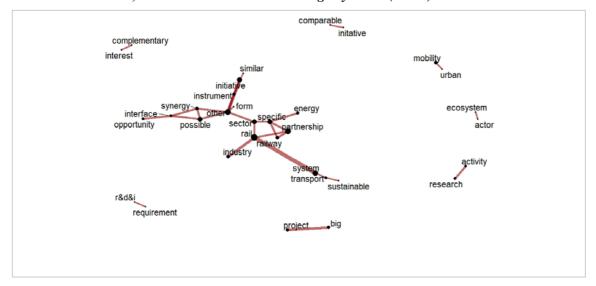
95 respondents (68.84%) indicated that it would be possible to rationalise the candidate European Institutionalised Partnership and its activities, and/or to better link it with other comparable initiatives. Respondents mentioned links with energy mobility and the future of energy as well as digital industry and comparable partnerships and joint undertakings in transport.

Companies were not persuaded that the partnership should be rationalised, however, they supported the case for establishing links with other relevant initiatives, including other partnerships within the Climate, Energy and Mobility Cluster and initiatives focused on sustainability and the development of multi-modal transport solutions.

EU citizens as well as other organisations similarly supported greater coordination of the activities of different initiatives while stopping short of endorsing substantial rationalisation of institutions.

For the respondents who answered negatively on the previous question, the results of the analysis resulted in the chart shown in Figure 14 showing the co-occurrences of keywords. The results show that respondents mention specific partnerships related to energy, railway system and the railway industry as well as comparable initiatives and the possibility of synergy.

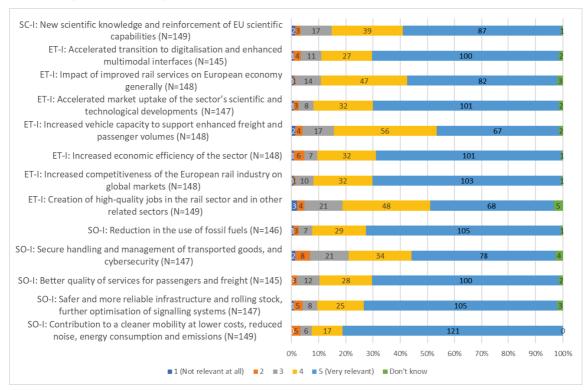
Figure 14: Assessment of open answers on the question why other comparable initiatives are not suitable to be linked, 30 most common co-occurring keywords (N=21)



Some respondents argued that both a rationalisation of partnerships and more links with other initiatives would be counter-productive. However, even among respondents expressing doubts about the potential for synergy and links with other initiatives, most indicated that some interaction with partnerships focused on carbon reduction as well as with initiatives concerned with transport would be beneficial.

Relevance of European Partnerships to deliver targeted scientific, economic/technological and societal impacts

Figure 15: Views of respondents on the relevance of the candidate European Institutionalised Partnership to various impacts



Among presented societal impact categories, a higher number of respondents, namely 121 out of 149 (81.21%), indicated that the Partnership would be 'very relevant' for contributing to a cleaner mobility at lower costs, reduced noise, energy consumption and emissions. Among economic/technological impacts, several categories were considered as 'very relevant' by around 70% of respondents. In contrast, the lowest number of respondents (namely, 67 and 68 respectively) suggest that the candidate Partnership would have a significant impact on increase of vehicle capacity to support enhanced freight and passenger volume, and on creation of high-quality jobs in the rail sector and in other related sectors. The only listed scientific impact category ("new scientific knowledge and reinforcement of EU scientific capabilities") received the highest score (5 'very relevant') by 87 out of 149 respondents (58.39%).

No statistical differences were found between the views of citizens and other respondents.

Summary of campaign results

Table 2: Overview of responses of campaign participants (N=29)

Question category	Summary of responses
Research and innovation problems	All answer categories are considered either 'very relevant' or 'relevant'. Among categories, the lowest score was given to "lack of alignment between basic research in rail sector and market needs".
Structural and resource problems	Most categories are considered either 'very relevant' or 'relevant' by consultation respondents. The lowest score (on average, 3) is given to the following categories: "deep coordination and alignment of public and private R&I funding" and "uncoordinated programming approach and poor alignment with EU policy goals".
Problems in uptake of digital innovations	The categories "slow deployment and limited market uptake of innovative solutions" received a high score (either 4 or 5). The other category ("regulatory framework that is not conducive to innovation) received mixed scores – ranging from 2 to 5.
Preferred Horizon Europe intervention	Institutionalised Partnership was selected by all respondents. When respondents were asked to explain their choice, all of them used different versions of the following quote: "Partnership supports bringing together supply Industry, operators, infrastructure managers and research centers and foster long-term commitments of all actors to ensure aligned specifications, development and deployment of innovations. Institutionalised Partnership covers product development cycles, prevents fragmentation among rail ecosystems and accelerates innovations".
Relevance of actors for setting join long-term agenda	Most answer categories received an average score (namely, 3) on the scale of 1 to 5. However, industry is considered 'very relevant' by the majority of respondents.
Relevance of actors for pooling and leveraging resources	Most answer categories received an average score (namely, 3) on the scale of 1 to 5. However, industry is considered 'very relevant' by the majority of respondents.
Partnership composition	Respondents consider the listed elements of partnership composition to be 'relevant' (score 4).
Implementation of activities	Almost all respondents rated all listed activities 'very relevant'.

Question category	Summary of responses
Relevance of the legal structure	Across all categories, respondents indicated that the legal structure would be relevant. Almost all respondents consider that the legal structure would be 'very relevant' to implement activities of the Partnership more effectively, to implement activities faster to respond to sudden market or policy needs, to facilitate synergies with other EU and national programmes, to facilitate collaboration with other relevant European Partnerships, and to obtain more buy-in and long-term commitment from other partners.
	All respondents considered that listed components of the candidate Partnership have right scope and coverage, with the exception of sectoral coverage. In that answer category, almost a third of respondents indicated that the scope and coverage are too narrow.
Scope and coverage of the candidate Partnership	Respondents were offered an opportunity to provide comments on the proposed scope and coverage of the Institutionalised Partnership. All of them included the following quote: "Programme of the rail iPPP shall be aligned with the vision of the rail sector presented: ERRAC 2050 and ERRAC 2030 R&I priorities. Key research areas: Assets for Automatic and Autonomous Operations, Rail Digitalisation, Maintenance of the future (including required equipment), Smart Integration for Door to Door Mobility, Multi-Modality, Environmental Sustainability and Carbon Free Mobility, Rail Freight, Network & Asset Management. Deployment shall also be included to speed up market uptake".
	The majority of respondents (18, or 64.29%) consider that it would be possible to rationalise the candidate Partnership and its activities, and/or to better link it with other comparable initiatives.
Rationalisation of the candidate Partnership and linking to other initiatives	Respondents were asked to explain their answer. Regardless of their answer choice, all of them inserted a following quote: "We do not consider possible nor sensible to rationalise further the proposed candidates for Institutionalised Partnerships. The competitiveness and industrial leadership of Europe would be, otherwise, hampered. However, we support ensuring better coordination between the different proposed initiatives. In particular, in the case of rail, coordination with the other initiatives falling within Clusters "Climate, Energy, Mobility" and "Digital, Industry and Space" would be important".
Societal impact	Majority of respondents considered that the candidate Partnership would be 'very relevant' to deliver on the listed societal impact.
Economic/technological impact	Most respondents consider that the candidate Partnership would be "very relevant for the following impacts: "increased competitiveness of the European rail industry on global markets", "increased economic efficiency of the sector", "accelerated market uptake of the sector's scientific and technological developments" and "accelerated transition to digitalisation and enhanced multimodal interfaces". Other categories, on average, received a score of 4.
Scientific impact	Most respondents consider that the candidate Partnership is 'very relevant' and 'relevant' for delivering on listed scientific impacts.

Annex 3 Who Is Affected And How?

1. PRACTICAL IMPLICATIONS OF THE INITIATIVE

The proposed Transforming Europe's Rail System Partnership will focus on a limited number of priorities designed to address emerging challenges of the rail sector, such as automation, digitalisation, decarbonisation and the need to increase the attractiveness of rail freight and its integration into digital multimodal mobility and logistics chains. It will also satisfy Horizon Europe's more demanding societal, economic and technological impact criteria and address the European Union's Green Deal objectives aimed at achieving climate neutrality by 2050. The following stakeholder groups are affected by the proposed initiative, as explained below:

- The private sector, in particular rail suppliers (including SMEs), operators and infrastructure managers, will contribute to the definition of the Programme, making significant commitments for its implementation. The private sector will benefit from a well-defined legal and financial framework, with partners contributing resources in accordance with legally binding requirements relating to the proportion of EU and partner funds, set out in a Council Regulation;
- European universities and research-based organisations will play a pivotal role to increase the scientific knowledge base and contribute to accelerate the development of rail innovations through collaboration with private enterprises;
- Civil society will benefit from the positive impact of rail innovation for passenger and freight transport as well as from the contribution of rail to tackle climate change. The proposed Transforming Europe's Rail System Partnership will enable rail to support the realisation of a people-centred economy in which EU citizens have access to an increasing range of employment, education and leisure opportunities through efficient, attractive and affordable public transport services;
- The support of Member States will be instrumental for the implementation of the programme and the achievement of its objectives (e.g. Green Deal targets). The proposed Transforming Europe's Rail System Partnership will provide a relevant scientific and technology evidence base as well as innovative solutions to make rail a significant part of the solution for the climate challenge and support Member States' efforts to decarbonise transport.

2. SUMMARY OF COSTS AND BENEFITS

I. Overview of Benefits (total for all provisions) – Preferred Option					
Description	Amount	Comments			
	Direct benefits				
Sustainable cost efficient mobility	Increased attractiveness, accessibility and services for rail passenger and freight through new concepts of operations enabled and system				

	integrated approach by breakthrough innovation	social inclusiveness.
More competitive rail industry	The transfer of innovative solutions to the market will boost the competitiveness of European suppliers involved in the partnership. The European rail industry will maintain its market leadership at global level by 2050	support across EU-up to 75% market uptake
Rail system transformation	Integrated approach enabling the delivery of EU policy objectives and the technical integration of rail innovations in the overall mobility digital eco-system for all modes of transport.	The Partnership will be part of a whole- system approach to investment, cutting across the various interfaces, which recognises the long-lived nature of railway assets.
	Indirect benefits	
Transport decarbonisation	Modal shift from more carbon intensive modes to rail will make a significant contribution to transport decarbonisation. In addition, the programme will help further reducing rail's carbon footprint.	objectives (e.g. shift substantial part of the 75% of inland freight carried today by road
Increased quality of life	Increasing rail attractiveness would result in integrated journeys with rail at the core of mobility and transport (high speed, regional and urban, freight) through a climate neutral concept of operations and based on a circular economy system.	emissions (e.g. expected CO2 reduction

⁽¹⁾ Estimates are relative to the baseline for the preferred option as a whole (i.e. the impact of individual actions/obligations of the <u>preferred</u> option are aggregated together); (2) Please indicate which stakeholder group is the main recipient of the benefit in the comment section;(3) For reductions in regulatory costs, please describe details as to how the saving arises (e.g. reductions in compliance costs, administrative costs, regulatory charges, enforcement costs, etc.; see section 6 of the attached guidance).

	II. Overview of costs – Preferred option						
		Citizens	s/Consumers	Busir	nesses	Admin	istrations
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Managem ent/ Administr ative costs	Direct costs						Yearly running costs other than Personnel: EUR 1.2 million (baseline 2019 AAR – Title 2) – 50% EC

	Indirect costs			
Personnel costs	Direct costs			Yearly running costs for Personnel: EUR 2.3 million (baseline 2019 AAR – Title 1 – 24 FTE [5 TA + 16 CA + 3 SNEs]) – 50% EC
	Indirect costs			

(1) Estimates to be provided with respect to the baseline; (2) costs are provided for each identifiable action/obligation of the <u>preferred</u> option otherwise for all retained options when no preferred option is specified; (3) If relevant and available, please present information on costs according to the standard typology of costs (compliance costs, regulatory charges, hassle costs, administrative costs, enforcement costs, indirect costs; see section 6 of the attached guidance).

REFIT Cost savings table

Not applicable for the proposed Transforming Europe's Rail System Partnership. The initiative will benefit from the existing organisation/structure (e.g. the Programme Office) already in place for the S2R 2 JU. There are no additional regulatory costs associated, and no specific simplification measures apply in this case.

Annex 4 Analytical Methods

The methodology for each impact assessment is based on the Commission Better Regulation Guidelines⁷ to evaluate and compare options with regards to their **efficiency**, **effectiveness** and **coherence**. This is complemented by integrating the **conditions and selection criteria** for European Partnerships, as well as requirements for setting up Institutionalised Partnerships.⁸

1. OVERVIEW OF THE METHODOLOGIES EMPLOYED

In terms of **methods and evidence used**, the set of impact assessments for all candidate Institutionalised European Partnerships draw on an external study covering all initiatives in parallel to ensure a high level of coherence and comparability of analysis ⁹ (Technopolis Group, 2020).

All impact assessment mobilised a mix of qualitative and quantitative data collection and analysis methods. These methods range from desk research and interviews to the analysis of the responses to the Open Consultation, stakeholder analysis and composition/portfolio analysis, bibliometrics/patent analysis and social network analysis, and a cost-effectiveness analysis.

The first step in the impact assessment studies consisted in the definition of the context and the problems that the candidate partnerships are expected to solve in the medium term or long run. The main data source in this respect was desk research. This includes grey and academic literature to identify the main challenges in the scientific and technologic fields and in the economic sectors relevant for the candidate partnerships, as well as the review of official documentations on the policy context for each initiative.

In the assessment of the problems to address, the lessons to be learned from past and ongoing partnerships were taken into account, especially from relevant midterm or ex-post evaluations.

The description of the context of the candidate institutionalised European Partnerships required a good understanding of the corresponding research and innovation systems and their outputs already measured. Data on past and ongoing Horizon 2020 projects, including the ones implemented through Partnerships, served as basis for descriptive statistic of the numbers of projects and their respective levels of funding, the type of organisations participating (e.g. universities, RTOs, large enterprises, SMEs, public administrations, NGOs, etc.) and how the funding was distributed across them. Special attention was given to analysing the participating countries (and groups of countries, such as EU, Associated Countries, EU13 or EU15) and industrial sectors, where relevant. The sectoral analysis required enriching the eCORDA data received from the European Commission services with

⁷ European Commission (2017), Better Regulation Guidelines (SWD (2017) 350)

⁸ A pivotal element of the present analysis is the so-called two-step 'necessity test' for European Partnerships, used to establish: step 1) the need for a partnership approach in the first place, followed by step 2) a justification for the form of Institutionalised Partnership. The necessity test is described in Annex 6. This impact assessment focuses on the second step of the test.

⁹ Technopolis Group (2020), Impact Assessment Study for Institutionalised European Partnerships under Horizon Europe

sector information extracted from ORBIS, using the NACE codification up to level 2. These data enabled the identification of the main and, where possible, emerging actors in the relevant systems, i.e. the organisations, countries and sectors that would need to be involved (further) in a new initiative.

A Social Network Analysis was performed by the contractors using the same data. It consisted in mapping the collaboration between the participants in the projects funded under the ongoing R&I partnerships. This analysis revealed which actors – broken down per type of stakeholders or per industrial sector – collaborate the most often together, and those that are therefore the most central to the relevant research and innovation systems.

The data provided finally served a bibliometric analysis run by the contractor aimed at measuring the outputs (patents and scientific publications) of the currently EU-funded research and innovation projects. A complementary analysis of the Scopus data enabled to determine the position and excellence of the European Union on the international scene, and identify who its main competitors are, and whether the European research and innovation is leading, following or lagging behind.

A cost modelling exercise was performed in order to feed into the efficiency assessments of the partnership options.

The conclusions drawn from the data analysis were confronted to the views of experts and stakeholders collected via three means:

- The comments to the inception impact assessments of the individual candidate institutionalised European Partnerships;
- The open public consultation organised by the European Commission from September to November 2019;
- The interviews (up to 50) conducted by each impact assessment study team conducted between August 2019 and January 2020 (policymakers, business including SMEs and business associations, research institutes and universities, and civil organisations, among others).

The views of stakeholders (and experts) were particularly important for determining the basic functionalities (see further below) that the future partnerships need to demonstrate to achieve their objectives as well as their most anticipated scientific, economic and technological, and societal impacts. The interviews allowed more flexibility to ask the respondents to reflect about the different types of European Partnerships. Furthermore, as a method for targeted consultation, it was used to get insights from the actors that both the Study Teams and the European Commission were deemed the most relevant. For the comparative assessment of impacts, the external contractors confronted the outcomes of the different stakeholder consultation exercises to each other with a view of increasing the validity of their conclusions, in line with the principles of triangulation.

Annex 2 includes also the main outcomes of the stakeholder consultation exercises.

2. METHOD FOR ASSESSING THE EFFECTIVENESS, EFFICIENCY AND COHERENCE OF EACH OPTION - THE USE OF FUNCTIONALITIES

Given the focus of the impact assessment on comparing different forms of implementation, the Better Regulation framework has been adapted to introduce "key functionalities needed" so as to link the intended objectives of the candidate European Partnerships and what would be crucial to achieve them in terms of implementation. The identification of "key functionalities needed" for each initiative as an additional step in the impact assessment is based on the distinguishing factors between the different options (see Section 2.2.1 in the main body of the impact assessment). In practical terms, each option is assessed on the basis of the degree to which it would allow for the key needed functionalities to be covered, as regards e.g. the type and composition of actors that can be involved ('openness'), the range of activities that can be performed (including additionality and level of integration), the level of directionality and integration of R&I strategies; the possibilities offered for coherence and synergies with other components of Horizon Europe, including other Partnerships (internal coherence), and the coherence with the wider policy environments, including with the relevant regulatory and standardisation framework (external coherence). This approach guides the identification of discarded options. It also allows for a structured comparison of the options as regards their effectiveness, efficiency and coherence, and also against a set of other key selection criteria for European Partnerships (openness, transparency, directionality).

Figure 3 Overview of key functionalities of each form of implementation of European Partnerships

Baseline: Horizon Europe calls	Option 1: Co- programmed	Option 2: Co- funded	Option 3.1: Institutionalised Article 185	Option 3.2: Institutionalised Article 187		
Type and composition of actors (including openness and roles)						
Partners: N.A., no common set of actors that engage in planning and implementation Priority setting: open to all, part of Horizon Europe Strategic planning Participation in R&I activities: fully open in line with standard Horizon Europe rules	Partners: Suitable for all types: private and/or public partners, foundations Priority setting: Driven by partners, open stakeholder consultation, MS in comitology Participation in R&I activities: fully open in line with standard Horizon Europe rules	Partners: core of national funding bodies or governmental research organisations Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: limited, according to national rules of partner countries	Partners: National funding bodies or governmental research organisation Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: fully open in line with standard Horizon Europe rules, but possible derogations	Partners: Suitable for all types: private and/or public partners, foundations Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: fully open in line with standard Horizon Europe rules, but possible derogations		
	 ctivities (including add	 	integration)	derogations		
Activities: Horizon Europe standards that allow broad range of individual actions Additionality: no additional activities and investments outside the funded	Activities: Horizon Europe standard actions that allow broad range of individual actions, support to market, regulatory or policy/ societal uptake Additionality:	Activities: Broad, according to rules/programmes of participating States, State-aid rules, support to regulatory or policy/ societal uptake	Activities: Horizon Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to systemic approach	Activities: Horizon Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to systemic approach		

Baseline: Horizon Europe calls	Option 1: Co- programmed	Option 2: Co- funded	Option 3.1: Institutionalised Article 185	Option 3.2: Institutionalised Article 187
Limitations: No systemic approach beyond individual actions	Activities/investment s of partners, National funding Limitations: Limited systemic approach beyond individual actions.	Additionality: National funding Limitations: Scale and scope depend on the participating programmes, often smaller in scale	Additionality: National funding	(portfolios of projects, scaling up of results, synergies with other funds. Additionality: Activities/investments of partners/ national
Directionality				funding
Priority setting: Strategic Plan and annual work programmes, covering max. 4 years. Limitations: Fully taking into account existing or to be developed SRIA/ roadmap	Priority setting: Strategic R&I agenda/ roadmap agreed between partners and COM, covering usually 7 years, including allocation of Union contribution Input to FP annual work programme drafted by partners, finalised by COM (comitology) Objectives and commitments are set in the contractual arrangement.	Priority setting: Strategic R&I agenda/ roadmap agreed between partners and COM, covering usually 7 years, including allocation of Union contribution Annual work programme drafted by partners, approved by COM Objectives and commitments are set in the Grant Agreement.	Priority setting: Strategic R&I agenda/ roadmap agreed between partners and COM, covering usually 7 years, including allocation of Union contribution Annual work programme drafted by partners, approved by COM Objectives and commitments are set in the legal base.	Priority setting: Strategic R&I agenda/ roadmap agreed between partners and COM, covering usually 7 years, including allocation of Union contribution Annual work programme drafted by partners, approved by COM (veto-right in governance) Objectives and commitments are set in the legal base.
Coherence: internal industrial strategies	(Horizon Europe) and	external (other Union	programmes, national	programmes,
Internal: Between different parts of the Annual Work programme can be ensured by COM External: Limited for other Union programmes, no synergies with national/regional programmes and activities	Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Limited synergies with other Union programmes and industrial strategies If MS participate, with national/regional programmes and activities	Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Synergies with national/regional programmes and activities	Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Synergies with national/ regional programmes and activities	Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Synergies with other Union programmes and industrial strategies If MS participate, with national/regional programmes and activities

In line with the Better Regulation Framework, the assessment of the effectiveness, efficiency and coherence of each option is made in comparison to the baseline. Therefore, for each of the above criteria, the performance of using traditional calls under Horizon Europe is first estimated and scored 0 to serve as a reference point. When relevant, this estimation also includes the costs/benefits of discontinuing existing implementation structures. The policy options are then scored compared to the baseline with a + and - system along a two-point

scale, to indicate limited (+ or -) or high (++ or --) additional/lower performance compared to the baseline. When a policy option is scored 0, this means that its impact is expected to be roughly equal to the baseline option.

On the basis of the evidence collected, the intervention logic of each initiative and the key functionalities needed, the impact assessments first evaluate the **effectiveness** of the various policy options to deliver on their objectives. To be in line with the Horizon Europe impact framework, the fulfilment of the specific objectives of the initiative is translated into 'expected impacts' - how success would look like -, differentiating between scientific, economic/ technological, and societal (including environmental) impacts. Each impact assessment considers to which extent the different policy options provides the 'key functionalities needed' to achieve the intended objectives. The effectiveness assessment does not use a compound score but shows how the options would deliver on the different types of expected impacts. This is done to increase transparency and accuracy in the assessment of options¹⁰.

A similar approach is followed to evaluate the coherence of options with the overarching objectives of the EU's R&I policy, and distinguishes between **internal** and **external coherence**. Specifically, internal coherence covers the consistency of the activities that could be implemented with the rest of Horizon Europe, including European Partnerships (any type). External coherence refers to the potential for synergies and/or complementarities (including risks of overlaps/gaps) of the initiative with its external environment, including with other programmes under the MFF 2021-27, but also the framework conditions at European, national or regional level (incl. regulatory aspects, standardisation).

To compare the expected costs and benefits of each option (efficiency), the thematic impact assessments broadly follow a cost-effectiveness approach¹¹ to establish to which extent the intended objectives can be achieved for a given cost. A preliminary step in this process is to obtain a measure of the expected costs of the policy options, to be used in the thematic assessments. As the options correspond to different implementation modes, relevant cost categories generally include the costs of setting-up and running an initiative. For instance, setup costs includes items such as the preparation of a European Partnership proposal and the preparation of an implementation structure. The running costs include the annual work programme preparation costs. Where a Partnership already exists, discontinuation costs and cost-savings are also taken into account¹². The table below provides an overview of the cost categories used in the impact assessment and a qualitative scoring of their intensity when compared to the baseline option (traditional calls). Providing a monetised value for these average static costs would have been misleading, because of the different features and needs

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¹⁰ In the thematic impact assessments, scores are justified in a detailed manner to avoid arbitrariness and spurious accuracy. A qualitative or even quantitative explanation is provided of why certain scores were given to specific impacts, and why one option scores better or worse than others.

¹¹ For further details, see Better Regulation Toolbox # 57.

¹² Discontinuation costs will bear winding down and social discontinuation costs and vary depending on e.g. the number of full-time-equivalent (FTEs) staff concerned, the type of contract (staff category and duration) and applicable rules on termination (e.g. contracts under Belgian law or other). If buildings are being rented, the cost of rental termination also apply. As rental contracts are normally tied to the expected duration of the current initiatives, these termination costs are likely to be very limited. In parallel, there would also be financial cost-savings related to the closing of the structure, related to operations, staff and coordination costs in particular. This is developed further in the individual efficiency assessments.

of each candidate initiative.¹³ The table shows the overall administrative, operational and coordination costs of the various options. These costs are then put into context in the impact assessments to reflect the expected co-financing rates and the total budget available for each of the policy options, assuming a common Union contribution (cost-efficiency):

- The costs related to the baseline scenario (traditional calls under Horizon Europe) are predominantly the costs of implementing the respective Union contribution via calls and project, managed by the executive agencies (around 4%, efficiency of 96% for the overall investment).
- For a Co-Programmed partnership the costs of preparation and implementation increase only marginally compared to the baseline (<1%), ¹⁴ but lead to an additional R&I investment of at least the same amount than the Union contribution ¹⁵ (efficiency of 98% for the overall investment).
- For a Co-Funded partnership the additional R&I investment by Member States accounts for 2,3 times the Union contribution ¹⁶. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the national programmes, can be estimated at 6% of the Union contribution (efficiency of 98% related to the overall investment). ¹⁷
- For an Article 185 initiative the additional R&I investment by Member States is equal to the Union contribution ¹⁸. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the dedicated implementation structure, can be estimated at 7% of the Union contribution (efficiency of 96% related to the overall investment).
- For an Article 187 initiative the additional R&I investment by partners is equal to the Union contribution¹⁹. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the dedicated implementation structure, can be estimated at 9% of the Union contribution (efficiency of 94% related to the overall investment).

¹³ A complete presentation of the methodology developed to assess costs as well as the sources used is described in the external study supporting this impact assessment (Technopolis Group, 2020).

¹⁴ Specifically, some additional set-up costs linked for example to the creation of a strategic research and innovation agenda (SRIA) and additional running costs linked with the partners role in the creation of the annual work programmes and the Commission's additional supervisory responsibilities. A CPP will have lower overall costs than each of the other types of European Partnership, as it will function with a smaller governance and implementation structure than will be required for a Co-Funded Partnership or an Institutionalised Partnership and – related to this – its calls will be operated through the existing HEU agencies and RDI infrastructure and systems.

¹⁵ Minimum contributions from partners equal to the Union contribution.

¹⁶ Based on the default funding rate for programme co-fund actions of 30%, partners contribute with 70% of the total investment.

¹⁷ These costs reflect set-up costs and additional running costs for partners, and the Commission, of the distributed, multi-agency implementation model.

¹⁸ Based on the minimum requirement in the legal basis that partners contribute at least 50% of the budget.

¹⁹ Based on the minimum requirement in the legal basis that partners contribute at least 50% of the budget.

Figure 4 - Intensity of additional costs compared with Horizon Europe Calls (for Partners, stakeholders, public and EU)

Cost items	Baseline: traditional calls	Option 1: Coprogrammed	Option 2 Co-funded	Option 3a - Art. 185	Option 3b -Art. 187		
Preparation and set-up costs	Preparation and set-up costs						
Preparation of a partnership proposal (partners and EC)	0		↑ ↑				
Set-up of a dedicated implementation structure		0		Existing: ↑ New: ↑↑	Existing: \\ New: \\\ \\		
Preparation of the SRIA / roadmap	0		$\uparrow \uparrow$				
Ex-ante Impact Assessment for partnership		0		↑ ↑	↑		
Preparation of EC proposal and negotiation		0		↑ ↑	\uparrow		
Running costs (Annual cycle of implementa	ition)						
Annual Work Programme preparation	0		1				
Call and project implementation	0	0 In case of MS contributions: ↑	\uparrow	\uparrow	↑		
Cost to applicants	Comparable, unless there are strong arguments of major differences in oversubscription			fferences in			
Partners costs not covered by the above	0	\uparrow	0	↑	↑		
Additional EC costs (e.g. supervision)	0 ↑ ↑		↑	↑	$\uparrow \uparrow$		
Winding down costs							
EC		0			$\uparrow \uparrow \uparrow$		
Partners	0	↑	0	↑	↑		

Notes: 0: no additional costs, as compared with the baseline; \uparrow : minor additional costs, as compared with the baseline; $\uparrow\uparrow$: medium additional costs, as compared with the baseline; $\uparrow\uparrow\uparrow$: higher costs, as compared with the baseline.

The cost categories estimated for the common model are then used to develop a scorecard analysis and further refine the assessment of options for each of the 12 candidate Institutionalised Partnerships. Specifically, the scores related to the set-up and implementation costs are used in the thematic impact assessments to consider the scale of the expected benefits and thereby allow a simple "value for money" analysis (**cost-effectiveness**)²⁰. In carrying out the scoring of options, the results of fieldwork, desk research and stakeholder consultation undertaken and taken into account.

3. METHOD FOR IDENTIFYING THE PREFERRED OPTION – THE SCORECARD ANALYSIS

For the **identification of the preferred option**, a scorecard analysis is used to build a hierarchy of the options by individual criterion and overall in order to identify a single preferred policy option or in case of an inconclusive comparison of options, a number of 'retained' options or hybrid. This exercise supports the systematic appraisal of alternative options across multiple types of monetary, non-monetary and qualitative dimensions. It also allows for easy visualisation of the pros and cons of each option. Each option is attributed a score of the adjudged performance against each criterion with the three broad appraisal dimensions of effectiveness, efficiency and coherence.

This scorecard approach also relies on a standard cost model developed for the external study supporting the impact assessment, as illustrated in **Error! Reference source not found.**. These costs essentially refer to the administrative, operational and coordination costs of the

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²⁰ More details on the methodology can be found in Annex 4.

various options. The figure shows how the scoring of costs range from a value of 0, in case an option does not entail any additional costs compared to the baseline (traditional calls), to a score of (-) for options introducing limited additional costs relative to the baseline and a score of (-) when substantial additional costs are expected in comparison with the baseline. Should the costs of a policy option be lower than those of the baseline, (+) and (++) are used.

Figure 5: Matrix on 'overall costs' and 'adjusted cost scoring'

	Baseline: Horizon Europe calls	Option 1: Co- programmed	Option 2: Co- funded	Option 3: Institutionalised
Administrative, operational and coordination costs	0	(-)	()	()
Administrative, operational and coordination costs adjusted per expected co-funding (i.e. cost-efficiency)	0	0	(-)	(-)

Notes: Score 0 = same costs as for the baseline; score (-) = limited additional costs compared to baseline; score (- -) = substantial additional costs compared to baseline.

The **baseline** (**regular calls**) has the lowest administrative, operational and coordination costs. This is based on two facts: firstly, that Horizon Europe traditional calls will not entail any additional one-off costs to be set up or discontinued at the end, where each of the other policy options will require at least some additional set-up and phasing out costs; and secondly, that Horizon Europe will not require any additional running costs, where each of the other policy options will involve additional efforts by the Commission and partners in the carrying out of necessary additional tasks (e.g. preparing annual work programmes).

A **co-programmed partnership** (Option 1 - CPP) will entail slightly higher overall costs as compared with the baseline. There will be some additional set-up costs linked for example with the creation of a strategic research and innovation agenda (SRIA) and additional running costs linked with the partners role in the creation of the annual work programmes and the Commission's additional supervisory responsibilities. A CPP will have lower overall costs than each of the other types of European Partnership, as it will function with a smaller governance and implementation structure than will be required for a Co-Funded Partnership or an Institutionalised Partnership and – related to this – its calls will be operated through the existing HEU agencies and RDI infrastructure and systems.

The Co-Funded Partnership (Option 2 - CFP) has been scored (- -) on overall cost. This reflects the additional set-up costs of this policy option and the substantial additional running costs for partners, and the Commission, of the distributed, multi-agency implementation model.

The **Institutionalised Partnership** (Option 3 - IP) has been **scored** (--) on overall cost. This reflects the substantial additional set-up costs of this policy option – and in particular the high costs associated with preparing the Commission proposal and negotiating that through to a legal document – and the substantial additional running costs for the Commission associated with the supervision of this dedicated implementation model.

It is considered that while there is a clear gradation in the overall costs of the policy options, the cost differentials are less marked when one takes into account the expected co-financing rates and the total budget available for each of the policy options, assuming a common Union contribution. From this perspective, there are only one or two percentage points that split the most cost-efficient policy options – the baseline (traditional calls) and the Co-Programmed policy options – and the least cost-efficient – the Institutionalised Partnership option. A score

of 0 is therefore assigned for **cost-efficiency** to the Co-Programmed option and a score of (-) for the Co-Funded and the Institutionalised Partnership policy options²¹.

4. OVERVIEW OF THE MODELLING FRAMEWORK DEVELOPED FOR THE ASSESSMENT OF IMPACTS OF THE CANDIDATE INSTITUTIONALISED PARTNERSHIPS FOR TRANSFORMING EUROPE'S RAIL SYSTEM

A number of economic/technological impacts have been estimated using a model developed for a 'Study on the Cost and Contribution of the Rail Sector', undertaken by Steer on behalf of the European Commission in 2015. The design of the model is illustrated in the figure below.

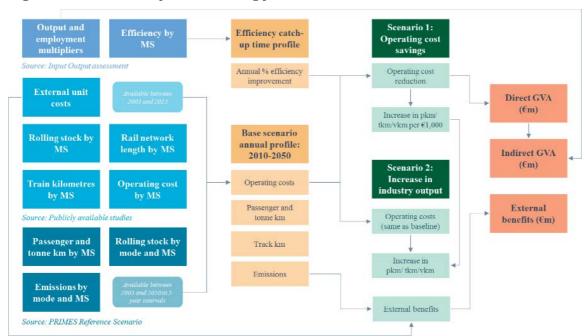


Figure 5: Illustration of the modelling framework

Source: Steer

The model uses the following inputs:

- An efficiency score for each of the Member States in the base year and a profile of how efficiency changes over time;
- Metrics measuring the scale of the current network (track kilometres), current operations (train kilometres), current fleet (number of vehicles) and operating costs for each Member State, as well as external cost unit rates; and
- Inputs from the PRIMES Reference Scenario, including activity (passenger and tonne kilometres), fleet composition and emissions for all modes and Member States up to 2050.

As originally specified, the model assesses two different scenarios by Member State:

²¹ The baseline (traditional calls) is scored 0, as explained above.

- One where the Member State railway industry becomes more efficient and the gains in efficiency are fully reflected through savings in operating costs passed on to passengers and freight customers; and
- One where the efficiency gains are fully reinvested in the railway industry, which results in increases in passenger and tonne kilometres.

However, it is possible to adapt the model to investigate the effect of different combinations of transport cost savings and investment.

The model has been used to calculate the external impacts of efficiency gains on traffic levels, mode share, employment and environmental emissions. It can also be used to generate estimates of impact on the economy, measured in terms of Gross Value Added (GVA).

The S2R JU release 2.0 KPI results showing the potential improvement in industry life cycle costs have been used to provide an assumption for the improvement in efficiency under the baseline. The model was then used to estimate the impact of the policy options based on assumptions of further progress towards meeting the KPI target in each case. These assumptions were informed by consideration of both the level of efficiency gains potentially achievable due to R&I activity under each option and the extent of market take-up in each case.

The following table provides an indication of matrix of assumptions used. As described in *Section 6* of the main report, the assumed potential for reductions in life cycle costs were combined with the market take-up value to generate a single value for the assumed efficiency savings to be input into the model.

Table 2: Key efficiency assumptions used in the impact assessment

Option	Potential reduction in life cycle costs by 2030 (assuming 100% market take-up)	Market take-up of R&I outputs	Commentary
Traditional open calls	Passenger: 16.5% reduction Freight: 26% reduction	25 - 33%	Cost reductions indicated by S2RJU KPI release 2.0 (averaged in the case of passenger) – assumed to be captured in baseline. Range of market take-up observed prior to establishment of the S2R JU, as reported by Foster Rail and previous studies.
Co-programmed partnership	Passenger: 25% reduction Freight: 35% reduction	45 - 60%	Assumes some further progress towards targets and a higher rate of market take-up than under the baseline. However, given that several aspects of the problem would persist under the baseline, we have assumed that the improvements are limited.
Article 187 partnership	Passenger: 50% reduction Freight: 50% reduction	50 - 75%	Assumes KPI targets for current JU are met. Market take-up reflects stakeholder views on

Source: Steer review of sources identified in the table

The model was used to generate estimates of changes in traffic levels and modal shift against the baseline on the assumption that 50% of efficiency improvements are passed on to rail passengers and freight customers in the form of, respectively, lower fares and lower freight rates, and that 50% are captured in the form of released funds for additional investment.

Annex 5 Subsidiarity Grid

1. Can the Union act? What is the legal basis and competence of the Unions' intended action?

1.1 Which article(s) of the Treaty are used to support the legislative proposal or policy initiative?

This proposal is based on (1) Article 185 TFEU which stipulates that in implementing the multiannual framework programme, the Union may make provision, in agreement with the Member States concerned, for participation in research and development programmes undertaken by several Member States, including participation in the structures created for the execution of those programmes; and (2) Article 187 TFEU according to which the Union may set up joint undertakings or any other structure necessary for the efficient execution of Union research, technological development and demonstration programmes (both Articles are under Title XIX of the TFEU - Research and Technological Development and Space).

The proposal aims to implement Article 8 of the Commission proposal for Horizon Europe - the future EU research and innovation (R&I) programme for 2021-2027, according to which, "European Partnerships shall be established for addressing European or global challenges only in cases where they will more effectively achieve objectives of Horizon Europe than the Union alone and when compared to other forms of support of the Framework programme". The Horizon Europe proposal has received the political agreement of the Council and the European Parliament.

1.2 Is the Union competence represented by this Treaty article exclusive, shared or supporting in nature?

Research is a shared competence between the EU and its Member States according to the TFEU. Article 4 (3) specifies that in the areas of research, technological development and space, the European Union can carry out specific activities, including defining and implementing programmes, without prejudice to the Member States' freedom to act in the same areas.

Subsidiarity does not apply for policy areas where the Union has **exclusive** competence as defined in Article 3 TFEU²². It is the specific legal basis which determines whether the proposal falls under the subsidiarity control mechanism. Article 4 TFEU²³ sets out the areas where competence is shared between the Union and the Member States. Article 6 TFEU²⁴ sets out the areas for which the Unions has competence only to support the actions of the Member States.

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²² https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12008E003&from=EN

https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12008E004&from=EN https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12008E006:EN:HTML

2. Subsidiarity Principle: Why should the EU act?

2.1 Does the proposal fulfil the procedural requirements of Protocol No. 2^{25} :

- Has there been a wide consultation before proposing the act?
- Is there a detailed statement with qualitative and, where possible, quantitative indicators allowing an appraisal of whether the action can best be achieved at Union level?

This proposal and the accompanying impact assessment were supported by a wide consultation of stakeholders, both during the preparation of the Horizon Europe proposal and - later on, all the candidates for European Partnerships. Member States were consulted via the Shadow Strategic configuration of the Horizon Europe Programme Committee. On candidates for institutionalised Partnerships based on Article 185/187 of the TFEU, an Open Public Consultation (OPC) was held between 11 September and 6 November 2019. Over 1 600 replies were received. In addition, targeted consultation activities were undertaken to prepare the present impact assessment. In particular, for each of the candidate partnerships, an external consultant interviewed a representative sample of stakeholders. The need for EU action as well as its added value were covered in those interviews.

The explanatory memorandum and the impact assessment (horizontal part, Section 3) contain a dedicated section on the principle of subsidiarity, as explained in question 2.2 below.

2.2 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the conformity with the principle of subsidiarity?

The impact assessment accompanying the proposal features a horizontal part on relevant common elements to all the candidate partnerships, including the conformity of the proposed initiative with the principle of subsidiarity (Section 3). Moreover, the individual assessments of each candidate partnership include additional details on subsidiarity, touching in particular on the specificities of a candidate partnership that could not be adequately reflected in the horizontal part of the impact assessment. This will also be reflected in the explanatory memorandum.

2.3 Based on the answers to the questions below, can the objectives of the proposed action be achieved sufficiently by the Member States acting alone (necessity for EU action)?

National action alone cannot achieve the scale, speed and scope of support to R&I needed for the EU to meet its long-term Treaty objectives, to deliver on the EU's strategic policy priorities (including the climate and energy goals set out in the Paris Agreement, and the European Green Deal), and to contribute to tackling global challenges and meeting the

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 $^{^{25}\} https://eur-lex.europa.eu/legal-content/\underline{EN/TXT/HTML/?uri=CELEX:12016E/PRO/02\&from=EN/2016E/PRO/02\&from=EN/2016E/PRO/02&from=EN/2016E/FRO/02&from=EN/2016E/FRO/02&from=EN/2016E/FRO/02&from=EN/2016E/FRO/02&from=EN/2016E/FRO/02&from=EN/2016E/FRO/02&from=EN/2016E/FRO/02&from=EN/2016E/FRO/02&from=EN/2016E/FRO/02&from=EN/2016E/FRO/02&from=EN/2016E/FRO/02&from=EN/2016E/FRO/02&from=EN/2016E/FRO/02&FRO/0$

Sustainable Development Goals (SDGs).

R&I funded at the national or organisational level, while potentially contributing to the broader development of the European rail system, is unlikely to enable the rail industry to meet European transport and broader policy objectives. Similarly, it is unlikely to ensure the European RSI's ability to compete in international rail product markets against suppliers based in China and other third countries actively building their indigenous rail sector capability, including through major R&I programmes.

(a) Are there significant/appreciable transnational/cross-border aspects to the problems being tackled? Have these been quantified?

The thematic areas covered by the candidate partnerships feature a series of challenges in terms of cross-border/transnational aspects, need to pool resources, need for a critical mass to meet intended policy objectives, need to coordinate different types of actors (e.g. academia, industry, national and regional authorities) across different sectors of the economy and society, which cannot be tackled to the same degree by Member States alone. This is particularly true for the research and innovation (R&I) dimension of the proposed initiative: the importance of a multi-centre and interdisciplinary approach, cross-country data collection and research, and the need to develop and share new knowledge in a timely and coordinated manner to avoid duplication of efforts are key to achieve high quality results and impact. The Interim Evaluation of Horizon 2020 and the impact assessment of Horizon Europe provide extensive qualitative and quantitative evidence on the above points. In addition, Sections 1 and 2 of the individual impact assessments on the candidate partnerships include more detail on the necessity to act at EU-level in specific thematic areas. Finally, it is worth noting that not all Member States have the same capacity or R&I intensity to act on these challenges. As the desired policy objectives can be fully achieved only if the intended benefits are widespread across the Member States, this requires action at the EU-level.

(b) Would national action or the absence of the EU level action conflict with core objectives of the Treaty²⁶ or significantly damage the interests of other Member States?

As per Article 4(3) TFEU, national action does not conflict with core objectives of the Treaty in the area of R&I. The absence of EU level action in this area would however prevent the achievement of core objectives of the Treaty. Indeed, national action alone cannot achieve the scale, speed and scope of support to R&I needed for the EU to meet its long-term Treaty objectives on e.g. competitiveness, to deliver on the EU's strategic policy priorities, and to contribute to tackling global challenges and meet the Sustainable Development Goals (SDGs).

(c) To what extent do Member States have the ability or possibility to enact appropriate measures?

As foreseen by Article 4(3) TFEU, this proposal does not hamper Member States' ability to

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²⁶ https://europa.eu/european-union/about-eu/eu-in-brief en

enact appropriate measures in the field of R&I. However, the scale and complexity of the policy objectives pursued by the present initiative cannot be fully addressed by acting at national level alone.

(d) How does the problem and its causes (e.g. negative externalities, spill-over effects) vary across the national, regional and local levels of the EU?

As described in the horizontal part of the impact assessment accompanying the present proposal, several problems (e.g. on competitiveness, global challenges, demographic change) and their underlying causes affect the EU as a whole rather than individual Member States. Where important differences between Member States are present, these are described in Sections 1 and 2 of the individual impact assessments.

(e) Is the problem widespread across the EU or limited to a few Member States?

The problem of coordinating R&I efforts in the thematic areas covered by the candidate partnerships affects all Member States, albeit to different degrees. However, from a general EU perspective, available evidence shows that the EU as a whole needs to step up efforts and investments in thematic areas that are crucial to tackle present and future policy challenges on several fronts, e.g. ageing population, global technological trends, and climate change to name a few. The way these problems affect the EU and its Member States is described in the horizontal part of the impact assessment and in Sections 1 and 2 of the individual impact assessments.

(f) Are Member States overstretched in achieving the objectives of the planned measure?

As indicated in the horizontal part of the impact assessment and in Sections 1 and 2 of the individual assessments, the sheer scale, speed and scope of the needed support to R&I would overstretch national resources, without guaranteeing the achievement of the intended objectives. Acting at EU-level would achieve greater impact in a more effective and efficient manner.

(g) How do the views/preferred courses of action of national, regional and local authorities differ across the EU?

No specific differences between the views of national, regional and local authorities emerged from the stakeholder consultation.

2.4 Based on the answer to the questions below, can the objectives of the proposed action be better achieved at Union level by reason of scale or effects of that action (EU added value)?

EU funded R&I activities, including those covered by the present proposal, produce

demonstrable benefits compared to the corresponding national and regional initiatives, due to the scale, speed and scope achievable by acting at the EU level. In addition, the proposed initiatives should be seen as complementary and reinforcing national and sub-national initiatives in the same area.

The development of a common European strategy and objectives for rail-related R&I would help to ensure a more coordinated, market-focused approach to R&I activities. It would provide a vehicle for aligning such activity with the EU policy objectives, and for ensuring collaboration among actors from across Europe and along the industry value chain to define projects and programmes designed to address market needs.

(a) Are there clear benefits from EU level action?

Quantitative and qualitative evidence of the benefits of EU level action are available in the interim evaluation of Horizon 2020 and in the impact assessment of Horizon Europe, among others. An analysis of the emerging challenges in each thematic areas, of the EU's competitive positioning, as well as feedback gathered from different types of stakeholders for the present impact assessment indicate that EU level action remains appropriate also for the present proposal. In addition, the benefits of acting at EU-level have been illustrated by the success and the impact achieved by the predecessors to the proposed initiative.

The coordination of R&I at the European level would help to improve the efficiency of the industry in two important ways. First, it would allow pooling of resources available for R&I and their distribution according to a common strategy, thereby reducing the potential for competing and conflicting projects focusing on the needs of national networks and tending to reinforce the geographical fragmentation discussed in the previous chapter. Second, it would encourage the RSI to develop products and systems that further enable the development of a fully integrated European rail system, thereby advancing the creation of a single European market for equipment and allowing them to exploit economies of scale in production more effectively.

(b) Are there economies of scale? Can the objectives be met more efficiently at EU level (larger benefits per unit cost)? Will the functioning of the internal market be improved?

EU funded R&I activities, including those covered by the present proposal, produce demonstrable benefits compared to the corresponding national and regional initiatives, due to the scale, speed and scope achievable by acting at the EU level. This is the case both in terms of effectiveness in achieving intended policy objectives, but also in terms of efficiency. Positive impact is also visible in terms of competitiveness: recent data on EU funded R&I activities indicate that EU-funded teams grow 11.8% faster and are around 40% more likely to be granted patents or produce patents applications than non-EU funded teams. Efficiency gains are also visible in terms of dissemination of results to users beyond national borders, including SMEs and citizens. EU funded R&I is more effective in leveraging private investment. Finally, there are clear additionality benefits (i.e. EU R&I funding does not displace or replace national funding), as the EU focuses on projects that are unlikely to be funded at national or regional level. Overall, this is beneficial to the functioning of the internal

market in several respects, including human capital reinforcement through mobility and training, the removal of barriers to cross-border activity for economic players including SMEs, easier access to finance and to relevant knowledge and research, and increased competition in the area of R&I.

(c) What are the benefits in replacing different national policies and rules with a more homogenous policy approach?

A homogeneous policy approach in the various thematic areas covered by the present proposal would reduce fragmentation and increase efficiency and effectiveness in meeting the intended policy objectives. Indeed fragmentation, persisting barriers in the internal market and differences in the resources available to Member States are some of the key problems that stand in the way of fully achieving the intended policy objectives and reaching the required critical mass to obtain tangible results. Specific detail on how these issues differ in each thematic area are illustrated in Sections 1 and 2 of the individual impact assessments, so as to reflect the specificities of each case.

(d) Do the benefits of EU-level action outweigh the loss of competence of the Member States and the local and regional authorities (beyond the costs and benefits of acting at national, regional and local levels)?

The proposed initiative does not lead to a loss of competence of the Member States. In fact, the proposed initiative should be seen as complementary and reinforcing national and subnational initiatives in the same area. Previous quantitative and qualitative assessments of Horizon Europe and Horizon 2020 have shown that the proposed EU-level action do not displace national ones and tend to concentrate on initiatives that would not have been funded by the Member States themselves, or would not have reached the same scale and ambition without EU-level intervention, due to their complexity and trans-national nature.

(e) Will there be improved legal clarity for those having to implement the legislation?

Yes. The proposed initiatives will be implemented in line with the Horizon Europe single set of rules for participation; this will ensure increased clarity and legal certainty for end beneficiaries, other stakeholders and programme administrators. It will also reduce the administrative burden for beneficiaries, and for the Commission services. In addition, the accessibility and attractiveness of the broader Horizon Europe programme, in particular for applicants with limited resources, would be sustained.

3. Proportionality: How the EU should act

3.1 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the proportionality of the proposal and a statement allowing appraisal of the compliance

of the proposal with the principle of proportionality?

The principle of proportionality underpins the entire analysis of the candidate partnerships. Specifically, the analysis included in the accompanying impact assessment is structured along the following logic: 1. Justification of the use of a partnership approach in a given area (including considerations on additionality, directionality, link with strategic priorities) instead of other forms of intervention available under Horizon Europe; 2. If the partnership approach is deemed appropriate, proportionality considerations guide the assessment of which type of partnership intervention (collaborative calls, co-programmed, co-funded or institutionalised partnership) is most effective in achieving the objectives. This will also be reflected in the explanatory memorandum.

3.2 Based on the answers to the questions below and information available from any impact assessment, the explanatory memorandum or other sources, is the proposed action an appropriate way to achieve the intended objectives?

The proposed initiative only focuses on areas where there is a demonstrable advantage in acting at the EU-level due to the scale, speed and scope of the efforts needed for the EU to meet its long-term Treaty objectives and deliver on its strategic policy priorities and commitments. In addition, the present proposal leaves full freedom to the Member States to pursue their own actions in the policy areas concerned. This will also be reflected in the explanatory memorandum.

(a) Is the initiative limited to those aspects that Member States cannot achieve satisfactorily on their own, and where the Union can do better?

The proposed initiative only focuses on areas where there is a demonstrable advantage in acting at the EU-level due to the scale, speed and scope of the efforts needed for the EU to meet its long-term Treaty objectives and deliver on its strategic policy priorities and commitments.

(b) Is the form of Union action (choice of instrument) justified, as simple as possible, and coherent with the satisfactory achievement of, and ensuring compliance with the objectives pursued (e.g. choice between regulation, (framework) directive, recommendation, or alternative regulatory methods such as co-legislation, etc.)?

For each of the candidate partnerships, the analysis carried out in the accompanying impact assessment has explored several options for implementation. A comparative assessment of the merits of each option also included an analysis of the simplicity of the intervention, its proportionality and effectiveness in achieving the intended objectives. This is reflected in the fact that a tailored approach has been suggested for each candidate partnership, ranging from looser forms of cooperation to more institutionalised ones, depending on the intended policy objectives, specific challenges, and desired outcome identified in each case.

(c) Does the Union action leave as much scope for national decision as possible while achieving satisfactorily the objectives set? (e.g. is it possible to limit the European action to minimum standards or use a less stringent policy instrument or approach?)

The proposed approach leaves full freedom to the Member States to pursue their own actions in the policy areas covered by the present proposal.

(d) Does the initiative create financial or administrative cost for the Union, national governments, regional or local authorities, economic operators or citizens? Are these costs commensurate with the objective to be achieved?

The proposed initiatives do create financial and administrative costs for the Union, national governments and, depending on the chosen mode of implementation, for regional and local authorities. In addition, economic operators and other stakeholders potentially involved in the candidate partnerships will also incur some costs linked to implementation. The financial cost of the proposed initiative is covered under the Horizon Europe programme. Its exact amount is still subject to political decision. As regards the candidate partnerships and the different modes of implementation (co-programmed, co-funded, institutionalised), the relevant costs and benefits are assessed in the individual impact assessments covering each candidate partnership. The additional administrative costs of implementation via partnerships are limited, when compared to the administrative costs of implementation through traditional calls. As indicated by comparable experience with previous initiatives and in feedback provided by a variety of stakeholders, these costs are expected to be fully justified by the benefits expected from the proposed initiative. Where available, additional details on costs are provided in Annex 3 of the impact assessment.

(e) While respecting the Union law, have special circumstances applying in individual Member States been taken into account?

Where relevant, differences between Member States in capacity and stage of advancement of R&I in specific thematic areas have been taken into account in the individual impact assessments.

Annex 6 Additional background information

1. BACKGROUND INFORMATION FOR ALL INITIATIVES

1.1. Selection criteria of European Partnerships

Partnerships based on Article 185 and 187 TFEU shall be implemented only where other parts of the Horizon Europe programme, including other forms of European Partnerships would not achieve the objectives or would not generate the necessary expected impacts, and if justified by a long-term perspective and high degree of integration. At the core of this impact assessment is therefore the need to demonstrate that the impacts generated through a Partnership approach go beyond what could be achieved with traditional calls under the Framework Programme – the Baseline Option. Secondly, it needs to assess if using the Institutionalised form of a Partnership is justified for addressing the priority.

The necessity test for a European Partnership (as set out in the Horizon Europe regulation) has two levels:

- 1. The justification for implementing a priority with a European Partnership to address Horizon Europe and EU priorities. This is linked to demonstrating that a European Partnership can produce added value beyond what can be achieved through other Framework Programme modalities, notably traditional calls in the work programmes (Option 0 Baseline).
- 2. The justification for the use of the form of Institutionalised Partnership: Once it has been demonstrated that a partnerships approach is justified, co-programmed and/or co-funded forms are considered for addressing the priorities as they are administratively lighter, more agile and easier to set-up (Options 1 and/or 2). As Institutionalised Partnerships require setting up a legal framework and the creation of a dedicated implementation structure, they have to justify higher set-up efforts by demonstrating that it will deliver the expected impacts in a more effective and efficient way, and that a long-term perspective and high degree of integration is required (Option 3).

The outcomes of the 'necessity test' is presented together with the preferred option.

Figure 6 Horizon Europe selection criteria for the European Partnerships

Common selection criteria & principles	Specifications
1. More effective	Delivering on global challenges and research and innovation objectives
(Union added value) clear impacts for the EU and its citizens	Securing EU competitiveness
	Securing sustainability
	Contributing to the strengthening of the European Research and Innovation Area
	Where relevant, contributing to international commitments

Specifications
Within the EU research and innovation landscape
Coordination and complementarity with Union, local, regional, national and, where relevant, international initiatives or other partnerships and missions
Identification of priorities and objectives in terms of expected results and impacts
Involvement of partners and stakeholders from across the entire value chain, from different sectors, backgrounds and disciplines, including international ones when relevant and not interfering with European competitiveness
Clear modalities for promoting participation of smes and for disseminating and exploiting results, notably by smes, including through intermediary organisations
Common strategic vision of the purpose of the European Partnership
Approaches to ensure flexibility of implementation and to adjust to changing policy, societal and/or market needs, or scientific advances, to increase policy coherence between regional, national and EU level
Demonstration of expected qualitative and significant quantitative leverage effects, including a method for the measurement of key performance indicators
Exit-strategy and measures for phasing-out from the Programme
A minimum share of public and/or private investments
In the case of institutionalised European Partnerships, established in accordance with article 185 or 187 TFEU, the financial and/or in-kind, contributions from partners other than the Union, will at least be equal to 50% and may reach up to 75% of the aggregated European Partnership budgetary commitments

1.2. Overview of potential functions for a common back office among Joint Undertakings

Functions	Current situation	Option of joint back- office	Comments
Organising calls for grant and proposal evaluations	Each JU organises this independently.	A central organisation of evaluation, logistics, contracting evaluators, managing the data of the evaluation results Central database of potential evaluators with domain expertise in thematic areas of partnerships	The evaluations would still need to be supervised by the Scientific staff of the individual Joint Undertakings (consensus meetings of expert evaluators etc)
Human Resources related matters	Each JU has own HR policy and resources Quite some resources spent on recruitment in some JUs	More generic resources and expertise for HR matters More consistency in HR	Ensuring consistency with EC HR policies is already in place

Financial management	Some HR facilities are procured from external contractors Some JUs have a Service Level Agreement with COM for HR Each JU conducts own financial contract management; differences between JUs Each JU is audited separately. Auditing at project level more frequent than in other Horizon 2020 parts and outsourced by JUs thus differences ECA: too many audits on JUs	policy Shared HR investment for specialised expertise (IP and legal) Financial management by one core team of financial staff Would reduce the number of interfaces for audits and simplifies the auditing of the all JUs Harmonisation of project auditing	Simplifies the harmonisation of financial management across JUs in line with Horizon Europe
Communication (internal and external)	Each JU has a separate communication strategies, teams and resources	A common back-office can support activities such as event organisation, dissemination of results, setting up website communication Can help create a more visible Partnership brand	A considerable share of communication activity is partnership specific (addressing particular target groups, synthesising project results) however there are generic communication activities that can be shared Needs to avoid duplication of efforts
Data management on calls, project portfolios, information on project results	Most JUs but not all use e- Corda for project data Overall IT integration of JUs still difficult	Harmonised data management Reduction of IT systems and support that is procured	This will need to happen regardless of the common back office but will likely be more smooth if managed centrally

2. BACKGROUND INFORMATION FOR THIS SPECIFIC INITIATIVE

General information on current transport policy

In 2011, the Commission published a 'Roadmap to a Single European Transport Area – towards a competitive and resource efficient transport system' (the Transport White Paper)²⁷, which set out a series of plans and associated targets for improving the competitiveness, efficiency and sustainability of European transport, removing barriers and bottlenecks in transport infrastructure and addressing societal challenges linked to increasing mobility and connectivity. It described a vision for the European transport network, broadly defined, which included several rail-related goals, in particular:

- A shift of 30% of road freight travelling over 300 km to rail or waterborne transport by 2030, and a shift of more than 50% by 2050, enabled through efficient rail freight corridors and further infrastructure development;
- Completion of the European high-speed rail network by 2050, with most medium-distance passenger transport moving by rail by the same date;
- The delivery of a fully functional, Union-wide and multimodal TEN-T core network by 2030 (with further quality and capacity enhancements completed by 2050);
- Connection of all core airports to rail (preferably high-speed rail) services and connection of all core seaports to rail freight networks by 2050; and
- Deployment of the European Rail Traffic Management System (ERTMS) (among other comparable transport management systems) in accordance with the associated deployment plan.

These goals have set the framework for EU rail policy during the period of Horizon 2020 and have been echoed in the objectives for both the S2R JU and the proposed new partnership for Transforming Europe's Rail System. The goals are critically dependent on the uptake of technological innovation that can help to deliver a fully integrated railway system for Europe and ensure a step-change in the attractiveness of rail services from the perspective of both passengers and freight customers.

The Fourth Railway Package

The proposal for a new partnership must also been seen in the context of recent rail industry reforms, notably the Fourth Railway Package, which completes the legal framework governing a process of industry restructuring, harmonisation and market opening that began some 30 years ago with Directive 91/440/EEC on the development of the Community's railways. The Fourth Railway Package is a set of six legislative texts²⁸ designed to implement the final elements of the Single European Railway Area (SERA) with a view to revitalising

²⁷ European Commission (2011), Roadmap to a Single European Transport Area – towards a competitive and resource efficient transport system, 28 March 2011, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52011DC0144&from=EN.

²⁸ Legislative texts, together with further information on the Fourth Railway Package is available at: https://ec.europa.eu/transport/modes/rail/packages/2013_en

the sector and making it more competitive relative to other transport modes. It is comprised of two pillars:

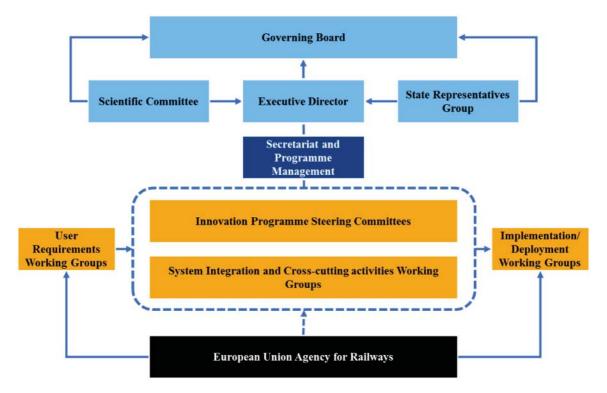
- A technical pillar focusing on a more streamlined, pan-European approach to safety certification and vehicle authorisation, measures to improve interoperability across different national rail networks and an enhanced role for the European Union Agency for Railways (ERA); and
- A market pillar, strengthening previous legislation designed to separate infrastructure management and train operation, providing a more level playing field for rail market access and for greater competitive tendering of public service contracts for rail services.

The implementation of a coordinated R&I effort under Horizon Europe will be complementary to the completion of SERA, since it can be expected to generate opportunities for innovation that can be exploited more effectively in a dynamic rail market environment. At the same time, it will provide a platform for collaboration between different industry players now subject to a greater degree of organisational separation than was previously the case.

The Shift2Rail Joint Undertaking

Organisation and governance

The organisation and governance of the S2R JU are illustrated in the figure below.



Source: Eric Fontanel, Roderick Smith, Heather Allen, Michael Dooms (2017)

As shown, the organisation comprises:

- A Governing Board, including representatives of the founding members, associate members and observers (from ERA and the States Representative Group);
- An Executive Director, supported by a secretariat and programme management department, responsible for oversight of the work programme and day-to-day management of the organisation;
- A series of Steering Committees overseeing each of the five Innovation Programmes (IPs) described below;
- A Scientific Committee and a States Representative Group, providing advice to both the Executive Director and the Governing Board; and
- Various Working Groups considering user requirements, implementation of the outputs of the R&I activity and integration across the IPs as well as various cross-cutting themes.

Innovation programme funding

The R&I activity coordinated by the JU is organised according to a number of innovation programmes (IPs). The table below sets out the budget allocation across IPs expected following adoption of the Annual Work Plan for 2020, as provided to us by the JU. At the time of writing this had not yet been formally approved.

Table 3: S2R JU Innovation Programmes and Cross Cutting Activities

Innovation Programmes/activity	Areas of activity
IP1 – cost-efficient and reliable trains, including high capacity and high-speed trains Budget: €212 M	Train interiors Doors and intelligent access systems Traction Train control and monitoring system Lighter car body shell Running gear Brakes
IP2 – advanced traffic management and control systems Budget: €197 M	Smart, fail-safe communication and positioning systems Traffic management evolution Automation Moving blocks and train integrity Smart procurement and testing Virtual coupling Cyber security
IP3 – cost-efficient, sustainable and reliable high-capacity infrastructure Budget: €153 M	New directions in switch and crossing Innovative track design and materials Cost-effective tunnel and bridge solutions Intelligent system maintenance Improved station concepts Energy efficiency
IP4 – IT solutions for attractive railway services	Technical framework Customer experience applications

Budget: €75 M	Multi-modal travel services	
IP5 – Technologies for sustainable attractive European freight Budget: €87 M	Implementation strategies and business analytics Freight electrification, brakes and telematics Access and operation Wagon design Novel terminals, hubs, marshalling yards and sidings New freight propulsion concepts Sustainable rail transport of dangerous goods Long term vision for an autonomous rail freight system	
IPX – Disruptive concepts and technologies and system architecture Budget: €20 M	Development of a functional system architecture for the next generation of railway systems	
Cross cutting activities		
Total budget: €31 M	Long-term needs and socio-economic research	
	Smart materials and processes	
	System integration, safety and interoperability	
	Energy and sustainability	
	Human capital	

C 4 1 4	4 -	- 1
Contribution	TA	administrative costs
Continuation	w	administrative costs

Budget share: €13.5	European Union
Budget share: €13.5	Industry

Source: S2R JU

Contribution to rail sector development

The Council Regulation establishing the JU requires it to meet several objectives that, inter alia, align its activities with the aims of Horizon 2020 and the completion of SERA. The Regulation also sets out key performance indicators (KPIs) that provide a means of measuring its impact on the European rail transport industry. More specifically, the JU is required "to develop, integrate, demonstrate and validate innovative technologies and solutions" that can be measured against the following five KPIs:

- A 50% reduction in the life-cycle costs of the rail system through greater efficiency in the provision of both infrastructure and rolling stock as well as greater energy efficiency;
- A 100% increase in the capacity of the system with a view to accommodating increased demand for both passenger and freight services;

- A 50% increase in the reliability and punctuality of rail services (expressed as a 50% reduction in the percentage of cancellations and late arrivals);
- Removal of the remaining obstacles to interoperability, particularly by closing outstanding open points in the Technical Specifications for Interoperability (TSIs) through the identification of appropriate technological solutions; and
- A reduction in noise, vibration, emissions and other environmental impacts arising from rail transport.

Status of Key Performance Indicators specific for the S2R JU²⁹

#	Key Performance Indicator	Objective	Baseline at the start of H2020	Target at the end of H2020	Automated	Result 2019
1	% reduction in the costs of developing, maintaining, operating and renewing infrastructure and rolling stock and increase energy efficiency compared to "State-of-the-art"	Reduce the life- cycle cost of the railway transport system	"State-of- the-art" 2014	> 50 %	No	See table IV
2	% increase the capacity of railway segments to meet increased demand for passenger and freight railway services compared to "State-of- the-art" 2014	Enhance the capacity of the railway transport system	"State-of- the-art" 2014	100%	No	See table IV
3	% decrease in unreliability and late arrivals compared to "State-of-the-art" 2014	Increase in the quality of rail services	"State-of- the-art" 2014	> 50%	No	See table IV
4	Reduce noise emissions and vibrations linked to rolling stock and respectively infrastructure compared to "State-of-the-art" 2014	Reduce the negative externalities linked to railway transport	"State-of- the-art" 2014	> 3 - 10 dBA	No	-2 dB overall noise limits (FINE1) -4 dB parking operation (FINE1) Specific examples: -6 dB noise damping mechanical absorption solutions (FR8RAIL) -15-20 dB reduced electromagnetic

²⁹ Source: Annual Activity Report 2019

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#	Key Performance Indicator	Objective	Baseline at the start of H2020	Target at the end of H2020	Automated	Result 2019
						noise on main transformer (PINTA)
5	Addressing open points in TSIs, compared to "State-of-the-art" 2014	Enhance interoperability of the railway system	"State-of- the-art" 2014		No	One open point of the TSI Infra (tender and IN2TRACK-2)
6	Number of Integrated Technology Demonstrators (ITDs) and System Platform Demonstrations (SPD)	Improve market uptake of innovative railway solutions through large- scale demonstration activities	Multi- Annual Action Plan	4 SPD	No	Updated SPD definition is available (IMPACT-2, deliverable D3.1)
7	Share of the fund allocated to the different Innovation Programmes and to cross-cutting themes	Ensure that funding covers the railway system as a whole	n.a.	> 80%	No	100% of the operational funding
8	Percentage of topics resulting in signature of GA	Ensure a sufficiently high call topics success rate	n.a.	> 90%	Yes	94%
9	% of resources consumption versus plan (members only)	WP execution by members - resources	n.a.	> 80%	Yes	* o/s
10	% of deliverables available versus plan (members only)	WP execution by members - deliverables	n.a.	> 80%	No	- 85.77% (2015-2019) - 81.82% (2019 only)



Brussels, 23.2.2021 SWD(2021) 37 final

PART 12/19

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT REPORT Accompanying the document

Proposal for a COUNCIL REGULATION establishing the Joint Undertakings under Horizon Europe

European Partnership for Integrated Air Traffic Management

{COM(2021) 87 final} - {SEC(2021) 100 final} - {SWD(2021) 38 final}

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Glossary

Term or acronym	Meaning or definition
EIT	European Institute of Innovation & Technology
R&I	Research and Innovation
SDGs	United Nations Sustainable Development Goals
SMEs	Small and Medium-sized Enterprises
TFEU	Treaty on the Functioning of the European Union
ANSP	Air Traffic Management
ATM	Air Traffic Management
FAA	Federal Aviation Authority
ICAO	International Civil Aviation Organisation
SES	Single European Sky
SESAR	Single European Sky ATM Research
TRL	Technology Readiness Level
UTM	Unmanned Air System Traffic Management

PART 1 - COMMON FOR ALL CANDIDATE INSTITUTIONALISED EUROPEAN PARTNERSHIPS

BACKGROUND AND CONTEXT TO EUROPEAN PARTNERSHIPS IN HORIZON EUROPE AND FOCUS OF THE IMPACT ASSESSMENT- WHAT IS DECIDED

1.1. Focus and objectives of the impact assessment

This impact assessment accompanies the Commission proposal for Institutionalised European Partnerships to be funded under Horizon Europe, the 2021-2027 Framework Programme for EU Research and Innovation (R&I). It sets out to help decide in a coordinated manner the right form of implementation for specific candidate initiatives based on a common approach and methodology to individual assessments². It also provides an horizontal perspective on the portfolio of candidate European Partnerships to identify further efficiency and coherence gains for more impact.

European Partnerships are initiatives where the Union, together with private and/or public partners (such as industry, public bodies or foundations) commit to support jointly the development and implementation of an integrated programme of R&I activities. The rationale for establishing such initiatives is to achieve the objectives of Horizon Europe more effectively than what can be attained by other activities of the programme.³

Based on the Horizon Europe Regulation, European Partnerships may be set up using three different forms: "Co-funded", "Co-programmed" and "Institutionalised". The setting-up of Institutionalised Partnerships involves new EU legislation and the establishment of dedicated implementing structures based on Article 185 or 187 of the Treaty on the Functioning of the EU (TFEU). This requires an impact assessment to be performed.

The Horizon Europe Regulation defines eight priority areas, scoping the domains in which Institutionalised Partnerships could be proposed⁴. Across these priority areas, 13 initiatives have been identified as suitable candidate initiatives for Institutionalised Partnerships because of their objectives and scope. This impact assessment aims to identify whether 12 of these initiatives⁵ need to be implemented through this form of implementation and would not deliver equally well with traditional calls of Horizon Europe or other lighter forms of European Partnerships under Horizon Europe. This means assessing whether each of these initiatives meets the necessity test set in the selection criteria for European Partnerships in the Horizon Europe Regulation, Annex III.

This assessment is done without any budgetary consideration, as the overall budget of the Multiannual Financial Framework of the EU – and hence of Horizon Europe – for the next financing period is not known at this stage.⁶

Set out in the

¹ Horizon Europe Regulation (common understanding), https://data.consilium.europa.eu/doc/document/ST-7942-2019-

Based on the European Commission Better Regulation framework (SWD (2017) 350) and supported by an external study coordinated by Technopolis Group (to be published in 2020).

For further details on these points, see below Section 1.2.2.

Annex Va of the Horizon Europe Regulation (common https://data.consilium.europa.eu/doc/document/ST-7942-2019-INIT/en/pdf

⁵ Only 12 are subject to this impact assessment, as one initiative on High Performance Computing has already been subject to an impact assessment in 2017 (SEC(2018) 47).

⁶ EU budget commitments to the European Partnership candidates can only be discussed and decided following the political agreement on the overall Multiannual Financial Framework and Horizon Europe budgetary envelopes. The level of EU contribution for individual partnerships should be determined once there are agreed objectives, and clear commitments from

1.2. The political and legal context

1.2.1. Shift in EU priorities and Horizon Europe framework

European priorities have evolved in the last decades, and reflect the social, economic, and environmental challenges for the EU in the face of global developments. In her Political Guidelines for the new European Commission 2019 – 2024⁷, the new Commission President put forward six overarching priorities, which reach well beyond 2024 in scope⁸. Together with the Sustainable Development Goals (SDGs), these priorities will shape future EU policy responses to the challenges Europe faces, and thus also give direction to EU research and innovation.

As part of the Multi-annual Financial Framework (MFF) 2021-27 the new EU Framework Programme for Research and Innovation Horizon Europe will play a pivotal role for Europe to lead the social, economic, and environmental transitions needed to achieve these European policy priorities. It will be more impact driven with a strong focus on delivering European added value, but also be more effective and efficient in its implementation. Horizon Europe finds its rationale in the daunting challenges that the EU is facing, which call for "a radical new approach to developing and deploying new technologies and innovative solutions for citizens and the planet on a scale and at a speed never achieved before, and to adapting our policy and economic framework to turn global threats into new opportunities for our society and economy, citizens and businesses." While Horizon Europe continues the efforts of strengthening the scientific and technological bases of the Union and foster competitiveness, a more strategic and impact-based approach to EU R&I investment is taken. Consequently, the objectives of Horizon Europe highlight the need to deliver on the Union strategic priorities and contribute to the realisation of EU objectives and policies, contribute to tackling global challenges, including the Sustainable Development Goals by following the principles of the Agenda 2030 and the Paris Agreement. 10

In this context, at least 35 % of the expenditure from actions under the Horizon Europe Programme will have to contribute to climate action. Furthermore, a Strategic Plan is codesigned with stakeholders to identify key strategic orientations for R&I support for 2021-2024 in line with the EU priorities. In the Orientations towards the first Strategic Plan for Horizon Europe, the need to strategically prioritise and "direct a substantial part of the funds towards the areas where we believe they will matter the most" is emphasised. The Orientations specify, that actions under Pillar II of Horizon Europe "Global Challenges and European Industrial Competitiveness" will target only selected themes of especially high impact that significantly contribute to delivering on the political priorities of the Union. Most of the candidate European Partnerships fall under this Pillar.

1.2.2. Key evolutions in the approach to partnerships in Horizon Europe

Since their start in 1984 the successive set of Framework Programmes uses a variety of instruments and approaches to support R&I activities, address global challenges and industrial

partners. Importantly, there is a ceiling to the partnership budgets in Pillar II of Horizon Europe (the legal proposal specifies that the majority of the budget in pillar II shall be allocated to actions outside of European Partnerships).

⁸ 1.A European Green Deal; An economy that works for people; A Europe fit for the Digital Age; Promoting our European way of life; A Stronger Europe in the World; and 6.A New push for European Democracy

⁹ EC (2018) A Modern Budget for a Union that Protects, Empowers and Defends. The Multiannual Financial Framework for 2021-2027. Communication from the Commission to the European Parliament, the European Council, the European Economic and Social Committee and the Committee of the Regions, COM(2018) 321 final

¹⁰ Article 3, Common understanding regarding the proposal for Horizon Europe Framework Programme.

competitiveness. Collaborative, competition-based and excellence-driven R&I projects funded through Work Programmes are the most traditional and long-standing approach for implementation. Since 2002, available tools also include **partnerships**, whereby the Union together with private and/or public partners commit to jointly support the development and implementation of a R&I programme. These were introduced as part of creating the European Research Area (ERA) to align national strategies and overcome fragmentation of research effort towards an increased scientific, managerial and financial integration of European research and innovation. Interoperable and integrated national research systems would allow for better flows of knowledge, technology and people. Since then, the core activities of the partnerships consist of building critical mass mainly through collaborative projects, jointly developing visions, and setting strategic agendas.

As analysed in the **interim evaluation of Horizon 2020**¹¹, a considerable repertoire of partnership initiatives have been introduced over time, with 8 forms of implementation ¹² and close to 120 partnership initiatives running under Horizon 2020 - without clear exit strategies and concerns about their degree of coherence, openness and transparency. Even if it is recognised that these initiatives allow setting long-term agendas, structuring R&I cooperation between otherwise dispersed actors, and leveraging additional investments, the evaluation points to the complexity generated by the proliferation of instruments and initiatives, and their insufficient contribution to policies at EU and national level.

Box 1 Key lessons from the interim evaluation of Horizon 2020 and R&I partnerships

- The **Horizon 2020 Interim Evaluation** concludes that the overall partnership landscape has become overly complex and fragmented. It identifies the need for rationalisation, improve their openness and transparency, and link them with future EU R&I missions and strategic priorities.
- The **Article 185 evaluation** finds that these public-public partnerships have scientific quality, global visibility and networking/structuring effects, but should in the future focus more on the achievement of policy impacts. From a systemic point of view, it found that the EU public-to-public cooperation (P2P) landscape has become crowded, with insufficient coherence.
- The **Article 187 evaluation** points out that Public-Private Partnership (PPP) activities need to be brought more in line with EU, national and regional policies, and calls for a revision of the Key Performance Indicators. As regards the **contractual PPPs (cPPPs)** their reviews identified challenges of coherence among cPPPs and the need to develop collaborations and synergies with other relevant initiatives and programmes at EU, national and regional level.

Over 80% of respondents to the Open Public Consultation (OPC) indicated that a significant contribution by future European Partnerships is 'fully needed' to achieve climate-related goals, to develop and effectively deploy technology, and for EU global competitiveness in specific sectors/domains. Views converged across all categories of respondents, including citizens, industry and academia.

¹² E.g. initiatives based on Article 187 (Joint Technology Initiatives), Article 185 TFEU, Contractual Public-Private Partnerships (cPPPs), Knowledge & Innovation Communities of the European Institute of Innovation & Technology (EIT-KICs), ERA-NETs, European Joint Programmes, Joint Programming Initiatives.

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¹¹ Interim evaluation of Horizon 2020, Commission Staff Working Document, SWD(2017)221 and 222 Interim evaluation of the Joint Undertakings operating under Horizon 2020 (Commission Staff Working Document, SWD(2017) 339); Evaluation of the Participation of the EU in research and development programmes undertaken by several Member States based on Article 185 of the TFEU, Commission Staff Working Document, SWD (2017)340)

The impact assessment of Horizon Europe identifies therefore the need to rationalise the EU R&I funding landscape, in particular with respect to partnerships, as well as to re-orient partnerships towards more impact and delivery on EU priorities. To address these concerns and to realise the higher ambition for European investments, Horizon Europe puts forward a major simplification and reform for the Commission's policy on R&I partnerships ¹³. Reflecting its pronounced systemic nature aimed at contributing to EU-wide 'transformations' towards the sustainability objectives, Horizon Europe indeed intends to make a more effective use of these partnerships with a more strategic, coherent and impact-driven approach. Key related changes that apply to all forms of European Partnerships encapsulated in Horizon Regulation are summarised in the Box below.

Box 2 Key features of the revised policy approach to R&I partnerships under Horizon Europe based on its impact assessment

- ✓ **Simpler architecture & toolbox** by streamlining 8 partnership instruments into 3 implementation forms (Co-Funded, Co-Programmed, Institutionalised), under the umbrella 'European Partnerships'
- ✓ More systematic and transparent approach to selecting, implementing, monitoring, evaluating and phasing out all forms of partnerships (criteria for European Partnerships):
 - The selection of Partnerships is embedded in the strategic planning of Horizon Europe, thereby ensuring coherence with the EU priorities. The selection criteria require that partnerships are established with stronger ex-ante commitment and higher ambition.
 - The implementation criteria stipulate that initiatives adopt a systemic approach in achieving impacts, including broad engagement of stakeholders in agenda-setting and synergies with other relevant initiatives to promote the take-up of R&I results.
 - A harmonised monitoring & evaluation system will be implemented, and ensures that progress is analysed in the wider context of achieving Horizon Europe objectives and EU priorities.
 - All partnerships need to develop an exit strategy from Framework Programme funding. This new approach is underpinned by principles of openness, coherence and EU added value.

✓ Reinforced impact orientation:

- Partnerships are established only if there is evidence they support achieving EU policy objectives
 more effectively than other Horizon Europe actions, by demonstrating a clear vision and targets
 (directionality) and corresponding long-term commitments from partners (additionality).
- European Partnerships are expected to provide mechanisms based on a concrete roadmap to join
 up R&I efforts between a broad range of actors towards the development and uptake of innovative
 solutions in line with EU priorities, serving the economy and society, as well as scientific progress.
- They are expected to develop close synergies with national and regional initiatives, acting as dynamic change agents, strengthening linkages within their respective ecosystems and along the value chains, as well as pooling resources and efforts towards the common EU objectives.

Under Horizon Europe, a 'European Partnership' is defined as "an initiative where the Union, prepared with early involvement of Member States and/or Associated Countries, together with private and/or public partners (such as industry, universities, research organisations, bodies with a public service mission at local, regional, national or international level or civil society organisations including foundations and NGOs), commit to jointly support the development and implementation of a programme of research and innovation activities, including those related to market, regulatory or policy uptake."

The Regulation further specifies that European Partnerships shall adhere to the "principles of Union added value, transparency, openness, impact within and for Europe, strong leverage effect on sufficient scale, long-term commitments of all the involved parties, flexibility in implementation, coherence, coordination and complementarity with Union, local, regional, national and, where relevant, international initiatives or other partnerships and missions."

¹⁴ Article 8 and Annex III of the Horizon Europe Regulation (common understanding))

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¹³ Impact assessment of Horizon Europe, Commission Staff Working Document, SWD(2018)307.

1.3. Why should the EU act

1.3.1. Legal basis

Proposals for Institutionalised European Partnerships are based on:

- 1) Article 185 TFEU which allows the Union to make provision, in agreement with the Member States concerned, for participation in research and development programmes undertaken by several Member States, including participation in the structures created for the execution of those programmes; or
- 2) Article 187 TFEU according to which the Union may set up joint undertakings or any other structure necessary for the efficient execution of Union research, technological development and demonstration programmes.¹⁵

1.3.2. Subsidiarity

The EU should act only in areas where there is demonstrable advantage that the action at EU level is more effective than action taken at national, regional or local level. Research is a shared competence between the EU and its Member States according to the TFEU. Article 4 (3) specifies that in the areas of research, technological development and space, the EU can carry out specific activities, including defining and implementing programmes, without prejudice to the Member States' freedom to act in the same areas. The candidate initiatives focus on areas where there is a demonstrable value added in acting at the EU level due to the scale, speed and scope of the efforts needed for the EU to meet its long-term Treaty objectives and deliver on its strategic policy priorities and commitments. In addition, the proposed initiatives should be seen as complementary and reinforcing national and sub-national activities in the same area. Overall European Partnerships find their **rationale in addressing a set of systemic failures**¹⁶:

- Their primary function is to create a platform for a strengthened **collaboration** and knowledge exchange between various actors in the European R&I system and an enhanced **coordination** of strategic research agendas and/or R&I funding programmes. They aim to address **transformational failures** to better align agendas and policies of public and private funders, pool available resources, create critical mass, avoid unnecessary duplication of efforts, and leverage sufficiently large investments where needed but hardly achievable by single countries.
- The concentration of efforts and pooling of knowledge on common priorities to solve multi-faceted societal and economic challenges is at the core of these initiatives. Specifically, enhanced cross-disciplinary and cross-sectoral collaboration and an improved integration of value chains and ecosystems are among the key objectives of these instruments. In the light of Horizon Europe, the aim is to **drive system transitions and transformations towards EU priorities**.
- Especially in fast-growing technologies and sectors such as ICT, there is a need to **react to emerging opportunities** and address systemic failures such as shortage in skills or critical mass or cross-sectoral cooperation along the value chains that would hamper attainment of future European leadership and/or strategic autonomy.
- They also aim to address **market failures** predominantly to enhancing industry investments thanks to the sharing of risks.

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¹⁵ Both Articles are under Title XIX of the TFEU - Research and Technological Development and Space.

¹⁶ The Interim Evaluation of Horizon 2020 and the impact assessment of Horizon Europe provide qualitative and quantitative evidence on these points. Sections 1 and 2 of each impact assessment on candidate European Partnerships include more detail on the necessity to act at EU level in specific thematic areas.

2. THE CANDIDATE EUROPEAN PARTNERSHIPS – WHAT NEEDS TO BE DECIDED

2.1. Portfolio of candidates for Institutionalised European Partnerships

The new approach for more objective-driven and impactful European Partnerships is reflected in the way candidate Partnerships have been identified. It involved a co-design exercise aiming to better align these initiatives with societal needs and policy priorities, while broadening the range of actors involved. Taking into account the 8 areas for Institutionalised European Partnerships set out in the Horizon Europe Regulation¹⁷, a co-design exercise as part of the Strategic Planning process of Horizon Europe lead to the identification of 49 candidates for Co-funded. Co-programmed Institutionalised or Partnerships¹⁸. Out of these, 13 were identified as suitable candidate Institutionalised Partnerships because of their objectives and scope¹⁹. Whilst the Co-Funded and Co-Programmed Partnerships are linked to the comitology procedure (including the adoption of the Strategic Plan and the Horizon Europe Work Programmes), Institutionalised Partnerships require the adoption of legislation and are subject to an impact assessment. The Figure below gives an overview of all candidate European Partnerships according to their primary relevance to Commission priorities for 2019-2024.

Figure 1 - Overview of the candidates for Co-Funded, Co-Programmed and Institutionalised European Partnerships according to Horizon Europe structure

Horizon Europe Pillar II - Global challenges & European industrial competitiveness							
Cluster 1: Health	Cluster 4: Digital, Industry & Space	Cluster. 5: Climate, Energy & Mobility	Cluster 6: Food, Bioeconomy, Agriculture,				
Innovative	Key digital technologies	Clean Hydrogen	Circular Bio-based Europe				
Health Initiative	Smart networks & services	Safe & automated road transport	Safe & sustainable food				
EU-Africa Global Health	High-Performance Computing	Transforming EU's rail system	system				
Large-scale	European Metrology	Clean Aviation	Climate-neutral, sustainable & productive blue bio-				
innovation &	AI-Data-Robotics	Integrated Air Traffic Management	economy				
health systems	Photonics	European industrial battery value	Animal Health				
Personalised	Made in Europe	chain	Water4All				
Medicine	Clean steel – low-carbon	Zero-emission waterborne transport	Accelerating farming				
ERA for Health	steelmaking Carbon neutral & circular	Zero-emission road transport	systems transitions				
Rare diseases	industry	Built environment & construction	Environmental observations for sustainable agriculture				
One-Health Anti Microbial	Global competitive space systems	Clean energy transition	Rescuing biodiversity				
Resistance Chemicals risk	Geological Service for Europe	Sustainable, smart & inclusive cities & communities	EIT Food				
assessment	EIT Digital	EIT Climate	Cluster 2: Culture, Creativity				
EIT Health	EIT Manufacturing	EIT InnoEnergy	& Inclusive Society				
EIT Raw Materials		EIT Urban Mobility EIT Cultural and Creat					
Horizon Europe I Innovative Europ	Cross_Dilla	rs					
Innovative SMEs	European Op	en Science Cloud					
	Candidate Institutiona	alised Partnerships EIT KIC Co-Program	nmed Co-Funded CP or CF				

Source: Technpolis group (2020)

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¹⁷ Horizon Europe Regulation (common understanding), Annex Va.

¹⁸ Shadow configuration of Strategic Programme Committee for Horizon Europe. The list of candidate European Partnerships is described in "Orientations towards the Strategic Plan of Horizon Europe" - Annex 7

Only 12 are subject to this impact assessment, as one initiative on High Performance Computing has already been subject to an impact assessment in 2017 (SEC(2018) 47)

There are only three partnerships for which implementation as an Institutionalised Partnership under Article 185 is an option, i.e. European Metrology, the EU-Africa Global Health partnership, and Innovative SMEs. Ten partnerships are candidates for Institutionalised Partnerships under Article 187. Overall the initiatives can be categorised into 'horizontal' partnerships and 'vertical' partnerships.

The 'horizontal' partnerships have a central position in the overall portfolio, as they are expected to develop methodologies and technologies for application in the other priority areas, ultimately supporting European strategic autonomy in these areas as well as technological sovereignty. These 'horizontal' partnerships are typically proposed as Institutionalised or Co-programmed Partnerships, in addition to a number of EIT KICs, they cover mainly the digital field in addition to space, creative industries and manufacturing, but also the initiative related to Innovative SMEs. 'Vertical' partnerships are focused on the needs and development of specific application areas, and are primarily expected to support enhanced environmental sustainability thereby addressing Green Deal related objectives. They also deliver on policies for more people centred economy, through improved wellbeing of EU citizen and the economy, like health related candidate European Partnerships.

2.2. Assessing the necessity of a European Partnership and possible options for implementation

Horizon Europe Regulation Article 8 stipulates that Institutionalised European Partnerships based on Article 185 and 187 TFEU shall be implemented only where other parts of the Horizon Europe programme, including other forms of European Partnerships would not achieve the objectives or would not generate the necessary expected impacts, and if justified by a long-term perspective and high degree of integration. At the core of this impact assessment is therefore the need to demonstrate that the impacts generated through a Partnership approach go beyond what could be achieved with traditional calls under the Framework Programme – the Baseline Option. Secondly, it needs to assess if using the Institutionalised form of a Partnership is justified for addressing the priority.

For all candidate Institutionalised European Partnerships the options considered in this impact assessment are the same, i.e.:

- Option 0 Baseline option Traditional calls under the Framework Programme
- Option 1 Co-programmed European Partnership
- Option 2 Co-funded European Partnership
- Option 3 Institutionalised Partnership
 - o Sub-option 3a Institutionalised Partnerships based on Art 185 TFEU
 - o Sub-option 3b Institutionalised Partnerships based on Art 187 TFEU

2.2.1. *Option 0 - Baseline option – Traditional calls*

Under this option, strategic programming for R&I in the priority area will be done through the mainstream channels of Horizon Europe. The related priorities will be implemented through **traditional calls** of Horizon Europe covering a range of actions, mainly R&I and/or innovation actions but also coordination and support actions, prizes or procurement. Most actions involve consortia of public and/or private actors in ad hoc combinations, while some actions are single actor (mono-beneficiary). There will be no dedicated implementation structure and no support other than what is foreseen in the related Horizon Europe Work Programme. This means that discontinuation costs/benefits of predecessor initiatives should be factored in for capturing the baseline situation when relevant.

Under this option, strategic planning mechanisms in the Framework Programme will allow for a high level of flexibility in the ability of traditional calls to respond to particular needs over time, building upon additional input in co-creation from stakeholders and programme committees involving Member States. The Union contribution to addressing the priority covers the full duration of the initiative, during the lifetime of Horizon Europe. Without a formal EU partnership mechanism, it is less likely that the stakeholders will develop a joint Strategic Research Agenda and commit to its implementation or agree on mutual commitments and contributions outside their participation in funded projects.

2.2.2. European Partnerships

Under this set of options, three different forms of implementation are assessed: Co-funded, Co-Programmed, Institutionalised European Partnerships. These have **commonalities that cannot serve as a distinguishing factor in the impact assessment process**. They are all based on agreed objectives and expected impacts and underpinned by Strategic Research and Innovation Agendas / roadmaps that are shared and committed to by all partners in the partnership. They all have to follow the same set of criteria along their lifecycle, as defined in the Horizon Europe Regulation (Annex III), including ex ante commitment from partners to mobilise and contribute resources and investments. The Union contribution is defined for the full duration of the initiative for all European Partnerships. The Horizon Europe legal act introduces few additional requirements for Institutionalised Partnerships, e.g. the need for long-term perspective, strong integration of R&I agendas, and financial contributions.

Figure 2 - Key differences in preparation and implementation of European Partnerships

Type	Legal form	Implementation			
Co-Programmed	Contractual arrangement / MoU	Division of labour , whereby Union contribution is implemented through Framework rogramme and partners' contributions under their responsibility.			
Co-Funded	Grant Agreement	Union provides co-funding for an integrated programme with distributed implementation by entities managing and/or funding national research and innovation programmes			
Institutionalised based on Article 185/187 TFEU	Basic act (Council regulation, Decision by European Parliament and Council)	Integrated programme with centralised implementation			

The main differences between the different forms of European Partnerships are in their preparation and in the way they function, as well as in the overall impact they can trigger. The Co-Programmed form is assessed as the simplest, and the Institutionalised the most complex to prepare and implement. The functionalities of the different form of Partnerships – compared to the baseline option – are presented in Figure 3. They relate to the types of actors Partnerships can involve and their degree of openness, the types of activities they can perform and their degree of flexibility, the degree of commitment of partners and the priority setting system, and their ability to work with their external environment (coherence), etc. These key distinguishing factors will be at the basis of the comparison of each option to determine their overall capacity to deliver what is needed at a minimised cost.

Figure 3 Overview of the functionalities provided by each form of European Partnerships, compared to the traditional calls of Horizon Europe (baseline)

Baseline: Horizon	Option 1: Co-	Option 2: Co-Funded	Option 3a: Institutio-	Option 3b:
Europe calls	Programmed		nalised Art 185	Institutionalised Art 187
* * * * * * * * * * * * * * * * * * * *	of actors (including openn	· · · · · · · · · · · · · · · · · · ·		
Partners: N.A., no common set of actors that engage in planning and implementation	Partners: Suitable for all types: private and/or public partners, foundations Priority setting: Driven	Partners: core of national funding bodies or govern-mental research organisations Priority setting: Driven	governmental research organisation Priority setting:	Partners: Suitable for all types: private and/or public partners, foundations Priority setting: Driven
Priority setting: open to all, part of Horizon Europe Strategic planning Participation in R&I activities: fully open in line with Horizon Europe rules	by partners, open stakeholder consultation, MS in comitology Participation in R&I activities: fully open in line with Horizon Europe rules	by partners, open stakeholder consultation Participation in R&I activities: limited, according to national rules of partner countries	Driven by partners, open stakeholder consultation Participation in R&I activities: fully open in line with Horizon Europe rules, but possible derogations	by partners, open stakeholder consultation Participation in R&I activities: fully open in line with Horizon Europe rules, but possible derogations
	vities (including additiona			A -4::4: IT:
Activities: Horizon Europe standards that allow broad range of individual actions Additionality: no additional activities and investments outside the funded projects Limitations: No systemic approach	Activities: Horizon Europe standard actions that allow broad range of individual actions, support to market, regulatory or policy/ societal uptake Additionality: Activities/investments of partners, National funding	Activities: Broad, according to rules/programmes of participating States, State-aid rules, support to regulatory or policy/societal uptake Additionality: National funding Limitations: Scale &	Activities: Horizon Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to systemic approach Additionality: National funding	Activities: Horizon Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to systemic approach (portfolios of projects, scaling up of results, synergies with other funds.
beyond individual actions	<u>Limitations:</u> Limited systemic approach beyond individual actions	scope depend on participating programmes, often smaller in scale		Additionality: Activities/investments of partners/ national funding
Priority-setting process		D	D : ::	District of the state of the st
Priority setting: Strategic Plan and annual work programmes, covering max. 4 years. Limitations: Fully taking into account existing or to be developed SRIA/	Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Input to FP annual work programme drafted by partners, finalised by EC	Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Annual work programme drafted by	Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Annual work	Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Annual work programme drafted by partners, approved by EC (veto-
roadmap	(comitology) Objectives & commitments set in contractual arrangement	partners, approved by EC Objectives & commitments set in Grant Agreement	programme drafted by partners, approved by EC Objectives & commitments set in legal act	right in governance) Objectives & commitments set in legal act
`	- ·			mes, industrial strategies)
Internal: Coherence between different parts of the FP Annual Work programme can be ensured by EC External: Limited for other Union programmes, no synergies with national/regional programmes & activities	Internal: Coherence among partnerships & with parts of the FP Annual Work programme can be ensured by partners & EC External: Limited synergies with other Union programmes & industrial strategies. If MS participate, with national/regional programmes & activities	Internal: Coherence among partnerships & with parts of the FP Annual Work programme can be ensured by partners & EC External: Synergies with national/ regional programmes & activities	Internal: Coherence among partnerships & with parts of the FP Annual Work programme can be ensured by partners & EC External: Synergies with national/regional programmes & activities	Internal: Coherence among partnerships & with parts of the FP Annual Work programme can be ensured by partners & EC External: Synergies with other Union programmes and industrial strategies If MS participate, with national/ regional programmes & activities

2.2.2.1. Option 1 - Co-programmed European Partnership

This form of European Partnership is **based upon a Memorandum of Understanding or a Contractual Arrangement** signed by the Commission and the private and/or public partners. Private partners are represented by industry associations, which also support the daily management of the partnership. This type of partnership would allow for a large degree of flexibility for the activities, partners and priorities to continuously evolve. The commitments of partners are political efforts described in the contractual arrangement and the contributions from partners are provided in kind more than financially. The priorities for the calls, proposed by the Partnership's members for integration in the Horizon Europe's Work Programmes, are subject to further input from Member States (comitology) and Commission services. The Union contribution is implemented within the executive agency managing Horizon Europe calls for research and innovation projects proposals. The full array of Horizon Europe instruments can be used, ranging from research and innovation (RIA) types of actions to coordination and support actions (CSA) and including grants, prizes, and procurement.

2.2.2.2. Option 2 – Co-funded European Partnership

The Co-funded European Partnership is **based on a Grant Agreement** between the Commission and a consortium of partners, resulting from a specific call in the Horizon Europe Work Programme. This form of implementation only allows to address public partners at its core. Typically these provide co-funding to a common programme of activities established and/or implemented by entities managing and/or funding national R&I programmes. The recipients of the EU co-funding implement the initiative under their responsibility, with national funding/resources pooled to implement the programme with co-funding from the Union. The expectation is that these entities would cover most if not all EU Member States. Calls and evaluations would be organised centrally, beneficiaries in selected projects would be funded at national level, following national funding rules.

2.2.2.3. Option 3 – Institutionalised European Partnership

This type of Partnership is the most complex and high-effort arrangement, and requires meeting additional requirements. Institutionalised European Partnership are based on a Council Regulation (Article 187 TFEU or a Decision by the European Parliament and Council (Article 185 TFEU) and are implemented by dedicated structures created for that purpose. These regulatory needs limit the flexibility for a change in the core objectives, partners, and/or commitments as these would require amending legislation. The basic rationale for this type of partnership is the need for a strong integration of R&I agendas in the private and/or public sectors in the EU in order to address a strategic challenge. It is therefore necessary to demonstrate that other forms of implementation would not achieve the objectives or would not generate the necessary expected impacts, and that a long-term perspective and high degree of integration is needed. For both Article 187 and 185 initiatives, contributions from partners can be in the form of financial and in-kind contributions. Eligibility for participation and funding follows by default the rules of Horizon Europe, unless a derogation is introduced in the basic act.

Option 3a - Institutionalised Partnerships based on Article 185 TFEU

Article 185 of the TFEU allows the Union to participate in programmes jointly undertaken by Member States and limits therefore the scope to **public partners** which are Member States and Associated Third Countries. This type of Institutionalised Partnership aims therefore at reaching the greatest possible impact through the integration of national and EU funding,

aligning national strategies in order to optimise the use of public resources and overcome fragmentation of the public research effort. It brings together R&I governance bodies of most if not all EU Member States (legal requirement: at least 40% of Member States) as well as Associated Third Countries that designate a legal entity (Dedicated Implementation Structure) of their choice for the implementation. By default, participation of non-associated Third Countries is not foreseen. Such participation is possible only if it is foreseen in the basic act and subject to conclusion of an international agreement.

Option 3b - Institutionalised Partnerships based on Article 187 TFEU

Article 187 of the TFEU allows the Union to set up joint undertakings or any other structure necessary for the efficient execution of EU research, technological development and demonstration programmes. This type of Institutionalised Partnership brings together a stable set of **public and private partners** with a strong commitment to taking a more integrated approach and requires the set-up of a dedicated legal entity (Union body, Joint Undertaking (JU)) that carries full responsibility for the management of the Partnership and implementation of the calls. Different configurations are possible:

- Partnerships focused on creating strategic industrial partnerships where, most often, the partner organisations are represented by one or more industry associations, or in some cases individual private partners;
- Partnerships coordinating national ministries, public funding agencies, and governmental research organisations in the Member States and Associated Countries;
- Or a combination of the two: the so-called tripartite model.

Participation of non-associated Third Countries is only possible if foreseen in the basic act and subject to conclusion of an international agreement.

2.3. Overview of the methodology adopted for the impact assessment

The methodology for each impact assessment is based on the Commission Better Regulation Guidelines²⁰ to evaluate and compare options with regards to their **efficiency**, **effectiveness** and coherence. This also integrates key selection criteria for European Partnerships.

Box 2 Summary of European Partnerships selection criteria²¹

- *Effectiveness* in achieving the related objectives and impacts of the Programme;
- Coherence and synergies of the European Partnership within the EU R&I landscape;
- *Transparency* & *openness* as regards the identification of priorities and objectives and the involvement of partners & stakeholders from the entire value chain, backgrounds & disciplines;
- Ex-ante demonstration of *additionality* and *directionality*;
- Ex-ante demonstration of the partners' *long term commitment*.

2.3.1. Overview of the methodologies employed

In terms of **methods and evidence used**, the impact assessments draw on an external study covering all candidate Institutionalised European Partnerships in parallel to ensure a high level of coherence and comparability of analysis, in addition to an horizontal analysis.²² For all initiatives, the understanding of the overall context of the candidate institutionalised

²¹ For a comprehensive overview of the selection criteria for European Partnerships, see Annex 6.

²⁰ European Commission (2017), Better Regulation Guidelines (SWD (2017) 350)

²² Technopolis Group (2020), Impact Assessment Study for Institutionalised European Partnerships under Horizon Europe, Final Report, Study for the European Commission, DG Research & Innovation

European Partnerships relied on desk research, including among others the lessons learned from previous partnerships. This was complemented by the analysis of a range of quantitative and qualitative evidence, including evaluations of past and ongoing initiatives; foresight studies; statistical analyses of Framework Programmes application and participation data, and Community Innovation Survey data; analyses of science, technology and innovation indicators; reviews of academic literature; sectoral competitiveness studies and expert hearings. The analyses included a portfolio analysis, a stakeholder and social network analysis in order to profile the actors involved as well as their co-operation patterns, and an assessment of the partnerships' outputs (bibliometrics and patent analysis). A cost modelling exercise was performed in order to feed into the efficiency assessments of the partnership options, as described below. Public consultations (both open and targeted) supported the comparative assessment of the policy options. For each initiative, up to 50 relevant stakeholders were interviewed by the external contractor (policymakers, business including SMEs and business associations, research institutes and universities, and civil organisations, among others). In addition, the analysis was informed by the results of the Open Public Consultation run between September and November 2019, the consultation of Member States through the Strategic Programme Committee and the online feedback received on the Inception Impact Assessments of the set of initiatives.

A more detailed description of the methodology and evidence base that were mobilised, completed by thematic specific methodologies, is provided in Annexes 4 and 6.

2.3.2. *Method for identifying the preferred option*

The first step of the assessments consisted in scoping the problems that the initiatives are expected to solve given the overall economic, technological, scientific and social context, including the lessons to be learned from past and ongoing partnerships on what worked well and less well. This supported the identification of the objectives of the initiative in the medium and long term with the underlying intervention logic – showing how to get there.

Given the focus of the impact assessment on comparing different forms of implementation, the Better Regulation framework has then been adapted to introduce "key functionalities **needed**" - making the transition between the definition of the objectives and what would be crucial to achieve them in terms of implementation. The identification of "key functionalities needed" for each initiative as an additional step in the impact assessment is based on the distinguishing factors between the different options (see Section 2.2.1). In practical terms, each option is assessed on the basis of the degree to which it would allow for the key needed functionalities to be covered, as regards e.g. the type and composition of actors that can be involved ('openness'), the range of activities that can be performed (including additionality and level of integration), the level of directionality and integration of R&I strategies; the possibilities offered for coherence and synergies with other components of Horizon Europe, including other Partnerships (internal coherence), and the coherence with the wider policy environments, including with the relevant regulatory and standardisation framework (external coherence). This approach guides the identification of discarded options while allowing at the same time a structured comparison of the options not only as regards their effectiveness, efficiency and coherence, but also against a set of other key selection criteria for European Partnerships (openness, transparency, directionality)²³.

In line with the Better Regulation Framework, the assessment of the effectiveness, efficiency and coherence of each option is made compared to the baseline. Therefore, for each of these

²³ The criterion on the ex-ante demonstration of partners' long term commitment depends on a series of factors that are unknown at this stage, and thus fall outside the scope of the analysis.

aspects the performance of using traditional calls under Horizon Europe is first estimated and scored 0 to serve as a reference point. This includes the discontinuation costs/benefits of existing implementation structures when relevant. The policy options are then scored compared to the baseline with a + and – system with a two-point scale, to show a slightly or highly additional/lower performance compared to the baseline. A scoring of 0 of a policy option means that it would deliver as much as the baseline option.

On the basis of the evidence collected, the intervention logic of each initiative and the key functionalities needed, the impact assessments first evaluate the **effectiveness** of the various policy options to deliver on their objectives. To be in line with the Horizon Europe impact framework, the fulfilment of the specific objectives of the initiative is translated into 'expected impacts' - how success would look like -, differentiating between scientific, economic/ technological, and societal (including environmental) impacts. Each impact assessment considers to which extent the different policy options provides the 'key functionalities needed' to achieve the intended objectives. The effectiveness assessment does not use a compound score but shows how the options would deliver on the different types of expected impacts. This is done to increase transparency and accuracy in the assessment of options²⁴.

A similar approach is followed to evaluate the coherence of options with the overarching objectives of the EU's R&I policy, and distinguishes between **internal** and **external coherence**. Specifically, internal coherence covers the consistency of the activities that could be implemented with the rest of Horizon Europe, including European Partnerships (any type). External coherence refers to the potential for synergies and/or complementarities (including risks of overlaps/gaps) of the initiative with its external environment, including with other programmes under the MFF 2021-27, but also the framework conditions at European, national or regional level (incl. regulatory aspects, standardisation).

To compare the expected costs and benefits of each option (efficiency), the thematic impact assessments broadly follow a cost-effectiveness approach²⁵ to establish to which extent the intended objectives can be achieved for a given cost. A preliminary step in this process is to obtain a measure of the expected costs of the policy options, to be used in the thematic assessments. As the options correspond to different implementation modes, relevant cost categories generally include the costs of setting-up and running an initiative. For instance, setup costs includes items such as the preparation of a European Partnership proposal and the preparation of an implementation structure. The running costs include the annual work programme preparation costs. Where a Partnership already exists, discontinuation costs and cost-savings are also taken into account²⁶. The table below provides an overview of the cost categories used in the impact assessment and a qualitative scoring of their intensity when compared to the baseline option (traditional calls). Providing a monetised value for these average static costs would have been misleading, because of the different features and needs of each candidate initiative.²⁷ The table shows the overall administrative, operational and

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²⁴ In the thematic impact assessments, scores are justified in a detailed manner to avoid arbitrariness and spurious accuracy. A qualitative or even quantitative explanation is provided of why certain scores were given to specific impacts, and why one option scores better or worse than others.

²⁵ For further details, see Better Regulation Toolbox # 57.

²⁶ Discontinuation costs will bear winding down and social discontinuation costs and vary depending on e.g. the number of full-time-equivalent (FTEs) staff concerned, the type of contract (staff category and duration) and applicable rules on termination (e.g. contracts under Belgian law or other). If buildings are being rented, the cost of rental termination also apply. As rental contracts are normally tied to the expected duration of the current initiatives, these termination costs are likely to be very limited. In parallel, there would also be financial cost-savings related to the closing of the structure, related to operations, staff and coordination costs in particular. This is developed further in the individual efficiency assessments.

A complete presentation of the methodology developed to assess costs as well as the sources used is described in the external study supporting this impact assessment (Technopolis Group, 2020).

coordination costs of the various options. These costs are then put into context in the impact assessments to reflect the expected co-financing rates and the total budget available for each of the policy options, assuming a common Union contribution (cost-efficiency):

- The costs related to the baseline scenario (traditional calls under Horizon Europe) are pre-dominantly the costs of implementing the respective Union contribution via calls and project, managed by the executive agencies (around 4%, efficiency of 96% for the overall investment).
- For a Co-Programmed partnership the costs of preparation and implementation increase only marginally compared to the baseline (<1%), but lead to an additional R&I investment of at least the same amount than the Union contribution²⁸ (efficiency of 98% for the overall investment).
- For a Co-Funded partnership the additional R&I investment by Member States accounts for 2,3 times the Union contribution²⁹. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the national programmes, can be estimated at 6% of the Union contribution (efficiency of 98% related to the overall investment).
- For an Article 185 initiative the additional R&I investment by Member States is equal to the Union contribution³⁰. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the dedicated implementation structure, can be estimated at 7% of the Union contribution (efficiency of 96% related to the overall investment).
- For an Article 187 initiative the additional R&I investment by partners is equal to the Union contribution³¹. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the dedicated implementation structure, can be estimated at 9% of the Union contribution (efficiency of 94% related to the overall investment).

Figure 4 - Intensity of additional costs compared with Horizon Europe Calls (for Partners, stakeholders, public and EU)

Cost items	Baseline: traditional calls	Option 1: Coprogrammed	Option 2 Co-funded	Option 3a - Art. 185	Option 3b -Art. 187
Preparation and set-up costs					
Preparation of a partnership proposal (partners and EC)	0		↑ ↑		
Set-up of a dedicated implementation structure		0		Existing: ↑ New: ↑↑	Existing: ↑↑ New: ↑↑↑
Preparation of the SRIA / roadmap	0		$\uparrow \uparrow$		
Ex-ante Impact Assessment for partnership		0		↑ ↑	↑
Preparation of EC proposal and negotiation		0		↑ ↑	↑
Running costs (Annual cycle of implementa	ntion)				
Annual Work Programme preparation	0		1		
Call and project implementation	0	0 In case of MS contributions: ↑	↑	1	↑
Cost to applicants Comparable, unless there are strong arguments of major differences in oversubscription					fferences in

²⁸ Minimum contributions from partners equal to the Union contribution

³¹ Based on the minimum requirement in the legal basis that partners contribute at least 50% of the budget.

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²⁹ Based on the default funding rate for programme co-fund actions of 30%, partners contribute with 70% of the total investment.

³⁰ Based on the minimum requirement in the legal basis that partners contribute at least 50% of the budget.

Cost items	Baseline: traditional calls	Option 1: Coprogrammed	Option 2 Co-funded	Option 3a - Art. 185	Option 3b -Art. 187
Partners costs not covered by the above	0	\uparrow	0	↑	↑
Additional EC costs (e.g. supervision)	0	↑	\uparrow	↑	$\uparrow \uparrow$
Winding down costs					
EC		0			$\uparrow\uparrow\uparrow$
Partners	0	↑	0	↑	↑

Notes: 0: no additional costs, as compared with the baseline; \uparrow : minor additional costs, as compared with the baseline; $\uparrow\uparrow$: medium additional costs, as compared with the baseline; $\uparrow\uparrow\uparrow$: higher costs, as compared with the baseline.

The cost categories estimated for the common model are then used to develop a scorecard analysis and further refine the assessment of options for each of the 12 candidate Institutionalised Partnerships. Specifically, the scores related to the set-up and implementation costs are used in the thematic impact assessments to consider the scale of the expected benefits and thereby allow a simple "value for money" analysis (**cost-effectiveness**)³². In carrying out the scoring of options, the results of fieldwork, desk research and stakeholder consultation undertaken and taken into account.

For the **identification of the preferred option**, the scorecard analysis builds a hierarchy of the options by individual criterion and overall in order to identify a single preferred policy option or in case of an inconclusive comparison of options, a number of 'retained' options or hybrid. This exercise supports the systematic appraisal of alternative options across multiple types of monetary, non-monetary and qualitative dimensions. It also allows for easy visualisation of the pros and cons of each option. Each option is attributed a score of the adjudged performance against each criterion with the three broad appraisal dimensions of effectiveness, efficiency and coherence.

As a last step, the alignment of the preferred option with key criteria for the selection of European Partnerships is described, reflecting the outcomes of the 'necessity test'. The monitoring and evaluation arrangements are concluding the assessment, with an identification of the key indicators to track progress towards the objectives over time.

2.4. Horizontal perspective on candidate Institutionalised European Partnerships

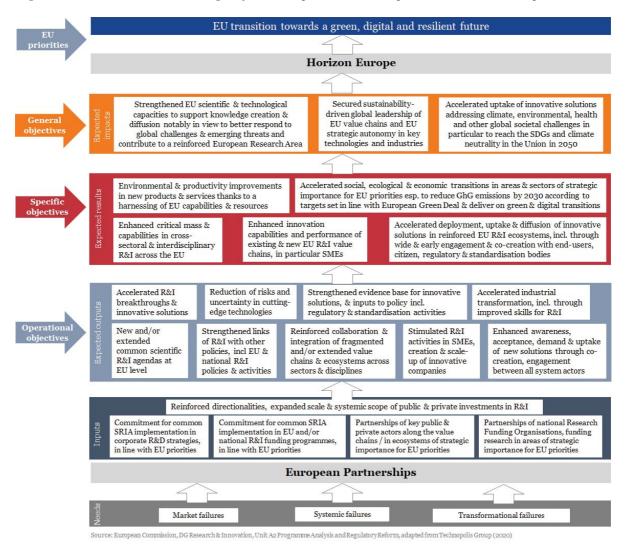
2.4.1. Overall impact orientation, coherence and efficiency needs

The consolidated **intervention logic** for the set of candidate Institutionalised European Partnerships in the Figure below builds upon the objectives as reported in the individual impact assessments.

³² More details on the methodology can be found in Annex 4.

³³Certain aspects of the selection criteria will be further addressed/ developed at later stages, notably in the context of preparing basic acts (e.g. Openness and Transparency; Coherence and Synergies), in the Strategic Research and Innovation Agendas (e.g. Directionality and Additionality), and by collecting formal commitments (Ex-ante demonstration of partners' long-term commitment).

Figure 5 – Overall intervention logic of the European Partnerships under Horizon Europe



When analysed as a package the 12 candidate Institutionalised European Partnerships are expected to support the achievement of the European policy priorities targeted by Horizon Europe by pursuing the following joint general objectives:

- Strengthening and integrating EU scientific and technological capacities to support knowledge creation and diffusion notably in view to better respond to global challenges and emerging threats and contribute to a reinforced European Research Area;
- b) Securing sustainability-driven global leadership of EU value chains and EU strategic autonomy in key technologies and industries; and
- c) Accelerate the uptake of innovative solutions addressing climate, environmental, health and other global societal challenges contributing to Union strategic priorities, in particular to reach the Sustainable Development Goals and climate neutrality in the Union in 2050.

In terms of specific objectives, they jointly aim to:

- a) Enhance the critical mass and scientific capabilities in cross-sectoral and interdisciplinary research and innovation across the Union;
- b) Accelerate the social, ecological and economic transitions in areas and sectors of strategic importance for Union priorities, in particular to reduce greenhouse gas

- emissions by 2030 according to the targets set in line with the European Green Deal, and deliver on the green and digital transition;
- c) Enhance the innovation capabilities and performance of existing and new European research and innovation value chains, in particular SMEs;
- d) Accelerate the deployment, uptake and diffusion of innovative solutions in reinforced European R&I ecosystems, including through wide and early engagement and cocreation with end-users, citizen and regulatory and standardisation bodies;
- e) Deliver environmental and productivity improvements in new products and services thanks to a harnessing of EU capabilities and resources.

In terms of their operations, taking an horizontal perspective on all initiatives allows for the identification of further possible collective efficiency and coherence gains for more impact:

- Coherence for impact: The extent and speed by which the expected results and impacts will be reached, will depend on the scale of the R&I efforts triggered, the profile of the partners involved, the strength of their commitments, and the scope of the R&I activities funded. To be fully effective it comes out clearly that future partnerships need to operate over their whole life cycle in full coherence with their environment, including potential end users, regulators and standardisation bodies. This relates also to the alignment with relevant EU, national or regional policies and synergies with R&I programmes. This needs to be factored in as of the design stage to ensure a wide take-up and/or deployment of the solutions developed, including their interoperability.
- Collaboration for impact: Effectiveness could also be improved collectively through enhanced cross-disciplinary and cross-sectoral collaboration and an improved integration of value chains and ecosystems. An adequate governance structure appears in particular necessary to ensure cross-fertilisation between all European Partnerships. This applies not only to initiatives where similar R&I topics are covered and/or the same stakeholders involved or targeted, but also to the interconnections needed between the 'thematic' and the 'vertical' Partnerships, as these are expected to develop methodologies and technologies for application in EU priority areas. Already at very early stages of preparing new initiatives, Strategic Research and Innovation Agendas and roadmaps need to be aligned, particularly for partnerships that develop enabling technologies that are needed in other Partnerships. The goal should be to achieve greater impacts jointly in light of common challenges.
- Efficiency for impact: Potential efficiency gains could also be achieved by joining up the operational functions of Joint Undertakings that do not have a strong context dependency and providing them through a common back-office³⁴. A number of operational activities of the Joint Undertakings are of a technical or administrative nature (e.g. financial management of contracts), or procured from external service providers (e.g. IT, communication activities, recruitment services, auditing) by each Joint Undertaking separately. If better streamlined this could create a win-win situation for all partners leading to better harmonization, economies of scales, and less complexity in supervision and support by the Commission services.

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³⁴ See Annex 6 for an overview of key functions/roles that could be provided by a common back office.

2.4.2. Analysis of coherence of the overall portfolio of candidate initiatives at the thematic level

Looking at the coherence of the set of initiatives at the thematic level, the "digital centric" initiatives have a strong focus on supporting the digital competitiveness of the EU ecosystem. Their activities are expected to improve alignment and coordination with Member States and industry for the development of world-competitive EU strategic digital technology value chains and associated expertise. Addressing the Key Digital Technologies, the 5G and 6G connectivity needs as part of a Smart Networks and Services initiative and the underlying supercomputing capacities through a European High Performance Computing initiative present potential for synergies that can be addressed through cooperative actions (e.g. joint calls, coordinated support activities, etc.). They may as well profit from and contribute to Partnerships envisaged for Photonics, AI, data, robotics, Global competitive space system and Made in Europe, together with the EIT Digital. Synergies between these initiatives and several programmes (Digital Europe and Connecting Europe as well as cohesion programmes) are needed in areas where EU industry has to develop leadership and competitiveness in the global digital economy. They are expected to impact critical value chains including on sectors where digital is a strong enabler of transformation (health, industrial manufacturing, mobility/transport, etc.).

The transport sector have to respond to systemic changes linked to decarbonisation and digitalisation. Large scale R&I actions are needed to prepare the transition of these complex sectors to provide clean, safer, digital and economically viable services for citizens and businesses. Past decades have shown that developing and implementing change is difficult in transport due to its systemic nature, many stakeholders involved, long planning cycles and large investments needed. A systemic modernisation of the air traffic management infrastructure through an Integrated Air Traffic Management initiative should ensure safety and sustainability of air transport, while a Clean Aviation initiative should focus on the competitiveness of tomorrow's clean aircrafts made in Europe. The initiative for Transforming Europe's rail system would comprehensively address the rail sector to make it a cornerstone in tomorrow's clean and efficient door-to-door transport services, affordable for every citizen as well as the most climate-friendly mode of transport for freight. Connected and Automated Mobility is the future of road transport, but Europe is threatened to fall behind other global regions with strong players and large harmonised markets. The initiative Safe and Automated Road Transport would bring stakeholders together, creating joint momentum in digitalising road transport and developing new user-based services. Stronger links and joint actions will be established between initiatives to enable common progress wherever possible. The Clean Hydrogen initiative would be fundamental to that regard. Synergies would also be sought with partnerships driving the digital technological developments.

To deliver a deep decarbonisation of highly emitting industrial sectors such as the steel, transport and chemical industries would require the production, distribution and storage of **hydrogen** at scale. The candidate hydrogen initiative would have a central positioning in terms of providing solutions to the challenges for sustainable mobility and energy, but also is expected to operate in synergies with other industry related initiatives. The initiative would interact in particular with initiatives on the zero emission road and water transport, transforming Europe's railway system, clean aviation, batteries, circular industry, clean steel and built environment partnerships. There are many opportunities for collaboration for the delivery and end-use of hydrogen. However, the Clean Hydrogen initiative would be the only partnership focused on addressing hydrogen production technologies.

Metrology, the science of measurement, is an enabler across all domains of R&I. It supports the monitoring of the Emissions Trading System, smart grids and pollution, but also

contributes to meeting demands for measurement techniques from emerging digital technologies and applications. More generally, emerging technologies across a wide range of fields from biotechnologies, new materials, health diagnostics or low carbon technologies are giving rise to demands requiring a world-leading EU metrology system.

The initiative for a **Circular Bio-based Europe** is intended to solve a shortage of industry investments in the development of bio-based products whose markets do not have yet certain long-term prospects. The **Innovative Health Initiative** and **EU-Africa Global Health** address the lack of investments in the development of solutions to specific health challenges. The initiative on **Innovative SMEs** supports innovation-driven SMEs in participating in international, collaborative R&I projects with other innovative firms and research-intensive partners. As a horizontal initiative it is expected to help innovative SMEs to grow and to be successfully embedded in global value chains by developing methodologies and technologies for potential application in the other partnership areas or further development by the instruments of the European Innovation Council.

The description of the interconnections between all initiatives for each Horizon Europe cluster is provided in the policy context of each impact assessment and further assessed in the coherence assessment for each option.

PART 2 - THE CANDIDATE EUROPEAN PARTNERSHIP FOR INTEGRATED AIR TRAFFIC MANAGEMENT

1. Introduction: Political and legal context

Free movement of people and goods within the internal market is one of the cornerstones of the European Union's society and economy. The EU transport policy ultimately aims to serve the interests of European citizens and businesses by providing ever greater connectivity³⁵, the highest level of safety and security and barrier-free markets.

Air Traffic Management (ATM³⁶) is an activity for air transport encompassing ground and airborne systems that assist all types of manned and unmanned aircraft to safely depart from an aerodrome, transit airspace, and land at a destination aerodrome. Typically, before a flight takes place, any aircraft files a Flight Plan and sends it to a central European repository. However, for safety reasons, Air Traffic Controllers (ATCOs) can handle only a limited number of aircraft at one time. Computers used for flow management across the European network calculate the intended trajectory where an aircraft will be at any given moment and check that the ATCOs in that airspace can safely cope with the flight. If they cannot, the aircraft has to wait on the ground until it is safe to take off.

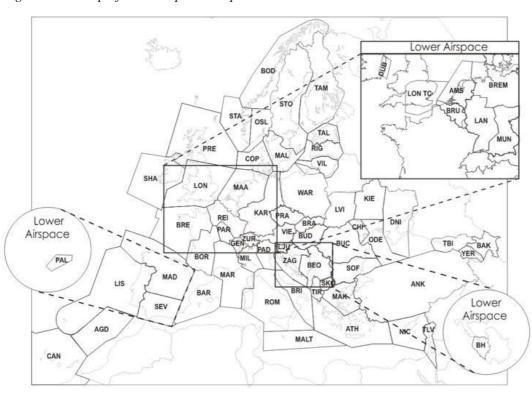


Figure 6 – A map of the European airspace

During the flight (en route) ATM ensures that aircraft are safely separated and safeguarded from adverse weather in the airspace and at the airports where they land and take off. Control

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³⁵ Connectivity is also key in ensuring the economic, social and territorial cohesion of Member States enshrined in the Lisbon Treaty as a fundamental objective of the Union

³⁶ Regulation (EC) No 549/2004, Article 2(10): 'air traffic management (ATM)' means the aggregation of the airborne and ground-based functions (air traffic services, airspace management and air traffic flow management) required to ensure the safe and efficient movement of aircraft during all phases of operations'

towers at airports are a concept familiar to the public, but aircraft are also separated en-route by various "invisible" Air Traffic Control Centres (ACCs) as illustrated in the map above³⁷.

The current areas of responsibility of ACCs are designed mainly based on national boundaries. There are some examples of ACCs involving cross-border management of airspace. Each ACC works with sub-divided portions of airspace called sectors which may be grouped together or operated individually depending on level of traffic.

These subdivisions are clearly suboptimal and were addressed by the Single European Sky initiative of the Union's in 2004 seeking to reform the European air traffic management system through a series of actions carried out in four different levels (institutional, operational, technological and control and supervision) with the aim of improving the performance of the European airspace in terms of capacity, safety, efficiency and environmental impact.

In this context, the Single European Sky ATM Research (SESAR) project constitutes the fundamental "technological pillar" of the Single European Sky initiative, driving the ATM innovation cycle that brings new concepts through inter-related definition, development and deployment activities into operations, as illustrated below:

Figure 7 –SESAR and the ATM innovation cycle



R&I is the core of the SESAR project, driven by the European ATM Master Plan³⁸. The Master Plan is periodically updated to reflect new technology breakthroughs, evolving aviation expectations, and evolutions in EU policy and economy adjusting to emerging challenges within ATM.

The latest version of the Master Plan, adopted in December 2019 and supported by the entire aviation community and the EU Member States, identifies the vision for achieving a Digital European Sky³⁹ by 2040. This is a vision of a digital aviation infrastructure which is resilient, flexible and able to handle the future growth and diversity of air traffic safely and efficiently,

https://www.sesarju.eu/masterplan

³⁷ Eurocontrol/Network Manager, 2018

³⁹ Blueprint for a Digital European Sky, Publication Office of the European Union, ISBN 978-92-9216-129-3

while minimising the environmental impact. The Master Plan defines what the current R&I programme is expected to deliver by 2035⁴⁰ and describes what the future programme still has to develop to implement the vision.

The Master Plan is therefore a clearly established and agreed roadmap for the future of ATM industrial and academic research, beyond the current or the potential upcoming partnership.

Building on the ATM Master Plan, parties interested to invest in the upcoming partnership have already prepared a detailed Strategic Research and Innovation Agenda laying down nine roadmaps for the technologies that need to be developed and demonstrated during the next Union long-term budget cycle.

It is to be noted that the brand 'SESAR' comprises development AND deployment (for more detail see Box 3 below). For the latter distinct financing and a distinct governance (outside the R&I domain) are in place.

This document focuses on assessing the most effective, efficient and coherent way of implementing an initiative under Horizon Europe that would focus on joint European research and innovation activities for modernising and integrating Air Traffic Management systems in Europe.

1.1. Emerging challenges in the field

Achieving the ambitious goal of climate neutrality by 2050 calls for the EU to ensure a deep decarbonisation of the air transport sector. The aviation industry has committed in the long-run to bring into service a new generation of aircraft that will be cleaner and quieter (based on alternative propulsion systems, new airframes and energy sources). However, this ambitious target cannot be achieved if ATM does not allow aircraft and airspace users to fully exploit their potential and thus to reduce emissions to a maximum.

Therefore, ATM must evolve at a faster pace than today to bring environmental benefits in the shorter term. Indeed, despite the ATM modernisation efforts undertaken in the past years, 5 to 10% of CO₂ emissions⁴¹ generated by flights are still thought to be avoidable and caused by a fragmented ATM infrastructure that does not fully exploit the advantages of digitalisation and automation. The avoidable emissions can be explained by unnecessarily long trajectories, congestion in the air and at airports, and thus higher CO₂ emissions, delays and higher costs for the provision of air navigation services.

Furthermore, while the economic outlook resulting from the COVID 19 pandemic is too early to predict, it is clear that due to its nature, air transport has been among the hardest hit sectors. IATA, the aviation industry's trade body, has warned that some 25 million jobs in both the aerospace and aviation sectors are at risk if governments do not step in with lifelines⁴². These are not normal times and the pressure on the ATM infrastructure to embrace a more digital future to become more cost efficient, resilient and scalable to fluctuations (up or down) in demand for air transport has never been higher. Moreover, experiences from previous crises situations have shown that traffic will pick-up and increase beyond the pre-crises levels.

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⁴⁰ Date at which it is deemed possible to secure full entry into operations of the technology and processes developed by the existing Programme

⁴¹ European ATM Master Plan Edition 2020

⁴² IATA Press Release No 28 07 April 2020

Innovation in ATM has progressed over the past decade thanks to the SESAR programme. However, there are still a number of remaining challenges, including the very sub-divided ATM systems as explained above, which will require a more rapid digitalisation of the ATM infrastructure to further focusing efforts and acceleration of the development, industrialisation and market uptake of innovations that would increase the level of collaboration and automation in ATM through a data rich and cyber-secured connected ATM ecosystem. Such an evolution also poses a number of regulatory challenges as the sovereignty of Member States in relation to their airspace needs to be respected and a higher degree of digitalisation and automation would make service delegation agreements between States less important.

The sector is still at the early stages of decarbonisation and digitalisation, and massive investments across the entire air transport value chain are necessary to shorten the innovation life cycles (from approximately 30 years today to 5-10 years). In order to achieve this acceleration, ATM must tackle risks such as market failure for first movers, fragmentation among players and lack of critical mass. The ATM industry supports a wide range of applications in transport (passengers and cargo, new emerging forms of mobility such as urban air mobility), defence & security (military, law enforcement), the digital economy (such as drones for the collection of data or to bring Internet connectivity to rural and remote communities).

Addressing these multiple challenges in a rapidly evolving and demanding context requires a significant collective effort in boosting cooperation and investment on breakthrough innovations that cannot be addressed by any single stakeholder or Member State alone as, by essence, aviation is international and requires common and coordinated action.

1.2. EU relative positioning in the field

Air transport is a key driver for European integration and economic prosperity. The aviation sector employs close to 2 million people and overall supports between 4.8 million and 5.5 million jobs in Europe⁴³, directly and indirectly. Altogether, this generates EUR 110 Billion in GDP in the EU, while the overall impact, including tourism, is as large as EUR 510 billion⁴⁴. Europe's citizens and businesses are connected today thanks to the 30 000 daily flights carrying about 1.1 billion passengers per year.

The European air traffic management (ATM⁴⁵) system supports mobility by providing the infrastructure to ensure the safe and secure separation of aircraft and the efficient flow of air traffic. It is a safety critical infrastructure, which is significantly regulated to ensure the highest possible performance standards. Put in other words, there can be no aircraft in the air without ATM which is currently provided in Europe at a cost to airspace users of about 10 billion EUR per year⁴⁶.

Europe hosts the world leaders in ATM technology and manufacturing industry^{47,48}. Considering the shared and complex nature of this infrastructure, no single company or state can realise that digital transformation alone.

⁴⁷ Frost & Sullivan, Global Commercial Air Traffic Management Market, Forecast to 2025

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⁴³ Aviation Strategy for Europe: Maintaining and promoting high social standards, COM(2019) 120 final

⁴⁴ Source: European Commission, an Aviation Strategy for Europe, COM/2015/0598 final

⁴⁵ Regulation (EC) No 549/2004, Article 2(10): 'air traffic management (ATM)' means the aggregation of the airborne and ground-based functions (air traffic services, airspace management and air traffic flow management) required to ensure the safe and efficient movement of aircraft during all phases of operations'

⁴⁶ Source Eurocontrol, Central Route Charge Office, 2018 Report on the Operation of the Route Charges System

Considering the cross-border and safety critical nature of air transport, developing the infrastructure and the underlying technology to support the realisation of the Single European Sky cannot be done by individual stakeholders or Member States.

The race for setting the next generation of standards requires more intensive global coordination in the context along the International Civil Aviation Organisation (ICAO). Europe's current leading position, through major players in ATM technology, SESAR and data platform providers, cannot be taken for granted. Competition is raising. New aviation nations like China are putting European leadership to the test, as is the renewed strengthening of protectionism worldwide. If the Union wants the European technology to continue to be backbone of global aviation infrastructure, the EU should continue its support for the European ATM innovation cycle⁴⁹. This cycle is a unique model of integration of different phases of innovation process involving a wide range of public and private partners governed by a dedicated EU-wide legal framework and incentive mechanisms linking technological innovation with policy and performance objectives. The political and economic weight of the initiative involving all EU Member States allows the Union to enjoy an influential position in global for a.

The safety of air traffic is and will continue to be the central focus of the partnership. This means that safety and cyber security are embedded in the design of every single solution coming out of SESAR and are regularly screened throughout validation and demonstration exercises under the close regulatory supervision of EASA, who should play an even bigger role in the upcoming partnership.

Box 3 Support for the field in the previous Framework Programmes – key strengths & weaknesses identified

What has been/is being done with EU research and innovation funding until now

European ATM Research & Innovation (R&I) is currently coordinated by the SESAR Joint Undertaking (SESAR JU)⁵⁰. Created in 2007⁵¹ under FP7 and extended in 2014⁵² under Horizon 2020, the SESAR JU currently manages the SESAR 2020 R&I programme (SESAR development phase) and will end its activities by 31 December 2024.

The objective of the SESAR JU is 53 "to ensure the modernisation of the European air traffic management system by coordinating and concentrating all relevant research and development efforts in the Community".

What has or is being achieved so far

The current partnership has laid down a solid foundation that will enable a rapid start of activities under the new partnership/configuration. More specifically, the Master Plan (coowned by industrial stakeholders, the Member States, the Commission and Eurocontrol)

⁴⁸ AeroSpace and Defence Industries Association of Europe (ASD) 2019 facts & figures report

⁴⁹ AeroSpace and Defence Industries Association of Europe (ASD) High-Level Position on Aeronautics in the next Framework Programme (FP9)

⁵⁰ an Institutionalised Partnership established under Article 187 of the Treaty on the Functioning of the European Union (TFEU)

⁵¹ See Council Regulation (EC) n°219/2007 of 27 February 2007

See Council Regulation (EU) No 721/2014 of 16 June 2014

As defined by Council Regulation (EC) No 219/2007 of 27 February 2007 on the establishment of a Joint Undertaking to develop the new generation European air traffic management system (SESAR), as amended.

provides both, the vision of where the European ATM system should be by at the end of the next Union long-term budget (2035) and the common roadmap to achieve it. The two generations of the partnership preceding the upcoming initiative have solidified a close cooperation model sustained by clear governance arrangements and a multitude of working arrangements used by various specialists to cooperate at technical level.

To date, the SESAR JU has delivered close to 100 ATM Solutions⁵⁴ that are being deployed and are delivering benefits at over 300 locations across Europe^{55,56}, under the coordination of the SESAR Deployment Manager.

Whether implemented individually or in combination, the SESAR solutions can bring benefits in key performance areas, such as cost and operational efficiency, capacity, safety, security and the environment.

The SESAR JU has also changed the mind-set of the industry, who has become more cooperative and dedicated to achieving the common Union policy priorities in ATM.

There is also a close and well-tested cooperation with the industrialisation and deployment processes in the sector.

The main intervention areas for the upcoming partnership have already been central to the work of the current partnership. Some key achievements include:

- *Digitalisation*: the partnership was able to significantly advance the maturity of technologies enabling the virtualisation of ATM (Virtual & Augmented Reality applications, Remote Tower operations, Virtual Centres) some of which are already in implementation across Europe (Remote Towers).
- *Environment*: the partnership was able to advance the maturity of technologies promising to enable the reduction of CO₂ emissions per flight by up to 4% some of which are already in implementation across Europe such as Free Route operations (to fly more direct trajectories)
- *Drones*: in 2017, the European Commission mandated the SESAR JU to coordinate all R&I activities related to the safe integration of drone integration into airspace. As a result, 19 project were launched covering exploratory research and large-scale demonstration projects that addressed all aspects of drone operations, as well as the enabling technologies and required services. The results of these projects helped shape the first regulatory proposal to establish an initial harmonised framework for drone operations in Europe (EASA regulation on U-space).

How the new partnership will integrate the findings of previous evaluations

The partnership approach has proven to work in the context of ATM. It contributes to focusing and rationalising Research & Innovation efforts and investments in Europe on agreed priorities driven by the Union's policy objectives. The upcoming partnership will not only continue to engage all current types of stakeholders but it will expand its membership to new emerging actors in the sector, including drones manufacturers or drones services providers, as well as actors from the space and communications sectors.

As identified by the evaluation report, the administrative procedures and IT systems have caused concerns for the beneficiaries. The Commission has simplified the rules for

Guidance Material for SESAR Deployment Programme Implementation Monitoring View 2019, SDM, September 2019

Interactive map available at: https://www.sesardeploymentmanager.eu/single-european-sky-deployment/.

https://www.sesarju.eu/newsroom/brochures-publications/sesar-solutions-catalogue

participation with the Proposal for the Horizon Europe Programme and has constantly been working to address IT concerns faced by the JUs and their members.

The work does not stop at the end of the research phase. To make a difference, the results of the partnership (SESAR solutions) have to be easy to standardise, certify and industrialise into products that can deliver tangible improvements into the real world operational environment.

To this end, the new Joint Undertaking will have a stronger role in coordinating and facilitating the industrialisation process for the SESAR solutions.

With the upcoming partnership, we also hope to break the traditional approach in aviation where innovation is often delayed by potential and non-documented safety concerns. The future partnership will develop & demonstrate the application of digital solutions (relying on higher levels of automation, AI, etc.) which will ultimately lead to smaller margins for human & system errors and improved safety.

What are the key areas for improvement & unmet challenges?

A number of systemic challenges already identified in the interim evaluation of SESAR JU⁵⁷ risk derailing the progress already achieved and will have to be better addressed in a new ATM research initiative. These challenges include:

- i) Defining and maintaining stable long-term objectives
- ii) Reinforcing the accountability of the SESAR JU and prioritising EU support to R&D solutions that promote defragmentation and a competitive environment⁵⁸.
- iii) Shortening the long research and industrialisation cycles, to secure a faster deployment and entry into operations of SESAR solutions;
- iv) Addressing funding concentration, and the need to ensure that there is enough transparency and openness to new participants, especially to entities from countries where participation was so far low;
- v) Improving knowledge management and transfer, links to academia and research institutes to improve the scientific base on ATM in the EU.

1.3. EU policy context beyond 2021

A new momentum to improve ATM is given by the "European Green Deal"⁵⁹, which identifies aviation as a key sector that needs a rapid change in paradigm to achieve the ambitious goal of climate neutrality by 2050. The European Green Deal refers explicitly to reducing aviation emissions.

The ATM infrastructure should be modernised at a more rapid pace to bring environmental benefits in the shorter term by improving the efficiency of ATM services in the European airspace. Digitalisation will radically transform Europe's ATM infrastructure contributing to a smarter, more sustainable, connected and accessible to all air transport.

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⁵⁷ Commission Staff Working Document - Interim Evaluation of the Joint Undertakings operating under Horizon 2020, SWD (2017) 339 final

European Court of Auditors Special Report No 18/2017

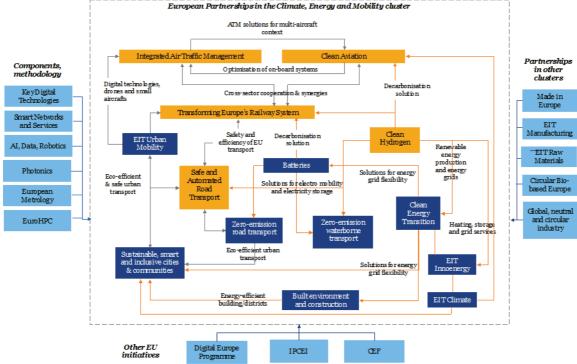
European Commission (2019), COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE EUROPEAN COUNCIL, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS, The European Green Deal, COM(2019) 640 final

Under the proposed Horizon Europe programme, the R&I activities funded under the **Pillar II Cluster Climate, Energy and Mobility** aim at contributing to the attainment of three of the six main ambitions for Europe: 'A European Green Deal', 'a people-centred economy' and 'A Digital Europe'. Pillar II supports several of the Sustainable Development Goals, particularly Climate Actions (SDG13), Sustainable Cities and Communities (SDG11) and Industry Innovation and Infrastructure (SDG9)⁶⁰.

The Integrated Air Traffic Management partnership is one of the European institutionalised Partnership candidates proposed to be established and funded under this cluster. It seeks to bring together a broad range of stakeholders in the sector (technology providers, innovators, start-ups, academia, airspace users, service providers and the military) to support the digital transformation of ATM infrastructure and services. It also falls under the new Commission's vision of a digital European sky⁶¹ that by 2040 would eliminate any environmental waste caused by the aviation infrastructure.

Building upon the experience of the current SESAR Joint Undertaking, it is one of the envisaged European Partnerships to "accelerate competitiveness, safety and environmental performance of EU air traffic, aviation and rail". There is a relatively high number of candidate partnerships in the mobility sub-cluster in different mobility application areas (i.e. air, rail and road transport). Fig. 1 shows the potential synergies between the candidate partnerships and the potential synergies with the energy and digital sub-clusters.

Figure 8: Potential interconnections between partnership initiatives in the Climate, Energy and Mobility cluster of Horizon European Partnerships in the Climate, Energy and Mobility cluster



Source: Technopolis Group (2020)

According to the European ATM Master Plan, the next generation of ATM systems underlying the digital European Sky shall be more automated and take greater advantage of

Information on ATM contribution to SDGs is presented in Annex 6

Blueprint for a digital European Sky, EU Publication Office, December 2019

digital technologies such as big data and artificial intelligence (AI). Future ATM R&I therefore needs to be connected with wider R&I on:

- Air Transport (e.g. link with the candidate partnership on Clean Aviation). Traffic data from Eurocontrol shows that CO₂ emissions from aviation have grown by a higher percentage than the traffic growth⁶². Improvements in the environmental efficiency of aircraft may thus be negatively balanced by a fragmented ATM infrastructure. Therefore, the R&I roadmaps for ATM and Clean Aviation must be coordinated to maximise benefits, in particular on the environment.
- *Multi-modal transport*: ATM systems should be synchronised and exchange data with other transport modes (e.g. rail) to increase predictability and to enable through-ticketing or luggage reconciliation.
- Digital technologies (e.g. link with Key Digital Technologies, Smart Networks and Services, AI, Data and Robotics) and climate science including the latest information on climate change and its impacts". In particular ATM needs to be aware of and adapt to the evolution of technologies for data manipulation and distribution, cyber security, legal aspects (e.g. on data ownership, responsibility and liability issues), advanced decision making, including big data and artificial intelligence as well as scientific understanding of climatic impacts.

2. PROBLEM DEFINITION

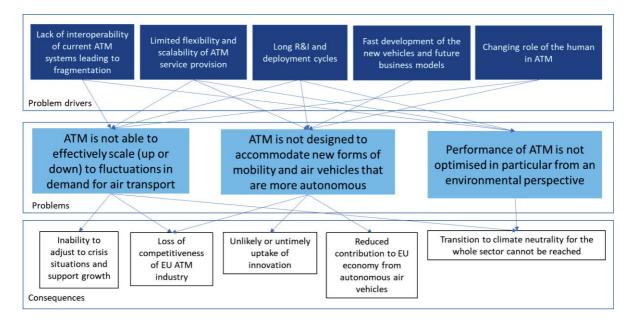
2.1. What are the problems?

Given the scale of the challenges identified in Section 1.1, the current scientific, technological and economic positioning of Europe in the field and the overarching Single European Sky policy context, three problems, all linked to limited scientific capacity and fragmentation of R&I efforts have been identified where coordinated EU research and innovation has an essential role to play:

- Technological: The current ATM systems and technologies in the EU are not digitalised and are therefore not able to effectively adapt to the fluctuations in demand for ATM services.
- Economic: The European ATM system and technologies are not designed to accommodate an increasing number of new forms of mobility and air vehicles that are more autonomous and use digital means of communication and navigation. Moreover, current technologies effectively prevent cross-border service provision in the internal market.
- Environmental: The performance of ATM is not optimised in particular from an environmental perspective resulting in unnecessary greenhouse gas emission of up to 10%.

Figure 9: Problem tree linked to the limited scientific capacity and fragmentation for the initiative on integrated Air Traffic Management

⁶² Comparison of January – October 2019 traffic vs January-October traffic 2017, for all Eurocontrol States departing flights: A 4.5% traffic increase generated a 7.5% increase in CO₂ emissions. Source: Eurocontrol, Network Manager.



2.1.1. The current ATM system has not been digitalised and is therefore not able to effectively scale (up or down) in line with fluctuations in demand for ATM services

Digitalisation has transformed a wide range of industries (with banking, media, retail, travel & tourism, and automotive as front runners) driven by data exchange, connectivity and automation. Transformation of the aviation industry and its supporting ATM infrastructure has already started, but in a post COVID 19 world, much deeper disruptions are expected to impact this traditional, vertically integrated, industry, characterised by slow development cycles and asset intensity.

These disruptions will come from increased and renewed demand to access the sky, new entrants reinventing mobility, new services enabled by data, faster innovation cycles, or customer expectations based on standards set by digital businesses.

They will come at a time of a very challenging outlook for the aviation industry that has been hit extremely hard by the COVID-19 crisis—even harder, perhaps, than by the events of 9/11 and the 2008 global financial crisis put together. However, this challenge will also come along with value migration within the value chain and between incumbents and new players – coming both from the digital industry and from regions such as Asia which may be in a position to benefit from the ongoing rebalancing of economic power.



The need to modernise the existing system though the development and application of emerging technologies such as digitalisation, automation and big data was a recurrent theme amongst the interviewed and throughout all the stakeholder categories⁶³.

Despite the successful deployment of some technologies developed under the SESAR project, Europe's ATM infrastructure is still fragmented⁶⁴ and operates with a low level of automation support⁶⁵ and data exchange intensity (the primary communication technology in ATM today is high frequency radio through which decisions are exchanged by voice between air traffic controllers and pilots). This is the result of years of bespoke operations by national air navigation service providers that have until recently not sufficiently embraced digitalisation

65 European ATM Master Plan, Edition 2020, Figure 4

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⁶³ For an overview of the consultation activities that were carried out, and the views of the stakeholders, see Annex 2.

⁶⁴ Single European Sky: a changed culture but not a single sky, Special Report 18/2017, European Court of Auditors.

and underlines the importance of acting on a this joint effort at European level. As such, the current systems are monolithic, rigid, not scalable (i.e. providing the service where it is needed, in the amounts needed) and unable to exploit emerging digital technologies.

As a result, the periodic (e.g. weekdays vs weekends schedule) or occasional capacity shortage (leading to congestion) caused by unexpected traffic developments cannot be adequately addressed, and the new challenges, mainly the emergence of new airspace users (e.g. delivery drones), risk worsening the situation unless a new impetus is given to ATM modernisation through innovation. Many of the innovations needed are not "business as usual" or incremental but breakthrough solutions that combine digital and physical infrastructure capabilities that needs to be deployed in the entire ecosystem by air navigation service providers, airlines or airports.

Bringing these innovations to scale in the market is challenging considering the high degree of technological, regulatory or market risk the aviation industry faces, which so far has deterred or delayed private investment in its infrastructure⁶⁶. Addressing the multiple ATM challenges requires significant R&I investment in boosting cooperation and investment on innovations that cannot be addressed by any single stakeholder or Member State alone as the ATM infrastructure is shared and needs to rely on homogeneous standards⁶⁷, fit for the digital age, to foster innovation.

As seen prior to SESAR, national R&I programmes aimed at solving local problems, rather than addressing the network perspective at European level. This resulted in duplication of efforts on similar topics⁶⁸, leading to the adoption of different solutions generating even more fragmentation and inefficiencies. Finally, substantial R&I effort and coordination is still needed to improve the manufacturability of tomorrows digital ATM platforms and time to market to reduce innovation cycle from about 30 years to about 5-10 years.

This is due to the complexity of facilitating interactions between innovators, early movers and regulators to help develop regulatory frameworks that allow the benefits of digital technologies to be fully realised in a safety critical sector of our economy.



The majority of stakeholders, across all stakeholder groups, indicated that deployment needs to be accelerated by paying more attention: to implementation challenges, change management for deployment, and gaps between R&I and industrialisation.

2.1.2. The European ATM system is not designed to accommodate new forms of mobility and air vehicles that are more autonomous

Over 23,000 daily flights carrying one billion passengers per year (in 2018) connect Europe's citizens, businesses, communities and cultures.

Hence, under normal circumstances with a saturated aviation infrastructure, air traffic in Europe is hitting its limits both in the air and on the ground, resulting in growing delays and unnecessary emissions. In addition, a multitude of new types of air vehicles, such as delivery drones and air taxis, will soon be seeking access to the airspace. The need for continued and more focussed coordinated R&I and validation of commonly agreed concepts is clear and urgent, in particular to support a robust economic recovery of Europe after the COVID 19 crisis.

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⁶⁶ Blueprint for a Digital European Sky, Publication Office of the European Union, ISBN 978-92-9216-129-3

The role of standards is discussed further in Annex 6.

R&I prior to SESAR is described in Annex 6

The current European ATM infrastructure is reaching its limit in terms of ability to manage an ever increasing volume of air traffic⁶⁹ which means that the problem will resume as the COVID 19 crisis is over (at the time of writing this report the estimated time to recovery for airlines is estimated at 3 to 18 months⁷⁰). In 2018, air traffic delay attributable to the ATM short-comings doubled⁷¹. With sustained long-term traffic growth forecasted for the next 17 years resulting in a total traffic increase of 50%⁷² there is a risk that the level of delays could be 15 times higher if the capacity of current systems is not increased⁷³.

Figure 9 shows the predicted levels of delay and congestion in 2035 if more flexible, scalable and interoperable ATM solutions are not developed and implemented.

Figure 10: The predicted levels of delays by 2035



Source: A proposal for the future architecture of the European airspace, SJU, 2019.

When the airspace management capacity limit is reached, in order to maintain safety, additional constraints are imposed on flights (e.g. delaying or re-routing flights to avoid the saturated zone), resulting in delayed and longer flights, which impact negatively on the environmental and performance goals⁷⁴ of ATM⁷⁵.

Aircrafts flying in European skies are also becoming more autonomous, more connected, more intelligent, and more diverse ⁷⁶. This means that there will be an emergence of a multitude of new types of air vehicles where there is no pilot to talk to: drones flying at low altitude, military medium altitude long endurance unmanned aircraft systems, automated air taxis, super-high altitude operating aircraft.

The markets for these "new entrants" are hindered by the lack of an integrated and harmonised traffic management concept and infrastructure that will allow the safe introduction of services and functionalities to support these operations in both new (e.g. urban) and traditional airspace. Without such systems to ensure safe operations, rules tend to be more restrictive and divers between EU Member States⁷⁷.

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⁶⁹ Annex 6 provides further details of the limitations of the current ATM system.

The Post-COVID-19 Flight Plan for Airlines, The Boston Consulting Group, March 31 2020

Eurocontrol Performance Review Report 2018: ATFM delay in 2018 was 1.74 minutes per flight; in 2017 it was 0.82 minutes per flight.

European Aviation in 2040 Challenges of Growth, Annex1 Flight Forecast to 2040, EUROCONTROL, 2018

A proposal for the future architecture of the European airspace, SJU, 2019

⁷⁴ ATM performance requirements are regulated under Commission Implementing Regulation (EU) 2019/317 of 11 February 2019 laying down a performance and charging scheme in the single European sky

In 2019, horizontal flight efficiency increased from 2.83% to 2.95% (https://www.eurocontrol.int/prudata/dashboard/vis/2019/) as a result of measures to reduce delay by diverting traffic from congested areas (https://www.eurocontrol.int/news/seven-measures-counteract-severe-delays).

⁷⁶ Blueprint for a Digital European Sky, Publication Office of the European Union, ISBN 978-92-9216-129-3

⁷⁷ See for example: <u>https://dronerules.eu/en/professional</u>



Interviews: A majority of stakeholders agree that one of the needs of R&I in ATM is the inclusion of the key emerging challenges such as drones, U-space and other aerospace vehicles into the current system. Airspace users, SMEs, staff and supplier stakeholder groups did not directly cite the inclusion of drones, but did endorse the European ATM

Master Plan as a good strategic agenda (which includes these emerging challenges).

2.1.3. The performance of ATM is not optimised in particular from an environmental perspective resulting in unnecessary greenhouse gas emission

There is growing pressure on the aviation sector to reduce its environmental footprint. Citizens in general and air passengers in particular increasingly expect eco-friendly, smart and personalised mobility options that allow them to travel seamlessly and efficiently. They want quick and reliable data to inform their travel choices, not only on schedules, prices and real-time punctuality, but increasingly also on environmental impacts. To deliver this new era in aviation, leveraging technology is key, as in the upcoming future new aircraft and infrastructure capabilities combined with regulatory changes hold the greatest promise to address climate changes in a post-pandemic aviation sector.

Indeed, while an energy transition (e.g. sustainable aviation fuels) is the only way in the long term (2050) to ensure carbon neutral air transport in the future, the ATM infrastructure in particular can be modernised at a more rapid pace and bring significant environmental benefits in the shorter term⁷⁸.

Today 5-10% of air transport's CO2 emissions could be avoided due to inefficiencies in the ATM infrastructure⁷⁹ as aircraft trajectories are not sufficiently optimised from gate-to-gate perspective to reduce the environmental footprint of each flight (see figure 10 below). This is not negligible and would save 28 million tonnes of CO2 per year, which is roughly equivalent to the CO2 produced by 3.2 million people or the population in the metropolitan area of a city like Madrid⁸⁰.

To further understand the problem it is important to stress that the contribution of ATM infrastructure in reducing the climate change impacts of aviation can best be achieved by enabling aircraft to fly on their optimum (where applicable cross-border) 4D trajectory on the ground, in the climb, on-route and descent phases of flight - the optimum horizontal path from departure to destination flown at the most fuel efficient altitude. This is not the case today as illustrated by Figure 11 below. There are several factors that may influence whether such an optimum trajectory may be flown. One factor is data sharing, as all actors (e.g. airline, airports at departure and arrival, network manager and often multiple national air navigation and data service providers) involved in the execution of a given flight will have to plan and execute their services based on a shared an agreed 4D trajectory⁸¹. This call for a very broad engagement of stakeholders in the future partnership as later described in section 4.

Figure 11: Breakdown of gate-to-gate excess CO₂ emissions for an average flight in Europe

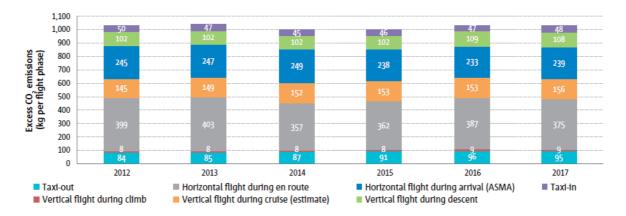
81 ICAO Environmental Report 2019

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⁷⁸ IATA, Aircraft Technology Roadmap to 2050 which provides an overview and assessment of technology opportunities for future aircraft, including improved engine efficiency, aerodynamics, lightweight materials and structures as well as radical new configurations and propulsion systems

⁷⁹ European ATM Mater Plan, Edition 2020, Figure 10

⁸⁰ European ATM Master Plan Companion Document on the Performance Ambitions and Business View



Source: European Aviation Environmental Report 2019, EASA, EEA and Eurocontrol.

Significant R&I effort is still needed to develop ATM technology enabling "perfect flights by design" (including for the next generation aircraft that will be cleaner and quieter) from an emission perspective eliminating all possible ATM infrastructure constraints that would result into a degradation of the optimum and thus generating extra emissions.

2.2. What are the problem drivers?

2.2.1. Lack of interoperability and fragmentation of current ATM systems

ATM infrastructure and services are provided by the Member States' air navigation service providers, over their territories⁸². The current infrastructure is the result of historical operational and technical evolutions, primarily conducted at the national level, which have led to today's fragmented system.

The cost of fragmentation of European ATM and communication and navigation services carries a high cost - around EUR 900m - EUR 1 400m annually, approximately 20-30% of the annual costs of air navigation service provision⁸³.

Initiatives such as SES and SESAR have led to improved interoperability and harmonisation but have not yet overcome this underlying fragmentation to enable truly seamless airspace operations⁸⁴.

To date however, as evidenced by the interim evaluation of the SESAR JU, the initiative has focussed on maturing solutions that optimise specific elements of ATM but has made slow progress on key enablers where there is limited industry consensus (for example, next generation datalinks and flight data processing) highlighting the need for greater emphasis on transformational technologies⁸⁵.



Stakeholder views: Interoperability was highlighted by many interviewees from ANSP, ATM institution, Member States, SESAR Joint Undertaking executives, staff, suppliers and U-space community stakeholder groups, as one of the key R&I needs and current problems of ATM. The responses show they believe that defragmentation is required in

This is the set-up for all the States members of ICAO. ICAO, Convention on International Civil Aviation, and its

Report commissioned by the Performance Review Commission - The impact of fragmentation in European ATM/CNS, Prepared by Helios Economics and Policy Services.

Single European Sky: a changed culture but not a single sky, Special Report 18/2017, ECA.

Interim evaluation of the SESAR Joint Undertaking (2014-2016) operating under Horizon 2020. Expert Group Report, European Commission (2017).

2.2.2. Limited flexibility and scalability of ATM service provision

Scalability is the capability to provide air traffic services at the right time and in the right place (in line with demand fluctuations – up or down). Although the situation has improved, each air navigation service provider optimises its resources and capacity locally (through airspace organisation and staff availability), with little coordination at European level. This is a crucial issue because the majority of flights in the EU airspace are cross-border. Today, this process takes a significant amount of time and results in limited flexibility for routing, flexibility for allocation of controllers, and leads ATM services to be either over or under-dimensioned at any given point in time.

As air traffic grows or is subject to severe fluctuations in demand (such as the ones observed during the COVID-19 crisis), it becomes more important to be able to take a network (or pan-European) view. Prior to the crisis some portions of the EU ATM network were running close to their structural capacity limit. In that case, any unplanned perturbation at local or network level results in significant disruptions and consequent delays and greater impact on the environment. "The analysis showed that the European core area where traffic density is highest remains the problem area".

2.2.3. Long R&I and deployment cycles

The ATM infrastructure is safety critical and shared across all Member States. Changes to this infrastructure therefore require working together across the whole aviation value chain (aircraft manufacturing, aircraft operations and infrastructure) and synchronising actions, even if some may have a negative business case on a given investment that needs to be addressed and overcome by creating confidence not only on technical feasibility but also in terms of on market uptake potential by a critical mass of early movers. That is why the ATM innovation cycles are long, as it often takes more than ten years from concept definition to deployment and entry in operations⁸⁷. The efforts of the SESAR JU have allowed reducing the R&I from about 10 to an average of 6 years, but a similar effort remains to be carried out for the industrialisation phase that ensures the transition of solutions from development to deployment.

ATM is heavily regulated: the safety and security-critical nature of the infrastructure is one of the reasons behind slow uptake, as each innovative solution needs to be proven not to decrease safety, or security and that it complies with national, regional and world-wide standards.

This in turn requires constant assessment of solutions as they are developed and matured across the TRL⁸⁸s. This can be a lengthy and often expensive process of collecting safety evidence, since no ATM procedure or tool can be implemented if it is not approved by either a local or European regulatory body.

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Performance Review Report: "An Assessment of Air Traffic Management in Europe during the Calendar Year 2018", Performance Review Commission, 2018.

For example, it took 15 years for Time Based Separation, which is a procedure aimed at more efficient management of arrivals into busy airports. See: EUROCONTROL Specification for Time-Based Separation (TBS) support tool for Final Approach - Ed. 1.0.

⁸⁸ Technology Readiness Level, as defined in the General Annexes of the Horizon 2020 Work Programme 2014-2015, Commission Decision C(2014) 4995,

https://ec.europa.eu/research/participants/data/ref/h2020/wp/2014 2015/annexes/h2020-wp1415-annex-g-trl en.pdf

During those time periods the solution under development evolves, due to the changing environment (i.e. economy, price of fuel, travel demand)⁸⁹. Innovations that are "robust", in the sense of being solutions that address the changing requirements have the best chance of reaching deployment.

The ultimate decision to implement a new technology would need to be accepted by all the involved organisations to ensure interoperability across Europe. Therefore, a high level of consensus from all the ATM stakeholders – airspace users (including new operators of drones), air navigation service providers, airports, regulatory and standardisation bodies - is required to finalise the R&I and transition towards industrialisation and deployment.

The need to accelerate innovation in ATM has been cited often in recent years 90.



The majority of stakeholders interviewed, across all stakeholder groups, indicated that deployment needs to be accelerated by paying more attention: to implementation challenges, change management for deployment, and gaps between R&I and industrialisation⁹¹.

2.2.4. Fast development of the new air vehicles and future business models

New forms of air vehicles are emerging at an unprecedented rate – in particular drones and air taxis for urban air transport. At the moment, the infrastructure that would allow for, and safely manage this type and magnitude of operations, does not exist. The USA, China and Europe are looking into the necessary concepts to develop an unmanned air vehicle traffic management (UTM) system⁹².

The fast evolution of drones – in terms of operational roles and platform capabilities creates new issues for the ATM system. The majority of drone operations (e.g. small drones that do not have the range to reach the altitudes in controlled airspace) are not expected to take place in traditional controlled airspace ⁹³. Instead, they will take place in what is currently referred to as uncontrolled airspace which is populated by general aviation flying by visual flights rules, and urban airspace which is not traditionally flown over but for which drones require access – for example for aerial photography, crowd surveillance or domestic deliveries.

This leads to three different issues:

a) How best to accommodate drones in controlled airspace, where they will be expected to operate in accordance with current rules and regulations, but where the varying levels of performance of the air vehicle can cause control/safety issues?

⁸⁹ Bolić, T., 2012. Innovation Adoption and Adaptation in Air Traffic Control – Interaction of Organizations. Journal of Sociotechnology and Knowledge Development

See for instance the Report of Wise Persons Group on the future of the Single European Sky, 2019

This statement from an R&D organisation stakeholder describes succinctly the issues around length of R&I and deployment cycles: "What often slows down the implementation is the development of standards and the regulatory approval. The direction and focus is really important to have – a good idea with a follow up plan (up to implementation) can bring about the innovation in ATM. Good idea without a follow up plan is not good, as is not good having a bad idea with the follow up plan. So, the screening of the ideas and results, and how they proceed through the research and development process is important."

In the USA: https://utm.arc.nasa.gov/index.shtml, https://utm.arc.nasa.gov/inde

European ATM Master Plan: Roadmap for the safe integration of drones into all classes of airspace, SJU, 2018.

- b) How best to accommodate drones in uncontrolled airspace where they will need technological solutions to detect and avoid manned aircraft? Again, the size and performance of the drones is critical to design solutions.
- c) How best to integrate multiple drones into urban airspace in a safe manner acceptable to the local population?

Creating a European U-space infrastructure will require significant R&I⁹⁴ in various areas of technology (e.g. conflict detection and resolution between the drones, the communication between the drones, their operators and other involved actors), interfaces with air traffic management, security and cyber reliance, along with the availability of authorised & safe testing environments. As the size and performance of drones are constantly changing, these issues even harder to address– particularly for an industry that has seen only limited change in aircraft operating performance in the past several decades.



ATM institutions and the U-space community, that were interviewed, stated that new markets such as drones develop quicker than the ATM solutions. In this area, the lack of coordinated R&I included in the ATM programme, would leave Europe behind other regions, like China and USA, which are investing heavily in drones and UTM research

and development.

2.2.5. The changing role of the human in ATM

ATM relies heavily on highly trained professionals able to solve complex situations on a regular basis. These professionals are able to handle a certain number of aircrafts and they represent about two thirds of the European ATM costs. On the other hand, the digital transformation of ATM triggers a radical increase in the dynamics of the system to secure its scalability (up - and also down, as the current crisis demonstrates) and resilience, ensuring that all air traffic is handled safely and efficiently, whatever the traffic scenario. In this context, the role of the human and of the interface between humans and the machines is a key driver for the success of the future system, as humans will continue to control the tools, use the support provided by machines to take decisions quickly and safely.

Digitalisation, automation virtualisation will generate a substantial change in the way ATM is organised and operated. No change of such magnitude can be successful without the implication and support of the staff concerned. R&I must have a strong connection with the operational staff and associate it to the development of the tools of the future, taking into full account the diversity of cultures, situations and labour laws within each State.

Change management, social dialogue, training and permanent staff involvement will be key requisites to the success of the European ATM modernisation and the achievement of the Digital European Sky.

2.3. How will the problem(s) evolve?

Unless the three problems linked to limited scientific capacity and fragmentation of R&I efforts are effectively addressed at EU level, it is likely that national programmes will re-

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⁹⁴ Section 4.2.4 of European ATM Master Plan: Digitalising Europe's Aviation Infrastructure. SJU, 2019.

emerge on an ad-hoc basis, especially in a post-COVID 19 world, to solve specific local issues generating increased fragmentation⁹⁵.

In these circumstances, the technological problem will lead to:

- Inability to adjust to crisis situations and to support growth: after the financial crisis in 2008 it took until 2016 for the number of flights in Europe to return to the levels seen in 2007. In the current situation, not only have we seen airlines either stop flying or operate at a "de minims" level, but airports close for flights too. Restarting is going to be a significant activity and should not be underestimated. This crisis provides nothing more than some "breathing space" for an ATM infrastructure that had already reached its structural capacity limits. The pressure on the ATM infrastructure to embrace a more digital future to become more cost efficient, resilient and scalable to fluctuations (up or down) in demand for air transport has therefore never been higher.
- Loss of competitiveness of European industry players: the industry has been one of the hardest hit with the COVID 19 crisis, with contracts cancelled, production halted and pleas for big bailouts. Unlike many other sectors in the digital economy, Europe is currently the world leader in aerospace and aviation infrastructure technology. Unless this opportunity is taken it is likely that Europe will lose its leadership position and become more dependent on imports from third countries.
- Unlikely or untimely uptake of innovation (i.e. lack of a common vision and needed evidence for standardisation and regulatory approval) that would therefore be less likely to be deployed to overcome inefficiencies at EU level, thus making it more difficult, time consuming and expensive to make the ATM system fit for addressing future challenges.

The economic problem described above will lead to:

• Reduced contribution to EU economy from autonomous air vehicles: drones provide new capabilities for government and defence applications, as wells as for commercial business opportunities. The spread and development of civil drones depends on their ability to operate in various areas of the airspace. This requires significant R&I on drone traffic management that, if not addressed, would reduce the estimated value of European drone market by EUR 10 billion annually by 2035 and over EUR 15 billion annually by 2050 to EUR 10 billion annually by 2035.

From an environmental perspective:

- Transition to climate neutrality for the whole sector cannot be reached: the aviation industry has committed in the long-run to bring into service a new generation of aircraft that will be cleaner and quieter (based on alternative propulsion systems, new airframes and energy sources) but this ambitious target cannot be achieved if ATM does not allow them to fly full exploiting their potential. ATM must evolve at a faster pace to bring environmental benefits in the shorter term.
- Aircraft will fly inefficient routes, increasing environmental impact: airspace congestion would impose inefficient routes on flights, increasing environmental

European Drones Outlook Study – Unlocking the value for Europe, SJU, 2016.

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See Annex X for further details on ATM R&I prior to SESAR.

Including technological solutions for conflict avoidance and better communications between the drones and other actors, security & cyber reliance, along with the availability of authorised & safe testing environments.

impact (additional 30 to 60 million tonnes of CO₂ over the period 2019-2035⁹⁸), and costs to airlines and passengers.

WHY SHOULD THE EU ACT?

Subsidiarity: Necessity of EU action

All identified problems described in Chapter 2 are currently being addressed at EU level:

- The Single European Sky defines the policy context;
- R&I is coordinated by the SESAR Joint Undertaking and
- Synchronised deployment is ensured through Common Projects.

Recent European Court of Auditors reports 99,100 found that the current policy, R&I and deployment initiatives have generated a change process, but that more efforts are needed in order to realise the full benefits of ATM modernisation: "It is therefore necessary to accelerate and better focus efforts on transforming the European ATM system into a digital, scalable and resilient network, through an approach coordinated at EU level".

This can only be achieved by transforming the current patchwork of national systems into a modern collaborative and distributed platform¹⁰¹, evolving from bespoke, product-based systems to a service, collaborative and adaptable network approach. Achieving an interoperable infrastructure is a prerequisite to unbundling the physical infrastructure from service provision and a fluid and secure access to ATM data. In this way air navigation services will be able to be provided irrespective of their physical location, at any moment and to any part of airspace. This requires significant R&I funding to develop and validate transformative technologies with a high degree of consensus from both Member States and the industry¹⁰².



Most stakeholders interviewed indicated that action from the EU was required to provide coordination and harmonisation across the ATM value chain. EU leadership will ensure that the European network benefits from a broad, synchronised implementation of the latest technology. Industrial stakeholders (suppliers and ANSPs) noted the need for long

term benefits justify investment and overcome their individual interests. They support developing solutions based on a common architecture rather than developing their own products in isolation.

Subsidiarity: Added value of EU action 3.2.

A modern, digital and efficient ATM system will support sustainable aviation growth in line with EU policies, namely the European Green Deal and achieving a Europe fit for the digital age.

It is estimated that by 2050, a harmonised European ATM system could generate over EUR 1,800bn in benefits for Europe¹⁰⁴ that will boost EU competitiveness, innovation capacity and

G.3.2 of A proposal for the future architecture of the European airspace, SJU, 2019.

Single European Sky: a changed culture but not a single sky, Special Report 18/2018, ECA.

The EU's regulation for the modernisation of air traffic management has added value – but the funding was largely unnecessary, Special Report 11/2019, ECA.

A proposal for the future architecture of the European airspace, SJU, 2019.

Further details on the necessary transformational technologies are provided Annex 6.

COM(2019) 640 final

See Table 38 in Annex 6 for a detailed breakdown.

the position of its industry in the global market. Realising the benefits will largely depend on the ability of the sector to create the conditions to shorten the innovation life cycle for infrastructure modernisation. If these conditions are not created, the transformation will likely take significantly longer with negative implications for the environment, jobs and growth in Europe.

Addressing this challenge in a rapidly evolving and demanding context requires a significant collective effort in boosting cooperation and investment on innovations that cannot be addressed by any single stakeholder or Member State alone as, by essence, aviation is international and requires common and coordinated action. This is particularly true for the European infrastructure supporting aviation due to the scale and cross-border nature of the problems and the wide range of stakeholders involved. Only action at EU level can improve results in such a fragmented sector.



All stakeholders interviewed indicated the need for EU funding on ATM research to provide directionality and coherence due to the cross border nature of operations and the need for interoperability.

4. OBJECTIVES: WHAT IS TO BE ACHIEVED?

4.1. General objectives of the initiative

Based on the identified problems, the overall objective of the proposed initiative is to develop and validate ATM technological solutions that support the achievement of the Digital European Sky making the European airspace the most efficient and environmentally friendly sky to fly in the world and support the competitiveness and recovery of the aviation sector in a post-COVID crisis Europe.

The work to be carried out by the initiative will enable a substantial transition from current ATM systems to the new Digital European Sky vision of the European ATM Master Plan and will produce noticeable, quantifiable contributions to growth and climate targets in 2030 and pave the way for climate neutrality by 2050.

There is a significant change in scope compared to the current SESAR JU, with more focus on breakthrough innovations, industrialisation and market uptake. The following general objectives have been identified:

- Strengthen and integrate the EU's research and innovation capacity in the ATM sector, helping bring the European ATM into the digital age to make it resilient, scalable to fluctuations in traffic while enabling the seamless operation of the next generation of aircraft, which will be cleaner, quitter and more autonomous,
- Strengthen through innovation the competitiveness of manned and unmanned EU air transport and of the ATM services market to support a robust economic growth and recovery in a post-COVID 19 world in the EU,
- Develop and accelerate market uptake of innovative solutions to establish the Single European Sky airspace as the most efficient and environmentally friendly sky to fly in the world

These objectives address the aviation value chain, which was severely affected by the COVID 19 crisis, from a broad perspective and are aligned with the objectives of the Horizon Europe framework. Their achievement will contribute to several Sustainable Development Goals with

the most impact on SDG 9 (Industry, Innovation and Infrastructure), SDG 13 (Climate Action) and SDG 8 (Decent work and economic growth).

4.2. Specific objectives of the initiative

The future partnership will only be successful if all partners will continue to remain committed to the objectives established by the European ATM Master Plan. Significantly more efforts and investment than in the past are needed from all stakeholders involved to ensure the delivery of technical solutions able to advance smoothly through standardisation and certification processes.

Therefore, in order to achieve the general objectives, six specific objectives are defined. They respond to each of the problem drivers discussed in Section 2.2.:

- Develop a R&I ecosystem covering the entire ATM and U-space value chains allowing to build the Digital European Sky¹⁰⁵ defined in the European ATM Master Plan, enabling the collaboration and coordination needed between air navigation services providers and with airspace users to ensure that a single harmonised EU ATM system for both manned and unmanned operations;
- Develop and validate breakthrough ATM solutions supporting high levels of automation;
- Develop and validate the technical architecture of the Digital European Sky;
- Support an accelerated modernisation of ATM infrastructure through a network of demonstrators and facilitate the development of standards for industrialisation.
- Maintain a consensus-led strategy for EU ATM modernisation

Meeting the afore-mentioned specific objectives should be measured against the capacity of the future partnership to execute the following core activities:

- Organise and coordinate the SESAR definition (maintenance of the European ATM Master Plan), development and industrialisation phases (further developed in the SRIA) to stimulate and reinforce the EU scientific, operational and industrial ecosystem for innovation in aviation infrastructure;
- Develop and validate breakthrough ATM solutions, supporting high levels of environmental performance, resilience and scalability. The objective by 2030 is to deliver the solutions identified in the European ATM Master Plan for Phase D ("Digital European Sky") at TRL 6;
- Accelerate market uptake by establishing a European network of large-scale digital sky demonstrators to build confidence and bridge the gap between research and implementation. The demonstrators should be closely connected to the standardisation and regulatory frameworks to advance the maturity of the solutions smoothly through standardisation and certification processes. The objective by 2030 is to accelerate market uptake (up to TRL 8) for a critical mass of "early movers" representing minimum 20% of the targeted operating environment in Europe.
- Facilitate interactions between innovators, early movers and regulators to help develop regulatory frameworks that allow the benefits of digital technologies to be fully realised with due consideration for the human dimension.

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^{&#}x27;Digital European Sky' refers to vision of the European ATM Master Plan, seeking to transform Europe's aviation infrastructure enabling it to handle the future growth and diversity of air traffic safely and efficiently, while minimising environmental impact.

• Support the Union in coordinating global interoperability efforts and promote European R&I results in relevant international fora.

It is important to note that issues related to the policy, regulatory and financial framework have to be addressed in parallel and/or factored in so that the initiative is able to achieve its objectives and effectively contribute to the relevant EU policies and targets from a broader perspective. This could be addressed by future developments of the regulatory framework and EU aviation relevant policies and strategies.

Many of the respondents to the Open Public Consultation took the opportunity to underline key messages regarding the initiative:

The initiative should bring together the key stakeholders of the value chain in order to agree on the key European issues whilst keeping it manageable. It is important, as commented by some stakeholders across all the categories, to cover the UTM value chain and include other actors such as business aviation, regulators, communication service providers and satellite communication service providers, and, as said by all, a strong involvement of EASA and standardisation bodies.

Air navigation service providers and manufacturers agree that European R&I ATM has a strong position worldwide due to having built over years a coordinated programme, which has allowed Europe to have a strong voice in ICAO and set trends parts of the world. Interviewees also noted that closer cooperation and involvement of EASA and EUROCAE would support narrowing of the gap between the R&I and industrialisation phases.

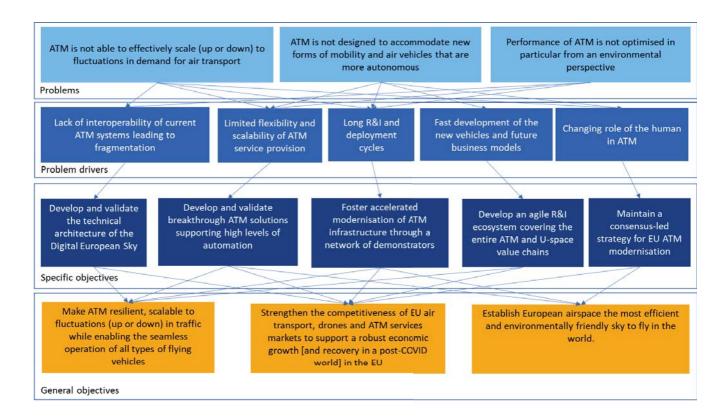
Stakeholders with long experience in ATM research recalled the period prior to the establishment of the SESAR JU and the adoption of the European ATM Master plan. They agree that in ATM, European network benefit is only achieved if efforts are coordinated and building on a commonly agreed Roadmap/Plan agreed between the industry, the Union and the Member States.

Stakeholders across all groups pointed out the need to close the industrialisation gap between R&I and deployment in order to support the pull through of breakthrough technologies.

4.3. Intervention logic

The relationship between the general and specific objectives of the initiative on integrated ATM R&I is shown in Figure 11.

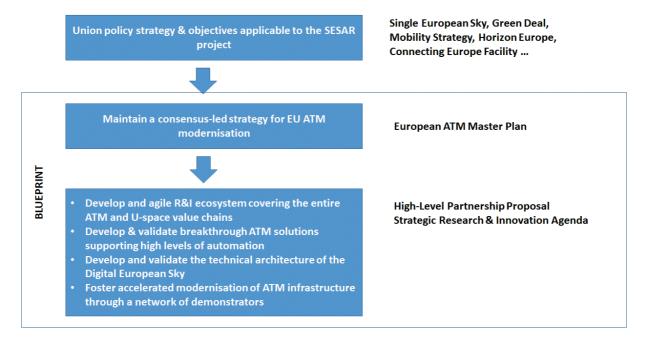
Figure 11: Intervention Logic for the initiative on integrated ATM



How the intervention logic fits in the broader policy context

As explained in Chapter 1, the investment into this initiative facilitates the development of technologies which support the success of the Single European Sky policy of the Union. Figure 12 below outlines how different planning instruments link with each other and relate to the policy.

Figure 12: Intervention Logic in the policy context



How would success look like?

Should the initiative deliver on its specific objectives, it is expected that it would result in the following impacts:

Scientific impacts

New scientific knowledge and reinforcement of EU scientific capabilities

If successful, the R&I ecosystem established and supported by this initiative would develop and validate new technological and operational ATM solutions that help develop new scientific knowledge and reinforcement of EU scientific capabilities. This impact should start being visible over the medium term and should continue even after the end of the R&I.

The development of ATM solutions would make use of new scientific methods, in particular digital technologies (e.g. big data, automation, AI, virtualisation). This would generate new data, use cases and applications that test and reinforce these technologies.

The planned R&I activities would require and involve a wide range of expertise from various scientific and engineering disciplines, such as aviation and infrastructure engineering, communications, operations research, computer science and thus helps build the cooperation and scientific exchanges between these branches.

Enhanced capacity among the next generation aviation professionals:

The benefits of bringing the ATM infrastructure into a digital age to users and businesses in the whole aviation value chain (i.e. including aircraft manufacturers and aircraft operators) and the economic growth that could come via their productivity contributions, are compelling ¹⁰⁶. This will not only contribute to a more resilient and sustainable EU economy that creates jobs but also help expand the knowledge base and skill sets of academia and companies' staff.

In order to be able to develop the needed ATM solutions, and to facilitate the best performing ATM in the future, next generation ATM professionals would need to be aware of this science. Apart from performing research, the goal of academia, in general, is to promote knowledge transfer to the next generation of professionals through the involvement of Ph.D. students and post-doctoral students in the R&I research activities. This would enhance the capacity among the next generation of aviation professionals, which would likely have a strong impact on the education of the next generation of experts. This impact would start being evident at the medium term and continue throughout the lifetime of the initiative.

Economic/technological impacts

Overall, this initiative will facilitate the setup of an aviation infrastructure that supports the growth and recovery of Europe in a post-COVID world and that opens up digital opportunities for people and business while enhancing Europe's position as a world leader in the digital economy.

If successful, the initiative would allow for an accelerated delivery of innovative ATM solutions needed for all types of aircraft operations that help improve the flexibility of the European ATM network and systems. This would allow for the **handing of additional flights and thus facilitating growth in the air transport sector**.

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¹⁰⁶ European ATM Master Plan Edition 2020

Safely and efficiently integrating drones and drones traffic management systems with the ATM systems would facilitate **the ramp up of drones-related economic activities**, opening up the market for new types of drones services operators and drones traffic management service providers.

A Europe-wide agreed ATM architecture relying on inter-operable ATM solutions standardised and certified at European level would give Europe a strong voice at international level, where European technologies can and should be the backbone of global ATM modernisation plans coordinated by ICAO. This would boost the EU industry globally by enabling international agreements and contracts.

The economic impacts have been evaluated as part of the recent European ATM Master Plan update campaign¹⁰⁷ and assume an effective roll-out of R&I results into operations are summarised in Table 1.

The figures represent an estimated direct gross domestic product (GDP) contribution generated by SESAR in the ATM value chain (ATM equipment manufacturers, aircraft manufacturers, military, airspace users, ANSPs, Network Manager and airports). All calculations are available in the supporting document to the European ATM Master Plan Edition 2020 (titled "Master Plan Companion Document on the Performance Ambitions and Business View").

Table 1: Expected economic impacts

Expected impacts	Quantification Method	Value
Ability to handle additional flights enabling growth in air transport	Direct benefits of ATM value chain Cumulative Benefit up to 2050	€510b
Enable new economic activity based on drones	Direct benefits of the U-space value chain Cumulative Benefit up to 2050	€350b
Boost EU industry globally through international agreements and the setting of global standards	Grow market share to 70% of the global market of approximately €4b per annum Cumulative Benefit up to 2050	€84b

Source: Master Plan Companion Document on the Performance Ambitions and Business View. 1.0, SJU, 2019.

Aviation is a resilient industry which has been hit by a number of shocks in the past. Whereas COVID-19 is currently creating unprecedented low traffic levels, in the medium to long term, there is little doubt that aviation will return to growth. Moreover, the COVID-19 crisis does not change the need for the European ATM system to become more automated, more scalable and more resilient in its support of European aviation while reducing the environmental impact and improving cost efficiency.

Societal impacts (including environmental impacts)

The contribution of ATM to passenger experience and to the implementation of efficient multimodality, including urban air mobility, will be a major factor in how the society will view the aviation industry in the future. The passenger experience will be optimised by

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Master Plan Companion Document on the Performance Ambitions and Business View. 1.0, SESAR, 2019.

focusing on departure and arrival punctuality on the aviation legs of the multimodal journey, reducing time spent at airports. Optimisation will also be achieved through the effective sharing of multimodal connection data with other modes of transport, enabling an integrated approach to reducing door-to-door travel time.

A digital European sky will ensure that passengers do not lose time at airports or in the air in Europe. In doing so, it could save yearly up to 14.5 million hours that passengers will be able to spend instead with their family or at work.

If the initiative is successful, and the R&I results implemented, the expected societal impacts would be reduced travel times, improved predictability, reduced delays and lower costs. This would improve both the passenger experience and business opportunities.

Table 2: Societal Impacts

Expected impacts	Quantification Method	Value
Improve passenger experience by reducing travel time, delays and costs	Indirect benefits for passengers and EU citizens. Cumulative Benefit up to 2050	€760 Bn

Source: Master Plan Companion Document on the Performance Ambitions and Business View. 1.0, 2019.

The figure of EUR 760bn corresponds to a monetisation of the societal impacts of SESAR to EU citizens. It was calculated by independent experts who assessed the passengers benefits from the additional mobility (more flight options) and time saved (lower delays and shorter flights). It also assesses the benefit for the European society of having lower air pollution and lower climate change impact - driven by lower fuel burn - per flight. All calculations are available in the supporting document to the European ATM Master Plan Edition 2020 (titled "Master Plan Companion Document on the Performance Ambitions and Business View" section 4.2.3.3. "Indirect benefits for passengers and European citizens").

In more concrete terms, focus areas include emission-free taxiing and solutions to optimise airport and terminal airspace operations, such as exceptional holdings and more continuous climb and descent operations, while curved, steep and/or segmented approaches and noise-preferential routes are being considered for deployment to address noise reduction. Urban air mobility will depend on electric or hydrogen-powered vehicles that will be emission free, with R&I ensuring that noise levels are minimised for the general public.

Environmental impacts

A digital European sky could save 28 million CO₂ tonnes per year, which is roughly equivalent to CO₂ produced by 3.2 million people or the population in the metropolitan area of a city like Madrid.

The technological progress resulting from this initiative would ultimately lead to optimising flight trajectories and traffic flow, i.e. planes being able to fly the cheapest, shortest route possible while maintaining the required high safety levels. This would contribute to the long-term goal of reducing aviation noise and gas emissions (i.e. 5-10% less CO₂ emissions per flight by 2035) from an ATM-operational perspective.

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¹⁰⁸ https://www.atmmasterplan.eu/

The EUR 12bn. estimated impact corresponds to the fuel savings (and reduced emissions) that could be realised by aircraft operators with the current fleet.

Table 3: Expected Environmental Impacts

Expected impacts	Quantification Method	Value
Reducing aviation noise and gas emissions	Reduction of 240 kg to 450 kg of $\rm CO_2$ on average per flight due to improved flight efficiency	€12b
CHIISSIOHS	Cumulative Benefit in terms of fuel savings up to 2050	

Source: A proposal for the future architecture of the European Airspace, SESAR, 2019.

Open public consultation: A majority of stakeholders, across all stakeholder groups, pointed out that the initiative can and should make a significant contribution to the EU efforts to achieve climate-related goals – 54% chose very relevant, and 29% relevant. The two identified campaigns stated that it was very relevant (59%), or relevant (40%).

Social impacts

In ATM as in all industries, the human capital is a critical and an integral element of the system. Changing demands on ATM require a radical increase in the dynamics of the system to secure its scalability (up and down) and resilience, ensuring that all air traffic is handled safely and efficiently, even under the highest traffic growth forecast or during stagnation or unexpected downturn.

The goal of automation is not to replace the human but to optimise the overall performance of the socio-technical ATM system and maximise human performance. This will require the development of the role of the human in parallel with ATM concepts and technological developments. New tools are needed to support continuous, system-wide monitoring of all critical processing, including during degraded modes of operation or, for example, cyberattacks. New tools must also enable humans to make effective decisions, including where collaborative, co-adaptive and joint intelligence modes of decision-making are used. A move from executive control to supervisory control will require a thorough understanding of the implications for the humans and their interaction with the systems. The human-totechnology balance is likely to vary between domains, where some problems might be solved by automation with little human intervention, while other areas might require a human, monitored by an automated safety capability to solve the problem. Research will need to address all the roles, responsibilities and tasks of the different actors (airborne and ground, ATM and U-space, operating and technical), training needs and change management for the evolving roles as per the recommendations provided by the Expert Group on the Human Dimension of the Single European Sky.

4.4. What is needed to achieve the objectives – Key functionalities needed

Given the focus of the impact assessment on comparing different forms of implementation, the identification of "key functionalities needed" allows making the transition between the definition of the objectives and what would be crucial to achieve them *in terms of implementation*. These functionalities relate to the type and composition of actors that have to be involved, the type of range of activities that should be performed, the degree of directionality needed and the linkages needed with the external environment.

4.4.1. Type and composition of the actors to be involved

The core objective of the proposed initiative is to support an ambitious modernisation of European ATM enabling collaborative service provision based on high levels of automation. It is important the ATM solutions proposed and matured by the R&I are supported by the full range of ATM stakeholders. The future R&I on integrated ATM should therefore be open to:

- a) Suppliers of "ATM solutions", i.e. air and ground system manufacturers and ATM data service providers.
- b) New entrants particularly active on emerging autonomy and connectivity solutions (such as but not limited to urban air mobility, U-space, mobile network operators).
- c) Operators and users of the system namely air navigation service providers, airport operators and airspace users including both civil and military organisations.
- d) The Meteorological community such as MET service providers
- e) EASA and national authorities to ensure smooth progress through certification and regulatory processes.
- f) EUROCAE and other standardisation bodies to deliver the next generation standards
- g) EUROCONTROL (an inter-governmental organisation) as a key actor in European ATM with a large R&I capability and specific operational roles in terms of managing the ATM network.
- h) The European Space Agency (ESA) and satellite communication providers as the sector may allow to develop highly innovative solutions for the benefit of aviation
- i) Research establishments that mainly perform applied research and are increasingly engaging in supporting the introduction of breakthrough innovation into the market
- j) The ATM R&I community of universities and specialist SMEs that currently support exploratory research.
- k) The professional staff associations to ensure the involvement of operational staff in the development of new concepts as well as R&D validation activities
- The wider R&I community that could support the adaptation of new technologies (e.g. digitalisation, earth observation, satellite navigation, climate science, et.) to the ATM context.

4.4.2. Type and range of activities needed

Flexibility in the selection of projects, implementation and membership will be crucial to ensure that the partnership is empowered enough to deliver. In practice, there is need for a balance between long term vision and stability of the programme and flexibility (e.g. evolution in partners, adjustments in investment levels to advance – or not – to higher TRL levels etc.) to ensure it remains relevant and responsive to new market, industry and technological developments.

In order to ensure flexibility of implementation so as to reach its intended objectives the initiative should conduct the following activities:

(I) Seek synergies with R&I programmes of other sectors and initiatives. In particular, strong links are already identified (but not limited to) with the candidate European Partnerships on clean aviation

- (II) Coordinating R&I actions ranging from concept to demonstration activities for a critical mass of early movers (covering all Technology Readiness Levels), ensuring inclusion of new actors and integration of extended value chains
- (III) Organising and coordinating the European ATM Master Planning activities defining the SESAR vision and the related development and deployment priorities and plans securing due involvement of all Member States
- (IV) Coordinating industrialisation processes fostering and acceleration of market uptake and solutions able to advance smoothly through open standardisation and certification processes
- (V) Co-creating solutions with end-users, emphasising the importance of flexibility in addressing different target groups over time (potential down-stream and end-users, public authorities and broader stakeholder communities), including industrial end users beyond the transport sector
- (VI) Facilitating flexible and efficient interactions between breakthrough innovators, early movers and regulators to help develop regulatory frameworks that allow the benefits of digital technologies to be fully realised with due consideration for the human dimension
- (VII) Coordinate global interoperability efforts and promote European R&I results in relevant open international fora and
- (VIII) Ensuring the necessary funding for these activities in accordance with the ATM Master Plan and SRIA.

4.4.3. Priority setting and level of directionality required

Europe's common vision to replace the current fragmented national systems with a new collaborative platform at EU level is the Digital European Sky defined in the European ATM Master Plan. The Master Plan is the basis on which the strategic research and innovation agenda (SRIA) for the future R&I programme is built, as it has the support of the ATM stakeholder community and of the Member States. It is critical that stakeholders with strategic roles in the sector remain committed to the partnership. Industry should be ready to continue to improve the performance, cost and reliability of solutions. A partnership naturally encourages the cooperation between stakeholders who are otherwise competitors, working together on the basis of a jointly agreed multi-annual plan addressing common goals for the sector.

A first draft of the SRIA was developed with the full involvement of the members of the current SESAR JU, as well as with potential future partners of the new partnership. The process for finalising it will include a public survey to solicit input and comments from the wider ATM stakeholder community, including new entrants.

Less mature solutions should also continue to be supported. Political support from both the Member States and the Union is needed and often the technological solutions (e.g. for safety) are not necessarily economically viable.

To conclude, the level of directionality should be as high as possible for the initiative to reach its expected impacts. The strategic vision should be shared and implemented as much as possible by the key stakeholders along the whole value chain.

4.4.4. Coherence needed with the external environment

As the infrastructure is shared but still fragmented across all EU Member States, often used by a wide (and ever widening due the potential offered by drones) range of both civil and

military use cases, ATM modernisation should be addressed through close collaboration frameworks with other programmes and initiatives to create synergies and limit duplications. Regarding other initiatives such as (but not limited to) Clean Aviation, it is crucial to share views on the ways to integrate the next generation of aircraft that will be cleaner and quieter and ideally to share a common vision to define where to concentrate efforts. Joint or coordinated calls, including their funding and management, would be the next step to ensure full coherence with other initiative's agendas. Beyond air transport ATM R&I should also ensure that it remains coherent with wider R&I initiatives such as:

- Multi-modal transport (such as candidate partnerships related to road, waterborne and rail transport), as ATM systems need to be aware of performance requirements to support multi-modal transport. For example, to ensure inter modal connections can be made by passengers.
- Digital technologies and Climate Science, where ATM needs to be aware of and adapt to the ATM context the technologies for data manipulation and distribution, cyber security, advanced decision making including big data, artificial intelligence and findings and recommendations on climate change.
- Similar R&I programmes in other World regions, in particular the US or China to ensure the global convergence of technologies, standards and ultimately of the operational environment for the airspace users.
- Promote synergies with programmes at EU, national and regional level (e.g. Connected Europe Facility Programme, Digital Europe Programme) to ensure deployment.

Due to its interlinkage with other sectors and research initiatives, the initiative should be set up in close collaboration with other programmes and initiatives to create synergies and limit duplications. It is essential to ensure that the governance of the initiative appropriately addresses these collaborations to improve administrative procedures. An initiative able to provide support to potential project partners could also simplify the administration, in line with the recommendations of the Interim Evaluation for the initiative^[1].

Other key elements related to the framework conditions will play a role in the ability of the initiative to reach its objectives. This concerns in particular the next steps after R&I activities, namely the wider scale (beyond a critical mass of early mover) market uptake of R&I results across Europe (including e.g. standards evolution). To ensure supportive framework conditions, the initiative should ensure close collaboration and engagement with end users, citizen, policy makers and regulators as a central step in spurring the setting up of suitable regulatory frameworks and the establishment of market uptake conditions. Furthermore there is a need to link with other crucial funding and financing mechanisms (CEF in particular) to create synergies and realise the targeted impact for the partnership. Beyond CEF complementarity with other funds such as (but not limited) the European Green Deal Investment Plan (EGDIP) and the European Defence Fund (EDF) as well as risk capital players should be sought to finance scaling up activities to the market.

Recommendation 4 of the Interim Evaluation Report on the SESAR JU 2014-2016 https://ec.europa.eu/research/evaluations/pdf/sesar2020.pdf

5. WHAT ARE THE AVAILABLE POLICY OPTIONS?

This section describes the specific functionalities that could be provided under the baseline scenario of traditional calls as well as the different options of different types of European partnerships

5.1. What is the baseline from which options are assessed?

The baseline scenario used in this impact assessment is a situation without a Partnership building on traditional calls of Horizon Europe. Given that there is an existing Partnership as well as other funding sources in the area, these will continue generating effects even if there is no new Partnership. In particular it is expected that these already existing initiatives will still have an impact in the coming years. This is taken into account in the effectiveness assessment.

In parallel, the baseline situation means that the current implementation structure of the Article 187 would be closed, which entails winding down and social discontinuation costs. There would also be financial cost-savings related to the closing of the structure, related to operations, staff and coordination costs in particular. This is taken into account in the efficiency assessment

Table 4: Key characteristics of the baseline situation, i.e. Horizon Europe calls

	Functionalities of the option
Enabling appropriate profile of participation (actors involved)	 The Commission would need to consult extensively with a wide range of stakeholders to translate the existing European ATM Master Plan (covering priorities for both R&I and implementation) into a more detailed R&I plan (a Strategic Research and Innovation Agenda (SRIA) and an annual work programme. A well-defined process would be needed to ensure that the programme committees were properly informed about ATM R&I priorities, including the need for key demonstration programmes. The specification of calls over the period of the Framework Programme will reflect the need for an evolving profile of participation, with different consortia forming at different stages to take different types of activity forward.
Supporting implementation of R&I agenda (activities)	 Implementation would be limited to running R&I projects relying on standard infrastructure underpinning the open calls procedure, drawing on resources of relevant executive agencies and Commission IT systems. Without proper coordination there is a risk for delays in transitioning the R&I results into deployment. Moreover, due to the complexity, fragmentation and safety critical nature of ATM, this could be challenging also from a scientific perspective. Administrative costs for the European Commission would be significantly reduced, but potential impacts, coverage and contribution to Union's policies are reduced as the full range of activities needed (see section 4.4.2.) could not be covered Calls for proposals would be published in the work programmes of Horizon Europe. Transparency and open publication of results would ensure their broad availability to all interested parties. Dissemination of knowledge among participants would only possibly take place within the consortia answering the calls. The individual consortia may have limited incentive to initiate and maintain the coordination activities with standardisation bodies.

Ensuring alignment with R&I agenda (directionality)

- Organising and coordinating at strategic level the European ATM Master Planning activities to
 ensure alignment between the R&I agenda and results into changes to the ATM infrastructure will
 be very difficult and may lead to reduced market uptake and a further lengthening of the
 innovation cycles in ATM.
- Annual Work programmes would need to reflect the requirement for R&I activity across TRLs, with input from representatives of all relevant stakeholders.
- Specification of calls for activity at higher TRLs, particularly demonstration programmes, would need substantial input from industry.
- Selection of high TRL projects would require provision of external and independent expert advice to the Commission.
- Commission input into specification of calls would help to ensure alignment with overarching policy objectives.

Securing leveraging effects (additionality)

- Progress of R&I effort would depend largely on EU funding, with no expectation of (significant) commitment and contribution from the side of the industry.
- Demonstration programmes would require significant in-kind support and collaboration from industry, but there is no certainty that critical mass could be reached.

Key differences compared to the current situation

- The long-term commitment to a common vision by a wide range of stakeholders would be lost at a time when the sector has been severely affected by the COVID-19 crisis.
- The position of Europe as a world leader in technology supporting aviation infrastructure may be lost to emerging challenges from e.g. China
- The leverage effect achieved today by the Union's intervention would be lost
- No additional synchronised investments by the industry
- The system would revert to a more national approach, undermining the achievements at EU level over the last 12 years.
- Integration into the SESAR innovation cycle and links with industrialisation and deployment would be weakened

5.2. Description of the policy options

Table 5: Key characteristics of Option 1 – Co-Programmed European Partnership

Implications of option Enabling • The option would enable participation of key private stakeholders committed to support the appropriate development and implementation of the programme of research and innovation activities (based profile on a joint strategic R&I agenda). participation • The direct participation of inter-governmental organisations and agencies who have already (actors involved) expressed interest to participate (Eurocontrol, European Space Agency) will be more difficult to secure compared to option 2. • It would need to consult with a wide range of stakeholders to ensure that the R&I agenda, and ultimately the work programme, is aligned with the broader industry and market needs. • Usually run by one or several associations or consortia, it is very flexible for new partners to join over time (e.g. to support new areas of activity in response to emerging results and changing priorities **Supporting** • Implementation of EU funding would rely on standard administrative infrastructure underpinning implementation the open calls procedure, drawing on resources of relevant executive agencies and Commission IT of R&I agenda systems. The full range of activities planned could be implemented. (activities) • Integrating and transferring the outcomes of R&I results into day-to-day operations while keeping a focus on accelerating market uptake and shortening innovation cycles as defined in the European ATM Master Plan will require to put in place complex inter-institutional arrangements at EU level as well as with inter-governmental organisations such as EUROCONTROL and the wider industry to leverage and recognise the results delivered by the coordinating association/consortium. • Calls for proposals would be published in the work programmes of Horizon Europe. • Work programmes would need to reflect the requirement for R&I activity across TRLs, with input from the various partners to achieve an appropriate balance of activities. • Partners implement their additional activities separately. A coordinating association/consortium would provide back-office that provides support to facilitate the coordination of activities (e.g. organising meetings, events, drafting inputs, papers, etc.)

• By using the HE standard implementation, calls are more transparent and accessible for applicants.

Ensuring alignment with R&I agenda (directionality)

- The partnership would be responsible for ensuring that priorities for calls were specified in line with R&I priorities across all TRL levels.
- R&I activity would be likely to focus on the medium-term needs of the industry.
- The partnership would be responsible for ensuring that priorities for calls were specified in line with RD&I priorities, including demonstration projects
- Programme Committee has an important role in ensuring alignment with overarching policy objectives and coordination with related programmes.
- Coordination of global interoperability efforts and the promotion of European R&I results in relevant international fora (such as ICAO) will be difficult to achieve

Securing leveraging effects (additionality)

- Aspirations for partner contributions would be clearly defined in the MoU.
- Commitments from the industry are expected to match the Union contribution (most likely only in-kind contributions).
- Expected in-kind contributions from the private sector would be identified in the work programme.
- The commitment of Eurocontrol to allocate financial resources to the initiative, matching the Union's contribution in value is at risk.

Key differences compared to the current situation

- No Union body to coordinate all ATM research & innovation in Europe and to provide policy and technical assistance to the Commission.
- Fewer mechanisms to project the Union's policy priorities versus the industry's individual goals.
- Limited/reduced participation from Eurocontrol.
- Limited ability to boost the European industry globally through international agreements and the setting of global standards.
- Limited ability to coordinate and reinforce the Union's scientific capabilities

Table 6: Key characteristics of Option 2 – Institutionalised European Partnership (Article 187 TFEU)

	Implications of option
Enabling appropriate profile of participation (actors involved)	 This option would enable participation of major key stakeholders (see section 4.4.1) through a clearly defined membership structure, including the participation of Eurocontrol or the European Space Agency. It will be more difficult for smaller players, like SMEs and academia to be able to join as full members. It would provide a platform for consulting stakeholders on R&I priorities and the work programme, ensuring that they were aligned with ATM in particular and aviation in general. Participation would be less flexible than under other options, but it might nevertheless be possible to change the profile of participation over time, with new partners joining to support new areas of activity in response emerging results and changing priorities.
Supporting implementation of R&I agenda (activities)	 A dedicated administrative structure would be established to coordinate the full range of activities defined in section 4.4.2, to manage implementation and report on the results (with administrative expenditure limited to up to 5% of the budget). Calls for proposals would be published broadly in the Funding & Tenders Portal by the administrative structure. Dissemination of knowledge and share of practices would happen among the stakeholders of the community, with potential diffusion activities managed by the partnership structure. As an EU body, upon a mandate from the Commission, this type of partnership can represent the EU at international bodies such as ICAO and with international governments – supporting the coherence and interoperability of ATM systems world-wide.
Ensuring alignment with R&I agenda (directionality)	 Based on a joint Agenda, this form of partnership allows the development of a work programme fully in line with the R&I priorities identified by the industry to fulfil the European policy needs, combining activities across low and high TRLs and in different areas. The work programme would build a synergy between the Union's policy objectives and the

	technical capabilities of the industry. • Commission participation in the partnership governance arrangements and approval of the work programme would help to ensure alignment with overarching policy objectives and enable integration with other programmes.	
Securing leveraging effects (additionality)	 Funding requirements would be clearly defined at the outset, with the private sector and intergovernmental organisation partners (EUROCONTROL) more leverage than a simple matching of Union funding. 	
Key differences compared to the current situation	1 1/1 &	

5.3. Options discarded at an early stage

The Co-funded Partnership and an Institutionalised Partnership created under Article 185 of the TFEU are not considered beneficial for the integrated Air Traffic Management initiative.

In the public-public partnership options (co-funded or Art. 185), the partners do not include private sector companies or private research organisations and instead include only public authorities who fund research (or governmental research organisations) and other public authorities at the core of the consortium. These types of partnerships rely on pooling and/or coordinating national programmes and policies with Union policies and investments, to help overcome fragmentation. Due to the limited existence of national R&I programmes in the area of ATM and the lack of relevant public bodies, there is little interest for Member States and their agencies to be involved in such partnerships.

Nevertheless, Member States are keen to be active in ATM R&I but through the national ATM service providers (funded by the airspace users) rather than the public purse.

Furthermore, the ATM R&I programme requires strong consensus to ensure that the results are directly deployable within the emerging architecture and are acceptable to the professionals that operate the system. This is best achieved by air navigation service providers working closely with the manufacturers and building on inputs received from the broad range of stakeholders in the ATM community.

The options dedicated to public-public partnerships are therefore not considered viable and not considered further.

6. How do the different policy options compare?

Based on the objectives pursued by the initiative and the key functionalities identified to be able to achieve them, each option for implementation is assessed in terms of effectiveness, efficiency and coherence compared to the baseline scenario of traditional calls. The analysis is primarily based on the degree to which the different options would cater for the key needed

functionalities. All options are compared to the baseline situation of traditional calls, which is thus consistently scored at 0 to serve as reference point.

6.1. Effectiveness

To be in line with the Horizon Europe impact framework, the fulfilment of the specific objectives of the initiative is translated into 'expected impacts' - how success would look like, differentiating between scientific, economic/technological, and societal (including environmental) impacts. This section considers to which extent the different policy options would allow delivering these expected impacts – confronting what is needed (functionalities) with what each form of implementation can provide in practice. The assessments in this section set the basis for the comprehensive comparative assessment of all retained options against all dimensions in Section 6.4, based on a scoring system ¹⁰⁹.

Scientific impacts

A) Strengthening the EU's scientific capabilities and improving the scientific knowledge in ATM can be achieved by continuing to support and reinforce an ATM R&I ecosystem that is capable of rapidly developing and validating modern technologies that build on the upcoming digital transformation elements, such as automation, AI, big data and cyber-security. Due to the specific challenges related to ATM infrastructure modernisation (safety critical, significantly regulated), without a long-term focus and commitment from both the research and the industry communities across multiple research disciplines, Europe's ATM sector will not be able to adapt quickly enough to help the aviation sector to grow out of the COVID-19 crisis more sustainable and smart.

The baseline option (open calls) is flexible to adapt to the changing needs of the sector, in particular concerning rapidly emerging technologies, such as drones. This option could manage fundamental/exploratory R&I activities well enough (and could be complementary to partnerships) if there was a centralised research agenda. However, this option does not provide an effective EU (and global) coordination platform for science transfer to advance the application of exploratory research results with industry to find common solutions to specific questions of a concrete nature.

Option 1 could deliver more impact than the baseline option, in particular concerning industrial research at higher TRL levels, where large players investing in a partnership could lead to a strong push for breakthrough technologies. SMEs and academia, as smaller stakeholders who find it harder to join the partnership may have a reduced role. The option scores **good** compared to the baseline (+).

Option 2 would ensure long-term coordination of the R&I programme to guarantee that the necessary scientific breakthroughs are prioritised to support long term evolution of ATM including adaptation of advanced digital solutions to enable automation. Whilst, the core membership may naturally prioritise short-term solutions that do not fully embrace the innovation agenda, the long term aim of an Institutionalised Partnership will ensure a balance between developing advanced solutions and maturing deployment-ready solutions ¹¹⁰. It score would therefore be **high** compared to the baseline (++).

¹⁰⁹ A more in depth and detailed analysis of each policy option is provided in Technopolis Group Study (2020)

As stated in interviews with stakeholders from both research and industry institutions available at https://www.sesarju.eu/interviews and notably the interviews titled "The new face of aviation research" as well as "Nothing 'elementary' about air traffic management research, says SESAR researcher"

B) Enhance capacity among next generation aviation professionals. The modernisation of ATM will have a fundamental effect on the professionals employed by the aviation community, including traffic controllers and engineers. It is thus essential to involve universities who train the next generations of experts in the R&I programme to secure a steady flow of competent professionals to the sector.

The baseline option provides for a dissemination platform allowing knowledge and ideas sharing, mostly in academic settings (e.g. conferences). The results are loosely linked with the industry. As work and coordination of various topics is linked to the duration of grants, it is unlikely that research results would be followed into high level education programmes, having thus a limited effect on upskilling for both researchers and aviation professionals.

Option 1: As long as the members of the partnership see the added value for strong sharing and knowledge transfers, there is potential to build strong relationships with academia and innovative SMEs or with other ATM R&I programmes beyond Europe. This option scores good compared to the baseline. A more stable structure improves the focus and continuity of links with educational programmes.

Similar to Option 1, an institutionalised body (Option 2) implementing all Union research activities in the sector can facilitate a steady flow of exchanges and cooperation activities with educational actors. The current JU has a good tradition of organising targeted events 111 that facilitate knowledge dissemination and transfer. This is a good practice that has proven valuable in the past. This option also scores **good** compared to the baseline (+).



Stakeholders view an institutional partnership for ATM as the best option to address the fragmented and conservative industry, which, without coordination will engage in stand alone research projects and lack of research continuity that will not help address the challenging tasks of R&I and deployment.

ATM has specific challenges that require research coordination, expertise and resources from the whole value chain including key actors. Solutions that are still under development and future challenges are best address by a dedicated institutional ATM partnership.

To ensure better transition through the R&I pipeline and acceleration of development processes. Exploratory research is essential to feed the SESAR innovation pipeline and must be reinforced whilst accepting uncertainty to allow innovation.

Stakeholders stated that in their view the initiative for integrated ATM is very relevant (44% of respondents) or relevant (24%) to deliver the impact on the education of the next generation of aviation professionals and encouragement of diversity and inclusion.

Economic/Technological impacts

C) An accelerated delivery of innovative ATM solutions needed for aircraft operations that help improve the flexibility of the European ATM network and systems allows for the handling of additional flights and thus facilitating economic recovery and growth in the air transport sector. It also increases the efficiency of the network, thereby reducing the environmental impact of aviation.

¹¹¹ E.g. SESAR Innovation days, Young Scientist Awards or Hackatons. See examples including stakeholder interviews at: https://www.sesarju.eu/news/young-talent-celebrated-2019-sesar-innovation-days as well as an article covering the Hackathon through the eyes of the winners https://www.sesarju.eu/news/innovation-aviation-digital-sky-challengethrough-eyes-winners

The baseline option has the potential to support the development of innovative concepts, without a coordinated approach of the industry there is little potential for industrialisation and deployment to make significant impacts on the real operations.

Option 1 would bring together a broader community of private stakeholders than the baseline, who coordinate their work to deliver R&I according to Union priorities. The limited role of the Union in managing interdependencies within the partnership could hamper the overall success if the industry's business models and priorities take precedence on what is delivered. This option scores **good** compared to the baseline (+).

Supported by long-term commitment from the industry, **Option 2** would build on the experience of the current JU who has built a successful Large Scale Demonstrations platform and accelerated the innovation pipeline, reducing the duration needed for a technical solution to reach the market¹¹². As a Union body coordinating the ATM research programme, the institutional partnership would be able to take an independent position towards diverse and diverging industry interests, pushing for Union priorities in the interest of European citizens and businesses¹¹³. This option scores **high** compared to the baseline (++).

D) Safely and efficiently integrating drones and drones traffic management systems with the ATM systems facilitates **the ramp up of drones-related economic activities**, opening up the market for new types of drones services operators and drones traffic management service providers ¹¹⁴.

The **baseline option** can support the innovation required to integrate drones into ATM systems, enabling new entrants to be involved without the overhead of fully committing to a partnership. However, the complex nature of the European airspace requires new solutions that are interoperable with an ever-changing ATM system and architecture. Without a strong coordination at EU level, open calls are unlikely to generate the momentum that would secure the interoperability needed to ramp up drones activities in the coming years¹¹⁵.

Option 1 would see an improvement compared to the baseline, as a coordinated industry approach where drones manufacturers and drones service providers play an active role would generate the appropriate levels of investments and technological progress to put in place a European drones' traffic management system that would in turn facilitate the ramp up of drones economic activities in the next decade. This option scores **high** compared to the baseline (++).

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As affirmed comprehensively in interviews with stakeholders from both research and industry institutions available at https://www.sesarju.eu/interviews

¹¹³ See Annex 2 Synopsis report on the stakeholder consultation

According to the European Drones Outlook Study (SESAR Joint Undertaking 2016) by 2050, it is estimated that there will be some 7 million consumer leisure drones in operation across Europe, including a fleet of 400 000 drones offering important services across the agricultural, energy, e-commerce, transport as well as public sectors. With an estimated value of EUR 15 billion annually, this market represents a huge potential for Europe and its global competitiveness. The full report is available at: https://www.sesarju.eu/index.php/newsroom/all-news/europe-needs-prepare-drone-market-boom-says-new-study

According to the European Drones Outlook Study (SESAR Joint Undertaking 2016) building a designated 'home' for the drone traffic management R&D at European level has extended benefits related to the creation of a single market.

Similar to Option 1, **Option 2** would be in a much better position than the baseline to put in place the framework necessary to ramp up the drones-related activities in the EU. The advantage of Option 2 is that it would build on the experience of the current JU who has already 4 years of experience with these activities, having already developed a European blueprint for U-space drones' traffic management systems¹¹⁶ and having carried out already multiple drones services demonstration projects, under Horizon 2020, CEF and EP Pilot Projects funding¹¹⁷. The option scores **high** compared to the baseline (++).

E) A Europe-wide agreed ATM architecture relying on inter-operable ATM solutions standardised and certified at European level will give Europe a strong voice at international level, where European technologies should remain the backbone of global ATM modernisation plans coordinated by ICAO. This should boost the EU industry globally by enabling international agreements and contracts.

The **baseline option** could provide for call provisions requiring beneficiaries to participate and support standardisation activities. This option would lack the access to global level fora and would have limited capacity to promote European technologies and standards internationally.

Option 1 would be in a better position than the baseline to support the market uptake of technical solutions. However, as an industry body (as opposed to a Union body), the partnership would have no access to decision making bodies at ICAO level and would wield less influence overseas with ATM organisations which tend to have government status. This option scores **good** compared to the baseline. (+)

Option 2 brings the added value of having a Union body responsible for coordinating activities and representing the Union (upon a mandate received from the Commission, as it is currently the case with the SESAR JU) and stakeholders involved in international negotiations and ATM standard setting activities. This option scores **high** compared to the baseline (++).

Stakeholders's opinion (based on the Open public consultation)

Baseline scenario of open calls is not an alternative to increase efficiency and speed up development or implementation of the Single European Sky of which EU economy and travelling public are the beneficiaries.

An institutional partnership for ATM is required due to the fragmented and conservative industry that without coordination will lead to stand alone research projects and lack of research continuity that will not help address the challenging tasks of R&I and deployment.

Take a holistic approach that includes an adapted regulatory framework, operational aspects and development and maturation of the critical enabling technologies. Standardisation, and implementation are crucial to develop an interoperable, scalable and harmonised EU ATM system that safe, efficient, sustainable, connected, airspace and air transport.

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Drafted by the SESAR Joint Undertaking, the U-space blueprint sets out the vision for the U-space, which aims to enable complex drone operations with a high degree of automation to happen in all types of operational environments, particularly in an urban context. When fully deployed, a wide range of drone missions that are currently being restricted will be possible thanks to a sustainable and robust European ecosystem that is globally interoperable. More information at: https://www.sesarju.eu/u-space-blueprint

SESAR U-space projects results published at https://www.sesarju.eu/news/sesar-u-space-projects-results-published

ATM Modernisation is a global issue and the partnership should keep a global mindset pushing towards harmonisation without leaving behind the R&I European focus. It should encourage networking and cooperation to promote EU standards at a global level in order to implement solutions that can be leveraged in terms of global industry. Solutions should be in line with ICAO recommendations and EASA regulations, especially for drones.

Diverging interests from the industry and service providers should not influence the research and development priorities but it should be kept customer and result driven. The focus should be on operational performance benefits for the whole network and society (including passengers).

The momentum, context and success of the SESAR Joint Undertaking should be followed up. The participation stability, resilience and experience acquired in the last 10 years by SESAR's systematic approach are required in order to follow the learning curve that will allow to address the future challenges.

Member States indicate strong agreement with the proposed objectives at short, medium and long term (82%) and the expected scientific, economic and societal impacts at European level (82%), with the remaining ones remaining neutral. 71% of countries consider the impacts very or somewhat relevant in the national context.

Societal impacts (including environment)

F) The technological progress resulting from this initiative would make the European airspace significantly more efficient and environmentally than today where 5-10% of air transport's CO₂ emissions could be avoided due to inefficiencies in the ATM infrastructure¹¹⁸.

With the European Green Deal driving the policy priorities, the **baseline option** would see significant funding allocated to open calls aimed at addressing the environmental challenges. However, without a coordinated approach across the whole industry, locally developed solutions would have limited impact on supporting end-to-end optimisation of flight paths.

Option 1 would improve the focus of R&I activities along the current Commission priorities. However, investment in climate research is expensive. However, conflicts of interest between industry interests may be difficult to effectively handle where there is no tangible direct benefits to the industry, leading to a risk of reduced innovation and delays in the delivery of sustainable solutions. This options scores **good** compared to the baseline (+).

Under **Option 2**, a Union Body would steer a common approach by all stakeholders in ATM and would be able to focus on the necessary ATM modernisation to enable environmental goals that can best be achieved by enabling aircraft to fly on their optimum 4D trajectory in the climb, on-route and descent phases of flight - the optimum horizontal path from departure to destination flown at the most fuel efficient flight level. This can only be achieved by compressive and wide coordination with all stakeholders that have been deeply impacted by the COVD 19 crisis (including intergovernmental organisations such as EUROCONTROL that have significant expertise in the domain) as defined in section 4.4.1. The Union body would ensure that the environmental priority is maintained as the R&I results require performance trade-offs (i.e. environment versus cost-efficiency - a trajectory with low environmental footprint is enabled by sufficient ATM capacity, which increases the ATM provision costs).

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¹¹⁸ European ATM Mater Plan, Edition 2020, Figure 10

In addition, as previously done with the SESAR JU, the Union body would be tasked by the Commission to develop technical support for EU Regulations in the sector, monitor the coherence between the results of R&I and the EU ATM Master Plan and the Single European Sky policy.

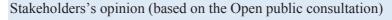
This is the Option that would best support ATM modernisation with the necessary coordination and acceleration leading to the timely environmental optimisation of ATM, hence this option scores **high** compared to the baseline (++).

G) The expected societal impacts are reduced travel times, improved predictability, reduced delays and lower costs. This improves both the passenger experience 119 and business opportunities.

The **baseline option** would facilitate the involvement of innovative SMEs. However, similar to the environmental impact, the lack of a mechanism to manage interdependencies between emerging solutions has a potential negative impact on the overall coherence of the R&I programme and may not lead to solutions needed for the emerging ATM architecture ¹²⁰.

Option 1 would use a coordinated approach to deliver solutions that improve the performance of the system. However, without a strong Union steering in the governance a partnership lead by air navigation service providers and airlines would prioritise solutions benefitting their economic activities, rather than the passenger experience or the interest of the citizen in general. The option scores **good** compared to the baseline (+).

Option 2 provides for a strong role for a Union steering in the governance of the partnership that would ensure that the priorities and activities take into consideration the interests of all stakeholders, including citizens¹²¹. This option scores **high** compared to the baseline (++).



The need to modernise the existing system though the application of emerging technologies such as digitalisation, automation and big data was a recurrent theme amongst the interviewed and throughout all the categories. Generally, and more specifically airspace users, see as the main challenge addressing environmental sustainability.

Links with Clean Aviation: while distinct partnerships are needed (as stakeholders and processes are different), there should be mechanisms for synergies and cross-fertilization in place as they share objectives - notably lowering emissions - and solutions need to be developed in a consistent way.

Fundamental Rights impacts

None of the above options is expected to impact fundamental rights in the EU or abroad.

Directionality and additionality required

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ACI Europe publication "SESAR and the digital transformation of Europe's airports" available at https://www.sesarju.eu/sites/default/files/documents/reports/SESAR%20and%20the%20digital%20transformation%20of%20europe%20airports.pdf

Results from the open calls under previous framework show that a partnership approach was required to support exploitation of the results.

As affirmed comprehensively in interviews with stakeholders from both research and industry institutions available at https://www.sesarju.eu/interviews

As regards the level of directionality and additionality required, **the baseline option** would not be able to facilitate the synchronised actions necessary to support policy objectives. Even if this option could ensure partial alignment with EU strategies, it would not be effective enough to significantly contribute to achieving them.

With the ability to prepare and implement a medium term plan, **Option 1** could ensure compliance with the Union and Member States strategies. However, in the absence of a strong EU involvement in the partnership, it would be more difficult to steer the industry-led partnership towards achieving the Union's policy priorities linked to the digital transformation of ATM or the ambitious environmental targets of 2030 and 2050.

A long-term vision and strategy for ATM is essential for successfully transforming the sector. By involving research organisations, all relevant types of economic actors and the public sector, **Option 2** is considered as the most appropriate since it ensures a long-term commitment. Integrating the Strategic R&I Agenda into a broader spectrum is also essential. Option 2 will ensure a coherent approach across the whole ATM innovation cycle, from R&I to market uptake, addressing in particular the "valley of death" challenge of industrialisation.

Table 7 summarises the scores assigned for each policy option, based upon the assessments above, as well as taking into account the support expressed by the different stakeholders.

Table 7: Overview of the options' effectiveness compared to the baseline

	Baseline: Horizon Europe calls	Option 1: Co- programmed	Option 2: Institutionalised Article 187 TFEU
Scientific impa	et		
New scientific knowledge and reinforcement of EU scientific capabilities	0	+	++
Enhanced capacity among the next generation aviation professionals	0	+	+
Economic/technologica	ıl impact		
Ability to handle additional flights enabling growth in air transport	0	+	++
Enable new economic activity based on drones	0	++	++
Boost EU industry globally through international agreements and the setting of global standards	0	+	++
Societal impact			
Reducing aviation noise and gas emissions	0	+	++
Improve customer experience and business opportunities by reducing travel time, improving predictability	0	+	++

Notes: Score ++: Option presenting a *high* potential compared to baseline; Score +: Option presenting a *good* potential compared to baseline; Score 0: Potential of the baseline.

6.2. Efficiency

In order to compare the policy options consistently in terms of their efficiency, a standard cost model was developed for the external study supporting the impact assessment for the set of candidate Institutionalised Partnerships. The model and the underlying assumptions and analyses are set out in the Common Part of this impact assessment, Section 2.3.2 and in the Methodology Annex 4. A dedicated Annex 3 also provides more information on who is affected and how by this specific initiative in line with the Better Regulation framework. The scores related to the costs set out in this context allow for a "value for money" analysis (cost-effectiveness) in the final scorecard analysis in Section 6.4.

In addition, for this specific initiative under the baseline scenario of traditional calls, there would be winding down (estimated at EUR 500K) and social discontinuation costs for the existing implementation structure of the current Article 187 initiative. There would also be longer term financial cost-savings related to the closing of the structure, related to operations, staff and coordination costs in particular. These can be estimated at EUR 4 million per year of operation (including Commission supervision costs saved). Overall it is estimated that the overall longer term cost savings from using traditional calls instead of an existing Article 187 initiative would thus considerably exceed the costs incurred for winding down operations. This overall situation is set as the starting point for the comparison of options. The score of this baseline scenario (traditional Horizon Europe calls) is set to 0 to be used as a reference point.

On this basis, the scores for the costs of the different options range from a value of 0, in case an option does not entail any additional costs compared to the baseline, to a score of (-) when an option introduces limited additional costs when compared to the baseline and a score of (-)(-) when substantial additional costs are expected in comparison with the baseline. In case the scores are lower than for the baseline scenario, (+) and (+)(+) are used.

It is considered that while there is a clear gradation in the overall costs of the policy options, the cost differentials are less marked when one takes into account the expected co-financing rates and the total budget available for each of the policy options, assuming a common Union contribution. From this perspective, there are only one or two percentage points that split the most cost-efficient policy options – the baseline (traditional calls) and the Co-Programmed policy options – and the least cost-efficient – the Institutionalised Partnership option. Indeed, in terms of cost-efficiency, the Co-Programmed Partnership (Option 1) is 2 percentage points more efficient than the baseline; and an Article 187 Partnership is 2 percentage points less cost-efficient than the baseline. A score of + is therefore assigned for **cost-efficiency** to the Co-Programmed options and a score of (-) for the Institutionalised Partnership policy option, as illustrated in Table 8 below 122.

More specifically for the ATM partnership, building on the assumptions outlined in Figure 4 of Annex 4 and the known real costs, e.g. from the current SESAR JU implementation, the additional costs compared to the baseline are about 6-7% of the Union's contribution. When considering the fact that over 60% of these administrative costs are covered by private and inter-governmental partners (i.e. Eurocontrol), re-establishing the JU is roughly similarly efficient to the baseline scenario (96%-97%), and only one percentage point behind in efficiency to the co-programmed partnership. Considering the fact that the Art 187 initiative has the highest ability to deliver the highest expected impacts, it delivers the best value for the Union budget investment.

Additional assumptions regarding these costs:

- The potential for the crowding-in effects for the industry have been taken into account when assessing the effectiveness of the policy options, above.
- For the overall administrative, operational and coordination costs, in the case of a partnership the industry (including EUROCONTROL for Art 187 only and other industry partners) would contribute to the running costs of the partnership, which significantly reduces the costs to the Union for this partnership. Based on experience to-date with the JU it is assumed that the industry partners other than the EU could

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¹²² The baseline (traditional calls) is scored 0, as explained above.

- together contribute to approximately 60% of the running costs, thus minimising the additional cost of an Article 187 option for the EU.
- The above considerations on cost-efficiency do not take account of the additional leverage created by the full involvement of EUROCONTROL in the ATM partnership: indeed, in the case of SESAR and an Article 187 option only, EUROCONTROL and the industry would each match funding for the EU budget, leading to a gross leveraging ratio of up to 1:2,5, as shown in Annex 4. This additional leverage could not be guaranteed for the Baseline option and would only be partial (not including EUROCONTROL who would be a beneficiary) for the Co-programmed option.
- This analysis is based on costs only but should also consider a number of positive qualitative elements for the Union:
 - The Union has a higher level of control on the use of funds through the application of the Commission's internal control framework, through regular oversight by the Commission and through the direct discharge procedure by the European Parliament;
 - o the added value in steering the overall activities and setting direction. The costs of setting up a Strategic Research and Innovation agenda are lower when using the currently established partnership as a platform to coordinate the preparation with the industry.

Based on the elements above, once leverage, sharing of running costs and level of control are taken into account, the overall costs are adjusted as follows:

Table 8: Matrix on 'overall costs' and 'adjusted cost scoring'

	Baseline: Horizon Europe calls	Option 1: Coprogrammed	Option 2: Institutionalised Article 187 TFEU
Administrative, operational and coordination costs	0	0	-
Administrative, operational and coordination costs adjusted per expected co-funding (i.e. cost-efficiency)	0	+	0

Notes: Score 0 = same costs as for the baseline; score (-) = limited additional costs compared with the baseline; score (-)(-) = substantial additional costs compared with the baseline.

6.3. Coherence

6.3.1. Internal coherence

In this section we assess the extent to which the policy options show the potential of ensuring and maximising coherence with other actions, programmes and initiatives under Horizon Europe, in particular European Partnerships (internal coherence).

Baseline: Horizon Europe calls

Under this option, coherence between activities in the area of ATM R&I with activities under Cluster 5 of Horizon Europe and the other initiatives presented in Figure 1 is ensured by the European Commission. However, exploitation of synergies with other initiatives, including exchanges of knowledge and experience between project teams and stakeholders, would require an additional level of coordination beyond Programme Committees. The Baseline option could easily manage individual R&I activities. However, this option would lack the ability to build the long term strategic collaboration between stakeholders needed to advance rapidly the research results through industrialisation and deployment.

Option 1: Co-Programmed European Partnership

Under the Co-Programmed option, synergies could be exploited more easily than under the baseline option. The European Commission could ensure coordination at the level of research agendas, while the partnership would bring together projects and stakeholders from various initiatives to work together on common problems or tackle common challenges. However, considering the specificities of ATM R&I (outlines previously in sections 1, 2 and 4 in particular), the Co-programmed option does not promote a sufficiently broad community engagement framework outside of project consortia, limiting its ability to establish an effective long-term framework and vision, nor increase cross-sector collaboration. Option 1 could better manage all types of R&I activities thanks to a better agenda setting. However, Option 1 is not considered optimum to address the complex structure of the ATM sector and the broad range of actors. Its score would therefore be **good** compared to the baseline with +.

Option 2: Institutionalised European Partnership under Article 187 TFEU

The Institutionalised Article 187 partnership structure provides clear roles for the European Commission and for the industrial partners and is built on a central coordination layer which can increase the effectiveness of its efforts. Since its management body organises the funding and implementation of projects, the integrated ATM partnership could (together with other institutionalised partnerships) set concrete objectives and lay out a roadmap of activities and projects that can be implemented.

A dedicated body responsible for the development of a long-term strategy and supporting work programmes for ATM R&I makes it easier to ensure that these are fully aligned with relevant strategies and programmes developed by other partnerships and initiatives within the EU research and innovation landscape. Option 2 would manage all TRLs related activities, from fundamental R&D up to market-readiness. Good knowledge management is also an asset under this option - to allow the initiative to adequately assess projects in the selection process, to provide technical assistance where needed and even to challenge the industries in order to increase the speed of development. This would translate into a **high** score compared to the baseline set at ++.



A big majority of stekeholders interviewed highlighted the need to build the link with other initiatives, such as Clean Aviation in order to avoid duplication, to improve coordination and synergies on the topics of automation and environment in aviation.

6.3.2. External coherence

In this section we assess the extent to which the policy options show the potential of ensuring and maximising coherence with their external environment, including EU-level programmes and initiatives beyond the Framework Programme and/or national and international programmes and initiatives, as well as with overarching framework conditions such as Regulations, standardisation, etc.

To achieve the ATM objectives, the proposed partnership needs to create close links with the SESAR deployment mechanism and international initiatives, particularly within ICAO and with other ATM modernisation programmes in USA, Japan and China.

Baseline: Horizon Europe calls

Under this option, some coordination with other Union initiatives is possible at the level of priorities, but coordination at the level of implementation is very limited or even not possible.

This option typically remains focused on EU27 and does not allow the pursuit of an international coherent cooperation strategy, nor does it allow for the involvement of the Member States.

Option 1: Co-Programmed European Partnership

Under this option, the European Commission can contribute to some extent to the coordination with Union non-research initiatives at the level of the strategy. The industry-led partnership would have limited access to international decision making bodies at ICAO level and thus limited influence amongst overseas organisations responsible for ATM, which tend to have government status.

The possible participation of Member States provides the opportunity for coordination with the national programmes and initiatives and the regional clusters. Member States could coordinate with the national and industry efforts to ensure alignment with their own R&D agendas. Score would therefore be good compared to the baseline with +.

Option 2: Institutionalised European Partnership under Article 187 TFEU

This option would establish a strong implementing body for research that closely cooperates with industrial, institutional, national, standardisation & certification actors active at different steps of the SESAR innovation cycle and in particular supporting the SESAR deployment phase, mandated by Commission Regulation¹²³ and supported financially by the Connecting Europe Facility Programme. This option offers the best opportunity to involve Member States to discuss priorities and synergies, which is critical to the success of the initiative.

This option also provides the European ATM research sector with the best mechanisms to cooperate at international level, e.g. setting up a Union body capable of representing the Union (upon a mandate from the Commission) in international fora where global ATM standards and regulations are discussed, such as ICAO. This option would allow the continuation of already existing cooperation agreements on ATM research as the one between SESAR JU and the FAA's NextGen in the USA who have worked for the last decade on ensuring the interoperability between the European and American systems. This would translate into a high score compared to the baseline with ++.



Throughout all the categories, stakeholders made the strong point that there is a need to build up a partnership which has a body that can steer the R&I coordinating key stakeholders from the whole value chain continuously, to achieve the common EU-wide long-term ATM vision. Thus, they do not consider open calls to be a feasible option.

In interviews, stakeholders with direct participation in the current JU have emphasised that continuing to have strong Union coordinated programme and a partnership/body that is able to take part in ICAO negotiations has given the EU a strong leadership position in ATM globally. This should continue.

Table 9 below, lists the scores assigned for each of the policy options, based upon the assessments above, as well as taking into account the views expressed by the different stakeholders.

Table 9: Overview of the options' potential for ensuring and maximizing coherence

Option 0: Horizon Europe calls

Option 1: Co-programmed

Option 2: Institutionalised Article
187 TFEU

¹²³ Commission Implementing Regulation (EU) No 409/2013 on the definition of common projects, the establishment of governance and the identification of incentives supporting the implementation of the European Air Traffic Management Master Plan

	Option 0: Horizon Europe calls	Option 1: Coprogrammed	Option 2: Institutionalised Article 187 TFEU
Internal coherence	0	+	++
External coherence	0	+	++

Notes: Score ++: Option presenting a *high* potential compared to baseline; Score +: Option presenting a *good* potential compared to baseline; Score 0: Potential of the baseline.

6.4. Tabular comparison of options and identification of preferred option

Building upon the outcomes of the analysis, this section presents a comparison of the options' 'performance' against the dimensions of effectiveness, efficiency and coherence.

Table 10: Overall scorecard of the policy options for all criteria

	Criteria	Baseline: Horizon Europe calls	Option 1: Co- programmed	Option 3: Institutionalised Art. 187
	Scientific impacts			
	New scientific knowledge and reinforcement of EU scientific capabilities	0	+	++
	Enhanced capacity among the next generation aviation professionals	0	+	+
	Economic/technological impacts			
Effectiveness	Ability to handle additional flights enabling growth in air transport	0	+	++
ffect	Enable new economic activity based on drones	0	++	++
区	Boosted EU industry globally through international agreements and the setting of global standards	0	+	++
	Societal impacts			
	Reducing aviation noise and gas emissions	0	+	++
	Improve customer experience and business opportunities by reducing travel time, improving predictability	0	+	++
rence	Internal coherence	0	+	++
Coherence	External coherence	0	+	++
ency	Overall cost	0	0	-
Efficiency	Adjusted Cost-scoring	0	+	0

Notes: Scores for effectiveness and coherence: Score ++: Option presenting a *high* potential compared to baseline; Score +: Option presenting a *good* potential compared to baseline; Score 0: Potential of the baseline Scores for efficiency: Score 0 = same costs as for the baseline; score (-) = limited additional costs compared with the baseline; score (-)(-) = substantial additional costs compared with the baseline

Overall the implementation of the **integrated ATM** initiative through an **institutionalised partnership established under Article 187 of TFEU is the preferred option** as it would best ensure that private and public sectors remain fully engaged in the development and implementation of a long-term strategy for ATM R&I.

When compared to the baseline and Option 1, an institutionalised partnership has the following advantages:

- Maximises the impact of Union funding and the leverage, as EUROCONTROL and industry would each provide matching funding to the EU budget, leading to a gross leveraging ratio of up to 300%.
- Accelerates R&I by harnessing the momentum and knowledge of the current partnership.
- Facilitates the active participation of all relevant ATM stakeholders
- Builds synergies with other partnerships and initiatives within and outside the Climate, Energy and Mobility cluster, with an emphasis of international cooperation on ATM research.
- Overall the marginally increased costs are considered acceptable for the greater likelihood of achieving the significant environmental and economic benefits of timely ATM modernisation.

Box 2 Comparison between the preferred option & the current partnership existing in the area taking into account lessons from past evaluations

What continues	What is different
 Art 187 Union Body, with EC and Eurocontrol as founding members. Blending of funds: Horizon, CEF Strong link with the single European sky policy & strategic planning at EU level through the European ATM Master Plan. Members contributing to running costs of the JU Active role of operational stakeholders in the partnership High leverage (beyond 200%) 	 Focus on breakthrough innovation Open innovation policy, open calls as basic principle More coherent life-cycle approach and higher impact of investments due to closer links with industrialisation/ market uptake Simplified architecture & toolbox Closer engagement of Member States in the Governance Better synergies with other Horizon and national initiatives

7. THE PREFERRED OPTION - HOW WILL ACTUAL IMPACTS BE MONITORED AND EVALUATED?

7.1. The preferred option

In Table 12, below, the alignment of the preferred option of Institutionalised European Partnership under Article 187 TFEU with the selection criteria for European Partnerships defined in Annex III of the Horizon Europe Regulation is depicted. Seeing that the design process of the candidate Institutionalised Partnerships is not yet concluded and several of the related topics are still under discussion, the criteria of additionality/directionality and long-term commitment are covered in terms of *expectations* rather than ex-ante demonstration.

Table 11: Alignment with the selection criteria for European Partnerships

Criterion	Alignment of the preferred option

Higher level of effectiveness	The Institutionalised Partnership is specifically designed to support pan-EU harmonisation of ATM leading to significant environmental, economic and social benefits. The stronger link to the SES policy is critical to reduce risk with transferring solutions from R&I to deployment and hence increase industry commitment.
Coherence and synergies	The Institutionalised Partnership will support synergies with related R&I in advanced digital solutions reducing the likelihood of the industry developing ATM specific solutions where these are not needed. The Institutionalised Partnership is able to build direct links with the deployment programme, supporting an accelerated handover of results leading to a faster accrual of benefits. The Institutionalised Partnership is also advantageous in its ability to represent the EU at ICAO and other international meetings ensuring that European solutions are embedded in future global plans and standards.
Transparency and openness	Through a drive to promote standards for developed solutions the Institutionalised Partnership will support transparency of results leading to increased exploitation both within the EU and globally. The membership process and types of activity including open calls need to ensure a wider participation than the core membership (particularly of academia and SMEs).
Additionality and directionality	The EU role in the governance of the Institutionalised Partnership is advantageous in ensuring that the modernisation of ATM is driven by policy needs and not slowed down by sometimes diverging national and industrial interests. An institutionalised partnership would be able to set up the appropriate approaches to ensure flexibility of implementation and to adjust to changing policy, societal and/or market needs, or scientific advances, to increase policy coherence between regional, national and EU level.
Long term commitment	The financial contribution of industry is anticipated to be 66% (33% from EUROCONTROL and 33% from the industry) of the aggregated European Partnership budgetary commitments. These commitments are in line with previous commitments to the existing programme over the last decade.



Feedback on the inception impact assessments: A big majority of stakeholders (70%) expressed support for establishing an Institutionalized partnership under Art 187.

7.2. Objectives and corresponding monitoring indicators

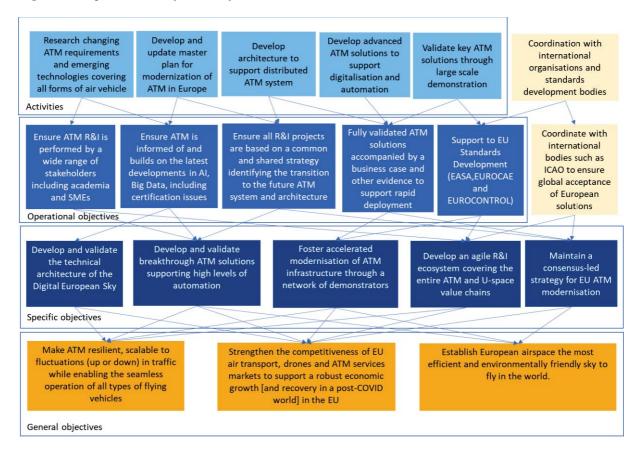
7.2.1. Operational objectives

Several operational objectives have been identified which would enable the partnership to achieve its specific objectives, as shown in Figure 11 below.

The figure also lists a range of actions and activities, going beyond R&I that can be implemented under Horizon Europe (which are highlighted in yellow). This reflects the definition of European Partnerships in the Horizon Europe Regulation as initiatives whereby the Union and its partners "commit to jointly support the development and implementation of a programme of research and innovation activities, including those related to market, regulatory or policy uptake."

¹²⁴ The European Commission received 28 responses to the inception impact assessment for integrated ATM. The responses are aligned with the stakeholder responses to the open public consultation and the interviews performed for this report. Therefore, we did not refer to this feedback in the report.

Figure 13: Operational objectives of the initiative



7.2.1. Monitoring indicators

In addition to Key Impact Pathways indicators set centrally in the Regulation of Horizon Europe, additional monitoring indicators have been identified to enable the tracking of progress of the partnership towards meeting its objectives. These are shown in Table 12.

The societal impact and performance of ATM in Europe is currently measured by the Performance Review Body established by the European Commission. This body could be used to monitor the success of the R&I programme in terms of actual operational performance of solutions. Current metrics are limited and could be improved:

- For environmental impact, the current metric could be extended to include the full trajectory (the current metric only measures horizontal efficiency in the cruise phase)¹²⁵.
- The current performance metrics cover safety, capacity (through measurement of delay) and cost-efficiency. This could be extended to include passenger centric measures that better reflect the value of improvements to EU citizens¹²⁶.

Table 12: Monitoring indicators in addition to the Horizon Europe key impact pathway indicators

	Short-term (typically as of year 1+)	Medium-term (typically as of year 3+)	Long-term (typically as of year 5+)
Scientific impact			

See for example: https://www.nats.aero/environment/3di/

Passenger-Oriented Enhanced Metrics, A. Cook, G. Tanner, S. Cristóbal and M. Zanin, SESAR Innovation Days 2012.

New scientific knowledge and reinforcement of EU scientific capabilities	Number of ATM solutions reaching TRL2	Number of ATM solutions reaching TRL4	Number of ATM solutions reaching TRL6	
Enhanced capacity among the next generation aviation professionals fostering diversity and inclusion	Number of researchers involved in upskilling (training, mentoring/coaching, mobility and access to R&I infrastructures)	Number and share of upskilled FP researchers with increased individual impact in ATM	Number and share of upskilled FP researchers with improved working conditions, including researchers' salaries	
Technological / economic impact				
Accelerated delivery of innovative solutions into operations	Number of innovative ATM solutions developed	Number of innovative ATM solutions demonstrated	Creation, growth & market shares of companies having developed FP innovations	
Enable new economic activity based on drones	Number of innovative U- spaces solutions developed	Number of innovative U-space solutions demonstrated	Creation, growth & market shares of companies having developed FP innovations	
Enable European industry competitiveness based on international agreements and EU/global standards	Number of standards identified as being required	Number of standards initiated	Number of standards published	
Societal impact				
Reducing aviation noise and gas emissions	Planned capability of ATM solutions to reduce CO ₂ emissions per flight	Validated capability of delivered solutions to reduce CO ₂ emissions per flight	Measured reduction in CO ₂ emissions per flight during operations	
Improve customer experience and business opportunities by reducing travel time, improving predictability	Planned capability of ATM solutions to improve ATM performance	Validated capability of delivered solutions to improve ATM performance	Measured performance improvement	

7.2.1. Evaluation framework

The evaluation of the Partnership will be done in full accordance with the provisions laid out in Horizon Europe Regulation Article 47 and Annex III, with external interim and ex-post evaluations feeding into the overall Horizon Europe evaluations. As set in the criteria for European Partnerships, the evaluations will include an assessment of the most effective policy intervention mode for any future action; and the positioning of any possible renewal of the Partnership in the overall European Partnerships landscape and its policy priorities. In the absence of renewal, appropriate measures will be developed to ensure phasing-out of Framework Programme funding according to conditions and timeline agreed with the legally committed partners ex-ante.



Brussels, 23.2.2021 SWD(2021) 37 final

PART 13/19

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT REPORT Accompanying the document

Proposal for a COUNCIL REGULATION establishing the Joint Undertakings under Horizon Europe

European Partnership for Integrated Air Traffic Management

{COM(2021) 87 final} - {SEC(2021) 100 final} - {SWD(2021) 38 final}

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Annex 1 Procedural information

1. LEAD DG, DECIDE PLANNING REFERENCES

Co-Lead DG: Directorate-General for Mobility and Transport (MOVE); Directorate General Research and Innovation (RTD)

Decide number: PLAN/2019/5393

2. ORGANISATION AND TIMING

Institutionalised partnerships are foreseen in Articles 185 and 187 of the Treaty on the Functioning of the European Union (TFEU). The preliminary agreement on Horizon Europe contained a list of possible areas for institutionalised partnerships based on Article 185 and 187. For each of these areas the Commission considered 12 potential institutionalised partnerships. Their set up involves new EU legislation and the establishment of dedicated implementing structures and therefore an impact assessment for each of these initiatives.

Following political validation in June 2019, the impact assessment process started with the publication of inception impact assessments for each initiative in August 2019.

An inter-service steering group (ISSG) on research and innovation partnerships under Horizon Europe was set up in May 2019 and held 4 meetings before submission of the Staff Working Document to the Regulatory Scrutiny Board (7 May 2019, 19 June 2019, 5 December 2019, 20 January 2020). The ISSG consisted of representatives of the Secretariat-General, Directorate-General for Budget, Directorate-General for Research and Innovation Directorate-General for Communications Networks, Content and Technology, Directorate-General for Mobility and Transport, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, Directorate-General for Energy, Directorate-General for Environment, Directorate-General for Climate Action, and the Legal Service.

An online public stakeholder consultation was launched between September and November 2019, gathering 1635 replies for all 12 initiatives.

3. CONSULTATION OF THE RSB

Two upstream meetings with the Regulatory Scrutiny Board of were held on 10 July 2019 and 30 September 2019.

In accordance with the feedback received from the Regulatory Scrutiny Board on 12.06.2020 the Staff Working Document has been revised as presented in Figure 1. The impact assessment was endorsed by the Inter Service Steering Group on 20.01.2020.

4. EVIDENCE, SOURCES AND QUALITY

To ensure a high level of coherence and comparability of analysis for all candidate initiatives, an external study was procured to feed into the impact assessments of the 12 candidate

institutionalised partnerships ¹ (Technopolis Group, 2020). It consisted of an horizontal analysis and individual thematic analyses for each of the initiatives under review.

For all initiatives, the evidence used includes desk research partly covering the main impacts and lessons learned from previous partnerships. A range of quantitative and qualitative data sources complement the evidence base, including evaluations; foresight studies; statistical analyses of Framework Programmes application and participation data and Community Innovation Survey data; analyses of science, technology and innovation indicators; reviews of academic literature; sectoral competitiveness studies and expert hearings. The analyses included a portfolio analysis, a stakeholder and social network analysis in order to profile the actors involved as well as their co-operation patterns, and an assessment of the partnerships' outputs (bibliometrics and patent analysis). A cost modelling exercise was performed in order to feed into the efficiency assessments of the partnership options. Public consultations (open and targeted) supported the comparative assessment of the policy options. For each initiative up to 50 relevant stakeholders were interviewed by the external contractor (policymakers, business including SMEs and business associations, research institutes and universities, and civil organisations, among others). In addition the analysis was informed by the results of the Open Public Consultation (Sep – Nov 2019), the consultation of the Member States through the Strategic Programme Committee and the online feedback received on the Inception Impact Assessments of the set of candidate Institutionalised European Partnerships.

A more detailed description of the methodology and evidence base used, completed by thematic specific methodologies, is provided in Annexes 4 and 6.

Figure 1 Modifications to the draft Staff Working Document based on comments received from the Regulatory Scrutiny Board

Comments from the Regulatory Scrutiny Board	Actions taken for the Staff Working Document
(1) The report does not sufficiently explain what the current joint undertaking has achieved. The report should better integrate evaluation findings on the current joint undertaking and explain how the new partnership would address them. The report should be clearer about the differences between the current joint undertaking and the future partnership.	Section 1.3, Box 3 was revised to provide additional information about the achievements of the current SESAR Joint Undertaking, as well as to provide information about how the new partnership will address them. Section 5.2, Tables 5 and 6 updated to include an outline of key differences between the current situation and different implementation methods.
(2) The report should clarify how the partnership will address air safety issues and to what extent this aspect will be considered in the development of innovative ATM solutions. The report should also elaborate on how far the partnership could enhance	Section 1 have been revised to clarify how safety has preserved its central role in the development of new technologies. The case for enhanced interoperability and reduced fragmentation was strengthened.

¹ Technopolis Group, 2020, forthcoming.

interoperability and reduce fragmentation.

(3) The report should better describe the wider context in which the new partnership would operate. It should clarify the link with the European Air Traffic Management Master Plan and the Digital European Sky blueprint. It should be more realistic on the baseline developments of European aviation and on what the partnership can achieve.

Section 1 and 4 have been revised to elaborate the link between the Master Plan and the blueprint and to set them in the context of the Single European Sky policy objectives.

(4) The report should further elaborate on the partnership's expected role in bringing together relevant stakeholders and Member States around a common research and alignment agenda of European ATM systems.

Section 1 and 4 were updated to provide additional information about how all relevant stakeholders will be European ATM Master Plan and the Strategic Research and Innovation Agenda (SRIA) for integrated ATM and about the involvement of stakeholders in preparing these documents.

(5) The report could explain better the links between problems and objectives, and between objectives, targeted impacts and functionalities. Section 4.3 was updated to better describe the impacts in relation to specific objectives and to describe the link between the intervention logic and the policy, as well as the planning tools, i.e. the European ATM Master Plan and the SRIA.

(6) The report should integrate the latest realistic expectations on the effects of the Covid-19 crisis on air traffic. It could consider these in the analysis of the problems, baseline and impacts.

Section 4, Economic and societal impacts were updated to reflect the current forecasts regarding the evolution of the aviation sector in the coming years. Overall, the impacts do not change significantly, as the initiative has a medium to long-term perspective. The Covid-19 crisis does not change the need for the European ATM system to become more resilient, scalable and sustainable.

Annex 2 Stakeholder Consultation

1. OVERVIEW FOR ALL CANDIDATE INSTITUTIONALISED EUROPEAN PARTNERSHIPS

1.1. Introduction

In line with the Better Regulation Guidelines,² the stakeholders were widely consulted as part of the impact assessment process of the 12 candidates for institutionalised partnerships, including national authorities, the EU research community, industry, EU institutions and bodies, and others. These inputs were collected through different channels:

- A feedback phase on the inception impact assessments of the candidate initiatives in August 2019, gathering 350 replies for all 12 initiatives on the "Have your say" web portal during a period of 3 weeks;
- A structured consultation of Member States performed by the EC services over 2019 through the Shadow Strategic Configuration of the Programme Committee of Horizon Europe (in line with the Article 4a of the Specific Programme of Horizon Europe). This resulted in 44 possible candidates for European Partnerships identified as part of the first draft Orientations Document towards the Strategic Plan for Horizon Europe (2021-2024), taking into account the areas for possible institutionalised partnerships defined in the Regulation.
- An online public stakeholder consultation administered by the EC, based on a structured questionnaire, open between September and November 2019, gathering 1635 replies for all 12 initiatives;
- A targeted consultation run by the external study contractors with a total of 608 interviews performed as part of the thematic studies by the different study teams between August 2019 and January 2020.

1.2. Horizontal results of the Open Public Consultation

The consultation was open to everyone via the EU Survey online system.³ The survey contained two main parts to collect views on general issues related to European partnerships (in Part 1) and specific responses related to one or more of the 12 candidate initiatives (as selected by a participant). The survey was open from 11 September till 12 November 2019. The consultation was available in English, German and French and advertised widely through the European Commission's online channels as well as via various stakeholder organisations.

1.2.1. Profile of respondents

In total, 1635 respondents filled in the questionnaire of the open public consultation. Among them, 272 respondents (16.64%) were identified to have responded to the consultation as part of a campaign (coordinated responses). Based on the Better Regulation Guidelines, the groups of respondents where at least 10 respondents provided coordinated answers were labelled as 'campaigns', segregated and analysed separately and from other responses. In total 11

³ https://ec.europa.eu/eusurvey/runner/ConsultationPartnershipsHorizonEurope

² https://ec.europa.eu/info/files/better-regulation-guidelines-stakeholder-consultation_en

campaigns were identified, the largest of them includes 57 respondents⁴. In addition, 162 respondents in the consultation also display similarities in responses but in groups smaller than 10 respondents. Hence, these respondents were not labelled as campaigns and therefore were not excluded from the general analysis.

Table 1: Country of origin of respondents (N=1635)

Country	Number of respondents	Percentage of respondents
Germany	254	15.54%
Italy	221	13.52%
France	175	10.70%
Spain	173	10.58%
Belgium	140	8.56%
The Netherlands	86	5.26%
Austria; United Kingdom	61	3.73%
Finland	49	3.00%
Sweden	48	2.94%
Poland	45	2.75%
Portugal	32	1.96%
Switzerland	28	1.71%
Czechia	24	1.47%
Greece	23	1.41%
Norway; Romania	22	1.35%
Denmark	20	1.22%
Turkey	19	1.16%
Hungary	14	0.86%
Ireland	12	0.73%
United States	11	0.67%
Estonia; Slovakia; Slovenia	10	0.61%
Bulgaria; Latvia	9	0.55%
Bosnia and Herzegovina	7	0.43%
Lithuania	4	0.24%
Canada; Croatia; Israel	3	0.18%
China; Ghana; Iceland; Japan; Luxembourg; Morocco	2	0.12%
Bhutan; Botswana; Cyprus; Iran; Malta; Mexico; Moldova; Mongolia; Palestine; Russia; Serbia; South Africa; Tunisia; Ukraine; Uruguay	1	0.06%

As shown in Figure 2, the three biggest **categories of respondents** are representatives of companies and business organisations (522 respondents or 31.9%), academic and research institutions (486 respondents or 29.7%) and EU citizens (283 respondents or 17.3%). Among the group of respondents that are part of campaigns, most respondents are provided by the same groups of stakeholders, namely company and business organisations (121 respondents or 44.5%), academic and research institutions (54 respondents or 19.8%) and EU citizens (42 respondents or 15.4%).

_

⁴⁴ The candidate Institutionalised Partnership Clean Hydrogen has the highest number of campaigns, namely 5. A few initiatives, such as Innovative SMEs, Smart Networks and Systems, were not targeted by campaigns. Some campaign respondents decided to provide opinions about several partnerships.

522 486 283 99 97 78 53

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

Company/business organisation Academic/research institution EU citizen

Business association Public authority Other

Non-governmental organisation (NGO) Non-EU citizen Consumer organisation

■ Trade union

Figure 2 Type of respondents (N=1635) - For all candidate initiatives

■ Environmental organisation

Among all consultation respondents, 1303 (79.69%) have been **involved in the on-going research and innovation framework programme** Horizon 2020 or the preceding Framework Programme 7, while 332 respondents (20.31%) were not. In the group of campaign respondents, the share of those who were involved in these programmes is higher (245 respondents out of 272 or 90.07%) than in the group of non-campaign respondents (1058 out of 1363 or 77.62%). When respondents that participated in the Horizon 2020 or in the preceding Framework Programme 7 were asked to indicate in which capacity they were involved in these programmes, the majority stated they were a beneficiary (1033 respondents) or applicant (852 respondents). The main stakeholder categories, e.g. companies/business organisation, academic/research institutions, etc., show a similar distribution across the capacities in which they 'have been involved in Horizon 2020 or in the Framework Programme 7' as the overall population of consultation respondents.

Among those who have been involved in Horizon 2020 or the preceding Framework Programme 7, 1035 respondents (79.43%) are/were involved in a partnership. The share of respondents from campaigns that are/were involved in a partnership is higher than for noncampaign respondents, 89.80% versus 77.03% respectively. The list of partnerships under Horizon 2020 or its predecessor Framework Programme 7 together with the numbers, percentages of participants is presented in Table 4Error! Reference source not found., the table also show the key stakeholder categories for each partnership. Most consultation respondents participated in the following partnerships: Fuel Cells and Hydrogen 2 (FCH2) Joint Undertaking, Clean Sky 2 Joint Undertaking, European Metrology Programme for Innovation and Research (EMPIR) and in Bio-Based Industries Joint Undertaking. The comparison between the non-campaign and campaign groups of respondents shows that the overall distribution is quite similar. However, there are some differences. For the campaign group almost a half of respondents is/was involved in the Fuel Cells and Hydrogen 2 (FCH2) Joint Undertaking, a higher share of campaign respondents is/was participating in Clean Sky 2 Joint Undertaking and in Single European Sky Air Traffic Management Research (SESAR) Joint Undertaking.

When respondents were asked in which **role**(s) **they participate**(d) in a **partnership**(s), over 40% indicated that they act(ed) as partner/member/beneficiary in a partnership. The second largest group of respondents stated that they applied for funding under a partnership. The roles selected by non-campaign and campaign respondents are similar.

Table 4: Partnerships in which consultation respondents participated (N=1035)

Name of the partnership	Number and % of respondents from both groups (n=1035)	Number and % of respondents from a non-campaign group (n=815)	Academic/researc h institutions	Business associations	Company/busines s organisations	Company/busines s organisations	EU citizens	NGOs	Public authority
Fuel Cells and Hydrogen 2 (FCH2) Joint Undertaking	354 (33.33%)	247 (30.31%)	97	9	37	43	41	8	5
Clean Sky 2 Joint Undertaking	195 (18.84%)	145 (17.79%)	57	2	10	27	37	1	7
European Metrology Programme for Innovation and Research (EMPIR)	150 (14.49%)	124 (15.21%)	64	0	13	9	14	2	19
Bio-Based Industries Joint Undertaking	142 (13.72%)	122 (14.97%)	39	8	20	27	14	1	6
Shift2Rail Joint Undertaking	124 (11.98%)	101 (12.40%)	31	7	5	31	14	3	7
Electronic Components and Systems for European Leadership (ECSEL) Joint Undertaking	111 (10.72%)	88 (10.80%)	42	2	7	20	12	0	5
Single European Sky Air Traffic Management Research (SESAR) Joint Undertaking	66 (6.38%)	46 (5.64%)	10	3	3	20	3	2	3
5G (5G PPP)	53 (5.12%)	47 (5.77%)	20	1	6	14	5	0	1
Eurostrars-2 (supporting research-performing small and medium-sized enterprises)	44 (4.25%)	40 (4.91%)	17	0	6	1	7	0	6
Innovative Medicines Initiative 2 (IMI2) Joint Undertaking	37 (3.57%)	35 (4.29%)	18	2	3	3	2	4	3
Partnership for Research and Innovation in the Mediterranean Area (PRIMA)	28 (2.71%)	26 (3.19%)	15	0	3	1	2	0	2
European and Developing Countries Clinical Trials Partnership	25 (2.42%)	24 (2.94%)	12	0	1	2	3	3	2
Ambient Assisted Living (AAL 2)	22 (2.13%)	21 (2.58%)	11	2	1	1	3	0	3
European High- Performance Computing Joint Undertaking (EuroHPC)	22 (2.13%)	18 (2.21%)	6	0	2	3	5	0	2

For the remaining of the consultation respondents could provide their views on each/several of the candidate initiatives. The majority of respondents (31.4%) provided their views on the Clean Hydrogen candidate partnership. More than 45% of respondents from the campaigns selected this partnership. Around 15% provided their views for European Metrology, Clean Aviation and Circular Bio-based Europe. The share of respondents in the campaign group that chose to provide views on the Clean Aviation candidate partnership is of 20%. The smallest number of respondents provided opinions on the candidate initiative 'EU-Africa research partnership on health security to tackle infectious diseases – Global Health'.

Table 5: Candidate Institutionalised Partnerships for which consultation respondents provide responses (N=1613)

Name of the candidate Institutionalised European partnership	Number and % of respondents from both groups (n=1613)	Number and % of respondents from a non-campaign group (n=1341)
Clean Hydrogen	506 (31.37%)	382 (28.49%)
European Metrology	265 (16.43%)	225 (16.78%)
Clean Aviation	246 (15.25%)	191 (14.24%)
Circular bio-based Europe	242 (15%)	215 (16.03%)
Transforming Europe's rail system	184 (11.41%)	151 (11.26%)
Key Digital Technologies	182 (11.28%)	162 (12.08%)
Innovative SMEs	111 (6.88%)	110 (8.20%)
Innovative Health Initiative	110 (6.82%)	108 (8.05%)
Smart Networks and Services	109 (6.76%)	107 (7.98%)
Safe and Automated Road Transport	108 (6.70%)	102 (7.61%)
Integrated Air Traffic Management	93 (5.77%)	66 (4.92%)
EU-Africa research partnership on health security to tackle infectious diseases – Global Health	49 (3.04%)	47 (3.50%)

1.2.2. Characteristics of future candidate European Partnerships

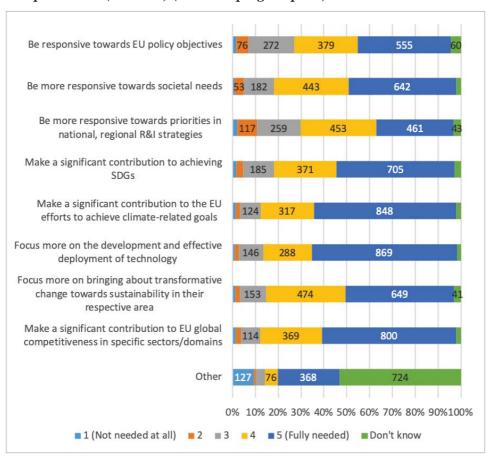
Respondents were asked to assess what areas, objectives, aspects need to be in the **focus of the future European Partnerships** under Horizon Europe and to what extent. According to Figure 6, a great number of respondents consider that a significant contribution by the future European Partnerships is 'fully needed' to achieve climate-related goals, to the development and effective deployment of technology and to EU global competitiveness in specific sectors/domains. Overall, respondents' views reflect that many aspects require attention of the Partnerships. The least attention should be paid to responding towards priorities of national, regional R&D strategies, including smart specialisation strategies, according to respondents.

Overall, only minor differences can be found between the main stakeholder categories. Academic/research institutions value the responsiveness towards EU policy objectives and focus on development and effective deployment of technology a little less than other respondents. Business associations, however, find that the future European Partnerships under Horizon Europe should focus a little bit more on the development and effective deployment of technology than other respondents. Furthermore, business associations, large companies as well as SMEs value the role of the future European Partnerships for significant contributions

to EU global competitiveness in specific sectors domains a little higher than other respondents. Finally, both NGOs and Public authorities put a little more emphasis on the role of the future European Partnerships for significant contributions to achieving the UN SDGs. The views of citizens (249, or 18.3%) do not reflect significant differences with other types of respondents. However, respondents that are/were directly involved in a partnership under Horizon 2020 or its predecessor Framework Programme 7 assign a higher importance of the future European Partnerships to be more responsive towards EU policy objectives and to make a significant contribution to achieving the UN's Sustainable Development Goals.

A qualitative analysis of the "other" answers highlights the importance of collaboration and integration of relevant stakeholders to tackle main societal challenges and to contribute to policy goals against which fragmentation of funding and research efforts across Europe should be avoided. Additionally, several respondents suggested that faster development and testing of technologies, acceleration of industrial innovation projects, science transfer and market uptake are needed. Next to that, many respondents provided answers related to the hydrogen and the energy transition, which corresponds to the high number of respondents that provided answers to the candidate initiative on this topic.

Figure 6: To what extent do you think that the future European Partnerships under Horizon Europe need to (N=1363) (non-campaign replies) For all candidate initiatives



1.2.3. Main advantages and disadvantages of Institutionalised European Partnerships

An open question asked to outline the main advantages and disadvantages of participation in an Institutionalised European Partnership (as a partner) under Horizon Europe (1551 respondents). The advantages mentioned focus on the development of technology, overall collaboration between industry and research institutions, and the long-term commitment. Disadvantages mentioned are mainly administrative burdens. An overview is provided below.

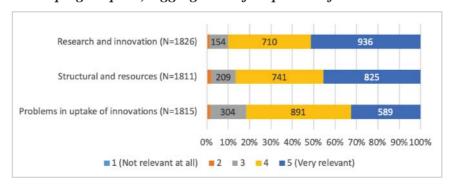
Advantages mentioned: Long term commitment, stability, and visibility in financial, legal, and strategic terms; Participation of wide range of relevant stakeholders in an ecosystem (large/small business, academics, researchers, experts, etc.); Complementarity with other (policy) initiatives at all levels EU, national, regional; Efficient and effective coordination and management; High leverage of (public) funds; Some innovative field require high levels of international coordination/standardisation (at EU/global level); Ability to scale up technology (in terms of TRL) through collaboration; Networking between members; Direct communication with EU and national authorities

Disadvantages mentioned: Slow processes; System complexity; Continuous openness to new players should be better supported as new participants often bring in new ideas/technologies that are important for innovation; Lower funding percentage compared to regular Horizon Europe projects; Cash contributions; Administrative burdens; Potential for IPR constraints.

1.2.4. Relevance of EU level to address problems in Partnerships' areas

Respondents were asked to rate the relevance of research and innovation efforts at EU level efforts to address specific problems in the area of partnerships. Research and innovation related problems were rated as most relevant across all candidate initiatives, followed by structural and resources problems and problems in the uptake of innovations. Overall, all three areas were deemed (very) relevant across the partnerships, as more than 80% of respondents found these challenges (very) relevant. Only minor differences were found between stakeholder categories. Research and innovation problems were found slightly more relevant by academic/research institutions, yet slight less relevant by large companies and SMEs. Structural and resource problems were indicated as slightly more relevant by NGOs, but slightly less by academic/research institutions. While both NGOs and public authorities find slightly more relevant to address problems in uptake of innovation than other respondents. The views of citizens are not differing significantly. Respondents that are/were directly involved in a current/preceding partnership find, however, the need to address problems related to the uptake of innovations slightly more relevant than other respondents.

Figure 9: To what extent do you think this is relevant for research and innovation efforts at EU level to address the following problems in relation to the candidate partnership in question? (non-campaign replies) Aggregation of responses of all candidate initiatives

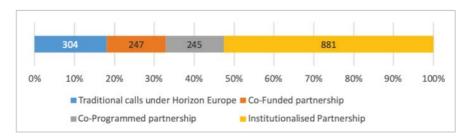


1.2.5. Horizon Europe mode of intervention to address problems

Respondents were asked to indicate how these challenges could be addressed through Horizon Europe intervention. Just over 50% of all respondents indicated that institutionalised partnerships were the best fitting intervention, with relatively strong differences between stakeholder categories. The use of Institutionalised Partnership was indicated more by business associations and large companies, but less by academic/research

institutions and SMEs. While academic/research institutions valued traditional calls more often, this was not the case for business associations, large companies and public authorities. Public authorities indicated a co-programmed intervention more often than other respondents. Citizens indicated slightly less often that institutionalised partnerships were the best fitting intervention. Respondents that are/were directly involved in a current/preceding partnership, selected the institutionalised partnership intervention in far higher numbers (nearly 70%).

Figure 10: In your view, how should the specific challenges described above be addressed through Horizon Europe intervention? (non-campaign replies) For all candidate initiatives



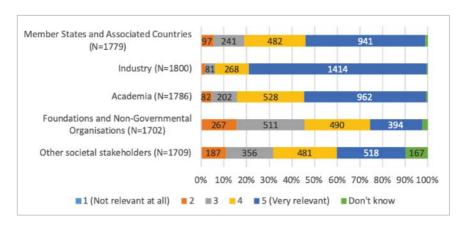
When asked to reflect on their answers, respondents that pointed to the need for using institutionalised partnership mentioned the long-term commitment of collaboration, a common and ambitious R&I strategy as well as the overall collaboration between industry and research institutions. Others shared positive experiences with other modes of interventions:

- Traditional calls, because of their flexibility and integration of a wide range of actors, as long as the evaluation panels do not deviate from the policy focus. This was mentioned by 94 participants, including companies (25), academics (26) and EU citizens (25).
- Co-funded partnership, as a mechanism to ensure that all participants take the effort seriously, while allowing business partnerships to develop. This approach was deemed suitable based on previous experiences with ERANETs. This was raised by 84 participants, 36 of them academic respondents, 18 companies and 16 EU citizens.
- Co-programmed partnerships, to tackle the need to promote and engage more intensively with the private sector. This was mentioned by 97 participants, most of them companies (34), followed by academics (22), business associations (15) and EU citizens (11).
 - 1.2.6. Relevance of a set of elements and activities to ensure that the proposed European Partnership would meet its objectives

Setting joint long-term agendas

Respondents were asked how relevant it is for the proposed European Partnerships to meet their objectives to have a strong involvement of specific stakeholder groups in setting joint long-term agenda. All respondents see stakeholders from industry as the most relevant, followed by academia and governments. The involvement of foundations and NGOs as well as other societal stakeholders were, however, still found to be (very) relevant by more than 50% of the respondents. Most respondents indicated the stakeholder group they belong to themselves or that represent them as relevant to involve.

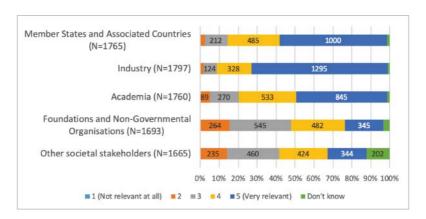
Figure 11: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives - Setting joint long-term agenda with strong involvement of: (non-campaign replies) For all candidate initiatives



Pooling and leveraging resources through coordination, alignment and integration with stakeholders

Respondents were asked how relevant it is for the proposed European Partnership to meet its objectives to pool and leverage resources (financial, infrastructure, in-kind expertise, etc.) through coordination, alignment and integration with specific groups of stakeholders. Respondents see stakeholders from industry as the most relevant, followed by academia and governments (Member States and Associated Countries). The involvement of foundations and NGOs as well as other societal stakeholders are also still found to be (very) relevant for more than 50% of the respondents. Similarly as described for the question on setting joint long-term agendas, most stakeholder categories valued their own involvement higher than other respondents – although also here differences between stakeholder categories were minor.

Figure 12: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives – Pooling and leveraging resources (financial, infrastructure, in-kind expertise, etc.) through coordination, alignment and integration with: (non-campaign replies) For all candidate initiatives

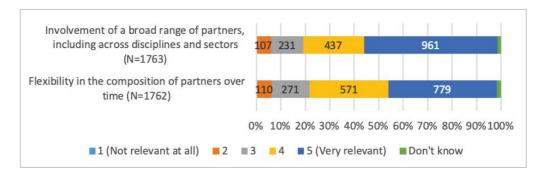


Composition of the partnerships

Regarding the composition of the partnership most respondents indicated that for the proposed European Partnership to meet its objectives the composition of partners needs to be flexible over time and that a broad range of partners, including across disciplines and sectors, should be involved (see Figure 13). When comparing stakeholder groups only minor

differences were found. Academic/research institutions and public authorities found the involvement of a broad range of partners and flexibility in the composition of partners over time slightly more relevant than other respondents, while large companies found both less relevant. SMEs mainly found the flexibility in the composition of partners over time less relevant than other respondents, while no significant differences were found regarding the involvement of a broad range of partners. Citizens provided a similar response to non-citizens. Respondents that are/were directly involved in a current/preceding partnership, when compared to respondents not involved in a current/preceding partnership, indicated a slightly lower relevance of the involvement of a broad range of partners and flexibility in the composition of partners over time.

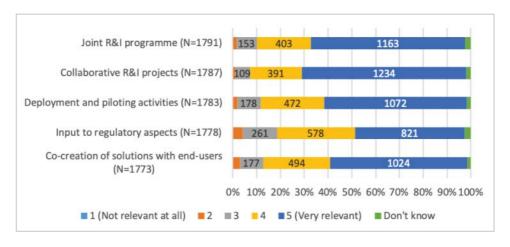
Figure 13: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives — Partnership composition (non-campaign replies) Aggregation of responses of all candidate initiatives



Implementation of activities

Most respondents indicated that implementing activities like a joint R&I programme, collaborative R&I projects, deployment and piloting activities, providing input to regulatory aspects and the co-creation of solutions with end-users are all (very) relevant for the partnerships to be able to meet its objectives. Minor differences were found between the main stakeholder categories, the differences found were in line with their profile. As such, academic/research institutions found joint R&I programme & collaborative R&I projects slightly more relevant and deployment and piloting activities, input to regulatory aspects and co-creation with end-users slightly less relevant than other respondents. For SMEs an opposite pattern is shown. Large companies, however, also found collaborative R&I projects slightly more relevant than other respondents, as well as input to regulatory aspects. The views of citizens are similar to non-citizens. Respondents that are/were directly involved in a current/preceding partnership, when compared to respondents not involved in a current/preceding partnership, show a slightly higher relevance across all activities.

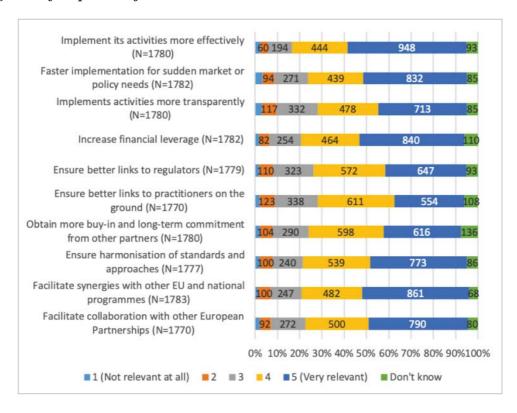
Figure 14: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives – Implementing the following activities (non-campaign replies) For all candidate initiatives



1.2.7. Relevance of setting up a legal structure (funding body) for the candidate European Partnerships to achieve improvements

Respondents were asked to reflect on the relevance of setting up a legal structure (funding body) for achieving a set of improvements, as shown in the Figure below. In general, 70%-80% of respondents find a legal structure (very) relevant for these activities. It was found most relevant for implementing activities in a more effective way and least relevant for ensuring a better link to practitioners on the ground, however differences are small.

Figure 15: In your view, how relevant is to set up a specific legal structure (funding body) for the candidate European Partnership to achieve the following? (non-campaign replies) Aggregation of responses of all candidate initiatives



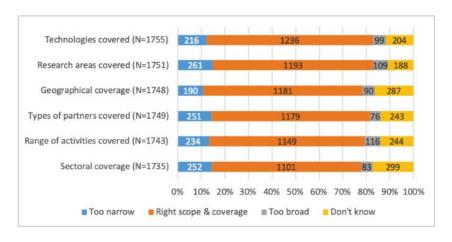
When comparing stakeholder categories there are only minor differences. Academic/research institutions indicated a slightly lower relevance for transparency, better links to regulators as well as obtaining the buy-in and long-term commitment of other partners. SMEs also

indicated a lower relevance regarding obtaining the buy-in and long-term commitment of other partners. Large companies showed a slightly higher relevance for implementing activities effectively, ensure better links to regulators, obtaining the buy-in and long-term commitment of other partners, synergies with other EU/MS programmes and collaboration with other EU partnerships. NGOs find it slightly more relevant to implement activities faster for sudden market or policy needs. Public authorities, however, find it slightly less relevant to facilitate collaboration with other European Partnerships than other respondents. The views of citizens show a slightly lower relevance for a legal structure in relation to implementing activities in an effective way. Respondents that are/were directly involved in a current/preceding partnership indicated a higher relevance across all elements presented.

1.2.8. Scope and coverage of the candidate European Partnerships based on their inception impact assessments

Consulted on the scope and coverage for the partnerships, based on their inception impact assessments, the large majority feels like the scope and coverage initially proposed in the inception impact assessments is correct. However, about 11% to 15% of the respondents indicated the scope and coverage to be too narrow. About 11%-17% of respondents answered "Don't know". Overall, differences between the main stakeholder categories were found to be minor. Academic/research institutions indicated slightly more often that the research area was "too narrow" then other respondents. SMEs on the other hand indicated slightly more often that the research area and the geographical coverage were "too broad". NGOs and public authorities, however, found the geographical coverage slightly more often "too narrow". Large companies found the range of activities slightly more often "too broad" and the sectoral focus slightly more often "too narrow" when compared to other respondents. The views of citizens are the same as for other respondents. Respondents that are/were directly involved in a current/preceding partnership more often indicated that the candidate institutionalised European Partnership have the "right scope & coverage".

Figure 16: What is your view on the scope and coverage proposed for this candidate institutionalised European Partnership, based on its inception impact assessment? (non-campaign replies) Aggregation of responses of all candidate initiatives



1.2.9. Scope for rationalisation and alignment of candidate European Partnerships with other initiatives

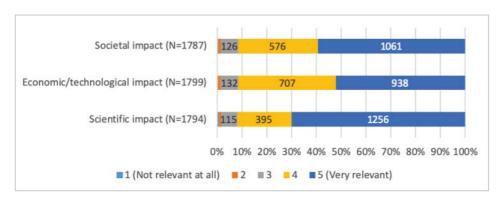
When asked whether it would be possible to rationalise a specific candidate European Institutionalised Partnership and its activities, and/or to better link with other comparable

initiatives, nearly two thirds of respondents answered "Yes" (1000, or 62%), while over one third answered "No" (609, or 39%). Nearly no differences were found between stakeholder categories, only large companies and SMEs indicated slightly more often "Yes" in comparison to other respondents. The views of citizens are the same as for other respondents. Respondents that are/were directly involved in a current/preceding partnership, indicated "No" more often, the balance is about 50/50 between "Yes" and "No" for this group.

1.2.10. Relevance of European Partnerships to deliver targeted scientific, economic/technological and societal impacts

Finally, respondents were asked to rate the relevance of partnership specific impacts in three main areas: Societal; Economic/technological; and Scientific impacts. All three areas were deemed (very) relevant across the candidate partnerships. Scientific impact was indicated as the most relevant impact, more than 90% of respondents indicated that this as (very) relevant. Only minor difference between stakeholder groups were found. Academic/research institutions found scientific impacts slightly more relevant, while large companies found economic and technological impacts slightly more relevant than other respondents. NGOs found societal impact slightly more relevant, while SMEs found this slightly less important. Citizens did not a significantly different view when compared to other respondents. Respondents that are/were directly involved in a current/preceding partnership find all impacts slightly more relevant than other respondents.

Figure 17: In your view, how relevant is it for the candidate European Institutionalised Partnership to deliver on the following impacts? (non-campaign replies) Aggregation of responses of all candidate initiatives



1.3. Stakeholder consultation results for this specific initiative

1.3.1. Feedback to the inception impact assessment on candidate initiatives for Institutionalised Partnerships

Following the publication of the inception impact assessment, a feedback phase of three weeks allowed any citizen to provide feedback on the proposed initiatives on the "Have your say" web portal. In total 350 feedbacks were collected for all initiatives.

For the initiative "Integrated Air Traffic Management" 28 individual feedbacks were collected, mainly from academic/research institutes, business associations, companies/business organisations and public authorities

Among the elements mentioned were:

- Institutional partnership under Article 187 of the TFEU is the one that best suits ATM.
- Baseline scenario of open calls is not an alternative to increase efficiency and speed up development or implementation of the Single European Sky of which EU economy and travelling public are the beneficiaries.
- A partnership for ATM is required due to the fragmented and conservative industry that without coordination will lead to stand alone research projects and lack of research continuity that will not help address the challenging tasks of R&I and deployment.
- ATM has specific challenges that require research coordination, expertise and resources from the whole value chain including key actors. Solutions that are still under development and future challenges are best address by a dedicated institutional ATM partnership
- The momentum, context and success of the SESAR Joint Undertaking should be followed up. The participation stability, resilience and experience acquired in the last 10 years by SESAR's systematic approach are required in order to follow the learning curve that will allow to address the future challenges.
- ATM due to its nature requires to ensure participation from cross-industry stakeholders, effective coordination and efficient execution across the network in order to bring economies of scale amongst a unified vision such as the current European ATM Master Plan, Flightpath 2050 goals or Single European Sky framework. In order to ensure this, political consensus in required.
- A free market will not lead to investments due to them being prohibitively high at an early stage. A European partnership is needed to ensure that R&I investments add value for the public and support job opportunities, sustainable, safety and innovative initiatives. This will allow to have a functioning international air traffic management that is beneficial for a transport network and a guarantor for the economic development in Europe.
- The partnership should create a systematic approach to successfully address the challenges of digitalisation (including augmented and virtual reality), Artificial Intelligence, big data, block chain, cyber security, automation, optimisation, sustainability, maximum environmental efficiency, accommodation of new airspace users, accommodation of traffic in complex airspace and single-pilot operations.
- Take a holistic approach that includes an adapted regulatory framework, operational aspects and development and maturation of the critical enabling technologies. Standardisation, and implementation are crucial to develop an interoperable, scalable and harmonised EU ATM system that safe, efficient, sustainable, connected, airspace and air transport.

- ATM Modernisation is a global issue and the partnership should keep a global mindset pushing towards harmonisation without leaving behind the R&I European focus. It should encourage networking and cooperation to promote EU standards at a global level in order to implement solutions that can be leveraged in terms of global industry. Solutions should be in line with ICAO recommendations and EASA regulations, especially for drones.
- To ensure better transition through the R&I pipeline and acceleration of development processes. Exploratory research is essential to feed the innovation pipeline and must be reinforced whilst accepting uncertainty to allow innovation. Reduction in bureaucracy, administrative overhead, funding flexibility and making results fully available could allow a smoother transition from R&I to development.
- Better regulation is key to close the gap between validation and industrialisation. It will enable to have a synchronized, coordinated and harmonized deployment of technologies based on positive Cost Benefit Analysis. Launch pilot and demonstration projects will also promote this.
- All types (and size) of stakeholders should contribute to the partnership, ensuring leader roles and responsibilities as well as a robust institutional governance. It is crucial to include the industrial or suppliers, social partners representing "human in the loop", service providers or operational stakeholders such as airspace users (this should be reinforced) and regulators like EASA. To enable this it should facilitate openness to enable newcomers to join and covering the whole European network including non-EU associate members that play a significant role.
- Diverging interests from the industry and service providers should not influence the research and development priorities but it should be kept customer and result driven. The focus should be on operational performance benefits for the whole network and society (including passengers).
- An ATM partnership should learn from other industries and domains whilst keeping a strong communication with affected communities. An example is to cooperate closely with Clean Sky. It should also apply lessons learned from previous ATM partnerships such as the SESAR Joint Undertaking.
- Coordination and clarity in the policy, vision, strategy/planning objectives and roles is necessary. The partnership should be in line with the European ATM Master Plan and ensure its maintenance, including recommendations of Airspace Architecture Study, Wise Person Group and European Court of Auditors report on the Single European Sky.

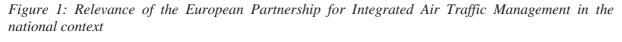
1.3.2. Structured consultation of the Member States on European partnerships

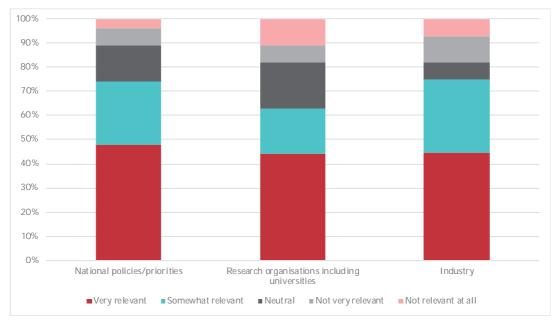
A structured consultation of Member States through the Shadow Strategic Configuration of the Programme Committee Horizon Europe in May/June 2019 provided early input into the preparatory work for the candidate initiatives.

For the initiative "Integrated Air Traffic Management" the following overall feedback was received from Member States. There is good agreement with the overall objectives, with some delegations proposing additional elements to strengthen the proposal – notably the research and innovation aspects. For smaller / EU-13 countries, better integration of aspects related to digitalisation, drones and small aircrafts into the EU ATM system would significantly increase the relevance of the partnership. Several countries highlight the need to elaborate on the involvement of Member States, the national services responsible for regulating and controlling air traffic. Comments also suggest broadening the partner composition with new categories of stakeholders.

Relevance and positioning in a national context

Overall the feedback from countries confirm the relevance of the proposed European Partnership for Integrated Air Traffic Management, with 74% considering it very or somewhat relevant for their national policies and priorities, and for their industry, and slightly less (63%) considering it relevant for their research organisations, including universities.





On the question of existing national/regional R&I strategies, plans and/ or programmes in support of the proposed Partnership, 17 countries report to have relevant elements in place. National R&I strategies or plans (52 %, AT, DE, ES, FR, HR, IE, IT, LV, NL, RO, SE, SI, NO) and national economic, sectoral strategy and/or plan with a strong emphasis on research and/or innovation (52 %, AT, ES, FI, FR, HR, HU, IE, IT, LV, NL, RO, SE, SI, NO) were identified most frequently. Countries reported to a lesser extent to having regional R&I and/or smart specialisation strategies (37 %, DE, ES, FR, HR, IE, IT, SE, SI, UK, NO), dedicated R&I funding programmes or instruments (30 %, DE, ES, FR, HR, IE, IT, RO, ES). 22% of countries (CZ, ES, HR, IE, SE, NO) reported other policies/ programmes, such as upcoming sectoral agenda, a national research innovation agenda, or R&I programmes focusing more broadly on disruptive technologies.

Delegations identified a number of aspects that could be reinforced in the proposal for this partnership that would increase its relevance for national priorities.⁵ Some delegations emphasised the need to more use of the results of the Airspace Architecture Study⁶ and the report of the Wise Persons Group on the Future of the Single European Sky⁷ that indicate a number of concrete recommendations aimed at optimising Europe's airspace organisation in such a way that can facilitate the uptake of new technologies, including research on the benefits, risks and effects of these proposals. Other individual comments make suggestions to further strengthen the following areas: reduction of departure/arrival delays, taxing and more

⁵ Comments on scope and content have to be assessed in the context of the overall priority setting to ensure coherence.

A proposal for the future architecture of the European airspace, SJU, 2019.

Report of Wise Persons Group on the future of the Single European Sky, 2019.

efficient local traffic management, Human Performance, Safety Performance and Cybersecurity, short term challenges like airspace capacity, integrating drones, and ATM efficiency and aviation safety. In the additional comments some countries reiterated the relevance of the Partnership and overall agreement with the proposed objectives, whilst others express the need for a more integrated/ systemic approach (including by merging the proposed partnership with the one on Clean Aviation), a stronger focus on research activities and better involvement of Member States in the agenda setting.

Most countries (63%) are at this stage undecided concerning their interest to participate, as a partner. At this stage 8 country (CZ, DE, ES, FR, CR, IE, IT, MT) express interest to join as a partner, and 4 (CY, EE, HU, IS) countries express no interest to participate.

A small share of countries report as potential partners or contributors regional R&I and /or smart specialisation strategies (33%), governmental research organisations (33%), research infrastructures (30%), and existing or planned national R&I programmes (30% and 26% respectively). Additional comments highlight countries wish to further clarify national involvement and contributions in the proposed partnerships. While some respondents express readiness for aligning national funding initiatives and contributing to the Partnership, others prefer to limit national involvement to aligning policies and exploiting synergies (notably with Cohesion Funds), but without any further commitment of funding.

While most are undecided concerning their participation, almost all countries (93%) expressed interest in having access to results produced in the context of the partnership.

Feedback on objectives and impacts

Overall there is a good agreement (74%) on the use of a partnership approach in addressing challenges related to air traffic management. There is strong agreement (70%) that the partnership is more effective in achieving the objectives and delivering clear impacts for the EU and its citizens, but to lesser degree that (56%) it would contribute to improving the coherence and synergies within the EU R&I landscape.

Member States indicate strong agreement with the proposed objectives at short, medium and long term (82%) and the expected scientific, economic and societal impacts at European level (82%), with the remaining ones remaining neutral. 71% of countries consider the impacts very or somewhat relevant in the national context. 70% of countries found the envisaged duration of the proposed partnership adequate, while 19% of countries need more information to assess this. Individual additional comments in relation to objectives highlight the following:

The need to address more research and innovation agendas;

The need to encourage deployment and implementation of new solutions;

Support stronger links with other related partnership candidates, notably to promote connectivity across transport modes;

More focus on accelerating digitalisation, integrating drones and small aircrafts into the EU ATM system, and security aspects (in addition to safety).

Views on partners, contributions and implementation

Majority of countries (62%) agree with the proposed type and composition of partners, and 26 % of respondents need more information for informed decision. In additional comments, several countries emphasised the need to move away from the current set up of the SESAR JU towards a model that facilitates the participation of smaller players and SMEs (e.g. in relation to the use of drones). Several countries highlight the need to elaborate on the involvement of Member States, in particular the national services responsible for regulating and controlling

air traffic. Comments also suggest to broaden the partner composition with new categories of stakeholders, such as communication and data service providers or regions with smaller airports represented by private partners and research organizations. Individual feedback also suggests increasing the level of cooperation with the military air traffic and European Union Aviation Safety Agency (EASA) to speed up the process of technology, and to engage citizens and civil society (as changes to the ATM will have impacts on when people will travel).

At this stage, most countries (74%) would need more information on contributions and level of commitments expected from partners.

The proposed use of Article 187 implementation mode is supported by 41% of countries, while 48% would require additional information. Whilst several countries express the added value of having an institutionalised partnerships, many also stress the need to ensure high level of openness and transparency of the JU model (notably by ensuring open competitive calls, and removing entry barriers for the participation of smaller organisation). At the same time, there are also some delegations expressing support to implementing this priority with a co-programmed partnership, and some who suggest a merger with the Partnership on Clean Aviation.

1.4. Targeted consultation of stakeholders

Targeted consultations with businesses, research organisations and other partners on different aspects of the potential on integrated Air Traffic Management.

Details about the methodology and specific interview are presented in the annexes of the Technopolis study.

Table 1: Number of interviews per stakeholder category

Stakeholder category	Number	Share (%)
Academia	2	4%
Airports	3	6%
Airspace user community	5	10%
Air navigation service providers (ANSPs)	7	14%
ATM institutions	7	14%
Member States/ Single European Sky (SES) Committee	3	6%
R&D organisations	2	4%
SESAR Joint Undertaking executive	8	16%
SMEs	2	4%
Staff	1	2%
Suppliers	6	12%
The UAV community	4	8%
TOTAL	50	

Key results/messages from the targeted consultation

It is worth noting that despite the variety of stakeholders' types, the responses to the stakeholder consultation show there is a strong consensus on their views of ATM R&I, with only slight differences, mainly in the details.

Emerging challenges

The need to modernise the existing system though the application of emerging technologies such as digitalisation, automation and big data was a recurrent theme amongst the interviewed and throughout all the categories. Generally, and more specifically airspace users, see as the main challenge addressing environmental sustainability. In addition, various stakeholders from the airspace user community, ANSPs, ATM institutions and Member States categories, brought up the fact that these challenges are very well reflected in the Airspace Architecture Study.⁸

In addition, airspace user community believe there should be further research in relation to manned and unmanned vehicle interaction.

⁸ SESAR Joint Undertaking (2019). A proposal for the future architecture of the European airspace. Available at https://www.sesarju.eu/node/3253.

EU positioning

Many stakeholders in the categories of ANSPs, ATM institutions and SESAR Joint Undertaking agree that European R&I ATM has currently a strong position worldwide, due to having built over the years a coordinated programme that has allowed them to have discussions at ICAO level and be an example for other parts of the world. Furthermore, some stakeholders, specially ATM institutions and the UAV community, stated the EU is losing its upfront position in some of the emerging markets since they develop quicker than the ATM solutions. In this area, the lack of coordinated R&I included in the ATM programme, would leave Europe behind other regions as China and USA which are investing heavily in the drones and UTM research and development.

Previous programmes

A typical comment, especially in the categories of ANSPs, Member States, staff and the SESAR Joint Undertaking executive, regarding the current R&I ATM partnership, SESAR Joint Undertaking (SJU), is that the past ten years allowed the programme to reach a mature situation creating a momentum in the industry, and the advantages of the partnership that has a common vision and will to implement it, can now be exhaustively exploited. SJU experience and results are the fruit of a continuous learning curve, which should be built upon, and lessons learned should be used for future improvements. Stakeholders across all the categories, stated that the SJU has achieved a balanced partnership, except for the need to involve EASA, standardisation bodies, and some new key players such as the UAV community.

There were comments from stakeholders that have been long time in the industry such as in ANSPs, ATM Institutions, suppliers and Member States that agree framework programmes previous to the SJU had a fragmented nature and were a proof that, in ATM, European network benefit is only achieved if there is coordination, and direction accomplished through the consensus across the whole industry. Furthermore, they agree we should not go back into those days given the challenges in front of the industry and national authorities.

Potential synergies between partnerships

A closer interaction with Clean Sky is required in order to avoid duplication, a greater coordination and synergies on the topics of automation and environment in aviation. However, almost every stakeholder interviewed in every category sees no benefit in merging. Merging the partnerships would not make sense due to their different *objectives*, *scope*, *timeline to deployment and KPIs*. In case of merger, we would have two subprogrammes under one partnership with funds distribution disputes and an increase in managerial complexity. This was further emphasised by the stakeholders that are involved in both partnerships.

With Shift to Rail the scope and the technologies to be researched are just too different. It would be a good idea to interact on the multimodality matters.

Directionality

Stakeholders across all the categories consider there is a need for EU funding on ATM research. They believe it provides directionality and coherence to an industry that cannot be developed nationally due to the cross-border nature of aviation operations which requires interoperability of national ATM systems. EU funding acts as a mechanism or framework to develop a common view on the future path and avoid singularities of nations or private companies.

Coordination

Action from EU, as stated by most stakeholders across all the categories, provides steering, avoids fragmentation and harmonises the whole value chain of ATM stakeholders. It ensures the benefits are accrued at European network level, thus providing latest technology to all stakeholders, in all geographical areas, not only for the most developed countries.

EU funding of R&I is required to attract investment and commitment from the industry. This is due to the need to outweigh the heavy administration, use of resources, and effort needed to participate in the EU funded R&I. Suppliers, R&D organisations and SMEs emphasised that they believe it is best to invest and commit to a future common path that benefits the whole European network. They need to see an eventual benefit that is worth the investment in order to overcome their individual interests of developing their own R&I and products in isolation, in the favour of a common architecture and goal. Industrial stakeholders such as suppliers and ANSPs stated this would happen if there was no EU funding.

European ATM Master Plan and Airspace Architecture Study as ATM R&I guidelines

Mentioned as a need by stakeholders in all the categories is the fact that a significant amount of future R&I is needed to complete the current research agenda and deliver the solutions under the latest edition of European ATM Master Plan.⁹

One of the objectives the potential partnership should have, to which all the stakeholders agree is the maintenance and update the European ATM Master Plan. The European ATM Master Plan sufficiently describes R&I needs in the long term, however the Airspace Architecture Study is a more detailed plan that prioritises the research needs in the shorter term. These need to be better linked with other strategic planning documents like EASA's European Plan for Aviation Safety, Deployment Programme, Network Strategic Plan. The European ATM Master Plan should also be more performance driven than it is today.

However, some stakeholders in various categories where critical regarding the heaviness of the document which requires changes so that is more understandable to members of public. There is some criticism of the Master Plan's lack of a far-seeing and innovative vision which the AAS does take into account. Thus, as said by stakeholders from airports, airspace user community, ANSPs, ATM institution, SESAR Joint Undertaking executive and suppliers, the Master Plan should include the AAS findings.

Furthermore, the European ATM Master Plan updates need to involve in consultation all the stakeholders as it is done currently.

R&I fragmentation

Many stakeholders across all categories directly or indirectly referred that the main problems of ATM are fragmentation of R&I and, consequently, operations. In the event of having no partnership, or a partnership without a neutral and strong coordinating body, fragmentation would be caused by two main reasons: diverging industry interests and sovereignty. This would worsen the current lack of interoperability. Most stakeholders, especially in the industrial and institutional side of the value chain: airspace user community, ANSPs, ATM institutions, Member States, SESAR Joint Undertaking executives, staff, suppliers and the

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SESAR Joint Undertaking (2019). European ATM Master Plan: Digitalising Europe's Aviation Infrastructure, Executive View, 2020 edition

EASA (2019). European Plan for Aviation Safety 2019-2023

SESAR Deployment Manager (2018). Deployment Programme edition 2018

EUROCONTROL (2015). Network Strategic Plan 2015-2019

UAV community, agree the interoperability is a key for a cross boundary industry such as aviation. Furthermore, they believe lack of interoperability is one of the key topics that needs further research in ATM since it leads to many issues. Thus, lack of coordination and direction in the ATM R&I would lead to R&I fragmentation, which has been highlighted as a problem that is a source of many other problems.

ATM system modernisation

Some stakeholders in the categories of service providers and suppliers mentioned that one of the needs is to develop a network centric system that is scalable, resilient and flexible to quickly adapt to external changes or new technologies. A system with these characteristics would solve the problem of airspace capacity which is strongly linked with other ATM inefficiencies.

As commented in the section on emerging challenges, stakeholders in all the categories make the point that R&I should focus on developing new technologies and concepts (e.g. automation or artificial intelligence) that aim at the overall system modernisation and digitalisation (ANSPs, suppliers and the UAV community emphasised the importance of digitalisation and automation).

R&I pace and its link with deployment

The pace of R&I is about right today. Acceleration, if needed, should not constrain quality nor safety. However, deployment does need to be accelerated through paying more attention to the implementation challenges (e.g. very large demonstrations and early demonstrators) and change management needed for deployment. This will allow to implement breakthrough technologies faster. Fundamental (exploratory), industrial and validation research activities are all needed, giving more importance to the validation exercises since it collects evidence for standards and regulations which facilitate deployment. There is a need to get closer to deployment and close gaps between the research and industrialisation phases. Eight of twelve stakeholder groups noted that closer cooperation and involvement of EASA and EUROCAE would support narrowing of the gap between the R&I and industrialisation phases. This issue was not commented on by academia, airports, R&D organisations and SMEs. Some stakeholders believe R&I should get a bit closer but to keep it separate from deployment while others believe it would be good to get very close or even into deployment using CEF funds. Airspace users agree that the end users such as ANSPs, airspace users and airports should be the ones driving R&I since they are more aware of the needs and it would avoid emergence of diverging interests among suppliers.

In addition, some stakeholders mentioned the need of prioritising R&I as it moves towards higher TRLs on its way to deployment.

Openness and transparency

Openness and transparency are important to be considered but there is a wide view that the current partnership, SESAR Joint Undertaking, addresses these values correctly. Fragmented data sharing needs to be tackled in order to enable the use of big data techniques. Communication of the research and solutions developed has to be kept as it is in the current partnership with expectations to keep improving it.

Comparative assessment of the policy options

Raseline

Throughout all the categories, stakeholders made the strong point that there is a need to build a partnership as a body that can steer the R&I coordinating key stakeholders continuously, to

achieve the common EU-wide long-term ATM vision. Thus, the baseline is not considered by them as a feasible option.

Co-programmed

A couple of stakeholders inside the categories of airports and the UAV community suggested that a co-programmed partnership could be a good idea in order to promote more competition between ideas and bring innovation whilst giving more opportunities and enhance the competitiveness of SMEs. However, a stakeholder from the SME category mentioned co-programmed could pick either the best or worst direction, and would likely be controlled by the big players. It was also seen as the preferred option by a stakeholder from the airspace user community since they believe it limits national influence. However, most of the stakeholders see it as a partnership type that lacks the cohesive strength required to move the R&I in the direction that has EU-wide benefits as a goal. Even if the European Commission may act as coordinating figure, it is not likely that the general Horizon Europe services would necessarily have core industry expertise to be able to coordinate R&I taking into account the long-term goals of deployment of results (as the services focus on R&I, not the uptake). The fact that it is non-legally binding creates a big risk in commitment from the key stakeholders leading to diverging interests.

Furthermore, many stakeholders, especially those at institutional level, agree that a co-programmed partnership would not have a necessary neutrality of coordination (given diverging interests). As co-programmed partnership would not have a status of a state institution, it would lose the ability to represent the EU ATM interests on international stage.

Institutional partnership under article 187

To progress the R&I in ATM and produce benefits for the entire society and network, there is a need to have legally binding commitments, strong leadership and steering because high efforts are required. In addition, the nature of ATM requires to have private members which have the industry experts but also public authorities such as EUROCONTROL and the European Commission in the centre to be the guiding light. Therefore, most of the stakeholders share the conviction that an institutionalised partnership (IP) under Article 187 with a similar set up to SESAR Joint Undertaking is the best option.

Furthermore, the current partnership achieved a unique vision for the future and the consensus between the stakeholders on the roadmap. The IP under Art 187 would push further the previous effort and make sure the last 10 years were not in vain.

Discarded options: co-founded and institutional partnership under article 185

Every interviewed stakeholder in all the categories, including stakeholders in the Member States category, made clear the point that in the ATM industry the relevant stakeholders are both in the public and in the private sector. The knowledgeable expertise can mainly be found in the private sector and the public sector is mainly composed by the Member States which do not get involved in R&I as such. This was highlighted when the Member States forwarded our interview invitation to their Single Sky Committee representatives (or advised to talk to their ANSP representative) as their role is in steering the R&I at a higher level, through providing opinion and approving the European ATM Master Plan.

Therefore, due to the low participation of public authorities in the R&I and the need to include the private industry, all the stakeholders (including those from Member States/SES) agreed that co-founded and institutional partnership under article 185 should be discarded.

The preferred option

Stakeholder involvement

One of the key added value of the current partnership is that it brings together the key stakeholders of the value chain to agree on the key European issues whilst keeping it manageable. This should be kept in the preferred option. However, some stakeholders across all the categories commented on the possibility of extending the partnership to the UAV community, business aviation, regulators, communication service providers and satellite communication service providers, and to have a stronger involvement of EASA (as a regulator) and standardisation bodies (e.g. EUROCAE). Airspace users, SMEs, staff and supplier stakeholder groups did not directly cite the inclusion of drones, but did endorse the European ATM Master Plan as a good strategic agenda (which includes these emerging challenges). There is a need to further involve airspace users and make R&I more market-driven for which EASA needs to be strongly involved. It would be interesting, if they exist, to involve experts in change management. Some stakeholders made the point of bringing innovative companies with cutting-edge solutions in the partnership, with the caveat to ensure they are stable.

Most of the airspace users stated that they do not have resources to participate directly in the research activities, but would like stronger involvement in the partnership similar to the current one. In the current one, they have a voice in the governance, but would like to expand that to the opportunity for higher involvement in the work.

Increase flexibility

There should be flexibility to enrol different stakeholders. Airspace users, the drone community, academia, SMEs and innovative companies should be enrolled in the partnership specially in topics where they can add significant value, but taking care to keep the governance manageable. In order to do so, some interviewees, especially in the ANSP and supplier category, suggested these could be involved as third party beneficiaries, through open calls or having different membership options with different membership fee and resource contribution. In having different membership options, it was mention that even if the contribution is different having members with different levels of say around the table adds complexity, so they should have the same say but not the same project engaging options.

Level of funding

The funding level of SESAR 2020 is the minimum needed. It must be borne in mind that if adding into the scope of the partnership, either by including new wide topics such as drones and digitalisation or by implementing Very Large Demonstration/ early adopters to get solutions closer to deployment, the funding should double. There is a threshold in the funding under which there is no leverage of the investment.

Winding down

Some suggestions from stakeholders, interviewed in the categories of ATM institutions and SESAR Joint Undertaking executive, on when to close down the institutional partnership include: once the European ATM Master Plan is achieved and the system only needs to be maintained in order make sure it does not degrade, once the process of digitalisation is sufficiently mature or once the industry is able to coordinate themselves following a strategic research and innovation agenda and overcoming individual interests.

This would slowly take place by reducing activity and switching from a strong coordinating body to a monitoring body.

1.5. Open Public Consultation

1.5.1. Characteristics of respondents

There are 66 respondents who have answered (part of) the consultation for the Integrated Air Traffic Management Partnership. Of these respondents, 10 (15.15%) were citizens. The largest group of respondents were businesses with 28 (42.42%) respondents. There were 8 respondents from academic and research institutions (12.12%) and 7 from both public authorities and business associations (10.61%). The remaining respondents were from NGO's (2, 3.03%), environmental organisations (1, 1.52%) and other (3, 4.55%). both with 123 respondents (32.20%). Over 3/4s of respondents, namely 51 (77.27%), have been involved in the on-going research and innovation framework programme, of which 38 respondents (74.51%) were directly involved in a partnership under Horizon 2020 or its predecessor Framework Programme 7.

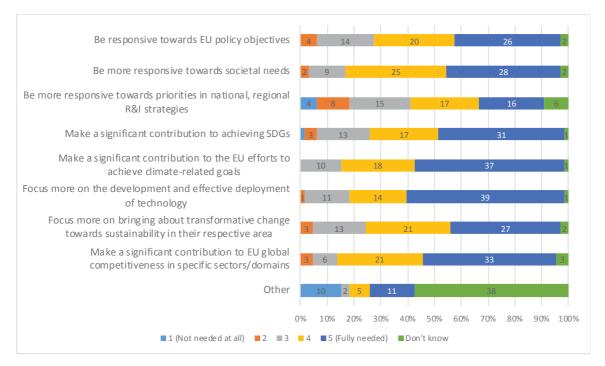
1.5.2. Results on general questions

Relevance of efforts of the candidate European Partnership to address problems

At the beginning of the consultation, the respondents were asked on their views of the needs of the future European Partnerships under Horizon Europe. All 66 respondents answered this question. Overall, respondents indicated that many of these needs were very relevant. The needs where most respondents indicated this, was focusing more on the development and effective deployment of technology (39, 59.09%) and making a significant contribution to EU efforts to achieve climate related goals (37, 56.06%). Aside from 'other', the options where the least amount of respondents indicated that they were very relevant, being more responsive towards priorities in national and/or regional R&I strategies (16, 24.24%). In the case of this option, the responses differ. This is also the only option (aside from other), where multiple respondents have indicated that it is not needed at all.

No statistical differences were found between the views of citizens and other respondents.

Figure 1: Views of the respondents in regard to the needs of future European Partnerships under Horizon Europe (N=66)



The respondents also had the option to indicate other needs. The results show that respondents have indicated needs around extensive support linkage, sustainable stakeholder development and safety.

The respondents also had the option to indicate other needs. Some indicated that ensuring the safety levels are taken into account is important. A few called for implementation of strategic research agenda and the long-term vision. Another topic was the importance of bridging the gap between the research and actual deployment of researched innovation. To finish with the call for paying attention to regulation from early research stages.

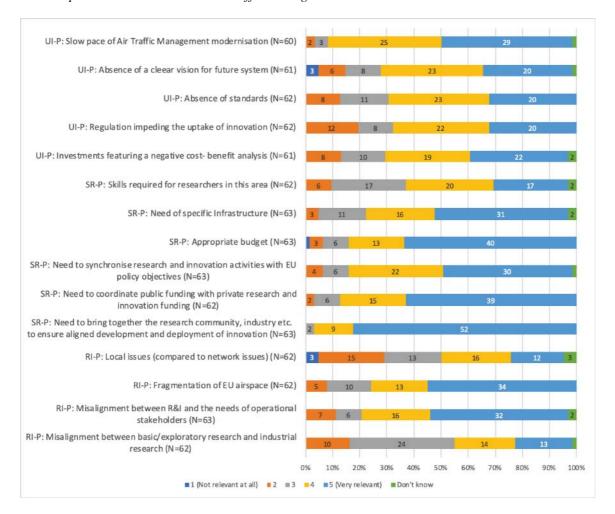
Main advantages and disadvantages of participation in the Institutionalised European Partnership

The respondents were asked what they perceived to be the main advantages and disadvantages of participation in an Institutionalised European Partnership (as a partner) under Horizon Europe. The keyword analysis used for open questions resulted in the graph shown in Figure 20. This analysis showed the respondents mentioned administrative burden, research and innovation programme framework and political agendas.

1.5.3. Results on the Integrated Air Traffic Management initiative

Relevance of research and innovation efforts at the EU level to address problems. In the consultation, respondents were asked to provide their view on the relevancy of research and innovation efforts at EU level to address the following problems in relation to air traffic management, specifically on three types of problems: problems in uptake of air traffic management innovations (UI-P), structural and resource problems (SR-P) and research and innovations problems (RI-P). In Figure 21, the responses to these answers are presented.

Figure 2: Views of respondents on relevance of research and innovation efforts at the EU level to address problems in relation to air traffic management



With regard to the uptake in innovation problems, 29 respondents have indicated that the research and innovation efforts at the EU level to address the issue of slow pace of Air Traffic Management modernisation is very relevant (48.33%), and further 25 stated it is relevant – 90% of all respondents, across all categories, find this as a relevant problem. Regarding other uptake of innovation problems, like absence of clear vision for future systems, regulation impeding the uptake of innovation and investments featuring negative cost-benefit analysis, about 60% of respondents stated that these are either very relevant or relevant. Furthermore, majority of individual stakeholders consider the absence of standards as one of the problems in uptake of air traffic management innovations (30% stated very relevant and 37% relevant problem). Majority of academic and half of business association stakeholders do not consider this problem as relevant.

There are large differences in the responses that the respondents have given with regard to structural and resource problems. 52 respondents have indicated that the need to bring together the Air Traffic Management research community is very relevant (82.54%). This problem has the most 'very relevant' answers of any of the problems that the respondents were asked to reflect on. About 85% of respondents stated that the questions of appropriate budget and the need to coordinate public funding with private research and innovation funding received are either very relevant or relevant. Another important finding is that 52 respondents (82%) stated that the need to synchronise research and innovation activities with EU policy objectives is very relevant or relevant in the ATM. While another of the structural

problems outlined: skills required for researchers in this area, only received 17 very relevant answers (27.42%). No specific differences in responses have been noted across different stakeholder categories.

Two of the research and innovation problems have received over 30 responses indicating that they are very relevant problems, namely the fragmentation of EU airspace and the misalignment between R&I and the needs of operational stakeholders. Almost 80% of stakeholders declared that fragmentation of EU airspace is relevant (13, or 21%) or very relevant (24, or 58%) problem to be addressed by research and innovation efforts at EU level. The two other problems only received a little over 10 of very relevant responses (12, 19.35% and 13, 20.97% respectively).

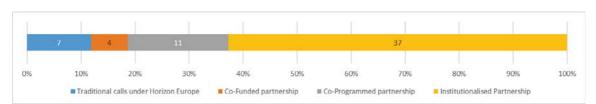
Slight statistical differences were found between the views of citizens and other respondents. Citizens found the "research and innovation problems related to more relevant and the structural and resource problems" less relevant. Respondents involved in a current or preceding partnership (Horizon 2020 or Framework Programme 7), found the uptake in innovation problems regarding regulation and the absence of a clear vision for future system less relevant.

Horizon Europe interventions to address problems

After providing their views on the relevance of problems, respondents were asked to indicate how these challenges could be addressed through Horizon Europe intervention. As shown in Figure 22, over 60% of respondents indicated that institutionalised partnerships were the best fitting intervention.

Citizens, compared to other respondents, indicated less often that institutionalised partnerships were the best fitting intervention.

Figure 3: Assessment of Horizon Europe intervention



The respondents were asked to briefly explain their answers to the question above. People who stated that an institutionalised partnerships was the best fitting answer, mentioned that the current partnership mechanism worked well, and that in order to achieve common EUlevel goals, this should be continued. The changes to the current settings mentioned by respondents relate to the need of more flexibility to be able to address changing goals in an agile manner. Further reasons included the statements that the entire ATM value chain is needed, where the respondents feel that the involvement of the value chain around the common strategic agenda in ATM is possible only through the Institutionalised Partnership. Further, the military cooperation on ATM issues should be formalised in the case of partnership continuation. Most of the respondents choosing this option mention the need to reduce as much as possible the administrative burden. Respondents choosing the Coprogrammed partnership (N=11) mentioned this being the middle ground between the offered options when complexity of the agenda, flexibility of partnership and costs are taken into account. The respondents choosing the Traditional calls mentioned that those are very well established (i.e. evaluation, management), and more open to competition, reducing the number of funding instruments. Most of the respondents choosing the Traditional calls are from citizen category.

Relevance of involvement of actors in setting joint long-term agenda

Respondents were asked how relevant the involvement of actors is in setting a joint long-term agenda to ensure that the proposed European Partnership would meet its objectives (Figure 24). The highest amount of respondents indicated that the involvement of Industry is very relevant (46 respondents or 69.70%). A large part of respondents also indicated that the involvement of Member States and Associated Countries (38, 57.58%) is very relevant. Less respondents indicated that the involvement of academia, foundations and NGO's and other stakeholders was very relevant. However over half of the respondents have indicated given academia and foundations either a score of 4 or 5 (very relevant) on the relevance scale. For other stakeholders this percentage is 37.87%.

No statistical differences were found between the views of citizens and other respondents.

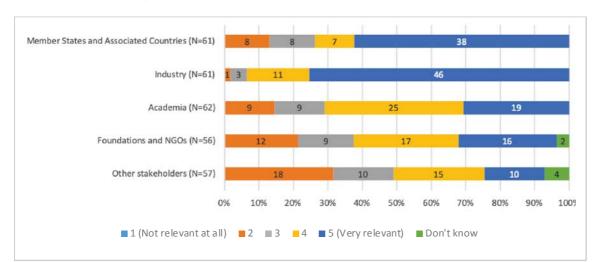


Figure 4: Views of respondents on relevance of actors in setting a joint long-term

Relevance of elements and activities in pooling and leveraging resources

With respect to the relevance of actors in pooling and leveraging resources, such as financial, infrastructure, in-kind expertise etc.), to meet Partnership objectives, the patterns are very similar. Most of the respondents (47, 75.81%) indicated that industry was very relevant. A large part of respondents also indicated that the involvement of Member States and Associated Countries (33, 55.93%) and Academia (22, 35.48%) is very relevant. Also, similar to the previous question, the Foundations and NGO's and other stakeholders were seen as less relevant and the opinions of the respondents seem divided on these types of stakeholders. No respondents indicated that any of the categories was Not relevant at all.

No statistical differences were found between the views of citizens and other respondents.

 Member States and Associated Countries (N=59)
 3
 11
 12
 33

 Industry (N=62)
 5
 10
 47

 Academia (N=62)
 9
 7
 24
 22

 Foundations and NGOs (N=57)
 14
 14
 19
 8
 2

 Other stakeholders (N=54)
 18
 11
 13
 7
 5

 0%
 10%
 20%
 30%
 40%
 50%
 60%
 70%
 80%
 90%
 100

 ■1 (Not relevant at all)
 ■2
 ■3
 4
 ■5 (Very relevant)
 ■ Don't know

Figure 5: Views of respondents on relevance of actors for pooling and leveraging resources

Relevance of the partnership composition

Respondents were asked about the relevance of Partnership composition, such as flexibility in the composition of partners over time and involvement of a broad range of partners (including across disciplines and sectors), to reach Partnership objectives. As it is visible in Figure 26, these questions were answered similarly. Ensuring involvement of a broad range of partners has slightly more 'very relevant' answers (26, 41.94%) than the flexibility in the composition of partners (23, 41.07%). Overall 75% of respondents have given flexibility either a score of 4 or 5 (very relevant) which is higher than the 70.97% who have given the broad range of partners a score of 4 or 5 (very relevant).

No statistical differences were found between the views of citizens and other respondents.

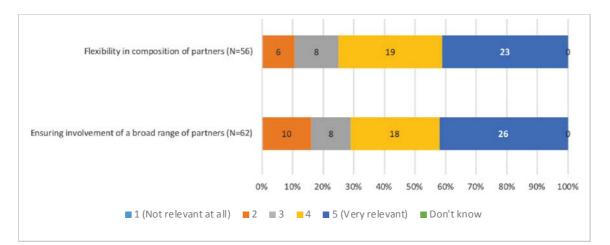


Figure 6: Views of respondents on relevance of partnership composition elements

Relevance of implementation of activities

Respondents were asked to provide opinions on relevance of implementation of several activities for meeting objectives of the Integrated Air Traffic Management Partnership. Among activities were listed – a joint R&D programme, collaborative R&D projects, deployment and piloting activities, input to regulatory aspects and co-creation of solutions with end-users. Out of 61 respondents, 49 (80.33%) indicated that co-creation of solutions

with end users were very relevant to ensure that the Partnership would meet its objectives. For all the other options, the majority (over 50%) of all respondents have indicated that these are very relevant. Respondents have answered 5 (fully relevant) the least in regard to deployment and piloting activities, although still 51,62% of respondents have given this answer. See Figure 27.

No statistical differences were found between the views of citizens and other respondents.

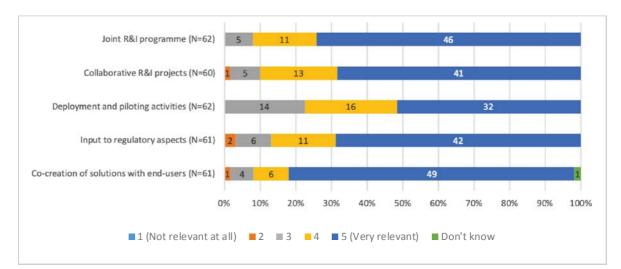


Figure 7: Views of respondents on relevance of implementation of the following activities

Relevance of a legal structure (funding body) to achieve specific objectives

Respondents were also asked to assess the relevance of a specific legal structure (funding body) for the candidate European Partnership to achieve several activities. According to Figure 28, respondents indicated that it was very relevant to set up a specific legal structure for the partnership to ensure harmonisation of standards and approaches (40, 64.52%), followed by the need to ensure better links with regulators (36, 58%). The implementation of activities more effectively is deemed relevant (21 respondents) or very relevant (32 respondents). The relevance of a specific legal structure to facilitate collaboration with other Partnerships is deemed the least relevant, as this question has received the most answers in category 3 of the 5 point relevance scale (20,97%) and the least 5 (very relevant) answers (24, 38.71%) of all the questions.

No statistical differences were found between the views of citizens and other respondents.

Implement its activities more effectively (N=60)
Implement activities faster to respond to sudden market or policy needs (N=62)
Implement activities more transparently (N=62)
Increase financial leverage (N=61)
Increase financial leverage (N=61)
Ensure better links to regulators (N=62)
Obtain more buy-in and long-term commitment from other partners (N=62)
Ensure harmonisation of standards and approaches (N=62)
Facilitate synergies with other EU and national programmes (N=62)
Facilitate collaboration with other relevant European Partnerships (N=59)

Figure 8: Views of respondents on relevance of a specific legal structure

Scope and coverage of the candidate European Partnership

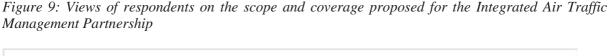
■ 1 (Not relevant at all) ■ 2 ■ 3

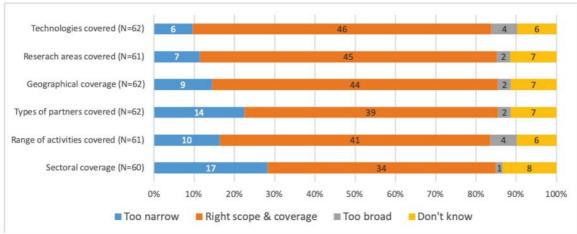
Respondents were asked to assess the scope and coverage of the Integrated Air Traffic Management, based on its inception impact assessment. The clear majority of the respondents have indicated that the partnership has the right scope and coverage across all areas. The respondents have been the most positive with regard to technologies covered, where 46 respondents (75.41%) have indicated the partnership has the right scope and coverage. Respondents found that the sectoral scope and coverage was right, the least often, while still over 56% of the respondents has indicated that it was the right scope. On average, the respondents who have indicated that the scope and coverage are too narrow, have done so as they feel that airspace users should be more involved in the new partnership than is the case today.

10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

■ 5 (Very Relevant) ■ Don't know

No statistical differences were found between the views of citizens and other respondents.





Aside from this multiple choice question, the respondents were also asked to provide any comment that they may have on the proposed scope and coverage for this candidate Institutionalised Partnership. Several responses (about 10 out of 34) mention the need for higher involvement of endusers, i.e. airspace users in the programme, taking into account their diversity (e.g. schedule, cargo, business airlines, general aviation). Several respondents just clarified that the assessment of scope and coverage was based on the current partnership, as they have not seen the proposal for the future partnership. Some stakeholders stated that the membership of the current partnership was not open to new entrants. The current partnership was mentioned as a good starting point for the future partnership. Furthermore, the need to reach sustainability goals was mentioned.

Alignment of the European Partnership with other initiatives

The respondents were also asked if they thought it would be possible to rationalise the candidate European Institutionalised Partnership and its activities, and/or to better link it with other comparable initiatives – 37 respondents (66.07%) have indicated that they think this is the case, 19 respondents (29%) have stated no (10 interviewees offered no responses). No statistical differences were found between the views of citizens and other respondents. The respondents who answered affirmative, where asked which other comparable initiatives it could be linked with. Thirteen respondents indicated that the Partnership should be linked to Clean Sky partnership. Several responses further stated that there should be no rationalisation, or that it was not clear what was meant by rationalisation. Key Digital Technologies and Smart Networks and Services initiatives were also mentioned as candidates for synchronisation and strong synergies.

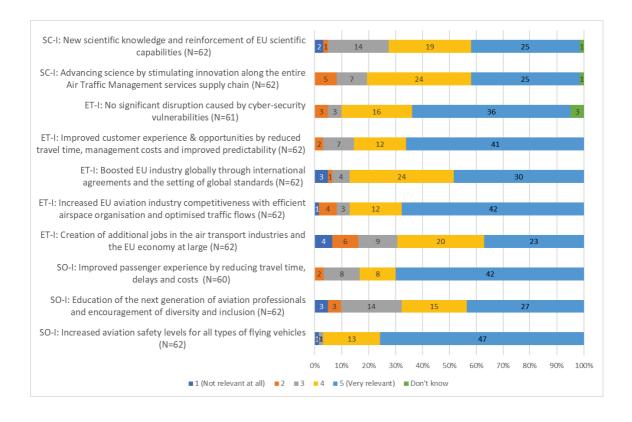
For the respondents who answered negatively on the previous question, respondents feel that there is almost no overlap on content of this initiative with other initiatives, but clear interfaces exist. According to them ATM R&I need very specific partners and expertise, and while it is already extremely complex, it must stay manageable.

Relevance of the Candidate European Partnership to deliver impacts

Respondents were asked to assess the relevance of the candidate European Institutionalised Partnership to deliver on listed impacts. According to Figure 33, the candidate Partnership is expected to be 'very relevant' for increasing aviation safety levels for all types of flying vehicles and for improving passenger experience by reducing travel time, delays and costs. In contrast, the impact on education of the next generation of aviation professionals and encouragement of diversity and inclusion is expected to be lower, as only 27 out of 62 respondents (43.55%) consider that the Partnership would be 'very relevant' for this, but further 39% of respondents find it relevant. Among listed economic/technological impacts, over 60% of respondents indicated that the candidate Partnership is relevant to achieve an impact on EU aviation industry competitiveness, on customer experience & opportunities by reduced travel time, management costs and improved predictability, and on the number of disruptions caused by cyber-security vulnerabilities. The pattern of responses about the scientific impacts are similar, however, a smaller number of respondents (about 40%) consider that the Partnership would have a very relevant effect on generation of new scientific knowledge and reinforcement of EU scientific capabilities, while further 30% of respondents find it relevant.

No statistical differences were found between the views of citizens and other respondents, except for the economic/technological impact related to the creation of additional jobs in the air transport industries and the EU economy at large which citizens found less relevant.

Figure 10: Views of respondents on the relevance of the candidate European Institutionalised Partnership to various impacts



Annex 3 Who is affected and how?

1. PRACTICAL IMPLICATIONS OF THE INITIATIVE

The proposed ATM R&I partnership aims to develop the technology needed to address the emerging challenges in the air traffic management sector, making the European airspace the most efficient and environmentally friendly sky to fly in the world. It will produce quantifiable contributions towards achieving two of the Commission's top priorities: the "European Green Deal" and a "Europe fit for the digital age" while supporting robust economic recovery of Europe and its hardly hit aviation sector after the COVID 19 crisis.

The following stakeholder groups are affected by the proposed initiative, as explained below:

- An aviation infrastructure that opens up digital opportunities for people and business and enhance Europe's position as a world leader in the digital economy will have a positive impact on private stakeholders across the whole aviation value chain. In particular airborne and ground system manufactures, air navigation and data service providers, airports and aircraft operators. This includes a number of European startups, SMEs and innovators that are challenging the status-quo in the field of drone technology.
- European universities and research-based organisations will play a pivotal role to increase the scientific knowledge base and contribute to accelerate the development of aviation innovations through collaboration with private enterprises.
- Citizens and the society will benefit from reduced emissions and noise as well as improved mobility by losing less time in airports and in the air, allowing European passengers to spend an additional 14.5 million hours currently lost with delays with their families or at work.
- Finally, in an increasingly globalized and interlinked world, there is pressure on policy makers and regulators to deliver rapid, functioning solutions to address climate change. The proposed Partnership will be instrumental in providing the relevant scientific and technology evidence in aviation to support those choice sand facilitating interactions between breakthrough innovators and early movers to help develop regulatory frameworks that allow the benefits of digital technologies to be fully realised.

2. SUMMARY OF COSTS AND BENEFITS

I. Overview of Benefits (total for all provisions) – Preferred Option						
Description Amount Comments						
Direct benefits						
Improve the Ability to handle additional flights enabling Direct benefits of ATM value chain Full scalability: creates the capacity needs to handle traffic in the most efficient was						

growth in air transport	Cumulative Benefit up to 2050: EUR 510bn	where and when capacity is needed.
		Safety: better trained humans using new technologies will increase safety beyond the current (already high) levels.
Enable new economic activity based on drones	Direct benefits of the U-space value chain Cumulative Benefit up to 2050: EUR 350bn	U-space and urban air mobility: A digitally native traffic management system will ensure the safe and secure integration of drones in the airspace especially in urban areas, taking into account new and existing air vehicles and autonomous operations. One of the most challenging use cases from U-space will be to enable urban air mobility, which is expected to advance autonomous technologies in a number of areas.
Boost EU industry globally through international agreements and the setting of global standards	Grow market share to 70% of the global market of approximately €4b per annum Cumulative Benefit up to 2050: EUR 84bn	Leadership of Europe in the world: Europe is currently the world leader in aerospace and aviation infrastructure technology. Unless this opportunity is taken it is likely that Europe will lose its leadership position and become more dependent on imports from third countries.
Reducing aviation noise and gas emissions	Reduction of 240 kg to 450 kg of CO ₂ on average per flight due to improved flight efficiency Cumulative Benefit in terms of fuel savings up to 2050: EUR 12bn	Zero environmental waste: eliminates environmental inefficiencies caused by the aviation infrastructure, ensuring that it offers solutions that will fully exploit the potential offered by the next generation aircraft for cleaner and quieter flight. A digital European sky could save 28 million CO ₂ tonnes per year, which is roughly equivalent to CO ₂ produced by 3.2 million people or the population in the metropolitan area of a city like Madrid.
	Indirect benefits	
Improve passenger experience by reducing travel time, delays and costs	Indirect benefits for passengers and EU citizens. Cumulative Benefit up to 2050: EUR 760bn	A digital and optimally managed European sky will ensure that passengers do not lose time at airports or in the air in Europe. In doing so, it could save yearly up to 14.5 million hours that passengers will be able to spend instead with their family or at work.

⁽¹⁾ Estimates are relative to the baseline for the preferred option as a whole (i.e. the impact of individual actions/obligations of the <u>preferred</u> option are aggregated together); (2) Please indicate which stakeholder group is the main recipient of the benefit in the comment section; (3) For reductions in regulatory costs, please describe details as to how the saving arises (e.g. reductions in compliance costs, administrative costs, regulatory charges, enforcement costs, etc.; see section 6 of the attached guidance).

(2) Estimates assume the successful roll-out into operations of the results of R&D as defined in the European ATM Master Plan which will be coordinated by the future partnership but will depend also on the evolution of the supporting regulatory framework which is outside of the direct control of the future partnership.

(3)

	II. Overview of costs – Preferred option						
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Administr ative Costs, including Personnel	Direct costs				EUR 6.1million (annual contribution for admin costs, jointly paid by the current 19 private partners + Eurocontrol)		EUR 3.3million (Union's annual contribution for administrative costs, including 39 FTEs)
	Indirect costs						
Action (b)	Direct costs						
	Indirect costs						

REFIT Cost savings table

Not applicable for the proposed ATM Partnership. The initiative will benefit from the existing organisation/structure (e.g. the Programme Office) already in place for the SESAR JU. There are no additional regulatory costs associated, and no specific simplification measures apply in this case.

Annex 4 Analytical Methods

The methodology for each impact assessment is based on the Commission Better Regulation Guidelines¹³ to evaluate and compare options with regards to their **efficiency**, **effectiveness** and **coherence**. This is complemented by integrating the **conditions and selection criteria** for European Partnerships, as well as requirements for setting up Institutionalised Partnerships.¹⁴

1. OVERVIEW OF THE METHODOLOGIES EMPLOYED

In terms of **methods and evidence used**, the set of impact assessments for all candidate Institutionalised European Partnerships draw on an external study covering all initiatives in parallel to ensure a high level of coherence and comparability of analysis ¹⁵.

All impact assessment mobilised a mix of qualitative and quantitative data collection and analysis methods. These methods range from desk research and interviews to the analysis of the responses to the Open Consultation, stakeholder analysis and composition/portfolio analysis, bibliometrics/patent analysis and social network analysis, and a cost-effectiveness analysis.

The first step in the impact assessment studies consisted in the definition of the context and the problems that the candidate partnerships are expected to solve in the medium term or long run. The main data source in this respect was desk research. This includes grey and academic literature to identify the main challenges in the scientific and technologic fields and in the economic sectors relevant for the candidate partnerships, as well as the review of official documentations on the policy context for each initiative.

In the assessment of the problems to address, the lessons to be learned from past and ongoing partnerships were taken into account, especially from relevant midterm or ex-post evaluations.

The description of the context of the candidate institutionalised European Partnerships required a good understanding of the corresponding research and innovation systems and their outputs already measured. Data on past and ongoing Horizon 2020 projects, including the ones implemented through Partnerships, served as basis for descriptive statistic of the numbers of projects and their respective levels of funding, the type of organisations participating (e.g. universities, RTOs, large enterprises, SMEs, public administrations, NGOs, etc.) and how the funding was distributed across them. Special attention was given to analysing the participating countries (and groups of countries, such as EU, Associated Countries, EU13 or EU15) and industrial sectors, where relevant. The sectoral analysis required enriching the eCORDA data received from the European Commission services with sector information extracted from ORBIS, using the NACE codification up to level 2. These data enabled the identification of the main and, where possible, emerging actors in the relevant systems, i.e. the organisations, countries and sectors that would need to be involved (further) in a new initiative.

¹³ European Commission (2017), Better Regulation Guidelines (SWD (2017) 350)

¹⁴ A pivotal element of the present analysis is the so-called two-step 'necessity test' for European Partnerships, used to establish: step 1) the need for a partnership approach in the first place, followed by step 2) a justification for the form of Institutionalised Partnership. The necessity test is described in Annex 6. This impact assessment focuses on the second step of the test.

¹⁵ Technopolis Group (2020), Impact Assessment Study for Institutionalised European Partnerships under Horizon Europe

A Social Network Analysis was performed by the contractors using the same data. It consisted in mapping the collaboration between the participants in the projects funded under the ongoing R&I partnerships. This analysis revealed which actors – broken down per type of stakeholders or per industrial sector – collaborate the most often together, and those that are therefore the most central to the relevant research and innovation systems.

The data provided finally served a bibliometric analysis run by the contractor aimed at measuring the outputs (patents and scientific publications) of the currently EU-funded research and innovation projects. A complementary analysis of the Scopus data enabled to determine the position and excellence of the European Union on the international scene, and identify who its main competitors are, and whether the European research and innovation is leading, following or lagging behind.

A cost modelling exercise was performed in order to feed into the efficiency assessments of the partnership options.

The conclusions drawn from the data analysis were confronted to the views of experts and stakeholders collected via three means:

- The comments to the inception impact assessments of the individual candidate institutionalised European Partnerships;
- The open public consultation organised by the European Commission from September to November 2019;
- The interviews (up to 50) conducted by each impact assessment study team conducted between August 2019 and January 2020 (policymakers, business including SMEs and business associations, research institutes and universities, and civil organisations, among others).

The views of stakeholders (and experts) were particularly important for determining the basic functionalities (see further below) that the future partnerships need to demonstrate to achieve their objectives as well as their most anticipated scientific, economic and technological, and societal impacts. The interviews allowed more flexibility to ask the respondents to reflect about the different types of European Partnerships. Furthermore, as a method for targeted consultation, it was used to get insights from the actors that both the Study Teams and the European Commission were deemed the most relevant. For the comparative assessment of impacts, the external contractors confronted the outcomes of the different stakeholder consultation exercises to each other with a view of increasing the validity of their conclusions, in line with the principles of triangulation.

Annex 2 includes also the main outcomes of the stakeholder consultation exercises.

2. METHOD FOR ASSESSING THE EFFECTIVENESS, EFFICIENCY AND COHERENCE OF EACH OPTION - THE USE OF FUNCTIONALITIES

Given the focus of the impact assessment on comparing different forms of implementation, the Better Regulation framework has been adapted to introduce "**key functionalities needed**" – so as to link the intended objectives of the candidate European Partnerships and what would be crucial to achieve them *in terms of implementation*. The identification of "key functionalities needed" for each initiative as an additional step in the impact assessment is

based on the distinguishing factors between the different options (see Section 2.2.1 in the main body of the impact assessment). In practical terms, each option is assessed on the basis of the degree to which it would allow for the key needed functionalities to be covered, as regards e.g. the type and composition of actors that can be involved ('openness'), the range of activities that can be performed (including additionality and level of integration), the level of directionality and integration of R&I strategies; the possibilities offered for coherence and synergies with other components of Horizon Europe, including other Partnerships (internal coherence), and the coherence with the wider policy environments, including with the relevant regulatory and standardisation framework (external coherence). This approach guides the identification of discarded options. It also allows for a structured comparison of the options as regards their effectiveness, efficiency and coherence, and also against a set of other key selection criteria for European Partnerships (openness, transparency, directionality)¹⁶.

Figure 3 Overview of key functionalities of each form of implementation of European Partnerships

Baseline: Horizon Europe calls	Option 1: Co- programmed	Option 2: Co- funded	Option 3.1: Institutionalised Article 185	Option 3.2: Institutionalised Article 187
Type and compositi	on of actors (including	openness and roles)		
Partners: N.A., no common set of actors that engage in planning and implementation Priority setting: open to all, part of Horizon Europe Strategic planning Participation in R&I activities: fully open in line with standard Horizon Europe rules	Partners: Suitable for all types: private and/or public partners, foundations Priority setting: Driven by partners, open stakeholder consultation, MS in comitology Participation in R&I activities: fully open in line with standard Horizon Europe rules	Partners: core of national funding bodies or governmental research organisations Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: limited, according to national rules of partner countries	Partners: National funding bodies or governmental research organisation Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: fully open in line with standard Horizon Europe rules, but possible derogations	Partners: Suitable for all types: private and/or public partners, foundations Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: fully open in line with standard Horizon Europe rules, but possible derogations
Type and range of a	ctivities (including add	itionality and level of	integration)	
Activities: Horizon Europe standards that allow broad range of individual actions Additionality: no additional activities and investments outside the funded projects Limitations: No systemic approach beyond individual actions	Activities: Horizon Europe standard actions that allow broad range of individual actions, support to market, regulatory or policy/ societal uptake Additionality: Activities/investment s of partners, National funding Limitations: Limited systemic approach beyond individual actions.	Activities: Broad, according to rules/programmes of participating States, State-aid rules, support to regulatory or policy/ societal uptake Additionality: National funding Limitations: Scale and scope depend on the participating programmes, often smaller in scale	Activities: Horizon Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to systemic approach Additionality: National funding	Activities: Horizon Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to systemic approach (portfolios of projects, scaling up of results, synergies with other funds. Additionality: Activities/investments of partners/ national

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¹⁶ The criterion on the ex-ante demonstration of partners' long term commitment depends on a series of factors that are unknown at this stage, and thus fall outside the scope of the analysis.

Baseline: Horizon Europe calls	Option 1: Co- programmed	Option 2: Co- funded	Option 3.1: Institutionalised Article 185	Option 3.2: Institutionalised Article 187
				funding
Directionality				
Priority setting: Strategic Plan and annual work programmes, covering max. 4 years. Limitations: Fully taking into account existing or to be developed SRIA/roadmap	Priority setting: Strategic R&I agenda/ roadmap agreed between partners and COM, covering usually 7 years, including allocation of Union contribution Input to FP annual work programme drafted by partners, finalised by COM (comitology) Objectives and commitments are set in the contractual arrangement.	Priority setting: Strategic R&I agenda/ roadmap agreed between partners and COM, covering usually 7 years, including allocation of Union contribution Annual work programme drafted by partners, approved by COM Objectives and commitments are set in the Grant Agreement.	Priority setting: Strategic R&I agenda/ roadmap agreed between partners and COM, covering usually 7 years, including allocation of Union contribution Annual work programme drafted by partners, approved by COM Objectives and commitments are set in the legal base.	Priority setting: Strategic R&I agenda/ roadmap agreed between partners and COM, covering usually 7 years, including allocation of Union contribution Annual work programme drafted by partners, approved by COM (veto-right in governance) Objectives and commitments are set in the legal base.
Coherence: internal industrial strategies	(Horizon Europe) and	external (other Union	programmes, national	programmes,
Internal: Between different parts of the Annual Work programme can be ensured by COM External: Limited for other Union programmes, no synergies with national/regional programmes and activities	Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Limited synergies with other Union programmes and industrial strategies If MS participate, with national/regional programmes and activities	Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Synergies with national/regional programmes and activities	Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Synergies with national/regional programmes and activities	Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Synergies with other Union programmes and industrial strategies If MS participate, with national/regional programmes and activities

In line with the Better Regulation Framework, the assessment of the effectiveness, efficiency and coherence of each option is made in comparison to the baseline. Therefore, for each of the above criteria, the performance of using traditional calls under Horizon Europe is first estimated and scored 0 to serve as a reference point. When relevant, this estimation also includes the costs/benefits of discontinuing existing implementation structures. The policy options are then scored compared to the baseline with a + and – system along a two-point scale, to indicate limited (+ or -) or high (++ or --) additional/lower performance compared to the baseline. When a policy option is scored 0, this means that its impact is expected to be roughly equal to the baseline option.

On the basis of the evidence collected, the intervention logic of each initiative and the key functionalities needed, the impact assessments first evaluate the **effectiveness** of the various policy options to deliver on their objectives. To be in line with the Horizon Europe impact framework, the fulfilment of the specific objectives of the initiative is translated into 'expected impacts' - how success would look like -, differentiating between scientific, economic/ technological, and societal (including environmental) impacts. Each impact assessment considers to which extent the different policy options provides the 'key functionalities needed' to achieve the intended objectives. The effectiveness assessment does not use a compound score but shows how the options would deliver on the different types of expected impacts. This is done to increase transparency and accuracy in the assessment of options¹⁷.

A similar approach is followed to evaluate the coherence of options with the overarching objectives of the EU's R&I policy, and distinguishes between **internal** and **external coherence**. Specifically, internal coherence covers the consistency of the activities that could be implemented with the rest of Horizon Europe, including European Partnerships (any type). External coherence refers to the potential for synergies and/or complementarities (including risks of overlaps/gaps) of the initiative with its external environment, including with other programmes under the MFF 2021-27, but also the framework conditions at European, national or regional level (incl. regulatory aspects, standardisation).

To compare the expected costs and benefits of each option (efficiency), the thematic impact assessments broadly follow a cost-effectiveness approach 18 to establish to which extent the intended objectives can be achieved for a given cost. A preliminary step in this process is to obtain a measure of the expected costs of the policy options, to be used in the thematic assessments. As the options correspond to different implementation modes, relevant cost categories generally include the costs of setting-up and running an initiative. For instance, setup costs includes items such as the preparation of a European Partnership proposal and the preparation of an implementation structure. The running costs include the annual work programme preparation costs. Where a Partnership already exists, discontinuation costs and cost-savings are also taken into account 19. The table below provides an overview of the cost categories used in the impact assessment and a qualitative scoring of their intensity when compared to the baseline option (traditional calls). Providing a monetised value for these average static costs would have been misleading, because of the different features and needs of each candidate initiative.²⁰ The table shows the overall administrative, operational and coordination costs of the various options. These costs are then put into context in the impact assessments to reflect the expected co-financing rates and the total budget available for each of the policy options, assuming a common Union contribution (cost-efficiency):

1

¹⁷ In the thematic impact assessments, scores are justified in a detailed manner to avoid arbitrariness and spurious accuracy. A qualitative or even quantitative explanation is provided of why certain scores were given to specific impacts, and why one option scores better or worse than others.

¹⁸ For further details, see Better Regulation Toolbox # 57.

¹⁹ Discontinuation costs will bear winding down and social discontinuation costs and vary depending on e.g. the number of full-time-equivalent (FTEs) staff concerned, the type of contract (staff category and duration) and applicable rules on termination (e.g. contracts under Belgian law or other). If buildings are being rented, the cost of rental termination also apply. As rental contracts are normally tied to the expected duration of the current initiatives, these termination costs are likely to be very limited. In parallel, there would also be financial cost-savings related to the closing of the structure, related to operations, staff and coordination costs in particular. This is developed further in the individual efficiency assessments.

²⁰ A complete presentation of the methodology developed to assess costs as well as the sources used is described in the external study supporting this impact assessment (Technopolis Group, 2020).

- The costs related to the baseline scenario (traditional calls under Horizon Europe) are pre-dominantly the costs of implementing the respective Union contribution via calls and project, managed by the executive agencies (around 4%, efficiency of 96% for the overall investment).
- For a Co-Programmed partnership the costs of preparation and implementation increase only marginally compared to the baseline (<1%),²¹ but lead to an additional R&I investment of at least the same amount than the Union contribution²² (efficiency of 98% for the overall investment).
- For a Co-Funded partnership the additional R&I investment by Member States accounts for 2,3 times the Union contribution²³. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the national programmes, can be estimated at 6% of the Union contribution (efficiency of 98% related to the overall investment).²⁴
- For an Article 185 initiative the additional R&I investment by Member States is equal to the Union contribution²⁵. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the dedicated implementation structure, can be estimated at 7% of the Union contribution (efficiency of 96% related to the overall investment).
- For an Article 187 initiative the additional R&I investment by partners is equal to the Union contribution²⁶. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the dedicated implementation structure, can be estimated at 9% of the Union contribution (efficiency of 94% related to the overall investment).

Figure 4 - Intensity of additional costs compared with Horizon Europe Calls (for Partners, stakeholders, public and EU)

Cost items	Baseline: traditional calls	Option 1: Coprogrammed	Option 2 Co-funded	Option 3a - Art. 185	Option 3b -Art. 187
Preparation and set-up costs					
Preparation of a partnership proposal (partners and EC)	0		$\uparrow \uparrow$		
Set-up of a dedicated implementation structure		0		Existing: ↑ New: ↑↑	Existing: \\ New: \\\ \\
Preparation of the SRIA / roadmap	0		$\uparrow \uparrow$		
Ex-ante Impact Assessment for partnership		0		11	↑
Preparation of EC proposal and negotiation		0		↑ ↑	\uparrow

²¹ Specifically, some additional set-up costs linked for example to the creation of a strategic research and innovation agenda (SRIA) and additional running costs linked with the partners role in the creation of the annual work programmes and the Commission's additional supervisory responsibilities. A CPP will have lower overall costs than each of the other types of European Partnership, as it will function with a smaller governance and implementation structure than will be required for a Co-Funded Partnership or an Institutionalised Partnership and – related to this – its calls will be operated through the existing HEU agencies and RDI infrastructure and systems.

 $^{^{\}rm 22}$ Minimum contributions from partners equal to the Union contribution.

²³ Based on the default funding rate for programme co-fund actions of 30%, partners contribute with 70% of the total investment.

²⁴ These costs reflect set-up costs and additional running costs for partners, and the Commission, of the distributed, multi-agency implementation model.

²⁵ Based on the minimum requirement in the legal basis that partners contribute at least 50% of the budget.

²⁶ Based on the minimum requirement in the legal basis that partners contribute at least 50% of the budget.

Cost items	Baseline: traditional calls	Option 1: Coprogrammed	Option 2 Co-funded	Option 3a - Art. 185	Option 3b -Art. 187
Running costs (Annual cycle of implementation)					
Annual Work Programme preparation	0		1		
Call and project implementation	0	0 In case of MS contributions: ↑	\uparrow	1	↑
Cost to applicants	Comparable, unless there are strong arguments of major differences is oversubscription			fferences in	
Partners costs not covered by the above	0	↑	0	↑	↑
Additional EC costs (e.g. supervision)	0	1	↑	↑	$\uparrow \uparrow$
Winding down costs					
EC		0			$\uparrow \uparrow \uparrow$
Partners	0	\uparrow	0	↑	↑

Notes: 0: no additional costs, as compared with the baseline; \uparrow : minor additional costs, as compared with the baseline; $\uparrow \uparrow$: medium additional costs, as compared with the baseline; $\uparrow \uparrow \uparrow$: higher costs, as compared with the baseline.

The cost categories estimated for the common model are then used to develop a scorecard analysis and further refine the assessment of options for each of the 12 candidate Institutionalised Partnerships. Specifically, the scores related to the set-up and implementation costs are used in the thematic impact assessments to consider the scale of the expected benefits and thereby allow a simple "value for money" analysis (cost-effectiveness). In carrying out the scoring of options, the results of fieldwork, desk research and stakeholder consultation undertaken and taken into account.

More specifically for the ATM partnership, building on the assumptions outlined in Figure 4 and the known real costs, e.g. from the current SESAR JU implementation, the additional costs compared to the baseline are about 6-7% of the Union's contribution. When considering the fact that over 60% of these administrative costs are covered by private and intergovernmental partners (i.e. Eurocontrol), re-establishing the JU is roughly similarly efficient to the baseline scenario (96%-97%), and only one percentage point behind in efficiency to the co-programmed partnership. Considering the fact that the Art 187 initiative has the highest ability to deliver the highest expected impacts, it delivers the best value for the Union budget investment.

3. METHOD FOR IDENTIFYING THE PREFERRED OPTION – THE SCORECARD ANALYSIS

For the **identification of the preferred option**, a scorecard analysis is used to build a hierarchy of the options by individual criterion and overall in order to identify a single preferred policy option or in case of an inconclusive comparison of options, a number of 'retained' options or hybrid. This exercise supports the systematic appraisal of alternative options across multiple types of monetary, non-monetary and qualitative dimensions. It also allows for easy visualisation of the pros and cons of each option. Each option is attributed a score of the adjudged performance against each criterion with the three broad appraisal dimensions of effectiveness, efficiency and coherence.

This scorecard approach also relies on a standard cost model developed for the external study supporting the impact assessment, as illustrated in **Error! Reference source not found.** Specifically, the scores related to the set-up and implementation costs are used in the thematic impact assessments to consider the scale of the expected benefits and thereby allow a simple "value for money" analysis (**cost-effectiveness**). In carrying out the scoring of options, the

results of fieldwork, desk research and stakeholder consultation undertaken and taken into account.

These costs essentially refer to the administrative, operational and coordination costs of the various options. The figure shows how the scoring of costs range from a value of 0, in case an option does not entail any additional costs compared to the baseline (traditional calls), to a score of (-) for options introducing limited additional costs relative to the baseline and a score of (-) when substantial additional costs are expected in comparison with the baseline. Should the costs of a policy option be lower than those of the baseline, (+) and (++) are used.

It is considered that while there is a clear gradation in the overall costs of the policy options, the cost differentials are less marked when one takes into account the expected co-financing rates and the total budget available for each of the policy options, assuming a common Union contribution. From this perspective, there are only one or two percentage points that split the most cost-efficient policy options – the baseline (traditional calls) and the Co-Programmed policy options – and the least cost-efficient – the Institutionalised Partnership option. A score of + is therefore assigned for **cost-efficiency** to the Co-Programmed and Co-Funded options, a score of 0 to the Article 185 option and a score of (-) for the Article 187 Institutionalised Partnership policy option²⁷.

Figure 5: Matrix on 'overall costs' and 'adjusted cost scoring'

	Baseline: Horizon Europe calls	Option 1: Co- programmed	Option 2: Co- funded	Option 3a: Institutionalised 185	Option 3b: Institutionalised 187
Administrative, operational and coordination costs	0	(0)	(-)	()	()
Administrative, operational and coordination costs adjusted per expected co-funding (i.e. cost- efficiency)	0	(+)	(+)	(0)	(-)

Notes: Score 0 = same costs as for the baseline; score (-) = limited additional costs compared to baseline; score (- -) = substantial additional costs compared to baseline.; score (+) = lower costs compared to baseline

²⁷ The baseline (traditional calls) is scored 0, as explained above.

Annex 5 Subsidiarity Grid

1. Can the Union act? What is the legal basis and competence of the Unions' intended action?

1.1 Which article(s) of the Treaty are used to support the legislative proposal or policy initiative?

This proposal is based on (1) Article 185 TFEU which stipulates that in implementing the multiannual framework programme, the Union may make provision, in agreement with the Member States concerned, for participation in research and development programmes undertaken by several Member States, including participation in the structures created for the execution of those programmes; and (2) Article 187 TFEU according to which the Union may set up joint undertakings or any other structure necessary for the efficient execution of Union research, technological development and demonstration programmes (both Articles are under Title XIX of the TFEU - Research and Technological Development and Space).

The proposal aims to implement Article 8 of the Commission proposal for Horizon Europe the future EU research and innovation (R&I) programme for 2021-2027, according to which, "European Partnerships shall be established for addressing European or global challenges only in cases where they will more effectively achieve objectives of Horizon Europe than the Union alone and when compared to other forms of support of the Framework programme". The Horizon Europe proposal has received the political agreement of the Council and the European Parliament.

1.2 Is the Union competence represented by this Treaty article exclusive, shared or supporting in nature?

Research is a shared competence between the EU and its Member States according to the TFEU. Article 4 (3) specifies that in the areas of research, technological development and space, the European Union can carry out specific activities, including defining and implementing programmes, without prejudice to the Member States' freedom to act in the same areas.

Subsidiarity does not apply for policy areas where the Union has **exclusive** competence as defined in Article 3 TFEU²⁸. It is the specific legal basis which determines whether the proposal falls under the subsidiarity control mechanism. Article 4 TFEU²⁹ sets out the areas where competence is shared between the Union and the Member States. Article 6 TFEU³⁰ sets out the areas for which the Unions has competence only to support the actions of the Member States.

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²⁸ https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12008E003&from=EN

https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12008E004&from=EN https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12008E006:EN:HTML

2. Subsidiarity Principle: Why should the EU act?

2.1 Does the proposal fulfil the procedural requirements of Protocol No. 2³¹:

- Has there been a wide consultation before proposing the act?
- Is there a detailed statement with qualitative and, where possible, quantitative indicators allowing an appraisal of whether the action can best be achieved at Union level?

This proposal and the accompanying impact assessment were supported by a wide consultation of stakeholders, both during the preparation of the Horizon Europe proposal and - later on, all the candidates for European Partnerships. Member States were consulted via the Shadow Strategic configuration of the Horizon Europe Programme Committee. On candidates for institutionalised Partnerships based on Article 185/187 of the TFEU, an Open Public Consultation (OPC) was held between 11 September and 6 November 2019. Over 1 600 replies were received. In addition, targeted consultation activities were undertaken to prepare the present impact assessment. In particular, for each of the candidate partnerships, an external consultant interviewed a representative sample of stakeholders. The need for EU action as well as its added value were covered in those interviews.

The explanatory memorandum and the impact assessment (horizontal part, Section 3) contain a dedicated section on the principle of subsidiarity, as explained in question 2.2 below.

2.2 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the conformity with the principle of subsidiarity?

The impact assessment accompanying the proposal features a horizontal part on relevant common elements to all the candidate partnerships, including the conformity of the proposed initiative with the principle of subsidiarity (Section 3). Moreover, the individual assessments of each candidate partnership include additional details on subsidiarity, touching in particular on the specificities of a candidate partnership that could not be adequately reflected in the horizontal part of the impact assessment. This will also be reflected in the explanatory memorandum.

2.3 Based on the answers to the questions below, can the objectives of the proposed action be achieved sufficiently by the Member States acting alone (necessity for EU action)?

National action alone cannot achieve the scale, speed and scope of support to R&I needed for the EU to meet its long-term Treaty objectives, to deliver on the EU's strategic policy priorities (including the climate and energy goals set out in the Paris Agreement, and the European Green Deal), and to contribute to tackling global challenges and meeting the

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³¹ https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12016E/PRO/02&from=EN

Sustainable Development Goals (SDGs).

(a) Are there significant/appreciable transnational/cross-border aspects to the problems being tackled? Have these been quantified?

The thematic areas covered by the candidate partnerships feature a series of challenges in terms of cross-border/transnational aspects, need to pool resources, need for a critical mass to meet intended policy objectives, need to coordinate different types of actors (e.g. academia, industry, national and regional authorities) across different sectors of the economy and society, which cannot be tackled to the same degree by Member States alone. This is particularly true for the research and innovation (R&I) dimension of the proposed initiative: the importance of a multi-centre and interdisciplinary approach, cross-country data collection and research, and the need to develop and share new knowledge in a timely and coordinated manner to avoid duplication of efforts are key to achieve high quality results and impact. The Interim Evaluation of Horizon 2020 and the impact assessment of Horizon Europe provide extensive qualitative and quantitative evidence on the above points. In addition, Sections 1 and 2 of the individual impact assessments on the candidate partnerships include more detail on the necessity to act at EU-level in specific thematic areas. Finally, it is worth noting that not all Member States have the same capacity or R&I intensity to act on these challenges. As the desired policy objectives can be fully achieved only if the intended benefits are widespread across the Member States, this requires action at the EU-level.

(b) Would national action or the absence of the EU level action conflict with core objectives of the Treaty³² or significantly damage the interests of other Member States?

As per Article 4(3) TFEU, national action does not conflict with core objectives of the Treaty in the area of R&I. The absence of EU level action in this area would however prevent the achievement of core objectives of the Treaty. Indeed, national action alone cannot achieve the scale, speed and scope of support to R&I needed for the EU to meet its long-term Treaty objectives on e.g. competitiveness, to deliver on the EU's strategic policy priorities, and to contribute to tackling global challenges and meet the Sustainable Development Goals (SDGs).

(c) To what extent do Member States have the ability or possibility to enact appropriate measures?

As foreseen by Article 4(3) TFEU, this proposal does not hamper Member States' ability to enact appropriate measures in the field of R&I. However, the scale and complexity of the policy objectives pursued by the present initiative cannot be fully addressed by acting at national level alone.

(d) How does the problem and its causes (e.g. negative externalities, spill-over effects)

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³² https://europa.eu/european-union/about-eu/eu-in-brief en

vary across the national, regional and local levels of the EU?

As described in the horizontal part of the impact assessment accompanying the present proposal, several problems (e.g. on competitiveness, global challenges, demographic change) and their underlying causes affect the EU as a whole rather than individual Member States. Where important differences between Member States are present, these are described in Sections 1 and 2 of the individual impact assessments.

(e) Is the problem widespread across the EU or limited to a few Member States?

The problem of coordinating R&I efforts in the thematic areas covered by the candidate partnerships affects all Member States, albeit to different degrees. However, from a general EU perspective, available evidence shows that the EU as a whole needs to step up efforts and investments in thematic areas that are crucial to tackle present and future policy challenges on several fronts, e.g. ageing population, global technological trends, and climate change to name a few. The way these problems affect the EU and its Member States is described in the horizontal part of the impact assessment and in Sections 1 and 2 of the individual impact assessments.

(f) Are Member States overstretched in achieving the objectives of the planned measure?

As indicated in the horizontal part of the impact assessment and in Sections 1 and 2 of the individual assessments, the sheer scale, speed and scope of the needed support to R&I would overstretch national resources, without guaranteeing the achievement of the intended objectives. Acting at EU-level would achieve greater impact in a more effective and efficient manner.

(g) How do the views/preferred courses of action of national, regional and local authorities differ across the EU?

No specific differences between the views of national, regional and local authorities emerged from the stakeholder consultation.

2.4 Based on the answer to the questions below, can the objectives of the proposed action be better achieved at Union level by reason of scale or effects of that action (EU added value)?

EU funded R&I activities, including those covered by the present proposal, produce demonstrable benefits compared to the corresponding national and regional initiatives, due to the scale, speed and scope achievable by acting at the EU level. In addition, the proposed initiatives should be seen as complementary and reinforcing national and sub-national initiatives in the same area.

(a) Are there clear benefits from EU level action?

Quantitative and qualitative evidence of the benefits of EU level action are available in the interim evaluation of Horizon 2020 and in the impact assessment of Horizon Europe, among others. An analysis of the emerging challenges in each thematic areas, of the EU's competitive positioning, as well as feedback gathered from different types of stakeholders for the present impact assessment indicate that EU level action remains appropriate also for the present proposal. In addition, the benefits of acting at EU-level have been illustrated by the success and the impact achieved by the predecessors to the proposed initiative.

(b) Are there economies of scale? Can the objectives be met more efficiently at EU level (larger benefits per unit cost)? Will the functioning of the internal market be improved?

EU funded R&I activities, including those covered by the present proposal, produce demonstrable benefits compared to the corresponding national and regional initiatives, due to the scale, speed and scope achievable by acting at the EU level. This is the case both in terms of effectiveness in achieving intended policy objectives, but also in terms of efficiency. Positive impact is also visible in terms of competitiveness: recent data on EU funded R&I activities indicate that EU-funded teams grow 11.8% faster and are around 40% more likely to be granted patents or produce patents applications than non-EU funded teams. Efficiency gains are also visible in terms of dissemination of results to users beyond national borders, including SMEs and citizens. EU funded R&I is more effective in leveraging private investment. Finally, there are clear additionality benefits (i.e. EU R&I funding does not displace or replace national funding), as the EU focuses on projects that are unlikely to be funded at national or regional level. Overall, this is beneficial to the functioning of the internal market in several respects, including human capital reinforcement through mobility and training, the removal of barriers to cross-border activity for economic players including SMEs, easier access to finance and to relevant knowledge and research, and increased competition in the area of R&I.

(c) What are the benefits in replacing different national policies and rules with a more homogenous policy approach?

A homogeneous policy approach in the various thematic areas covered by the present proposal would reduce fragmentation and increase efficiency and effectiveness in meeting the intended policy objectives. Indeed fragmentation, persisting barriers in the internal market and differences in the resources available to Member States are some of the key problems that stand in the way of fully achieving the intended policy objectives and reaching the required critical mass to obtain tangible results. Specific detail on how these issues differ in each thematic area are illustrated in Sections 1 and 2 of the individual impact assessments, so as to reflect the specificities of each case.

(d) Do the benefits of EU-level action outweigh the loss of competence of the Member States and the local and regional authorities (beyond the costs and benefits of acting at

national, regional and local levels)?

The proposed initiative does not lead to a loss of competence of the Member States. In fact, the proposed initiative should be seen as complementary and reinforcing national and subnational initiatives in the same area. Previous quantitative and qualitative assessments of Horizon Europe and Horizon 2020 have shown that the proposed EU-level action do not displace national ones and tend to concentrate on initiatives that would not have been funded by the Member States themselves, or would not have reached the same scale and ambition without EU-level intervention, due to their complexity and trans-national nature.

(e) Will there be improved legal clarity for those having to implement the legislation?

Yes. The proposed initiatives will be implemented in line with the Horizon Europe single set of rules for participation; this will ensure increased clarity and legal certainty for end beneficiaries, other stakeholders and programme administrators. It will also reduce the administrative burden for beneficiaries, and for the Commission services. In addition, the accessibility and attractiveness of the broader Horizon Europe programme, in particular for applicants with limited resources, would be sustained.

3. Proportionality: How the EU should act

3.1 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the proportionality of the proposal and a statement allowing appraisal of the compliance of the proposal with the principle of proportionality?

The principle of proportionality underpins the entire analysis of the candidate partnerships. Specifically, the analysis included in the accompanying impact assessment is structured along the following logic: 1. Justification of the use of a partnership approach in a given area (including considerations on additionality, directionality, link with strategic priorities) instead of other forms of intervention available under Horizon Europe; 2. If the partnership approach is deemed appropriate, proportionality considerations guide the assessment of which type of partnership intervention (collaborative calls, co-programmed, co-funded or institutionalised partnership) is most effective in achieving the objectives. This will also be reflected in the explanatory memorandum.

3.2 Based on the answers to the questions below and information available from any impact assessment, the explanatory memorandum or other sources, is the proposed action an appropriate way to achieve the intended objectives?

The proposed initiative only focuses on areas where there is a demonstrable advantage in acting at the EU-level due to the scale, speed and scope of the efforts needed for the EU to meet its long-term Treaty objectives and deliver on its strategic policy priorities and commitments. In addition, the present proposal leaves full freedom to the Member States to

pursue their own actions in the policy areas concerned. This will also be reflected in the explanatory memorandum.

(a) Is the initiative limited to those aspects that Member States cannot achieve satisfactorily on their own, and where the Union can do better?

The proposed initiative only focuses on areas where there is a demonstrable advantage in acting at the EU-level due to the scale, speed and scope of the efforts needed for the EU to meet its long-term Treaty objectives and deliver on its strategic policy priorities and commitments.

(b) Is the form of Union action (choice of instrument) justified, as simple as possible, and coherent with the satisfactory achievement of, and ensuring compliance with the objectives pursued (e.g. choice between regulation, (framework) directive, recommendation, or alternative regulatory methods such as co-legislation, etc.)?

For each of the candidate partnerships, the analysis carried out in the accompanying impact assessment has explored several options for implementation. A comparative assessment of the merits of each option also included an analysis of the simplicity of the intervention, its proportionality and effectiveness in achieving the intended objectives. This is reflected in the fact that a tailored approach has been suggested for each candidate partnership, ranging from looser forms of cooperation to more institutionalised ones, depending on the intended policy objectives, specific challenges, and desired outcome identified in each case.

(c) Does the Union action leave as much scope for national decision as possible while achieving satisfactorily the objectives set? (e.g. is it possible to limit the European action to minimum standards or use a less stringent policy instrument or approach?)

The proposed approach leaves full freedom to the Member States to pursue their own actions in the policy areas covered by the present proposal.

(d) Does the initiative create financial or administrative cost for the Union, national governments, regional or local authorities, economic operators or citizens? Are these costs commensurate with the objective to be achieved?

The proposed initiatives do create financial and administrative costs for the Union, national governments and, depending on the chosen mode of implementation, for regional and local authorities. In addition, economic operators and other stakeholders potentially involved in the candidate partnerships will also incur some costs linked to implementation. The financial cost of the proposed initiative is covered under the Horizon Europe programme. Its exact amount is still subject to political decision. As regards the candidate partnerships and the different modes of implementation (co-programmed, co-funded, institutionalised), the relevant costs and benefits are assessed in the individual impact assessments covering each candidate partnership. The additional administrative costs of implementation via partnerships are

limited, when compared to the administrative costs of implementation through traditional calls. As indicated by comparable experience with previous initiatives and in feedback provided by a variety of stakeholders, these costs are expected to be fully justified by the benefits expected from the proposed initiative. Where available, additional details on costs are provided in Annex 3 of the impact assessment.

(e) While respecting the Union law, have special circumstances applying in individual Member States been taken into account?

Where relevant, differences between Member States in capacity and stage of advancement of R&I in specific thematic areas have been taken into account in the individual impact assessments.

Annex 6 Additional background information

1. BACKGROUND INFORMATION FOR ALL INITIATIVES

1.1. Selection criteria of European Partnerships

Partnerships based on Article 185 and 187 TFEU shall be implemented only where other parts of the Horizon Europe programme, including other forms of European Partnerships would not achieve the objectives or would not generate the necessary expected impacts, and if justified by a long-term perspective and high degree of integration. At the core of this impact assessment is therefore the need to demonstrate that the impacts generated through a Partnership approach go beyond what could be achieved with traditional calls under the Framework Programme – the Baseline Option. Secondly, it needs to assess if using the Institutionalised form of a Partnership is justified for addressing the priority.

The necessity test for a European Partnership (as set out in the Horizon Europe regulation) has two levels:

- 1. The justification for implementing a priority with a European Partnership to address Horizon Europe and EU priorities. This is linked to demonstrating that a European Partnership can produce added value beyond what can be achieved through other Framework Programme modalities, notably traditional calls in the work programmes (Option 0 Baseline).
- 2. The justification for the use of the form of Institutionalised Partnership: Once it has been demonstrated that a partnerships approach is justified, co-programmed and/or co-funded forms are considered for addressing the priorities as they are administratively lighter, more agile and easier to set-up (Options 1 and/or 2). As Institutionalised Partnerships require setting up a legal framework and the creation of a dedicated implementation structure, they have to justify higher set-up efforts by demonstrating that it will deliver the expected impacts in a more effective and efficient way, and that a long-term perspective and high degree of integration is required (Option 3).

The outcomes of the 'necessity test' is presented together with the preferred option.

Figure 5 Horizon Europe selection criteria for the European Partnerships

Common selection criteria & principles	Specifications
1. More effective	Delivering on global challenges and research and innovation objectives
(Union added value) clear impacts for the EU and	Securing EU competitiveness
its citizens	Securing sustainability
	Contributing to the strengthening of the European Research and Innovation Area
	Where relevant, contributing to international commitments

Common selection	Specifications
criteria & principles	Specifications
2. Coherence and synergies	Within the EU research and innovation landscape
syller gies	Coordination and complementarity with Union, local, regional, national and, where relevant, international initiatives or other partnerships and missions
3. Transparency and openness	Identification of priorities and objectives in terms of expected results and impacts
	Involvement of partners and stakeholders from across the entire value chain, from different sectors, backgrounds and disciplines, including international ones when relevant and not interfering with European competitiveness
	Clear modalities for promoting participation of smes and for disseminating and exploiting results, notably by smes, including through intermediary organisations
4. Additionality	Common strategic vision of the purpose of the European Partnership
and directionality	Approaches to ensure flexibility of implementation and to adjust to changing policy, societal and/or market needs, or scientific advances, to increase policy coherence between regional, national and EU level
	Demonstration of expected qualitative and significant quantitative leverage effects, including a method for the measurement of key performance indicators
	Exit-strategy and measures for phasing-out from the Programme
5. Long-term	A minimum share of public and/or private investments
commitment of all the involved parties	In the case of institutionalised European Partnerships, established in accordance with article 185 or 187 TFEU, the financial and/or in-kind, contributions from partners other than the Union, will at least be equal to 50% and may reach up to 75% of the aggregated European Partnership budgetary commitments

1.2. Overview of potential functions for a common back office among Joint Undertakings

Functions	Current situation	Option of joint back- office	Comments
Organising calls for grant and proposal evaluations	Each JU organises this independently.	A central organisation of evaluation, logistics, contracting evaluators, managing the data of the evaluation results Central database of potential evaluators with domain expertise in thematic areas of partnerships	The evaluations would still need to be supervised by the Scientific staff of the individual Joint Undertakings (consensus meetings of expert evaluators etc)
Human Resources related matters	Each JU has own HR policy and resources Quite some resources spent on recruitment in some JUs	More generic resources and expertise for HR matters More consistency in HR	Ensuring consistency with EC HR policies is already in place

Financial management	Some HR facilities are procured from external contractors Some JUs have a Service Level Agreement with COM for HR Each JU conducts own financial contract management; differences between JUs Each JU is audited separately. Auditing at project level more frequent than in other Horizon 2020 parts and outsourced by JUs thus differences ECA: too many audits on JUs	policy Shared HR investment for specialised expertise (IP and legal) Financial management by one core team of financial staff Would reduce the number of interfaces for audits and simplifies the auditing of the all JUs Harmonisation of project auditing	Simplifies the harmonisation of financial management across JUs in line with Horizon Europe
Communication (internal and external)	Each JU has a separate communication strategies, teams and resources	A common back-office can support activities such as event organisation, dissemination of results, setting up website communication Can help create a more visible Partnership brand	A considerable share of communication activity is partnership specific (addressing particular target groups, synthesising project results) however there are generic communication activities that can be shared Needs to avoid duplication of efforts
Data management on calls, project portfolios, information on project results	Most JUs but not all use e- Corda for project data Overall IT integration of JUs still difficult	Harmonised data management Reduction of IT systems and support that is procured	This will need to happen regardless of the common back office but will likely be more smooth if managed centrally

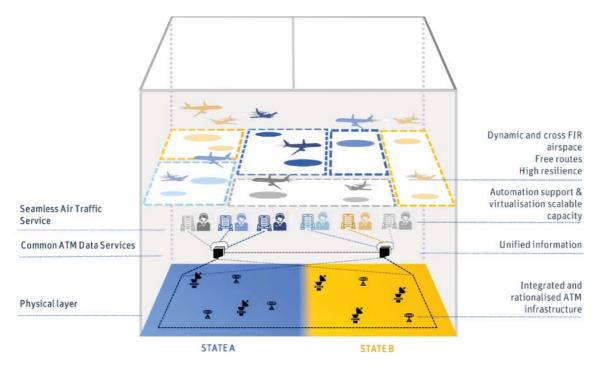
2. BACKGROUND INFORMATION FOR THIS SPECIFIC INITIATIVE

2.1. European ATM Master Plan – scenarios and economic impacts

Future R&I Needs

The European ATM Master Plan defines the vision for the digital transformation of ATM infrastructure. The vision was developed to accelerate modernisation of ATM using an architectural approach that brings together the airspace, operations and infrastructure in a harmonised manner across the EU. The main principles of this architecture are shown in Figure 6.

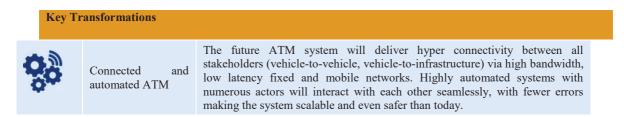
Figure 6: Proposed Future Architecture



Source: A proposal for the future architecture of the European airspace, SJU, 2019.

The proposal is based on a number of key transformations that require R&I as defined in Table 2. The R&I needs are a step change to the current programme: rather than focussing on contained individual ATM solutions that support marginal performance improvement of specific functions the need is now to focus on a small number of breakthrough technologies that together create a step change in overall system performance.

Table 2: Key transformations to achieve the future airspace architecture



	Air-ground integration and autonomy	The progressive move towards autonomous flying enabled by self-piloting technologies requires a closer integration between vehicle and infrastructure capabilities so that the infrastructure can act as a digital twin of the aircraft.
	AI for aviation	Tomorrow's aviation infrastructure will be more data intensive and thanks to the application of machine learning, deep learning and big data analytics we will be able to design an ATM system that is smarter and safer by constantly analysing and learning from the ATM environment.
**	U-space and urban air mobility	A digitally native traffic management system will ensure the safe and secure integration of drones in the airspace especially in urban areas, taking into account new and existing air vehicles and autonomous operations. One of the most challenging use cases from U-space will be to enable urban air mobility, which is expected to advance autonomous technologies in a number of areas.
کٹائے	Virtualisation and cyber-secure data sharing	Service provision will be decoupled from the physical infrastructure, enabling air traffic and data service providers, irrespective of national borders, to plug in their operations where needed in a secure manner.
:ii	Capacity-on- demand and dynamic airspace	Technology will enable the dynamic reconfiguration and the activation of cross-border capacity-on-demand services to maintain smooth traffic services at busy times.
	Civil/military interoperability and coordination	Dual-use technologies such as those for communications, navigation and surveillance, and other solutions that allow real-time exchange trajectory information will improve the predictability of military operations and overall network capacity.

In addition to scientific R&I, significant research is also required into regulatory issues:

- Ability of Member States to dynamically change responsibility for ATS in their airspace,
- Certification and approval of highly automated systems,
- Economic regulation of different elements of the value chain.

Importance of Architecture

The specific objectives place high importance of developing a service oriented architecture to develop and maintain consensus.

Many of the limitations of the current system have been caused by a lack of a defined architecture. Rather, bespoke national systems have been connected together using a range of bespoke interface standards specific to ATM. This has led to limited interoperability, high maintenance costs and significant difficulty in achieving widespread deployment of new systems (due to the high level of local adaptation required).

The required transition needs to be highly coordinated and based on commonly agreed service and infrastructure principles. The proposed architecture is the framework to achieve those agreements.

Once established, the architecture will allow different parts of the system to develop at different speeds depending on local needs whilst maintaining an overall coherence at network level. The wider implication of this is the ATM R&I would then need to be less coordinated and innovations would be developed within the common framework.

Importance of standards

As a highly regulated industry, ATM has many standards, at global level as annexes to ICAO's Chicago Convention³³ and at regional level – in Europe ATM standards and

See: https://www.icao.int/publications/pages/doc7300.aspx

specifications are developed by EUROCAE, EUROCONTROL and the European Standardisation Organisation.

However, it is still possible to implement a change to an ATM system without a standard. In this case the ANSP prepares a detailed safety case for the regulator demonstrating that the proposed change is safe and interoperable. This route has enabled piecewise modernisation of the current fragmented system – in which the level of local adaptation can outweigh the benefits of standardisation.

Adoption of a common architecture reduces the need for local adaptation and increases the needs for standards. Many of the existing standards may need to be updated to suit the new architecture. Proposals are being developed within the architecture to separate key concerns leading to new forms of standards, for example:

- Operational services The ATM services (separation, sequencing),
- Information services The information services required to provide ATM services,
- Infrastructure requirements The technical performance of the underlying infrastructure to provide the information services,
- Hardware requirements Specifications of specific physical equipment (radars, radios etc).

A key output of the R&I will be the evidence required by the standards development organisations to develop and validate the required standards.

Economic impact

The European ATM Master Plan,³⁴ identified two rollout scenarios differentiated by the extent to which the ATM community joins forces and changes working methods to accelerate the R&I lifecycle:

- Option 1: Full implementation of the SESAR vision by 2040 (requires strong partnership approach)
- Option 2: Full implementation of the SESAR vision by 2050

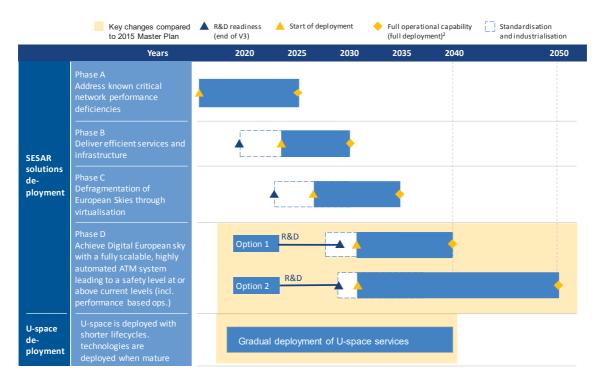
Figure 7 illustrates the roll-out of the SESAR Vision, supported by the existing SESAR programme, including the implementation of an optimised European airspace architecture and the 'fast tracking' of the deployment of U-space services during the next MFF.

The two options for the rollout of technology enabling the completion of phase D of the Master Plan (which related to the R&I required during the Horizon Europe timeframe) are shown; option 1 requires an earlier start of implementation and thus industry and stakeholders' consensus and commitment.

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European ATM Master Plan, Edition 2020, SJU.

Figure 7: SESAR Roll Out Plan



Source: European ATM Master Plan Edition 2020, SJU, 2019.

The economic benefits are summarised in Table 3, where:

- All monetary figures are expressed in EUR billion.
- The table shows the cumulative results for the period 2019 to 2050 (both years included).
- Although Option 1 is fully deployed by 2040, the benefits continue to be accrued until 2050.

Table 3: Economic Value of SESAR Roll-out scenarios

	Option 1	Option 2	Delta
Level of investment	37	53	16
Direct benefits of the ATM value chain	510	490	20
Indirect benefits of additional GDP	170	160	10
Indirect benefits for passengers and EU citizens	760	730	30
Total benefits for Manned Aviation	1440	1380	60
Benefits of deploying U-space	350 to 400	250 to 300	Over 100
Total Benefits	1790 to 1840	1630 to 1680	Over 160

Source: SJU analysis of Business Cases developed for the European ATM Master Plan Updated Programme.

Achieving option 1 would make it possible to reap crucial benefits about a decade earlier and at a lower cost, thanks to cutting on transition costs and going straight to the performing solutions and organisation. This requires new ways of working:

- More agility: creating solutions through prototypes and demonstrations developed in smaller teams with shorter time frames; developing solutions by addressing servicerelated challenges without prejudging upfront what the optimal technical solution is; creating innovation labs to fast-track R&D, perform quick prototyping and incubate new ideas.
- Openness, in the form of increased collaboration between 'traditional' engineering domains and new entrants that are now likely to attract more capital.
- Coordination to reduce innovation cycles from about 30 years to about 5-10 years, focusing on disruptive innovation. To achieve this, the development and deployment of the integration of drones into the airspace, and in particular the development and implementation of U-space services, may be used as a 'laboratory' that can support faster life cycles in the manned aviation environment; in addition, 'sandboxing' between organisations may allow faster times to market.

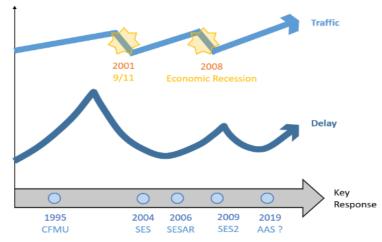
A regulatory framework that will also be required to support innovation — through market take-up, incentives for early movers and focus on delivery of services, with an emphasis on what services should be provided and how, rather than on what technologies should be implemented.

This innovative approach would allow better connections and synchronisation between ground-based developments and the airborne industry, whose plans and expectations for the future are already known.

The need for SESAR

Figure 8 illustrates the historical evolution of air traffic delays in Europe, also referred to as en-route Air Traffic Flow Management delay. This is the delay accumulated due to the lack of capacity of portions of airspace dedicated to cruise phase of the flights (also referred to as en-route). When capacity is reached, all aircraft planned to enter that portion of airspace subsequently are delayed.

Figure 8: Evolution of en-route Air Traffic Flow Management delay in Europe.



Source: Authors analysis of PRR2018.

The three peaks in delay are worthy of note. In late 1990s significant delays led to two forms of intervention:

- The creation by EUROCONTROL of the Central Flow Management Unit (CFMU)³⁵ and successful implementation of key capacity enablers including RVSM³⁶ and B-RNAV.³⁷
- The development of the Single European Sky initiative, leading to the first package of legislation in 2004.

In the early 2000's delays were growing, and a similar delay crisis was predicted - but with limited confidence that technical solutions existed. This led to the creation of the SESAR programme. The crisis did not materialise due to fall in air traffic following the 2008 financial crisis.

In 2018 significant delays returned. Potential solutions from the current SESAR programme have been identified in the Airspace Architecture Study³⁸ to resolve the problem. The proposed integrated ATM partnership would have the objective of accelerating the development and deployment of the necessary solutions.

SESAR in the **SES** Context

The EU competence in Air Traffic Management, exercised through the Single European Sky, is designed to drive performance improvement at EU level through a range of measures including economic regulation³⁹ and network functions.⁴⁰. As the recent Court of Auditors report makes clear,⁴¹ the SES initiative is justified but not yet fully effective.

The Single European Sky (SES) was the Commission's response to the significant air transport delays that plagued the 1990s. The SES legislation promotes the development, modernisation, and harmonisation of Air Traffic Management (ATM) across Europe. Over the years, SES has developed into a performance-oriented system in which the service providers (or ANSPs) are incentivised to adopt new concepts and technologies (as well as new ways of managing the business) to achieve the SES High Level goals.

In 2006, the European Commission launched the SESAR programme, "technological pillar" of the Single European Sky: "It aims to improve Air Traffic Management (ATM) performance by modernising and harmonising ATM systems through the definition, development, validation and deployment of innovative technological and operational ATM solutions". 42

Thus, the SESAR programme consists of definition of the strategic research and innovation agenda, R&I activities and deployment activities, all linked through the SESAR innovation lifecycle. The SESAR innovation lifecycle is central to the SES policy. SESAR is designed to mature and validate operational concepts and systems necessary for the modernisation of ATM. European airspace is amongst the busiest and most complex in the world. Traditionally Air Navigation Services have been provided by a patchwork of different national systems operated by national providers known as Air Navigation Service Providers (ANSPs).

The SESAR programme is defined as a continuous lifecycle that steers the R&I programme to effectively close performance gaps in the deployed system as illustrated in Figure 9.

³⁵ The Central Flow Management Unit (CFMU) provides Air Traffic Flow Management across Europe and is now a central part of the Network Manager, and changed the name to Network Manager Operations Centre (NMOC).

³⁶ Reduced Vertical Separation Minima (RVSM) allowed the vertical separation minima to be reduced from 2000 to 1000 ft in en-route airspace and provided a large capacity increase.

³⁷ Basic Area Navigation (B-RNAV) is a forerunner of Required Navigation Performance (RNP5) for en-route airspace and enabled a flight efficient and capacity benefit.

³⁸ A proposal for the future architecture of the European airspace, SJU, 2019.

³⁹ Commission Implementing Regulation (EU) 2019/317 of 11 February 2019 laying down a performance and charging scheme in the single European sky and repealing Implementing Regulations (EU) No 390/2013 and (EU) No 391/2013.

⁴⁰ Commission Implementing Regulation (EU) 2019/123 of 24 January 2019 laying down detailed rules for the implementation of air traffic management (ATM) network functions and repealing Commission Regulation (EU) No 677/2011.

⁴¹ Single European Sky: a changed culture but not a single sky, Special Report 18/2017, European Court of Auditor.

⁴² Source: https://ec.europa.eu/transport/modes/air/sesar_en

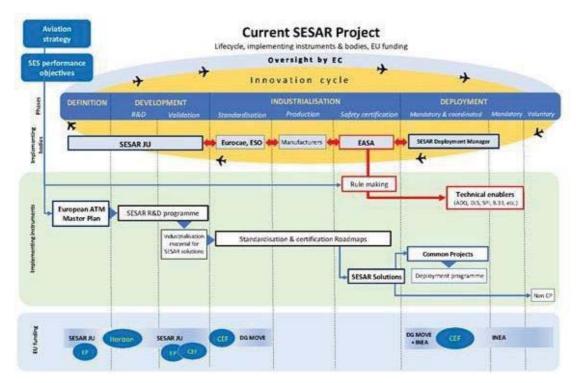


Figure 9: SESAR Innovation Lifecyle⁴³

Source: DG-MOVE.

Key issues for accelerating deployment in ATM are:

- Reducing the implementation risks for both equipment supplier and ANSPs by ensuring that regulators and standardisation bodies have the current evidence to support operational approval and standards development. This is referred to as closing the industrialisation gap⁴⁴ and should be an objective of the future integrated ATM partnership.
- Ensuring a common and agreed evolution of systems hence reducing the commercial risk in developing products in Europe this is achieved through the ATM Master Plan.
- Enabling synchronised deployment to reduce the time between system deployment and accruing benefits by ensuring that national ANSPs invest in a coherent manner this is an objective of the SESAR deployment phase and common project legislation. 45

R&I Prior to SESAR

Prior to SESAR, significant R&D was being undertaken in Air Traffic Management:

• EUROCONTROL spent about €150-200m a year on R&D;

⁴³ Source: DG-MOVE, European Commission

⁴⁴ Interim evaluation of the SESAR Joint Undertaking (2014-2016) operating under Horizon 2020, Experts Group Report.

⁴⁵ Commission Implementing Regulation (EU) No 716/2014 of 27 June 2014 on the establishment of the Pilot Common Project supporting the implementation of the European ATM Master Plan Text with EEA relevance.

- The Commission funding for ATM under the Fifth Framework Programme amounted to €20.8m between 1998 and 2002, and by around €100m over the 2002-2006 period;
- The European Investment Bank also contributed €390m to support ATM in Europe between 1999 and 2003. 46

A 2006 review of existing R&D identified 58 initiatives; including:⁴⁷

- FP6 funded 44 ATM⁴⁸ related research projects. The topics covered wide range, and some, became central to the SESAR Development Phase work programme, for example:
 - EPISODE 3 set foundation for the SESAR operational concept and performance framework
 - SWIM-SUIT project came up with the precursors of the current SWIM solutions.
 - The ART project laid groundwork for SESAR remote tower solutions.
 - The EMMA projects pioneered A-SMGCS solutions.
- EUROCONTROL research included the PHARE programme which included research on 4D trajectory management and formed the basis of the concept developed within the SESAR Definition Phase. PHARE included strong input from the national programmes including Netherlands (NLR), Germany (DLR), France (DSNA) and the UK (NATS, DERA).
- National Programmes which fed into the procurement plans of ANSPs. In particular, LFV in Sweden had a strong national programme.

Despite the reasonable level of research, the programmes overlapped with each other and the results were fragmented leading to low value for money. The combined research effort was leading to competing rather than a common view of the future of ATM.

A key objective of SESAR was to coordinate all European ATM research towards a common goal, which was mandated by the SESAR Joint Undertaking regulation.⁴⁹

The SESAR Joint Undertaking⁵⁰

Scope and objectives

The SESAR Joint Undertaking was initially established in 2007 with the objectives and tasks defined in Table 4.

Table 4: Objectives and tasks of the SESAR Joint Undertaking

Objectives and tasks of the SESAR Joint Undertaking

The aim of the Joint Undertaking shall be to ensure the modernisation of the European air traffic management system by coordinating and concentrating all relevant research and development efforts in the Community. It shall be responsible for the execution of the European ATM Master Plan and in particular for carrying out the following tasks:

• organising and coordinating the activities of the development phase of the SESAR project, in accordance with the

⁴⁸ The R&I tended to be conducted by research organisations and ANSPs, with limited involvement from airspace users and airport operators. Total ATM related research received €167m in funding (with the total budget of €289m).

 $^{^{\}rm 46}$ SEAME CBA and Governance Study, Steer Davies Gleave, 2005.

⁴⁷ SESAR Consortium DLT-0507-221-00-02, 2006.

⁴⁹ Council Regulation (EC) No 219/2007 of 27 February 2007 on the establishment of a Joint Undertaking to develop the new generation European air traffic management system (SESAR)

⁵⁰ Interim Evaluation of the SESAR Joint Undertaking (2014-2016) operating under Horizon 2020, Experts Group Report.

Objectives and tasks of the SESAR Joint Undertaking

European ATM Master Plan, resulting from the definition phase of the project managed by EUOCONTROL, by combining and managing under a single structure public and private sector funding,

- ensuring the necessary funding for the activities of the development phase of the SESAR project in accordance with the European ATM Master Plan,
- ensuring the involvement of the stakeholders of the air traffic management sector in Europe, in particular: air navigation service providers, airspace users, professional staff associations, airports, and manufacturing industry; as well as the relevant scientific institutions or the relevant scientific community,
- organising the technical work of research and development, validation and study, to be carried out under its authority while avoiding fragmentation of such activities,
- ensuring the supervision of activities related to the development of common products duly identified in the European ATM Master Plan and if necessary, to organise specific invitations to tender.

Source: Council Regulation (EC) No 219/2007 of 27 February 2007 on the establishment of a Joint Undertaking to develop the new generation European air traffic management system (SESAR).

At the core of the activities of the SESAR Joint Undertaking is the European ATM Master Plan which acts as the strategic research and innovation agenda for the partnership.

The first version of the European ATM Master Plan was developed prior to the establishment of the SESAR Joint Undertaking and endorsed by the European Council in 2009. Since then, the European ATM Master Plan has been regularly updated by the SESAR Joint Undertaking following widespread stakeholder consultation. Each version requires approval of Member States through a positive opinion of the Single Sky Committee.⁵¹

Table 25 defines the main changes in each subsequent version of the European ATM Master Plan.

Table 5: Versions of the European ATM Master Plan

Edition	Addit	ional Changes	MS S	State Endorsement
2009	9]	Initial version created by the SESAR Definition Phase		Council Decision ⁵²
2012		Increase the ATM community's awareness and focusing efforts of manageable set of essential operational changes.	on a	SSC Opinion
		Prepare for SESAR deployment phase, developing clear stakehoroadmaps which provide a temporal view of the ATM.	older	
		Promote and ensure interoperability at global level, in particular with US ATM Modernisation programme, NextGen and ICAO.	n the	
		Promote synchronisation of ATM R&I and Deployment Programmon ensure global interoperability.	es to	
201:		Introduced a vision for the future European ATM system, inclu Common Support Services and cybersecurity.	iding	SSC Opinion
]	Explicitly introduces drones and rotorcraft as airspace users.		
		Incorporates the results of more comprehensive military involves through the European Defence Agency (EDA).	ment	
2020	(Addresses new challenges: tackling the unprecedented increase in tr demand from both manned, and unmanned aviation, enabling emergence of new business models, while supporting the sustainabili	the	SSC Opinion

⁵¹ The Single Sky Committee is the comitology committee for the Single European Sky.

⁵² Council resolution on the endorsement of the European Air Traffic Management Master Plan 2935th TRASPORT, TELECOMMUICATIONS and EERGY Council meeting, Brussels, 30 March 2009. Available at: https://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/trans/106966.pdf

⁵³ European ATM Master Plan, Edition 2012, SJU. Available at: https://ec.europa.eu/transport/sites/transport/files/modes/air/sesar/doc/2012_10_23_atm_master_plan_ed2oct2012.pdf)

⁵⁴ European ATM Master Plan, Edition 2015, SJU. Available at: https://ec.europa.eu/transport/sites/transport/files/modes/air/sesar/doc/eu-atm-master-plan-2015.pdf

aviation.

Enables digital transformation of the aviation infrastructure to accommodate aerial vehicles, which are set to become more autonomous, more connected and more intelligent.

Source: authors analysis of each edition of the European ATM Master Plan.

In 2014, the Council agreed that continuation of SESAR was the most effective way to achieve ATM modernisation^{55,56} in Europe and extended the duration of the SESAR Joint Undertaking from 2016 to 2024,⁵⁷ leading to two distinct phases of the SESAR R&I programme, see Table 6.

Table 6: Phases of the SESAR Joint Undertaking

Phase	Dates	EC Contribution	Total Available Budget
SESAR1	2008 – 2016	TEN-T: €350 M FP7: €350	€2.1 b
SESAR2020	2015 – 2024	H2020: €585	€1.8 b

Source: Interim Evaluation of the SESAR Joint Undertaking (2014-2016) operating under Horizon 2020, Experts Group Report.

SESAR is the only source for funding of air traffic management R&I funding under Horizon 2020.

SESAR Joint Undertaking Work Programme

The main elements of the SESAR Joint Undertaking R&I programme are ⁵⁸ presented in Table 7

Table 7: Main elements of SESAR Joint Undertaking R&I Programme

Programme	Forms of R&I	Budget	Type of call
Core Programme	 Industrial Research and Validation Very Large Scale Demonstrations Transversal Activities (including ATM Master Plan maintenance) 	80%	Restricted to SJU members
Exploratory Research Programme	Fundamental Scientific ResearchATM Application Oriented Research	20%	Open Calls

Source: SESAR Single Programming Document, SJU, 2019.

The structure of the SESAR work programme is illustrated in Figure 10.

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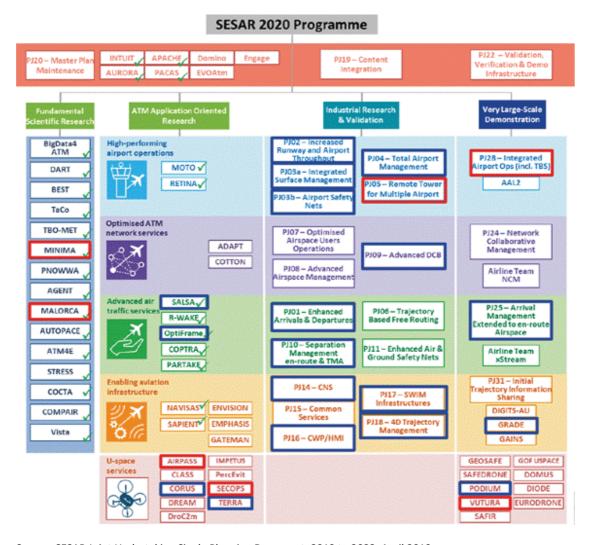
⁵⁵ SJU Extension - Impact Assessment Study, Ernst and Young, 31 July 2012.

⁵⁶ COMMISSION STAFF WORKING DOCUMENT Revision of Council Regulation (EC) N°219/2007 of 27 February 2007 on the establishment of a Joint Undertaking to develop the new generation European air traffic management system (SESAR).

⁵⁷ Council Regulation (EU) No 721/2014 of 16 June 2014 amending Regulation (EC) No 219/2007 on the establishment of a Joint Undertaking to develop the new generation European air traffic management system (SESAR) as regards the extension of the Joint Undertaking until 2024.

⁵⁸ SESAR Joint Undertaking Single Planning Document, SJU, 2019.

Figure 10: Structure of the SESAR2020 Programme



 $Source: SESAR\ Joint\ Undertaking\ Single\ Planning\ Document,\ 2019\ to\ 2022,\ April\ 2019.$

SESAR Joint Undertaking Membership

SESAR Joint Undertaking membership includes the main stakeholders of the European ATM industry including air navigation service providers, airports, equipment manufacturers and R&I laboratories. There are currently 19 SESAR Joint Undertaking members composed of 37 individual companies (see Table 8). In addition, EUROCONTROL is a founding Member.

Table 8: Members of the SESAR Joint Undertaking

Member	Beneficiary	Sector	Country
AT-ONE	DLR	Research Org	Germany
	NLR	Research Org	Netherlands
B4	PANSA	Service Provider	Poland
	ANS CR	Service Provider	Czech Republic
	ORO Navigacija	Service Provider	Lithuania
	LPS SR	Service Provider	Slovak Republic
COOPANS	Naviair	Service Provider	Denmark
	Croatia Control Ltd	Service Provider	Croatia
	LFV	Service Provider	Sweden
	AustroControl	Service Provider	Austria
	IAA	Service Provider	Ireland
FSP	Frequentis AG	Ground Industry	Austria
	Atos Belgium SA/NV	Ground Industry	Belgium
	HungaroControl	Service Provider	Hungary
NATMIG	Sintef	Ground Industry	Norway
	AirTel ATN Ltd	Ground Industry	Ireland
	SaaB AB	Ground Industry	Sweden
SEAC2020	Heathrow Airport Ltd	Airport	UK
	Munich Airport	Airport	Germany
	Aeroports de Paris	Airport	France
	Zurich Airport	Airport	Switzerland
	Schiphol Airport	Airport	Netherlands
	Avinor AS	Airport	Norway
	Swedavia AB	Airport	Sweden
Airbus SAS	Airbus SAS	Airborne Industry	France
Dassault Aviation	Dassault Aviation	Airborne Industry	France
Honeywell Aerospace SAS	Honeywell Aerospace SAS	Airborne Industry	France
Thales Avionics SAS	Thales Avionics SAS	Airborne Industry	France
Finmeccanica – Leonardo	Finmeccanica – Leonardo	Ground Industry	Italy
Indra Sistemas SA	Indra Sistemas SA	Ground Industry	Spain
Thales Air Systems SAS	Thales Air Systems SAS	Ground Industry	France
DFS	DFS	Service Provider	Germany
DSNA	DSNA	Service Provider	France
ENAIRE	ENAIRE	Service Provider	Spain
ENAV SpA	ENAV SpA	Service Provider	Italy
NATS EnRoute Plc	NATS EnRoute Plc	Service Provider	UK
Skyguide	SkyGuide	Service Provider	Switzerland

 $Source: Interim\ Evaluation\ of\ the\ SESAR\ Joint\ Undertaking\ (2014-2016),\ Experts\ Group\ Report.$

Approximately 80% of SESAR R&I is performed by the members following "closed calls". The members' supply chains support their contributions as third link parties or as subcontractors to the members.

SESAR Joint Undertaking membership does not directly include Universities and SMEs. However, the remaining 20% of R&I activities is performed by a range of academia and SMEs following open calls – mostly of Exploratory Research. In total, there have been 268 individual participants in the SESAR2020 programme (both open and closed calls). The private sector dominates with almost 70%, with the 18% of participation from Higher education sector, and 9% coming from Research organisations, as depicted in Figure 11.

3% 9% 18%

Figure 11: Type of participants in the SESAR Joint Undertaking.

Source: DG RTD data, calculation: Technopolis Group.

Figure 12 and Figure 13 illustrate the forms and geographical spread of SESAR Joint Undertaking beneficiaries.

Research organisations

■ Private companies

Other

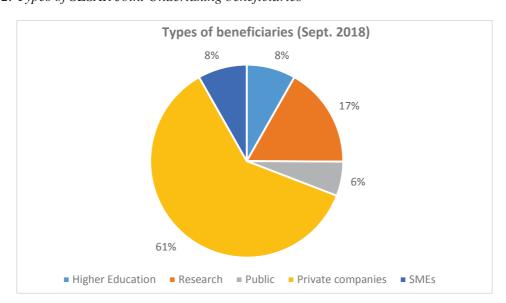


Figure 12: Types of SESAR Joint Undertaking beneficiaries

Higher education

Public sector

Source: DG RTD data, calculation: Technopolis Group.



Figure 13: Location of SESAR Joint Undertaking beneficiaries

Source: DG RTD data, calculation: Technopolis Group.

Achievements of the SESAR Joint Undertaking

The focus of the current R&I programme is to develop and validate advanced solutions and concepts for the future air traffic management system in line with the European ATM Master Plan. Each solution represents a change in the way air traffic management is performed, and is supported by:

- A business case,
- A safety case,
- A performance case,
- A human performance case,
- A specification or similar material to support standardisation.

The SESAR Solutions Catalogue⁵⁹ defines 63 such solutions that have reached a sufficient maturity for deployment. EUROCAE and EUROCONTROL have developed over 50 standards to support deployment of SESAR solutions.⁶⁰

For **scientific and technological analysis** of the current partnership, it is important to bear in mind the type of partners involved and the field of partnership, which is ATM. Scientific publications can be

⁵⁹ SESAR Solutions Catalogue 2019 Third edition, SJU, 2019.

Source: https://ec.europa.eu/transport/sites/transport/files/ec-716-2014 article4b standardisatregulatroadmap.pdf

expected predominantly from the academic partners and from research organisations, but much less so from industry partners.

Based on the data available through DG RTD, 24 of the SESAR projects produced 32 publications in the field of 'Smart, green and integrated transport' (see Table 9).

Table 9: Number and share of publications by year.

Smart, green and integrated transport	2016	2017	2018	2019	Total
Total	5	22	4	1	32
Share	16%	69%	13%	3%	100%

Source: DG RTD, calculation: Technopolis Group

Table 10: Main journals from SESAR Joint Undertaking publications.

Journal Title	Total	Journal Title	Total
IEEE Transactions on Intelligent Transportation Systems	3	IEEE Access	1
IEEE Transactions on Visualization and Computer Graphics	3	IEEE Transactions on Biomedical Engineering	1
ANADOLU UNIVERSITY JOURNAL OF SCIENCE AND TECHNOLOGY A - Applied Sciences and Engineering	2	IEEE Wireless Communications Letters	1
Computer Graphics Forum	2	IFAC-PapersOnLine	1
Frontiers in Neuroscience	2	Informatics	1
Journal of Applied Meteorology and Climatology	2	Journal of Aircraft	1
Aerospace	1	Journal of Geophysical Research: Atmospheres	1
Atmospheric Measurement Techniques	1	Journal of Guidance, Control, and Dynamics	1
Augmented Reality, Virtual Reality, and Computer Graphics - Lecture Notes in Computer Science	1	Journal of The Royal Society Interface	1
Augmented Reality, Virtual Reality, and Computer Graphics - Lecture Notes in Computer Science, 9768	1	MATEC Web of Conferences	1
Brain Sciences	1	Transportation Research Part A: Policy and Practice	1
Frontiers in Human Neuroscience	1	Transportation Research Procedia	1

Source: DG RTD, calculation: Technopolis Group

The search of SCOPUS database produced 93 scientific papers in the period 2012-2019 (87 in the period 2014-2019) that listed as the source of funding SESAR Joint Undertaking. A number of these papers have been presented at the conferences (which are indexed in SCOPUS), as in some of the disciplines that are participating in the ATM, conferences are of more importance than the publications in journals.

The three main, peer-reviewed conferences in the ATM are:

- 1. The ATM Seminar, organised biannually, jointly by the Federal Aviation Administration and EUROCONTROL, aimed at established researchers (www.atmseminarus.org);
- 2. International Conference on Research in Air Transportation (ICRAT), organised biannually, jointly by the Federal Aviation Administration and EUROCONTROL, aimed at young researchers (www.icrat.org);
- 3. SESAR Innovation Days, organised by the SESAR Joint Undertaking, every year (https://www.sesarju.eu/sesarinnovationdays).

Conference proceedings are publicly available on the conference websites, and are indexed in the SCOPUS database. The last three editions of ATM Seminar (2013-2017, as listed in SCOPUS) include 217 peer-reviewed papers. The ATM Seminar confers awards for best papers in each session and best conference paper. In the last two editions of the ATM Seminar, about half of the awards were won by European researchers, a significant number working on SESAR Joint Undertaking funded projects. ⁶²

The SESAR Innovation Days conference is open to any research in the field of ATM, and is aimed at reviewing and showcasing the research performed in the SESAR Joint Undertaking. There have been eight editions of the conference so far, and the number of accepted papers has been growing.

In summary, the research produced under the current partnership is of high scientific value, when assessed across the indicators that are important in the field – participation and awards received at the main conferences.

The **technological achievements** of the partnership are presented in terms of patent analysis and the technological solutions developed and implemented.

Patents can be expected from industry partners since they have a genuine interest in protecting their innovation. However, due to competition, business practices and the pre-competitive nature of collaborative R&I projects at EU-level, etc. most industrial partners in the field of ATM are not likely to apply for IPR. Therefore, the numbers of IPs recorded in the DG RTD database are of little use to describe properly the technological achievements of the partnership. IPRs can be found as outputs from three projects: two applied for a patent and one for a trademark.

The more important technological achievement of the partnership can be found in the catalogue of mature ⁶³ ATM solutions produced by the partnership: SESAR Solutions Catalogue 2019, ⁶⁴ containing 63 mature solutions and 79 solutions being developed. These solutions have been tested in over 200 validation exercises, at over 50 test beds across Europe.

Figure 14 displays a sample of locations deploying the SESAR solutions. The blue markers denote the airports deploying SESAR Solutions that are mandated through the EU's Pilot Common Project⁶⁵, while the green markers point to the sample of locations where local SESAR deployments⁶⁶ are taking place.

⁶¹ It takes a while for the proceedings to be indexed in SCOPUS, which is why the last ATM Seminar from June of 2019 and several SESAR Innovation Days proceedings are not yet available.

⁶² Source: www.atmseminarus.org

Mature from the R&I point of view, which is to say passing TRL 6.

⁶⁴ SESAR Solutions Catalogue, SJU, 2019.

⁶⁵ Commission Implementing Regulation (EU) No 716/2014 of 27 June 2014 on the establishment of the Pilot Common Project supporting the implementation of the European Air Traffic Management Master Plan Text with EEA relevance.

The detailed implementation data is available at: https://www.atmmasterplan.eu/deployment

Airports deploying SESAR Solutions as part of the EU's Pilot Common Project (Synchronised deployment)

Sample of locations where local SESAR deployments are taking place

Figure 14: Locations where SESAR Joint Undertaking solutions are being deployed

Source: SESAR Solutions Catalogue 2019.

The current deployment programme encompasses 349 projects with total costs of \in 2.9 billion with \in 1.2 billion co-funding the Connecting Europe Facility.

In summary, the current partnership (and as such the ATM R&I in Europe) produces high-quality scientific knowledge and a number of technological achievements are available and are being deployed, not only in Europe.

Outcomes and (expected) impacts

Since its inception in 2008, the SESAR Joint Undertaking has successfully coordinated European ATM R&I. The success of SESAR is best illustrated by the European ATM Master Plan, culminating in the 2015 edition,⁶⁷ and SESAR Solutions Catalogue.⁶⁸ To date 63 ATM solutions have been developed.

In addition, SESAR is strong brand demonstrating EU leadership in ATM in a competitive global landscape.⁶⁹ Indeed, the SESAR Joint Undertaking played a strong role in the development of global plans at ICAO level and in maintaining international interoperability of ATM systems through coordination with the FAA (Federal Aviation Authority) and other similar initiatives.⁷⁰

⁶⁷ European ATM Master Plan, Edition 2020, SJU.

⁶⁸ SESAR Solutions Catalogue 2019 Third edition, SJU, 2019.

⁶⁹ Interim Evaluation of the SESAR Joint Undertaking (2014-2016) operating under Horizon 2020, Experts Group Report.

Section 2.5 of SESAR Joint Undertaking Single Programming Document 2019-2021, SJU, 2019.

The SESAR Joint Undertaking has also supported the European Commission's development of aviation and ATM policy through key studies performed at the request of DG-MOVE, including datalink communications, ⁷¹ U-space ⁷² and the recent Airspace Architecture Study. ⁷³

The SESAR Joint Undertaking results have therefore contributed to improvement of ATM both in the EU and globally. The key strengths of the SESAR Joint Undertaking are:

- Strong global brand supporting EU leadership,
- SESAR solutions demonstrably improving ATM performance,
- Integrated R&I platform including users, providers, suppliers, staff and regulators.

Identified needs for action

Previous assessments stress the importance of SESAR and the SESAR Joint Undertaking as key enablers for the implementation of the wider SES policy"⁷⁴. However, two key weaknesses were found:

- Limited exploitation of advanced external R&I and internal exploratory research in the core ("closed call") programme. This illustrates a potential issue in the limited membership of the SESAR Joint Undertaking not enabling the beneficiaries of Exploratory Research to continue on the topic in the core programme.
- Limited progress on key enablers where there is limited industry consensus (for example, next generation datalinks and flight data processing) potentially highlighting the need for greater emphasis on transformational technologies.

In 2018, the SESAR Joint Undertaking performed a study on behalf of the European Parliament and European Commission to develop a proposal for a Future Airspace Architecture. Whilst the proposal is largely based on the current European ATM Masterplan, it also represents a step change in requiring both more transformational technologies and faster pull through from scientific research of digital enablers to support enhanced automation.

The European Court of Auditors has considered both SES⁷⁵ and SESAR Deployment,⁷⁶ other parts of the SESAR innovation lifecycle. The former provided three recommendations relevant to the SESAR Joint Undertaking and to the future ATM research and development activities:

- Review the EU's support structure to ATM R&I in light of its objectives including the need to justify continued support and whether a temporary structure is appropriate.
- Reinforce the accountability of the SESAR Joint Undertaking by defining clear milestones and regular reports on progress with the implementation of the European ATM Master Plan.
- Prioritise EU support to R&I solutions that promote defragmentation and a competitive environment.

Delivering the Single European Sky and ensuring ATMs role in a sustainable aviation sector requires a much greater transformation than has hitherto been achieved. The level of transformation is discussed in Annex F.

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⁷¹ Source: https://www.sesarju.eu/newsroom/brochures-publications/vdlm2-%E2%80%93-measurements-analysis-and-simulation-campaign-elsa-study

⁷² Source: https://www.sesarju.eu/U-space

⁷³ Source: https://www.sesarju.eu/news/airspace-architecture-study-presented-european-parliament

⁷⁴ Interim Evaluation of the SESAR Joint Undertaking (2014-2016) operating under Horizon 2020, Experts Group Report.

⁷⁵ Single European Sky: a changed culture but not a single sky, Special Report 18/2017, European Court of Auditors.

⁷⁶ The EU's regulation for the modernisation of air traffic management has added value – but the funding was largely unnecessary, Special Report 11/2019, European Court of Auditors.

Aviation contribution to SustAainable Development Goals

"The 2030 Agenda for Sustainable Development, adopted by all United Nations Member States in 2015, provides a shared blueprint for peace and prosperity for people and the planet, now and into the future. At its heart are the 17 Sustainable Development Goals (SDGs), which are an urgent call for action by all countries - developed and developing - in a global partnership."

Aviation as a provider of transport and mobility is able to support a number of SGDs. ATM as an enabler of efficient transport contribute to multiple Sustainable Development Goals:

- SDG 9 (Industry, Innovation and Infrastructure)
- SDG 11 (Sustainable Cities and Communities)
- SDG 13 (Climate Action)

Indirect positive impact is expected for example in:

- SDG 3 (Good health and well-being)
- SDG 8 (Decent work and economic growth)
- SDG 12 (Responsible production and consumption)⁷⁸

The following table has been developed from a report developed by Air Transport Action Group (ATAG) to illustrate how aviation can contribute to 11 SDGs.⁷⁹

Table 11: How aviation can contribute to 11 Sustainable Development Goals

CDC	How Aviation can support			
SDG	Direct	Indirect	Induced	
1. No poverty	Creating jobs in air transport connected places	Continuity of remittances is supported by the maintenance of family and cultural ties is aided by air transport links.		
2. Zero hunger		The World Food Programme (WFP), in partnership with the UN Humanitarian Air Service, is tasked with getting food to those in the midst of war, civil conflict and natural disasters. Because many of these zones are inaccessible by road, air transport is the only option.		
3. Good health and well-being		The industry, too, has a vital role to play in responding to disaster. In 2010, Airlink was established to help coordinate responses to emergencies by the air transport industry.	Aviation also has a crucial role to play in pandemic response. When a viral outbreak occurs, it is vital that the air transport sector acts quickly to work with governments and international institutions to ensure that the virus does not travel further.	

 $^{^{77} \} Sustainable \ development \ goals \ knowledge \ platform. \ Available \ at: \ \underline{https://sustainabledevelopment.un.org/sdgs}$

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⁷⁸ European Commission (2019) Orientations towards the first Strategic Plan implementing the research and innovation framework programme Horizon Europe. Co-Design via web open consultation.

⁷⁹ Aviation Benefits Beyond Borders, ATAG, October 2018.

SDC	How Aviation can support		
SDG	Direct	Indirect	Induced
4. Quality education		Ensuring inclusive and equitable quality education and promoting lifelong learning opportunities for many means travelling to another country, sometimes in another region of the globe. For students from developing countries, the opportunity to travel to established universities for higher education is invaluable.	Air transport connectivity make these ambitions far more likely to be realised.
7. Affordable and clean energy		Airport planning and design also takes into consideration environmental aspects to maximise efficiency with the minimal possible impact on the environment.	
8. Decent work and economic growth	Creating jobs that directly serve passengers at airlines, airports and air navigation service providers (ASNPs)	Employment and activities of suppliers to the air transport industry	Spending of those directly or indirectly employed in the air transport sector supports additional jobs in other industries
9. Industry, innovation and infrastructure	Since the dawn of air travel, aviation has been at the forefront of technological innovation, researching and developing disruptive, ground-breaking technology with each new generation of aircraft or each new control technique.		Connectivity contributes to improved productivity by encouraging investment and innovation, improving business operations and efficiency.
10. Reduced inequalities	The greatest increase in propensity to travel is in developing economies, reducing geographical inequalities.		In developed economies the connectivity to rural areas is increasing, making it more accessible to everyone.
11. Sustainable cities and communities	New technology will enable some remote and seasonal airports to remain open and viable improving sustainability.	Smaller airports within a network generate traffic that ensures the sustainability of larger airports, resulting in improved load factors and optimal aircraft utilisation by airlines.	
12. Responsible consumption and production	Once an aircraft reaches the end of its service life, it can be recycled to ensure safe disposal and to take advantage of the many high-quality components and materials of which it is made. The idea is to move this idea into the ATM industry too by recycling and not having an excess of radars. Virtual centres allow to have a responsible use of air traffic services.	It is the role of countries to ensure that improvements in ATM infrastructure are properly financed. As there are long lead times for procuring new equipment, such as air traffic control centres and the latest surveillance equipment, ATM investment needs long-term planning.	

CDC	How Aviation can support				
SDG	Direct	Indirect	Induced		
13. Climate action	In 2008 industry leaders announced a climate action plan based on three global goals, which the entire sector has committed to: 1. Achieve a 1.5% average annual fuel efficiency improvement from 2009 to 2020 (already being surpassed, average 2.1% per year). 2. Stabilise net CO2 emissions at 2020 levels through carbonneutral growth. 3. Reduce net emissions to 50% of what they were in 2005 by 2050.	While the aviation industry is prioritising fuel efficiency to try and reduce its climate change impact, there are a number of ways in which a changing climate could impact air transport operations.			
17. Partnerships for the goals	For the potential of new navigational technology to be realised, the industry needs the engagement and cooperation of governments and international institutions. Airspace is governed by sovereign states, meaning that any reform needs governmental buy-in. But aviation transcends national boundaries.	Encouraging progress has been made on the first three pillars of the industry's environmental strategy. However, to achieve the goal of carbon-neutral growth from 2020 other measures need to be taken.			

Source: Aviation Benefits Beyond Borders, ATAG, October 2018.



Brussels, 23.2.2021 SWD(2021) 37 final

PART 14/19

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT REPORT Accompanying the document

Proposal for a COUNCIL REGULATION establishing the Joint Undertakings under Horizon Europe

European Partnership for Clean Aviation

{COM(2021) 87 final} - {SEC(2021) 100 final} - {SWD(2021) 38 final}

www.parlament.gv.at

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Glossary

Term or acronym	Meaning or definition
ACARE	Advisory Council for Aviation Research and Innovation in Europe
ASD	Aerospace and Defence Industries Association of Europe, industry association
ATAG	Air Transport Action Group
ATM	Air traffic management
CAGR	Compound Annual Growth Rate
CEF	Connecting Europe Facility
CORSIA	ICAO's Carbon Offsetting and Reduction Scheme for International Aviation
EASA	European Union Aviation Safety Agency
EASN	European Aeronautics Science Network
EREA	Association of European Research Establishments in Aeronautics
EU ETS	European Emissions Trading System
GHG	Greenhouse gas
Horizon 2020	European Union research and innovation research framework programme 2014-2020
Horizon Europe	European Commission's proposed research framework programme for research and innovation to succeed Horizon 2020, from 2021 to 2027
H_2	Hydrogen
IADP	Innovative Aircraft Demonstration Platform
IATA	International Air Transport Association
ICAO	International Civil Aviation Organisation
ITD	Integrated Technology Demonstrators
JU	Joint Undertaking.
MRO	Maintenance, repair and overhaul
NACE	Statistical classification of economic activities in the European Community
NO _X	Nitrous Oxide
PM	Particulate matter
R&I	Research and innovation
RTO	Research and technology organisations
SAF	Sustainable aviation fuels
SOx	Sulphur Oxides
SDG	Sustainable Development Goal
SESAR	Single European Sky Air Traffic Management Research
SME	Small and medium-sized enterprises
SRG	States' Representative Group
SRIA	Strategic Research and Innovation Agenda
TRL	Technology readiness level
ufPM	Ultrafine particulate matter

1. BACKGROUND AND CONTEXT TO EUROPEAN PARTNERSHIPS IN HORIZON EUROPE AND FOCUS OF THE IMPACT ASSESSMENT—WHAT IS DECIDED

1.1. Focus and objectives of the impact assessment

This impact assessment accompanies the Commission proposal for Institutionalised European Partnerships to be funded under Horizon Europe, the 2021-2027 Framework Programme for EU Research and Innovation (R&I). It sets out to help decide in a coordinated manner the right form of implementation for specific candidate initiatives based on a common approach and methodology for individual assessments². It also provides a horizontal perspective on the portfolio of candidate European Partnerships to identify further efficiency and coherence gains for more impact.

European Partnerships are initiatives where the Union, together with private and/or public partners (such as industry, public bodies or foundations) commit to support jointly the development and implementation of an integrated programme of R&I activities. The rationale for establishing such initiatives is to achieve the objectives of Horizon Europe more effectively than what can be attained by other activities of the programme.³

Based on the Horizon Europe Regulation, European Partnerships may be set up using **three different forms**: "Co-funded", "Co-programmed" and "Institutionalised". The setting up of **Institutionalised Partnerships** involves new EU legislation and the establishment of dedicated implementing structures based on Article 185 or 187 of the Treaty on the Functioning of the EU (TFEU). This requires an impact assessment to be performed.

The Horizon Europe Regulation defines **eight priority areas**, scoping the domains in which Institutionalised Partnerships could be proposed⁴. Across these priority areas, **13 initiatives** have been identified **as suitable candidate initiatives** for Institutionalised Partnerships due to their objectives and scope. This impact assessment aims to identify whether 12 of these initiatives⁵ need to be implemented through this arrangement, and would not carry out their activities equally well with traditional calls of Horizon Europe or other lighter forms of European Partnerships under Horizon Europe. This means assessing whether each of these initiatives meets the necessity test set in the **selection criteria** for European Partnerships in the Horizon Europe Regulation, Annex III.

This assessment is done **without any budgetary considerations**, as the overall budget of the Multiannual Financial Framework of the EU – and hence of Horizon Europe – for the next financing period is not known at this stage.⁶

⁴ Set out in the Annex Va of the Horizon Europe Regulation (common understanding). https://data.consilium.europa.eu/doc/document/ST-7942-2019-INIT/en/pdf

¹ Horizon Europe Regulation (common understanding), https://data.consilium.europa.eu/doc/document/ST-7942-2019-INIT/en/pdf

² Based on the European Commission Better Regulation framework (SWD (2017) 350) and supported by an external study coordinated by Technopolis Group (to be published in 2020).

³ For further details on these points, see below Section 1.2.2.

⁵ Only 12 are subject to this impact assessment, as one initiative on High Performance Computing has already been subject to an impact assessment in 2017 (SEC(2018) 47).

⁶ EU budget commitments to the European Partnership candidates can only be discussed and decided following the political agreement on the overall Multiannual Financial Framework and Horizon Europe budgetary envelopes. The level of EU contribution for individual partnerships should be determined once there are agreed objectives, and clear commitments

1.2. The political and legal context

1.2.1. Shift in EU priorities and Horizon Europe framework

European priorities have evolved in the last decades, and reflect the social, economic, and environmental challenges for the EU in the face of global developments. In her Political Guidelines for the new European Commission 2019 – 2024⁷, the Commission President put forward six overarching priorities, which reach well beyond 2024 in scope⁸. Together with the Sustainable Development Goals (SDGs), these priorities will shape future EU policy responses to the challenges Europe faces, and thus also give direction to EU research and innovation.

As part of the Multi-annual Financial Framework (MFF) 2021-27 the new EU Framework Programme for Research and Innovation Horizon Europe will play a pivotal role for Europe to lead the social, economic, and environmental transitions needed to achieve these European policy priorities. It will be more impact driven with a strong focus on delivering European added value, but also be more effective and efficient in its implementation. Horizon Europe finds its rationale in the daunting challenges that the EU is facing, which call for "a radical new approach to developing and deploying new technologies and innovative solutions for citizens and the planet on a scale and at a speed never achieved before, and to adapting our policy and economic framework to turn global threats into new opportunities for our society and economy, citizens and businesses." While Horizon Europe continues the efforts of strengthening the scientific and technological bases of the Union and foster competitiveness, a more strategic and impact-based approach to EU R&I investment is taken. Consequently, the objectives of Horizon Europe highlight the need to deliver on the Union strategic priorities and contribute to the realisation of EU objectives and policies, contribute to tackling global challenges, including the Sustainable Development Goals by following the principles of the Agenda 2030 and the Paris Agreement. 10

In this context, at least 35 % of the expenditure from actions under the Horizon Europe Programme will have to contribute to climate action. Furthermore, a Strategic Plan is co-designed with stakeholders to identify key strategic orientations for R&I support for 2021-2024 in line with the EU priorities. In the Orientations towards the first Strategic Plan for Horizon Europe, the need to strategically prioritise and "direct a substantial part of the funds towards the areas where we believe they will matter the most" is emphasised. The Orientations specify, that actions under Pillar II of Horizon Europe "Global Challenges and European Industrial Competitiveness" will target only selected themes of especially high impact that significantly contribute to delivering on the political priorities of the Union. Most of the candidate European Partnerships fall under this Pillar.

from partners. Importantly, there is a ceiling to the partnership budgets in Pillar II of Horizon Europe (the legal proposal specifies that the majority of the budget in pillar II shall be allocated to actions outside of European Partnerships).

https://ec.europa.eu/info/strategy/priorities-2019-2024_en

⁸ 1.A European Green Deal; An economy that works for people; A Europe fit for the Digital Age; Promoting our European way of life; A Stronger Europe in the World; and 6.A New push for European Democracy

⁹ EC (2018) A Modern Budget for a Union that Protects, Empowers and Defends. The Multiannual Financial Framework for 2021-2027. Communication from the Commission to the European Parliament, the European Council, the European Economic and Social Committee and the Committee of the Regions, COM(2018) 321 final

¹⁰ Article 3, Common understanding regarding the proposal for Horizon Europe Framework Programme.

Key evolutions in the approach to partnerships in Horizon Europe 1.2.2.

Since their start in 1984, the successive set of Framework Programmes uses a variety of instruments and approaches to support R&I activities, address global challenges and industrial competitiveness. Collaborative, competition-based and excellence-driven R&I projects funded through Work Programmes are the most traditional and long-standing approach for implementation. Since 2002, available tools also include partnerships, whereby the Union together with private and/or public partners commit to jointly support the development and implementation of a R&I programme. These were introduced as part of creating the European Research Area (ERA) to align national strategies and overcome fragmentation of research effort towards an increased scientific, managerial and financial integration of European research and innovation. Interoperable and integrated national research systems would allow for better flows of knowledge, technology and people. Since then, the core activities of the partnerships consist of building critical mass mainly through collaborative projects, jointly developing visions, and setting strategic agendas.

As analysed in the interim evaluation of Horizon 2020¹¹, a considerable repertoire of partnership initiatives has been introduced over time, with eight forms of implementation¹² and close to 120 partnership initiatives running under Horizon 2020 - without clear exit strategies and concerns about their degree of coherence, openness and transparency. Even if it is recognised that these initiatives allow for setting long-term agendas, structuring R&I cooperation between otherwise dispersed actors, and leveraging additional investments, the evaluation points to the complexity generated by the proliferation of instruments and initiatives, and their insufficient contribution to policies at EU and national level.

Box 1 Key lessons from the interim evaluation of Horizon 2020 and R&I partnerships

- The Horizon 2020 Interim Evaluation concludes that the overall partnership landscape has become overly complex and fragmented. It identifies the need for rationalisation, to improve their openness and transparency, and link them with future EU R&I missions and strategic priorities.
- The Article 185 evaluation finds that these public-public partnerships have scientific quality, global visibility and networking/structuring effects but should, in the future, focus more on the achievement of policy impacts. From a systemic point of view, it found that the EU public-topublic cooperation (P2P) landscape has become crowded, with insufficient coherence.
- The Article 187 evaluation points out that Public-Private Partnership (PPP) activities need to be brought more in line with EU, national and regional policies, and calls for a revision of the Key Performance Indicators. As regards the contractual PPPs (cPPPs) their reviews identified challenges of coherence among cPPPs and the need to develop collaborations and synergies with

Over 80% of respondents to the Open Public Consultation (OPC) indicated that a significant contribution by future European Partnerships is 'fully needed' to achieve climate-related goals, to develop and effectively deploy technology, and for EU global competitiveness in specific sectors/domains. Views converged across all categories of respondents, including citizens, industry and academia.

¹¹ Interim evaluation of Horizon 2020, Commission Staff Working Document, SWD(2017)221 and 222 Interim evaluation of the Joint Undertakings operating under Horizon 2020 (Commission Staff Working Document, SWD(2017) 339); Evaluation of the Participation of the EU in research and development programmes undertaken by

several Member States based on Article 185 of the TFEU, Commission Staff Working Document, SWD (2017)340) ¹² E.g. initiatives based on Article 187 (Joint Technology Initiatives), Article 185 TFEU, Contractual Public-Private Partnerships (cPPPs), Knowledge & Innovation Communities of the European Institute of Innovation & Technology (EIT-KICs), ERA-NETs, European Joint Programmes, Joint Programming Initiatives.

The impact assessment of Horizon Europe identifies therefore the need to rationalise the EU R&I funding landscape, in particular with respect to partnerships, as well as to reorient partnerships towards more impact and delivery on EU priorities. To address these concerns and to realise the higher ambitions for European investments, Horizon Europe puts forward a major simplification and reform for the Commission's policy on R&I partnerships¹³. Reflecting its systemic nature which aims to contribute to EU-wide 'transformations' towards the sustainability objectives, Horizon Europe indeed intends to make a more effective use of these partnerships with a more strategic, coherent and impact-driven approach. Key related changes that apply to all forms of European Partnerships encapsulated in the Horizon Europe Regulation are summarised in the Box

Box 2 Key features of the revised policy approach to R&I partnerships under Horizon Europe based on its impact assessment

- ✓ **Simpler architecture & toolbox** by streamlining eight partnership instruments into 3 implementation forms (Co-Funded, Co-Programmed, Institutionalised), under the umbrella 'European Partnerships'
- ✓ More systematic and transparent approach to selecting, implementing, monitoring, evaluating and phasing out all forms of partnerships (criteria for European Partnerships):
 - The selection of Partnerships is embedded in the strategic planning of Horizon Europe, thereby ensuring coherence with the EU priorities. The selection criteria require that partnerships are established with stronger ex-ante commitment and higher ambition.
 - The implementation criteria stipulate that initiatives adopt a systemic approach in achieving impacts, including broad engagement of stakeholders in agenda-setting and synergies with other relevant initiatives to promote the take-up of R&I results.
 - A harmonised monitoring & evaluation system will be implemented, and ensures that progress is analysed in the wider context of achieving Horizon Europe objectives and EU priorities.
 - All partnerships need to develop an exit strategy from Framework Programme funding. This new approach is underpinned by principles of openness, coherence and EU added value.

✓ Reinforced impact orientation:

- Partnerships are established only if there is evidence they support achieving EU policy objectives
 more effectively than other Horizon Europe actions, by demonstrating a clear vision and targets
 (directionality) and corresponding long-term commitments from partners (additionality).
- European Partnerships are expected to provide mechanisms based on a concrete roadmap to join
 up R&I efforts between a broad range of actors towards the development and uptake of innovative
 solutions in line with EU priorities, serving the economy and society, as well as scientific progress.
- They are expected to develop close synergies with national and regional initiatives, acting as dynamic change agents, strengthening linkages within their respective ecosystems and along the value chains, as well as pooling resources and efforts towards the common EU objectives.

below.

Under Horizon Europe, a 'European Partnership' is defined as "an initiative where the Union, prepared with early involvement of Member States and/or Associated Countries, together with private and/or public partners (such as industry, universities, research organisations, bodies with a public service mission at local, regional, national or international level or civil society organisations including foundations and NGOs), commit to jointly support the development and implementation of a programme of research and innovation activities, including those related to market, regulatory or policy uptake."

The Regulation further specifies that European Partnerships shall adhere to the "principles of Union added value, transparency, openness, impact within and for Europe, strong leverage effect on sufficient scale, long-term commitments of all the involved parties, flexibility in implementation, coherence, coordination and complementarity with Union, local, regional, national and, where relevant, international initiatives or other partnerships

¹⁴ Article 8 and Annex III of the Horizon Europe Regulation (common understanding))

¹³ Impact assessment of Horizon Europe, Commission Staff Working Document, SWD(2018)307.

1.3. Why should the EU act

1.3.1. Legal basis

Proposals for Institutionalised European Partnerships are based on:

- 1) Article 185 TFEU which allows the Union to make provision, in agreement with the Member States concerned, for participation in research and development programmes undertaken by several Member States, including participation in the structures created for the execution of those programmes; or
- 2) Article 187 TFEU according to which the Union may set up joint undertakings or any other structure necessary for the efficient execution of Union research, technological development and demonstration programmes.¹⁵

1.3.2. Subsidiarity

The EU should act only in areas where there is demonstrable advantage that the action at EU level is more effective than action taken at national, regional or local level. Research is a shared competence between the EU and its Member States according to the TFEU. Article 4 (3) specifies that in the areas of research, technological development and space, the EU can carry out specific activities, including defining and implementing programmes, without prejudice to the Member States' freedom to act in the same areas. The candidate initiatives focus on areas where there is a demonstrable added value in acting at the EU level due to the scale, speed and scope of the efforts needed for the EU to meet its long-term Treaty objectives and deliver on its strategic policy priorities and commitments. In addition, the proposed initiatives should be seen as complementary and reinforcing national and subnational activities in the same area. Overall European Partnerships find their **rationale in addressing a set of systemic failures**¹⁶:

- Their primary function is to create a platform for a strengthened **collaboration** and knowledge exchange between various actors in the European R&I system and an enhanced **coordination** of strategic research agendas and/or R&I funding programmes. They aim to address **transformational failures** to better align agendas and policies of public and private funders, pool available resources, create critical mass, avoid unnecessary duplication of efforts, and leverage sufficiently large investments where needed but which are not achievable by single countries.
- The concentration of efforts and pooling of knowledge on common priorities to solve multi-faceted societal and economic challenges is at the core of these initiatives. Specifically, enhanced cross-disciplinary and cross-sectoral collaboration and an improved integration of value chains and ecosystems are among the key objectives of these instruments. In the light of Horizon Europe, the aim is to **drive system transitions and transformations towards EU priorities**.
- Especially in fast-growing technologies and sectors such as ICT, there is a need to react to emerging opportunities and address systemic failures such as a shortage in skills or critical mass or cross-sectoral cooperation along the value chains that would hamper attainment of future European leadership and/or strategic autonomy.
- They also aim to address market failures predominantly to enhancing industry

¹⁵ Both Articles are under Title XIX of the TFEU - Research and Technological Development and Space.

¹⁶ The Interim Evaluation of Horizon 2020 and the impact assessment of Horizon Europe provide qualitative and quantitative evidence on these points. Sections 1 and 2 of each impact assessment on candidate European Partnerships include more detail on the necessity to act at EU level in specific thematic areas.

investments due to the sharing of risks.

2. THE CANDIDATE EUROPEAN PARTNERSHIPS – WHAT NEEDS TO BE DECIDED

2.1. Portfolio of candidates for Institutionalised European Partnerships

The new approach for more objective-driven and impactful European Partnerships is reflected in the way candidate Partnerships have been identified. It involved a co-design exercise aiming to better align these initiatives with societal needs and policy priorities, while broadening the range of actors involved. Taking into account the 8 areas for Institutionalised European Partnerships set out in the Horizon Europe Regulation 17, a co-design exercise as part of the Strategic Planning process of Horizon Europe led to the identification of 49 candidates for Co-funded, Co-programmed or Institutionalised European Partnerships 18. Out of these, 13 were identified as suitable candidate Institutionalised Partnerships because of their objectives and scope 19. Whilst the Co-Funded and Co-Programmed Partnerships are linked to the comitology procedure (including the adoption of the Strategic Plan and the Horizon Europe Work Programmes), Institutionalised Partnerships require the adoption of legislation and are subject to an impact assessment. The Figure below gives an overview of all candidate European Partnerships according to their primary relevance to Commission priorities for 2019-2024.

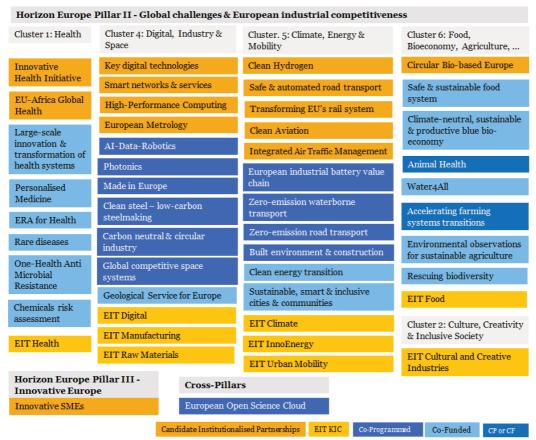
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 $^{^{\}rm 17}$ Horizon Europe Regulation (common understanding), Annex Va.

¹⁸ Shadow configuration of Strategic Programme Committee for Horizon Europe. The list of candidate European Partnerships is described in "Orientations towards the Strategic Plan of Horizon Europe" - Annex 7

¹⁹ Only 12 are subject to this impact assessment, as one initiative on High Performance Computing has already been subject to an impact assessment in 2017 (SEC(2018) 47)

Figure 1 - Overview of the candidates for Co-Funded, Co-Programmed and Institutionalised European Partnerships according to Horizon Europe structure



Source: Technpolis group (2020)

There are only three partnerships for which implementation as an Institutionalised Partnership under Article 185 is an option, i.e. European Metrology, the EU-Africa Global Health partnership, and Innovative SMEs. Ten partnerships are candidates for Institutionalised Partnerships under Article 187. Overall, the initiatives can be categorised into 'horizontal' partnerships and 'vertical' partnerships.

The 'horizontal' partnerships have a central position in the overall portfolio, as they are expected to develop methodologies and technologies for application in the other priority areas, ultimately supporting European strategic autonomy in these areas as well as technological sovereignty. These 'horizontal' partnerships are typically proposed as Institutionalised or Co-programmed Partnerships, in addition to a number of EIT KICs, they cover mainly the digital field in addition to space, creative industries and manufacturing, but also the initiative related to Innovative SMEs. 'Vertical' partnerships are focused on the needs and development of specific application areas, and are primarily expected to support enhanced environmental sustainability thereby addressing European Green Deal's objectives. They also deliver on policies for a more people-centred economy, through improved wellbeing of EU citizens and the economy.

2.2. Assessing the necessity of a European Partnership and possible options for implementation

Article 8 of the Horizon Europe Regulation stipulates that Institutionalised European Partnerships based on Article 185 and 187 TFEU shall be implemented only where other parts of the Horizon Europe programme, including other forms of European Partnerships would not achieve the objectives or would not generate the necessary expected impacts, and

if justified by a long-term perspective and high degree of integration. At the core of this impact assessment is, therefore, the need to demonstrate that the impacts generated through a Partnership approach go beyond what could be achieved with traditional calls under the Framework Programme – the Baseline Option. Secondly, it needs to assess if using the Institutionalised form of a Partnership is justified for addressing the priority.

For all candidate Institutionalised European Partnerships the options considered in this impact assessment are the same, i.e.:

- Option 0 Baseline option Traditional calls under the Framework Programme
- Option 1 Co-programmed European Partnership
- Option 2 Co-funded European Partnership
- Option 3 Institutionalised Partnership
 - o Sub-option 3a Institutionalised Partnerships based on Art 185 TFEU
 - Sub-option 3b Institutionalised Partnerships based on Art 187 TFEU

2.2.1. Option 0 - Baseline option – Traditional calls

Under this option, strategic programming for R&I in the priority area will be done through the mainstream channels of Horizon Europe. The related priorities will be implemented through **traditional calls** of Horizon Europe covering a range of actions, mainly R&I and/or innovation actions but also coordination and support actions, prizes or procurement. Most actions involve consortia of public and/or private actors in ad hoc combinations, while some actions are single actor (mono-beneficiary). There will be no dedicated implementation structure and no support other than what is foreseen in the related Horizon Europe Work Programme. This means that discontinuation costs/benefits of predecessor initiatives should be factored in for capturing the baseline situation, when relevant.

Under this option, strategic planning mechanisms in the Framework Programme will allow for a high level of flexibility for traditional calls to respond to particular needs over time, building upon additional co-creation input from stakeholders and programme committees involving Member States. The Union contribution to addressing the priority covers the full duration of the initiative, during the lifetime of Horizon Europe. Without a formal EU partnership mechanism, it is less likely that the stakeholders will develop a joint Strategic Research and Innovation Agenda (SRIA) and commit to its implementation or agree on mutual commitments and contributions outside their participation in funded projects.

2.2.2. European Partnerships

Under this set of options, three different forms of implementation are assessed: Co-funded, Co-Programmed, Institutionalised European Partnerships. These have **commonalities that cannot serve as a distinguishing factor in the impact assessment process**. They are all based on agreed objectives and expected impacts and underpinned by Strategic Research and Innovation Agendas/ roadmaps that are shared and committed to by all partners in the partnership. They all have to follow the same set of criteria along their lifecycle, as defined in the Horizon Europe Regulation (Annex III), including ex ante commitment from partners to mobilise and contribute resources and investments. The Union contribution is defined for the full duration of the initiative for all European Partnerships. The Horizon Europe legal act introduces few additional requirements for Institutionalised Partnerships, e.g. the need for a long-term perspective, strong integration of R&I agendas, and financial contributions.

Figure 2 - Key differences in preparation and implementation of European Partnerships

Type	Legal form	Implementation		
Co-Programmed	Contractual arrangement/ MoU	Division of labour , whereby Union contribution is implemented through Framework rogramme and partners' contributions under their responsibility.		
Co-Funded	Grant Agreement	Union provides co-funding for an integrated programme with distributed implementation by entities managing and/or funding national research and innovation programmes		
Institutionalised	Basic act (Council regulation,	Integrated programme with centralised		
based on Article	Decision by European	implementation		
185/187 TFEU	Parliament and Council)			

The main differences between the different forms of European Partnerships are in their preparation and in the way they function, as well as in the overall impact they can trigger. The Co-Programmed form is assessed as the simplest, and the Institutionalised form as the most complex to prepare and implement. The functionalities of the different form of Partnerships – compared to the baseline option – are presented in Figure 3. They relate to the types of actors Partnerships can involve and their degree of openness, the types of activities they can perform and their degree of flexibility, the degree of commitment of partners and the priority setting system, and their ability to work with their external environment (coherence), etc. These key distinguishing factors will be at the basis of the comparison of each option to determine their overall capacity to deliver what is needed at a minimised cost.

Figure 3 Overview of the functionalities provided by each form of European Partnerships, compared to the traditional calls of Horizon Europe (baseline)

Baseline: Horizon Europe calls	Option 1: Co- Programmed		Option 3a: Institutio- nalised Art 185	Option 3b: Institutionalised Art 187			
Type and composition of actors (including openness and roles)							
Partners: N.A., no common set of actors that engage in planning and implementation Priority setting: open to all, part of Horizon Europe Strategic planning Participation in R&I activities: fully open in line with Horizon Europe rules	Partners: Suitable for all types: private and/or public partners, foundations Priority setting: Driven by partners, open stakeholder consultation, MS in comitology Participation in R&I activities: fully open in line with Horizon Europe rules	Partners: core of national funding bodies or govern-mental research organisations Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: limited, according to national rules of partner countries	Partners: National funding bodies or governmental research organisation Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: fully open in line with Horizon Europe rules, but possible derogations	Partners: Suitable for all types: private and/or public partners, foundations Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: fully open in line with Horizon Europe rules, but possible derogations			
Type and range of acti	Type and range of activities (including additionality and level of integration)						
Activities: Horizon Europe standards that allow broad range of individual actions Additionality: no additional activities and investments outside the funded projects Limitations: No systemic approach beyond individual actions	Activities: Horizon Europe standard actions that allow broad range of individual actions, support to market, regulatory or policy/ societal uptake Additionality: Activities/investments of partners, National funding Limitations: Limited systemic approach beyond individual actions	Activities: Broad, according to rules/programmes of participating States, State-aid rules, support to regulatory or policy/societal uptake Additionality: National funding Limitations: Scale & scope depend on participating programmes, often smaller in scale	Activities: Horizon Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to systemic approach Additionality: National funding	Activities: Horizon Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to systemic approach (portfolios of projects, scaling up of results, synergies with other funds. Additionality: Activities/investments of partners/ national funding			

Baseline: Horizon Europe calls	Option 1: Co- Programmed	Option 2: Co-Funded	Option 3a: Institutio- nalised Art 185	Option 3b: Institutionalised Art 187			
Priority-setting process and directionality							
Priority setting: Strategic Plan and annual work programmes, covering max. 4 years. Limitations: Fully taking into account existing or to be developed SRIA/roadmap	Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Input to FP annual work programme drafted by partners, finalised by EC (comitology) Objectives & commitments set in contractual arrangement	Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Annual work programme drafted by partners, approved by EC Objectives & commitments set in Grant Agreement	Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Annual work programme drafted by partners, approved by EC Objectives & commitments set in legal act	Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Annual work programme drafted by partners, approved by EC (vetoright in governance) Objectives & commitments set in legal act			
Coherence: internal (H	lorizon Europe) & externa	d (other Union program	mes, national program	nmes, industrial strategies			
Internal: Coherence between different parts of the FP Annual Work programme can be ensured by EC External: Limited for other Union programmes, no synergies with national/regional programmes & activities	Internal: Coherence among partnerships & with parts of the FP Annual Work programme can be ensured by partners & EC External: Limited synergies with other Union programmes & industrial strategies. If MS participate, with national/regional programmes & activities	Internal: Coherence among partnerships & with parts of the FP Annual Work programme can be ensured by partners & EC External: Synergies with national/ regional programmes & activities	Internal: Coherence among partnerships & with parts of the FP Annual Work programme can be ensured by partners & EC External: Synergies with national/regional programmes & activities	Internal: Coherence among partnerships & with parts of the FP Annual Work programme can be ensured by partners & EC External: Synergies with other Union programmes and industrial strategies If MS participate, with national/regional programmes & activities			

2.2.2.1. Option 1 - Co-programmed European Partnership

This form of European Partnership is **based upon a Memorandum of Understanding or a Contractual Arrangement** signed by the Commission and the private and/or public partners. Private partners are represented by industry associations, which also support the daily management of the partnership. This type of partnership would allow for a large degree of flexibility for the activities, partners and priorities to continuously evolve. The commitments of partners are political efforts described in the contractual arrangement and the contributions from partners are provided in kind more than financially. The priorities for the calls, proposed by the Partnership's members for integration in the Horizon Europe's Work Programmes, are subject to further input from Member States (comitology) and Commission services. The Union contribution is implemented within the executive agency managing Horizon Europe calls for research and innovation projects proposals. The full array of Horizon Europe instruments can be used, ranging from research and innovation (RIA) types of actions to coordination and support actions (CSA) and including grants, prizes, and procurement.

2.2.2.2. Option 2 – Co-funded European Partnership

The Co-funded European Partnership is **based on a Grant Agreement** between the Commission and a consortium of partners, resulting from a specific call in the Horizon Europe Work Programme. This form of implementation only allows to address public partners at its core. Typically these provide co-funding to a common programme of activities established and/or implemented by entities managing and/or funding national R&I programmes. The recipients of the EU co-funding implement the initiative under their responsibility, with national funding/resources pooled to implement the programme with co-

funding from the Union. The expectation is that these entities would cover most if not all EU Member States. Calls and evaluations would be organised centrally, beneficiaries in selected projects would be funded at national level, following national funding rules.

2.2.2.3. Option 3 – Institutionalised European Partnership

This type of Partnership is the most complex and high-effort arrangement, and requires meeting additional requirements. Institutionalised European Partnership are based on a Council Regulation (Article 187 TFEU or a Decision by the European Parliament and Council (Article 185 TFEU) and are implemented by dedicated structures created for that purpose. These regulatory needs limit the flexibility for a change in the core objectives, partners, and/or commitments as these would require amending legislation. The basic rationale for this type of partnership is the need for a strong integration of R&I agendas in the private and/or public sectors in the EU in order to address a strategic challenge. It is therefore necessary to demonstrate that other forms of implementation would not achieve the objectives or would not generate the necessary expected impacts, and that a long-term perspective and high degree of integration is needed. For both Article 187 and 185 initiatives, contributions from partners can be in the form of financial and in-kind contributions. Eligibility for participation and funding follows by default the rules of Horizon Europe, unless a derogation is introduced in the basic act.

Option 3a - Institutionalised Partnerships based on Article 185 TFEU

Article 185 of the TFEU allows the Union to participate in programmes jointly undertaken by Member States and limits therefore the scope to **public partners** which are Member States and Associated Third Countries. This type of Institutionalised Partnership aims therefore at reaching the greatest possible impact through the integration of national and EU funding, aligning national strategies in order to optimise the use of public resources and overcome fragmentation of the public research effort. It brings together R&I governance bodies of most if not all EU Member States (legal requirement: at least 40% of Member States) as well as Associated Third Countries that designate a legal entity (Dedicated Implementation Structure) of their choice for the implementation. By default, participation of non-associated Third Countries is not foreseen. Such participation is possible only if it is foreseen in the basic act and subject to conclusion of an international agreement.

Option 3b - Institutionalised Partnerships based on Article 187 TFEU

Article 187 of the TFEU allows the Union to set up joint undertakings or any other structure necessary for the efficient execution of EU research, technological development and demonstration programmes. This type of Institutionalised Partnership brings together a stable set of **public and private partners** with a strong commitment to taking a more integrated approach and requires the set-up of a dedicated legal entity – a Union body, Joint Undertaking (JU) – that carries full responsibility for the management of the Partnership and implementation of the calls. Different configurations are possible:

- Partnerships focused on creating strategic industrial partnerships where, most often, the partner organisations are represented by one or more industry associations, or in some cases individual private partners;
- Partnerships coordinating national ministries, public funding agencies, and governmental research organisations in the Member States and Associated Countries;
- Or a combination of the two: the so-called tripartite model.

Participation of non-associated Third Countries is only possible if foreseen in the basic act and subject to conclusion of an international agreement.

2.3. Overview of the methodology adopted for the impact assessment

The methodology for each impact assessment is based on the Commission Better Regulation Guidelines²⁰ to evaluate and compare options with regards to their **efficiency**, **effectiveness** and coherence. This also integrates key selection criteria for European Partnerships.

Box 2 Summary of European Partnerships selection criteria²¹

- Effectiveness in achieving the related objectives and impacts of the Programme;
- Coherence and synergies of the European Partnership within the EU R&I landscape;
- *Transparency & openness* as regards the identification of priorities and objectives and the involvement of partners & stakeholders from the entire value chain, backgrounds & disciplines;
- Ex-ante demonstration of *additionality* and *directionality*;
- Ex-ante demonstration of the partners' *long term commitment*.

2.3.1. Overview of the methodologies employed

In terms of **methods and evidence used**, the impact assessments draw on an external study covering all candidate Institutionalised European Partnerships in parallel to ensure a high level of coherence and comparability of analysis, in addition to an horizontal analysis.²² For all initiatives, the understanding of the overall context of the candidate institutionalised European Partnerships relied on desk research, including among others the lessons learned from previous partnerships. This was complemented by the analysis of a range of quantitative and qualitative evidence, including evaluations of past and ongoing initiatives; foresight studies; statistical analyses of Framework Programmes application and participation data, and Community Innovation Survey data; analyses of science, technology and innovation indicators; reviews of academic literature; sectoral competitiveness studies and expert hearings. The analyses included a portfolio analysis, a stakeholder and social network analysis in order to profile the actors involved as well as their co-operation patterns, and an assessment of the partnerships' outputs (bibliometrics and patent analysis).

A cost modelling exercise was performed in order to feed into the efficiency assessments of the partnership options, as described below. Public consultations (both open and targeted) supported the comparative assessment of the policy options. For each initiative, up to 50 relevant stakeholders were interviewed by the external contractor (policymakers, business including SMEs and business associations, research institutes and universities, and civil organisations, among others). In addition, the analysis was informed by the results of the Open Public Consultation that ran between September and November 2019, the consultation of Member States through the Strategic Programme Committee and the online feedback received on the Inception Impact Assessments of the set of initiatives.

A more detailed description of the methodology and evidence base that were mobilised, completed by thematic specific methodologies, is provided in Annexes 4 and 6.

²¹ For a comprehensive overview of the selection criteria for European Partnerships, see Annex 6.

²⁰ European Commission (2017), Better Regulation Guidelines (SWD (2017) 350)

²² Technopolis Group (2020), Impact Assessment Study for Institutionalised European Partnerships under Horizon Europe, Final Report, Study for the European Commission, DG Research & Innovation

2.3.2. Method for identifying the preferred option

The first step of the assessments consisted in scoping the problems that the initiatives are expected to solve given the overall economic, technological, scientific and social context, including the lessons to be learned from past and ongoing partnerships on what worked well and less well. This supported the identification of the objectives of the initiative in the medium and long term with the underlying intervention logic – showing how to get there.

Given the focus of the impact assessment on comparing different forms of implementation, the Better Regulation framework has then been adapted to introduce "**key functionalities needed**" - making the transition between the definition of the objectives and what would be crucial to achieve them *in terms of implementation*. The identification of "key functionalities needed" for each initiative as an additional step in the impact assessment is based on the distinguishing factors between the different options (see Section 2.2.1).

In practical terms, each option is assessed on the basis of the degree to which it would allow for the key needed functionalities to be covered, as regards e.g. the type and composition of actors that can be involved ('openness'), the range of activities that can be performed (including additionality and level of integration), the level of directionality and integration of R&I strategies; the possibilities offered for coherence and synergies with other components of Horizon Europe, including other Partnerships (internal coherence), and the coherence with the wider policy environments, including with the relevant regulatory and standardisation framework (external coherence). This approach guides the identification of discarded options while allowing at the same time a structured comparison of the options not only as regards their effectiveness, efficiency and coherence, but also against a set of other key selection criteria for European Partnerships (openness, transparency, directionality)²³.

In line with the Better Regulation Framework, the assessment of the effectiveness, efficiency and coherence of each option is made compared to the baseline. Therefore, for each of these aspects, the performance of using traditional calls under Horizon Europe is first estimated and scored 0 to serve as a reference point. This includes the discontinuation costs/benefits of existing implementation structures when relevant. The policy options are then scored compared to the baseline with a + and - system with a two-point scale, to show a slightly or highly additional/lower performance compared to the baseline. A scoring of 0 of a policy option means that it would deliver as much as the baseline option.

On the basis of the evidence collected, the intervention logic of each initiative and the key functionalities needed, the impact assessments first evaluate the **effectiveness** of the various policy options to deliver on their objectives. To be in line with the Horizon Europe impact framework, the fulfilment of the specific objectives of the initiative is translated into 'expected impacts' – how success would look like – differentiating between scientific, economic/ technological, and societal (including environmental) impacts. Each impact assessment considers to which extent the different policy options provides the 'key functionalities needed' to achieve the intended objectives. The effectiveness assessment does not use a compound score but shows how the options would deliver on the different

²³ The criterion on the ex-ante demonstration of partners' long-term commitment depends on a series of factors that are unknown at this stage, and thus fall outside the scope of the analysis.

types of expected impacts. This is done to increase transparency and accuracy in the assessment of options²⁴.

A similar approach is followed to evaluate the coherence of options with the overarching objectives of the EU's R&I policy, and distinguishes between **internal** and **external coherence**. Specifically, internal coherence covers the consistency of the activities that could be implemented with the rest of Horizon Europe, including European Partnerships (any type). External coherence refers to the potential for synergies and/or complementarities (including risks of overlaps/gaps) of the initiative with its external environment, including with other programmes under the MFF 2021-27, but also the framework conditions at European, national or regional level (incl. regulatory aspects, standardisation).

To compare the expected costs and benefits of each option (efficiency), the thematic impact assessments broadly follow a cost-effectiveness approach²⁵ to establish to which extent the intended objectives can be achieved for a given cost. A preliminary step in this process is to obtain a measure of the expected costs of the policy options, to be used in the thematic assessments. As the options correspond to different implementation modes, relevant cost categories generally include the costs of setting-up and running an initiative. For instance, set-up costs includes items such as the preparation of a European Partnership proposal and the preparation of an implementation structure. The running costs include the annual work programme preparation costs. Where a Partnership already exists, discontinuation costs and cost-savings are also taken into account²⁶. The table below provides an overview of the cost categories used in the impact assessment and a qualitative scoring of their intensity when compared to the baseline option (traditional calls). Providing a monetised value for these average static costs would have been misleading, because of the different features and needs of each candidate initiative.²⁷ The table shows the overall administrative, operational and coordination costs of the various options. These costs are then put into context in the impact assessments to reflect the expected co-financing rates and the total budget available for each of the policy options, assuming a common Union contribution (cost-efficiency):

- The costs related to the baseline scenario (traditional calls under Horizon Europe) are pre-dominantly the costs of implementing the respective Union contribution via calls and project, managed by the executive agencies (around 4%, efficiency of 96% for the overall investment).
- For a Co-Programmed partnership, the costs of preparation and implementation increase only marginally compared to the baseline (<1%), but lead to an additional R&I investment of at least the same amount than the Union contribution²⁸ (efficiency of 98% for the overall investment).
- For a Co-Funded partnership, the additional R&I investment by Member States accounts for 2.3 times the Union contribution²⁹. The additional costs compared to the

²⁶ Discontinuation costs will bear winding down and social discontinuation costs and vary depending on e.g. the number of full-time-equivalent (FTEs) staff concerned, the type of contract (staff category and duration) and applicable rules on termination (e.g. contracts under Belgian law or other). If buildings are being rented, the cost of rental termination also apply. As rental contracts are normally tied to the expected duration of the current initiatives, these termination costs are likely to be very limited. In parallel, there would also be financial cost-savings related to the closing of the structure, related to operations, staff and coordination costs in particular. This is developed further in the individual efficiency assessments.

²⁴ In the thematic impact assessments, scores are justified in a detailed manner to avoid arbitrariness and spurious accuracy. A qualitative or even quantitative explanation is provided of why certain scores were given to specific impacts, and why one option scores better or worse than others.

²⁵ For further details, see Better Regulation Toolbox # 57.

²⁷ A complete presentation of the methodology developed to assess costs as well as the sources used is described in the external study supporting this impact assessment (Technopolis Group, 2020).

²⁸ Minimum contributions from partners equal to the Union contribution

²⁹ Based on the default funding rate for programme co-fund actions of 30%, partners contribute with 70% of the total investment.

baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the national programmes, can be estimated at 6% of the Union contribution (efficiency of 98% related to the overall investment).

- For an Article 185 initiative, the additional R&I investment by Member States is equal to the Union contribution³⁰. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the dedicated implementation structure, can be estimated at 7% of the Union contribution. (efficiency of 96% related to the overall investment).
- For an Article 187 initiative, the additional R&I investment by partners is equal to the Union contribution³¹. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the dedicated implementation structure, can be estimated at 9% of the Union contribution. (efficiency of 94% related to the overall investment).

Figure 4 - Intensity of additional costs compared with Horizon Europe Calls (for Partners, stakeholders, public and EU)

Cost items	Baseline: traditional calls	Option 1: Coprogrammed	Option 2 Co-funded	Option 3a -Art. 185	Option 3b -Art. 187	
Preparation and set-up costs						
Preparation of a partnership proposal (partners and EC)	0	11				
Set-up of a dedicated implementation structure		0		Existing: ↑ New: ↑↑	Existing: ↑↑ New: ↑↑↑	
Preparation of the SRIA / roadmap	0	↑ ↑				
Ex-ante Impact Assessment for partnership		0			$\uparrow \uparrow \uparrow$	
Preparation of EC proposal and negotiation	0			$\uparrow \uparrow \uparrow$		
Running costs (Annual cycle of imple	mentation)					
Annual Work Programme preparation	0	↑				
Call and project implementation	0	0 In case of MS contributions: ↑	↑	\uparrow	\uparrow	
Cost to applicants Comparable, unless there are strong arguments of major in oversubscription				differences		
Partners costs not covered by the above	0	↑	0	↑	↑	
Additional EC costs (e.g. supervision)	0	↑	↑	↑	$\uparrow \uparrow$	
Winding down costs						
EC	0			$\uparrow \uparrow \uparrow$		
Partners	0	↑	0	↑	↑	

Notes: 0: no additional costs, as compared with the baseline; \uparrow : minor additional costs, as compared with the baseline; $\uparrow \uparrow$: medium additional costs, as compared with the baseline; $\uparrow \uparrow \uparrow$: higher costs, as compared with the baseline.

The cost categories estimated for the common model are then used to develop a scorecard analysis and further refine the assessment of options for each of the 12 candidate Institutionalised Partnerships. Specifically, the scores related to the set-up and implementation costs are used in the thematic impact assessments to consider the scale of

³¹ Based on the minimum requirement in the legal basis that partners contribute at least 50% of the budget.

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³⁰ Based on the minimum requirement in the legal basis that partners contribute at least 50% of the budget.

the expected benefits and thereby allow a simple "value for money" analysis (**cost-effectiveness**)³². In carrying out the scoring of options, the results of fieldwork, desk research and stakeholder consultation undertaken and taken into account.

For the **identification of the preferred option**, the scorecard analysis builds a hierarchy of the options by individual criterion and overall in order to identify a single preferred policy option or in case of an inconclusive comparison of options, a number of 'retained' options or hybrid. This exercise supports the systematic appraisal of alternative options across multiple types of monetary, non-monetary and qualitative dimensions. It also allows for easy visualisation of the pros and cons of each option. Each option is attributed a score of the adjudged performance against each criterion with the three broad appraisal dimensions of effectiveness, efficiency and coherence.

As a last step, the alignment of the preferred option with key criteria for the selection of European Partnerships is described, reflecting the outcomes of the 'necessity test'. The monitoring and evaluation arrangements are concluding the assessment, with an identification of the key indicators to track progress towards the objectives over time.

2.4. Horizontal perspective on candidate Institutionalised European Partnerships

2.4.1. Overall impact orientation, coherence and efficiency needs

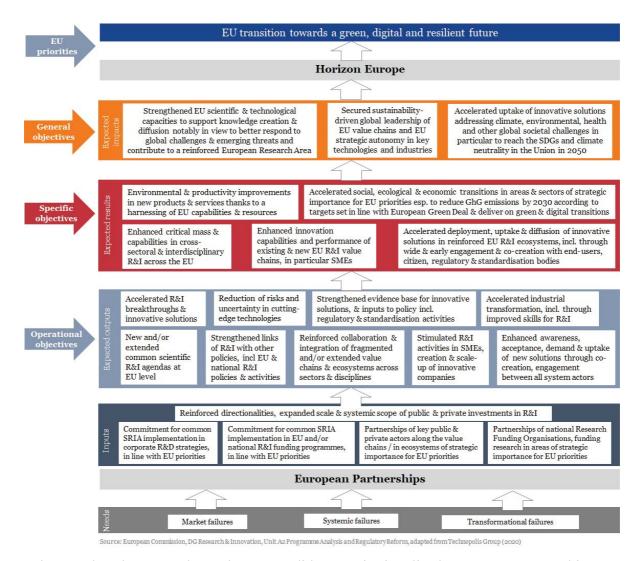
The consolidated **intervention logic** for the set of candidate Institutionalised European Partnerships in the Figure below builds upon the objectives as reported in the individual impact assessments.

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³² More details on the methodology can be found in Annex 4.

³³Certain aspects of the selection criteria will be further addressed/ developed at later stages, notably in the context of preparing basic acts (e.g. Openness and Transparency; Coherence and Synergies), in the Strategic Research and Innovation Agendas (e.g. Directionality and Additionality), and by collecting formal commitments (Ex-ante demonstration of partners' long-term commitment).

Figure 5 – Overall intervention logic of the European Partnerships under Horizon Europe



When analysed as a package the 12 candidate Institutionalised European Partnerships are expected to support the achievement of the European policy priorities targeted by Horizon Europe by pursuing the following joint general objectives:

- a) Strengthening and integrating EU scientific and technological capacities to support knowledge creation and diffusion notably in view to better respond to global challenges and emerging threats and contribute to a reinforced European Research Area;
- b) Securing sustainability-driven global leadership of EU value chains and EU strategic autonomy in key technologies and industries; and
- c) Accelerate the uptake of innovative solutions addressing climate, environmental, health and other global societal challenges contributing to Union strategic priorities, in particular to reach the Sustainable Development Goals and climate neutrality in the Union in 2050.

In terms of specific objectives, they jointly aim to:

- a) Enhance the critical mass and scientific capabilities in cross-sectoral and interdisciplinary research and innovation across the Union;
- b) Accelerate the social, ecological and economic transitions in areas and sectors of strategic importance for Union priorities, in particular to reduce greenhouse gas

- emissions by 2030 according to the targets set in line with the European Green Deal, and deliver on the green and digital transition;
- c) Enhance the innovation capabilities and performance of existing and new European research and innovation value chains, in particular SMEs;
- d) Accelerate the deployment, uptake and diffusion of innovative solutions in reinforced European R&I ecosystems, including through wide and early engagement and co-creation with end-users, citizen and regulatory and standardisation bodies;
- e) Deliver environmental and productivity improvements in new products and services thanks to a harnessing of EU capabilities and resources.

In terms of their operations, taking an horizontal perspective on all initiatives allows for the identification of further possible collective efficiency and coherence gains for more impact:

- Coherence for impact: The extent and speed by which the expected results and impacts will be reached, will depend on the scale of the R&I efforts triggered, the profile of the partners involved, the strength of their commitments, and the scope of the R&I activities funded. To be fully effective, it comes out clearly that future partnerships need to operate over their whole life cycle in full coherence with their environment, including potential end users, regulators and standardisation bodies. This relates also to the alignment with relevant EU, national or regional policies and synergies with R&I programmes. This needs to be factored in from the design stage to ensure a wide take-up and/or deployment of the solutions developed, including their interoperability.
- Collaboration for impact: Effectiveness could also be improved collectively through enhanced cross-disciplinary and cross-sectoral collaboration and an improved integration of value chains and ecosystems. An adequate governance structure appears in particular necessary to ensure cross-fertilisation between all European Partnerships. This applies not only to initiatives where similar R&I topics are covered and/or the same stakeholders involved or targeted, but also to the interconnections needed between the 'thematic' and the 'vertical' Partnerships, as these are expected to develop methodologies and technologies for application in EU priority areas. Already at very early stages of preparing new initiatives, Strategic Research and Innovation Agendas and roadmaps need to be aligned, particularly for partnerships that develop enabling technologies that are needed in other Partnerships. The goal should be to achieve greater impacts jointly in light of common challenges.
- Efficiency for impact: Potential efficiency gains could also be achieved by joining up the operational functions of Joint Undertakings that do not have a strong context dependency and providing them through a common back-office³⁴. A number of operational activities of the Joint Undertakings are of a technical or administrative nature (e.g. financial management of contracts), or procured from external service providers (e.g. IT, communication activities, recruitment services, auditing) by each Joint Undertaking separately. If better streamlined this could create a win-win situation for all partners leading to better harmonization, economies of scale, and less complexity in supervision and support by the Commission services.
 - 2.4.2. Analysis of coherence of the overall portfolio of candidate initiatives at the thematic level

Looking at the coherence of the set of initiatives at the thematic level, the "digital centric"

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³⁴ See Annex 6 for an overview of key functions/roles that could be provided by a common back office.

initiatives have a strong focus on supporting the digital competitiveness of the EU ecosystem. Their activities are expected to improve alignment and coordination with Member States and industry for the development of world-competitive EU strategic digital technology value chains and associated expertise. Addressing the Key Digital Technologies, the 5G and 6G connectivity needs as part of a Smart Networks and Services initiative and the underlying supercomputing capacities through a European High Performance Computing initiative present potential for synergies that can be addressed through cooperative actions (e.g. joint calls, coordinated support activities, etc.). They may as well profit from and contribute to Partnerships envisaged for Photonics, AI, data, robotics, Global competitive space system and Made in Europe, together with the EIT Digital. Synergies between these initiatives and several programmes (Digital Europe and Connecting Europe as well as cohesion programmes) are needed in areas where EU industry has to develop leadership and competitiveness in the global digital economy. They are expected to impact critical value chains including on sectors where digital is a strong enabler of transformation (health, industrial manufacturing, mobility/transport, etc.).

The **transport** sector face systemic changes linked to decarbonisation and digitalisation. Large scale R&I actions are needed to prepare the transition of these complex sectors to provide clean, safer, digital and economically viable services for citizens and businesses. Past decades have shown that developing and implementing change is difficult in transport due to its systemic nature, many stakeholders involved, long planning cycles and large investments needed.

A systemic change of the air traffic network through an Integrated Air Traffic Management initiative should ensure safety and sustainability of aviation, while a Clean Aviation initiative should focus on the competitiveness of tomorrow's clean aircraft made in Europe. The initiative for Transforming Europe's Rail System would comprehensively address the rail sector to make it a cornerstone in tomorrow's clean and efficient door-to-door transport services, affordable for every citizen as well as the most climate-friendly mode of transport for freight.

Connected and Automated Mobility is the future of road transport, but Europe risks falling behind other global regions which have strong players and large harmonised markets. The initiative Safe and Automated Road Transport would bring stakeholders together, creating joint momentum in digitalising road transport and developing new user-based services. Stronger links and joint actions will be established between initiatives to enable common progress wherever possible.

The Clean Hydrogen initiative would be fundamental in that regard. Synergies would also be sought with those partnerships driving digital technological developments To deliver a deep decarbonisation of highly emitting industrial sectors – such as the steel, transport and chemical industries – would require the production, distribution and storage of **hydrogen** at scale. The candidate hydrogen initiative would have a central positioning in terms of providing solutions to the challenges for sustainable mobility and energy, but also is expected to operate in synergies with other industry related initiatives.

The initiative would interact in particular with initiatives on the zero emission road and water transport, transforming Europe's railway system, clean aviation, batteries, circular industry, clean steel and built environment partnerships. There are many opportunities for collaboration for the delivery and end-use of hydrogen. However, the Clean Hydrogen initiative would be the only partnership focused on addressing hydrogen production technologies.

Metrology, the science of measurement, is an enabler across all domains of R&I. It supports the monitoring of the Emissions Trading System, smart grids and pollution, but also

contributes to meeting demands for measurement techniques from emerging digital technologies and applications. More generally, emerging technologies across a wide range of fields from biotechnologies, new materials, health diagnostics or low carbon technologies are giving rise to demands requiring a world-leading EU metrology system.

The initiative for a **Circular Bio-based Europe** is intended to solve a shortage of industry investments in the development of bio-based products, whose markets do not have yet certain long-term prospects. The **Innovative Health Initiative** and **EU-Africa Global Health** address the lack of investments in the development of solutions to specific health challenges. The initiative on **Innovative SMEs** supports innovation-driven SMEs in participating in international, collaborative R&I projects with other innovative firms and research-intensive partners. As a horizontal initiative, it is expected to help innovative SMEs to grow and to be successfully embedded in global value chains by developing methodologies and technologies for potential application in the other partnership areas or further development by the instruments of the European Innovation Council.

The description of the interconnections between all initiatives for each Horizon Europe cluster is provided in the policy context of each impact assessment, and further assessed in the coherence assessment for each option.

PART 2 - THE CANDIDATE EUROPEAN PARTNERSHIP FOR CLEAN AVIATION

1. Introduction: Political and legal context

Aviation brings major positive social and economic benefits. It connects people, countries and cultures, it enables trade, and generates tourism. Aviation underpins the freedom of movement of persons and goods, one of the European Union founding principles. It connects European citizens and businesses with each other and with the world. Beyond transportation of people and goods, aviation plays a pivotal role in the emergency services, search and rescue, disaster relief, maritime surveillance, police, and border control operations.

The disadvantage is that aviation comes with an environmental cost. Emissions generated by the growing fleet of aircraft, flying with fossil fuels, are rising in line with increasing air traffic.

Reducing fuel consumption has an environmental as well as an economic benefit. Researchers have been successfully reducing fuel consumption by optimising engines and improving the aerodynamic performance of aircraft. Unfortunately, these incremental improvements cannot keep pace with the growth in air traffic, and further large gains within the current technology portfolio seem more and more improbable.

Challenged by the growing environmental concerns, researchers are envisaging several disruptive alternatives to the standard civil aircraft configuration. These include alternative energy sources such as hydrogen or electricity stored in batteries, which could lead to new types of propulsion, innovative aerodynamic configurations reducing air friction, and advanced IT systems that optimise operations.

Such new aircraft technologies come under the term Clean Aviation', which is the research and innovation pillar for achieving carbon neutral aviation in the EU by 2050. The complexity of this endeavour lies in the selection and maturing of the most promising technologies, and their demonstration (i.e. integration and testing) in realistic aircraft configurations.

The journey to a climate neutral aviation system is well beyond the private sector's capability and capacity to invest on its own. Equally, no single country in Europe has the financial, technological and industrial capability to affect the transformation, nor the ability to promote and support the required changes to global rules and operative frameworks, which are necessary to implement those solutions.

This document focuses on assessing the most effective, efficient and coherent way of implementing an initiative which would focus on joint European research and innovation activities on Clean Aviation under Horizon Europe.

1.1. Emerging challenges in the field

Aviation is valuable for social and economic development, brings the world closer together and drives global growth and prosperity. While precise data differs slightly depending on the source and calculation methods, all analysis shows significant and sustained growth of both aviation traffic and its ecological footprint.

COVID-19: This growth has been abruptly impacted by the current, on-going COVID-19³⁵ crisis. Thus, it is worth noting that much of the information and data in this impact assessment dates from before the global onset of the COVID-19 crisis. While previous pandemic outbreaks have demonstrated the resilience of the sector to bounce back relatively swiftly, it must be recognised that the COVID-19 crisis is of unprecedented scale and magnitude. A full recovery is not expected before 2025-30.

The expected impact of COVID is explained in more detail in annex 6.2. The evolution of this crisis is being closely monitored by the Commission to ensure that the Clean Aviation initiative reaches its objectives despite the changed economical context.

The aviation sector, which is probably one of the most affected by the crisis, has been the recipient of various national aid packages. The Commission's recent proposals for a post COVID-19 recovery package focus on the European Green Deal as part of the EU's post-pandemic response, with the aim of bridging the gap between economic crisis response and transforming Europe into a sustainable and climate neutral economy.



Stakeholders involved in the CS3PG (the private side's preparatory group for Clean Aviation) underline that the initiative should maintain a clear strategic direction towards climate neutrality, instead of turning towards short-term solutions in response to the current crisis.

The proposed Clean Aviation initiative should not aim to resolve COVID-19 related difficulties but aim at providing a clear strategic direction for the aviation sector and its efforts to become climate neutral.

Environmental concerns:³⁶. ³⁷Over the past decades, the aviation sector has successfully transformed the way Europeans travel and has brought significant socio-economic benefits for people and businesses. Airlines transport over four billion passengers annually, with revenue passenger kilometres totalling nearly eight trillion in 2017³⁸. Air transport carries around 35% of world trade by value and less than 1% by volume.

In 2016, aviation was accountable for 3.6% of the total EU-28 greenhouse gasses emissions and for 13.4% of the emissions from transport³⁹. By 2040, CO₂ and NOx (nitrogen oxides) emissions are predicted to increase by at least 21% and 16% respectively.

Further growth in aviation would result in a further increase of the adverse impact of carbon dioxide and non-carbon dioxide emissions, as well as from noise, if worldwide investments in new clean and sustainable technologies do not drastically increase. Movements such as "Stay Grounded" and "Flight Shame" alone could halve the growth in air traffic, according to a survey by the bank UBS⁴².

³⁵ A brief discussion on COVID-19 and its impact on aviation R&I is in annex 6.2.

³⁶ The environmental impact of aviation is discussed in annex 6.3.

³⁷ https://www.easa.europa.eu/eaer/climate-change/aviation-environmental-impacts

³⁸ https://aviationbenefits.org/media/166344/abbb18_full-report_web.pdf

³⁹ https://www.easa.europa.eu/eaer/executive-summary

⁴⁰ https://stav-grounded.org/

 $^{{\}color{red}^{41}} \; \underline{\text{https://www.theguardian.com/money/2019/jun/09/flight-airline-travel-rail-family-environment}}$

⁴² https://www.ubs.com/global/en/investment-bank/in-focus/2019/electric-planes.html

If the aviation sector fails to take effective technology-based measures to address its climate impact, it may be confronted with a range of market based measures which could undermine its growth.

Health concerns: Public health issues, linked to the release of gaseous pollutants, air pollutants and noise emissions, primarily near airports, are a cause of increasing health concerns on the top of disrupted sleep and stress. A report from Queen Mary, University of London⁴³ summarises the strength of evidence for aircraft noise effects on cardiovascular health, sleep disturbance, annoyance, psychological well-being, and effects on children's cognition and learning. The EU has recently confirmed these causal links by embedding them into binding legislation⁴⁴.

1.2. EU relative positioning in the field

The EU is a global leader in this field⁴⁵, with Airbus and the US company, Boeing, operating largely as a duopoly in the global commercial aircraft market. Half of the global commercial aircraft fleet is designed and manufactured by a European company.

Research and innovation is a fundamental building block for European competitiveness and global leadership in the aviation ecosystem. In 2018, the Aerospace and Defence Industries Association of Europe (ASD) estimated that the European aeronautics industry invested EUR 9 billion in R&D annually, although this figure includes product development, which is significantly more expensive than technology development envisaged by the Clean Aviation initiative.

As regards the R&D investments in the field, EU companies are well-positioned compared to the rest of the world according to the 2019 Industrial R&D Scoreboard. The top 39 companies of the aerospace and defence sector in terms of R&D investment invested close to EUR 20 billion in R&D in 2018 worldwide, where EU companies represent 46% of the investments, slightly more than the USA.

In terms of scientific performance, the EU-28 shows a good performance compared to the rest of the world based on scientific publications in the field of aerospace engineering. Based on Scopus data, EU-28 publications represents 23% of all publications in the field with close to 40,000 publications between 2014 and 2019, involving close to 60,000 authors. Worldwide the most prolific country is China with more than 50,000 publications, followed by the United States (40,000).

In terms of technological performance, between 2010 and 2016 the EU overall has maintained a stable higher performance compared to the USA.

In terms of aviation R&I performance and in particular on **patents and scientific publications**, Europe shows strong leadership, especially in peer-reviewed publications and references with high impact factor.

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⁴³https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/446311/noise-aircraft-noise-effects-on-health.pdf

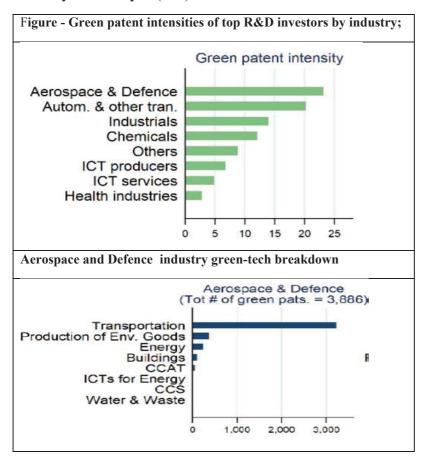
⁴⁴ Commission Directive 2020/367 ... as regards the establishment of assessment methods for harmful effects of environmental noise [https://eur-lex.europa.eu/legal-

content/EN/TXT/?uri=uriserv%3AOJ.L .2020.067.01.0132.01.ENG&toc=OJ%3AL%3A2020%3A067%3ATOC]

⁴⁵ An overview of the positioning of the European industry in aviation is available in annex 6.3.

- Out of the 50 journals on aerospace engineering⁴⁶ worldwide, 26 are based in Europe, including a clear lead in the total citations over the last three years.
- In terms of patents, leading European aeronautics companies hold an extensive portfolio (Airbus⁴⁷: 37,000, Safran⁴⁸: 38,000, Thales⁴⁹: 15,000).

When looking in the EU industrial R&D Scoreboard at the share of green patenting with respect to the total technological inventions of the biggest R&D investors worldwide, the highest share of green over total patents is revealed by companies operating in transport-related industries, including aerospace and defence (23.2%), totalising almost 3,900 green over more than 17,000 patents in the period 2012-2015, and automobiles and other transports (20.1%). These companies concentrate their green inventions in green transportation technologies. From the top 25 green inventors among the top R&D investors, green patents represent 28% of the patents of the company United Technologies (USA), 20% of the patents filed by Airbus (EU), and 34% of the patents filed by Rolls Royce (UK).



Note: Share (left panel) and number of green patents (right panel) by industry (ICB) and environmental technology (CPC), 2012-2015. Caption: CCS = "Carbon Capture and Storage", ICT = "Information and Communication Technologies" CCAT =

Finally, a report from Intereconomics on the impact of Horizon 2020 on innovation in Europe confirms (table 3⁵⁰) that Europe has technological advantages in aerospace.

Hence, Europe is in an excellent position to contribute to a clean aviation on condition that all the available R&I resources are mobilised for this research and innovation effort.

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⁴⁶ https://www.scimagojr.com/journalrank.php?category=2202&area=2200&type=all

⁴⁷ https://www.airbus.com/careers/working-for-airbus/innovations-of-tomorrow.html

⁴⁸ https://www.safran-group.com/media/safran-third-ranked-patent-filings-france-7th-year-row-20180406

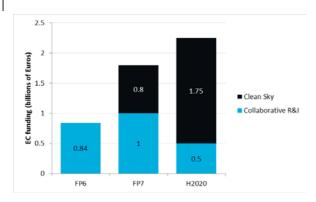
https://www.thalesgroup.com/en/group/journalist/press-release/thales-once-again-amongst-top-100-global-innovators-clarivate

https://www.intereconomics.eu/contents/year/2015/number/1/article/the-impact-of-horizon-2020-on-innovation-in-europe.html

Box 3 Support for the field in the previous Framework Programmes⁵¹ – key strengths & weaknesses identified.

Below is a summary of different sources of evidence on the performance of Clean Sky 2, which includes the mid-term evaluation⁵² but also inputs from the study for this impact assessment.

The Clean Sky initiatives⁵³



Dedicated R&I activities related to transport and aviation in particular have been supported since 1994 (FP4) through the Framework Programmes. This covers traditional (collaborative) projects but also support provided through the Clean Sky Joint Undertakings (CS1 and CS2) under Horizon 2020.

The Clean Sky Joint Undertaking is a partnership between the EU and the aviation

industry set up in 2008, with a total budget of EUR 1.6 billion for CS1 and EUR 4bn for CS2 and focussing on delivering technologies for reducing aircraft emission.

More than 75% of the EU aviation research funding in Horizon 2020 was provided through CS2, whereas under FP7, CS1 only accounted for just under 50% of the total EU research funding.

The maximum EU contribution to CS2 is EUR 1.7 billion, to be funded from Horizon 2020⁵⁴. The private members of the JU are expected to contribute resources of at least EUR 2.2 billion over the life span of the JU. Of this amount, private members have to incur costs of at least EUR 965 million in implementing additional activities outside the work plan of the Clean Sky Joint Undertaking. Details on the way the Joint Undertaking functions are available in annex 2.7 and annex 2.8.

What has or is being achieved so far?

Numerous promising climate neutral solutions have been researched under former public and private research and innovation programmes, either in the EU (starting from the 4th research and development programme), national or regional programmes. A number of those technologies, that reached high maturity levels in the Clean Sky and Clean Sky 2 research programmes, have been assessed in the Technology Evaluator under FP7-Clean Sky and it was found that if taken-up in new aeroplanes, they have the potential to reduce emissions up to 30% compared to a state-of-the-art aircraft available on the market in the year 2000.

⁵³ The Clean Sky public-private partnerships are detailed in annex 6.7. A more complete overview of the European aviation research is available in annex 6.5.

⁵¹ Annex 6.8 provides an introduction to the H2020 aviation research landscape

⁵² https://ec.europa.eu/research/evaluations/pdf/cs2.pdf

⁵⁴ Article 3(1) of Regulation (EU) No 558/2014

Technological advances in aviation have significantly impacted aviation emissions; current aircraft are about 80% more fuel efficient, per passenger kilometre, than aeroplanes in the 1960's.

The Interim Evaluation⁵⁵ of the Joint Undertakings operating under Horizon 2020⁵⁶ concluded that JU-based public-private partnerships (PPPs) have demonstrated efficiency improvements in comparison to FP7, despite a few identified shortcomings to be addressed.

While it is too soon to draw conclusions for CS2 (which runs until 2024), preliminary assessments show that it is well on track to achieve its objectives of demonstrating and validating technologies reducing CO₂ and NOx emissions by 20 to 30% compared to state-of-the-art aircraft entering into service as from 2014⁵⁷. A growing number of publications and patent applications support the good progress of the main demonstrators⁵⁸. Unfortunately, the introduction of those technologies into aeroplanes on the market is anything but certain, because this is largely determined by market forces.

CS2 has been successful in attracting over 800 participants – including industry, research and technology organisations (RTOs), academia, and many SMEs – with a good geographical distribution. However, funding is concentrated within a limited number of industrial leaders, core partners and their associated supply chain with a large part of the funding (40%) earmarked upfront for the Leaders⁵⁹ and Core Partners (30%) and only the remaining 30% available through open calls.

What are the key areas for improvement ⁶⁰ & unmet challenges?

The Interim Evaluation of CS2⁶¹, published in 2017, raises various questions, summarised below and outlined in more detail in annex 2.10 (see also the study by Steer and Technopolis supporting which⁶² identified a set of issues from the experience of the CS2 JU).

The summary of the issues across both reports is:

Concentration of funding

• Project participation rates are distributed in favour of a relatively limited number of organisations. A large share of the funding is reserved to Leaders and Core Partners. There is a risk that SMEs or EU-13⁶³ Member States participants may find it difficult to join it, as project participation in the CS2 JU is concentrated among a relatively limited number of players reflecting the composition of Leaders and Core Partners.

⁵⁹ The structure of the Clean Sky and Clean Sky 2 programmes are explained in Annex 6.7

⁵⁵ More information on the Interim Evaluation, its recommendations and the initial Clean Aviation response are available in Annex 6.7.3

⁵⁶ Commission SWD - Interim Evaluation of the Joint Undertakings operating under Horizon 2020, {SWD (2017) 339 final}

https://ec.europa.eu/research/evaluations/pdf/20171009_a187_swd.pdf

⁵⁷https://www.cleansky.eu/sites/default/files/inline-files/CS-GB-2019-06-27%20AAR%202018 published.pdf

⁵⁸ Clean sky 2 Annual Activity report 2019

⁶⁰ A brief overview of the Clean Aviation responses to clean sky 2 perceived shortcomings is available in annex 6.11

⁶¹ https://ec.europa.eu/research/evaluations/pdf/cs2.pdf

⁶² Technopolis Group, Steer (2020, forthcoming), Impact Assessment Study for Institutionalised European Partnerships under Horizon Europe -Candidate Institutionalised European Partnership on Clean Aviation

⁶³ Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Romania, Slovakia and Slovenia

• The imbalance between the relatively small budget for collaborative aviation R&I, over the last decade, compared to the large budget for demonstration, has adversely affected the availability and spectrum of lower technology readiness levels (TRL)⁶⁴ technologies to the European aviation research chain.

Operations

- Aspects of the design and implementation of the CS2 JU have limited effectiveness: certain aspects of its governance arrangements such as the role of the States' Representative Group, which is not always as well attended as could be and its opinions are only advisory.
- The lack of structural involvement of the European Union Agency for Safety Aviation (EASA) in CS and CS2 may have a negative impact on the "time to market", which benefits from the assessment of potential safety risks and environmental standards related to certification of new products and technologies. Safety topics and certification issues regarding environmental protection may also have been excluded from the scope of CS2 R&I by narrow industrial interests.
- Similarly, the CS2 JU complex membership structure is constraining the R&I effort. There is arguably a need for greater flexibility and for reduction in the administrative burden. There are also some communication improvements that could be made.
- It is not always easy to establish what the precise outcomes of CS1 and CS2 have been.

Policy coordination

- There is a lack of multi-level policy coordination, e.g. between the EU and Member States' level, whilst horizontal coordination between research, technology and innovation policies is good in the European aviation sector.
- Although some Member States have quite elaborated aviation research programmes, one of the weaknesses of the European research landscape is that there is no systematic alignment, and no single roadmap, of the various aviation related research programmes leading to overlaps, ineffective investment and sometimes to duplications.
- Overall, the CS2 programme has not contributed to the alignment of national and EU aviation research programmes apart from creating some synergies with EU regional funds⁶⁵ as outlined in the CS2 2018 Annual Activity Report. In addition, efforts to develop more electric systems as well as composite aero structures were often duplicated by partners, while opportunities for synergies were not exploited.

In addition, the interim evaluation of CS2 recommended increased transparency and energising academic participation to better spread the newly acquired knowledge.

1.3. EU policy context beyond 2021

Aviation research has been of particular interest for the EU since the fourth framework programme. However, the political context has evolved drastically in the last five years with all Member States of the EU having signed and ratified the Paris Agreement, and the EU committing to contributing to delivering the Sustainable Development Goals (SDGs).

https://ec.europa.eu/research/participants/data/ref/h2020/other/wp/2016-2017/annexes/h2020-wp1617-annex-ga_en.pdf (Annex G for a definition of Technology Readiness Levels)

 $^{^{65}\} https://www.cleansky.eu/sites/default/files/inline-files/CS-GB-2019-06-27\%20AAR\%202018_published.pdf$

In order to contribute to EU policies, as well as increasing the integration of aviation research into relevant policies, the forthcoming Clean Aviation initiative must take into account the surrounding environment and the regulatory framework.

Policy communications provide the direction the initiative should follow:

- In 2018, the European Commission published "A Clean Planet for All" the strategic long-term vision of the EU for a prosperous, modern, competitive, and climate-neutral economy by 2050.
- The European Green Deal⁶⁷ puts a high emphasis on preventing climate change and protecting the health of citizens especially children. It identifies, through research and innovation, a way to drive the transformation to modernise the EU's economy and society and re-orient them towards a just and sustainable future and becoming the world's first climate-neutral continent by 2050.
- The COVID-19 recovery package⁶⁸ is presented as an opportunity to redesign a sustainable, inclusive economy, revitalising industry, preserving vital biodiversity systems, and tackling climate change.

The European Green Deal Communication specifically mentions aviation, suggesting market-based measures such as a revision and strengthening of the EU Emissions Trading Scheme (ETS⁶⁹) which could trigger aviation stakeholders to develop more environmental friendly practice.

The European Green Deal Communication further aims at the improvement of air quality near airports by tackling the emissions of pollutants by aeroplanes and airport operations, and the modernisation of Trade Defence Instruments.

The European Green Deal will also re-orient the lending policy of the European Investment Bank⁷⁰. European Investment Bank (EIB) financing and InvestEU can be effective multipliers in areas of the supply chain where access to commercial finance is limited. An important option could be 'green finance' for airlines: enabling earlier and more aggressive rollout of new aircraft in their fleets.

The implication for an R&I initiative on Clean Aviation is that breakthrough technologies based on green energy sources become more attractive for the market, in turn motivating the acceleration of clean aviation research.

The EU is investigating the use of EU and/or global emissions trading schemes to foster further improvements in air quality, as well as greater use of sustainable aviation fuels that have lower emissions.

The ECOFIN Council on 5 December 2019⁷¹ gave its support to an update of the legal framework for energy taxation (including aviation, taking into account their specificities and

⁶⁶ European Commission (2018), A Clean Planet for all, COM(2018)773

⁶⁷https://ec.europa.eu/info/sites/info/files/european-green-deal-communication_en.pdf

⁶⁸ https://ec.europa.eu/info/strategy/recovery-plan-europe_en

https://ec.europa.eu/clima/sites/clima/files/factsheet_ets_en.pdf https://ec.europa.eu/commission/presscorner/detail/en/qanda_20_24

⁷¹ https://www.consilium.europa.eu/media/41646/st14851-en19.pdf

existing exemptions and international dimension), which will contribute to wider economic and environmental policy objectives⁷².

• Regulations put the boundaries for the initiative to operate while supporting sustainability-driven innovation in the sector. Two directives regulate aviation noise, mainly at airports. Directive 2000/14/EC on noise emitted by non-transport outdoor equipment, and Directive 2002/49/EC on noise mapping. These two pieces of legislation are currently under revision in order to be aligned with the recent World Health Organisation guidelines. The implication for an R&I initiative on Clean Aviation are similar as for previous point.

In Horizon Europe, the aviation research is part of the research and innovation activities under Cluster 5 "Climate, Energy and Mobility" under pillar 2. Aviation has been identified as one of the industry sectors with the highest need for new technological solutions to contribute to meeting the goals of the Paris Agreement, such as sustainable mobility and health.

The proposed mandate and scope of the Clean Aviation initiative is to focus exclusively on highly disruptive new technologies with the greatest potential to contribute to the ambitious European Green Deal objective of full decarbonisation by 2050;

The Horizon Europe collaborative calls for proposals should, in turn, concentrate on lower TRL research, including topics covered by the new industrial strategy⁷³ and the European digital agenda⁷⁴;

This two-pronged approach enables a very focussed Clean Aviation initiative alongside a highly complementary collaborative research programme.

Other aspects of the aviation sector's comprehensive decarbonisation strategy (e.g. incremental improvements in energy efficiency of engines and aircraft design, drop-in sustainable aviation fuels) should be supported by industry's own R&D budgets, or by national resources.

A **set of policies are relevant** to be considered as regards the field of clean aviation, in particular:

Trade policies: Both the EU and the USA have been found at fault by the WTO dispute settlement system⁷⁵ for continuing to provide certain unlawful subsidies to their aircraft manufacturers.

Industrial policies: This includes the linkages between European strategic value chains that have been identified ⁷⁶ and integrated industrial aviation activities with great potential to contribute to Europe's green and digital transformation and to improve Europe's industrial competitiveness.

⁷² More information is available in the external studies, performed on behalf of the European Commission, which are linked with the EU-ETS and new sustainable energy carriers for aviation towards 2050.

⁷³ https://ec.europa.eu/info/strategy/priorities-2019-2024/europe-fit-digital-age/european-industrial-strategy_en https://ec.europa.eu/info/sites/info/files/communication-shaping-europes-digital-future-feb2020 en 4.pdf

⁷⁵ https://trade.ec.europa.eu/doclib/press/index.cfm?id=2068

⁷⁶ Report of the Strategic Forum for Important Projects of Common European Interest, EC, DG GROW.

Competition policies: Considering that, in 2019, the global aerospace and defence mergers and acquisitions increased by 62% to EUR 86 billion⁷⁷, when compared with 2018, it is of importance to safeguard the intellectual property rights (IPR) of the European aviation supply chain as a result of EU-funded pre-competitive R&I.

Energy policies: In line with the Energy Union objectives for transport towards achieving deep emissions reductions, aviation R&I paths will need to contribute to the required integrated system approach for overall aircraft efficiency.

Transport policies: In line with the objectives of the European Strategy on Sustainable and Smart Mobility, towards achieving 90% reduction in emissions by 2050, due consideration should be taken of all four principles that will guide transport's contribution to the European Green Deal:

- Making the transport system as whole more sustainable;
- Making sustainable alternative solutions available to EU citizens and businesses;
- Respecting the polluter-pays principle in all transport modes;
- Fostering connectivity and access to transport for all.

In addition, the policy context is also influenced by the European Aviation Strategy⁷⁸ (including the objectives towards a Single European Sky) as well as all initiatives towards a transparent and effective phase 4 trading period (2021-2030)⁷⁹ of the EU Emissions Trading System (i.e. ending fossil-fuel subsidies, revising the Energy Taxation Directive, addressing current tax exemptions, and reducing the quantity of free allowances allocated to airlines).

Health policies: In post-COVID-19 times, attention needs to be paid to communicable diseases in all public transport vehicles and their infrastructures. European aviation R&I needs to take account of related mitigation and preparedness actions, with an eye towards the next outbreak. Technological and societal solutions should be in-line with the national and European health plans, ECDC⁸⁰ and ICAO revised guidelines. Preliminary considerations are laid out in Annex 6.2.4.

The initiative has to operate in synergy with its environment to support the adoption of clean technologies. In particular supporting horizontal synergies and efficiencies beyond Horizon Europe, other instruments and initiatives can take the partnership's activities further and strengthen its impact:

- The Connecting Europe Facility (CEF) can facilitate market uptake where deployment is strongly dependent on infrastructure development.
- As is currently developing, the link to the European Innovation Council (EIC) can provide significant opportunities for transferring R&I results delivered by SMEs into the next phase of development and market deployment.
- Other European Partnerships might be a source of solutions or of markets for Clean Aviation solutions:
 - For technology solutions: e.g. the Clean Hydrogen initiative
 - For improved digitalisation: e.g. the Key Digital Technologies initiative

https://www.ecdc.europa.eu/en/covid-19-pandemic

https://www.pwc.com/us/en/industries/industrial-products/library/aerospace-defense-quarterly-deals-insights.html

https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=COM:2015:598:FIN

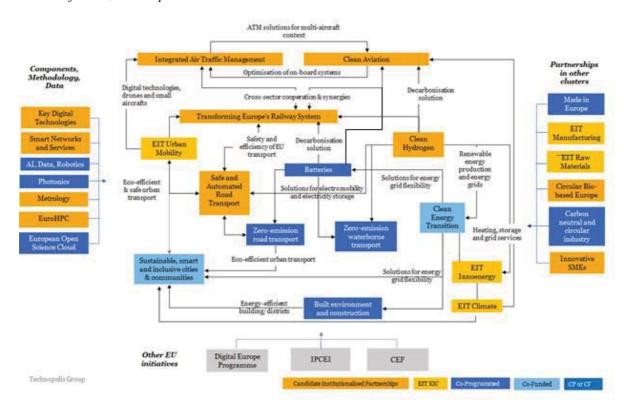
⁷⁹ https://ec.europa.eu/clima/policies/ets/revision_en

• For improved deployment: e.g. the Integrated Air Traffic Management initiative

A separate institutionalised partnership (to succeed the SESAR Joint Undertaking) is proposed to optimise air traffic control and co-ordination between national authorities in this area. A mapping of the potential links between the different initiatives put forward as candidate European Partnerships under this cluster is provided in the Figure below. These potential links are explained in annex.

Overall, an initiative on Clean Aviation would have a set of potential interconnections with other partnerships. This highlights the five possible candidate initiatives and the synergies between them and with other initiatives. Four of these can be considered as 'application' sector partnerships with the other (Clean Hydrogen) being more 'technology' orientated. The central position of batteries and hydrogen, as enablers of zero emission transport and the clean energy transition, is also clear from the analysis. Likewise, there are synergies with the other technology-related partnerships, particularly in the digital area, and those that are manufacturing or materials-orientated. This also highlights the twin challenges of digitisation and decarbonisation for the future energy/mobility sectors.

Potential interconnections between partnership initiatives in the Climate, Energy and Mobility cluster of Horizon Europe



2. PROBLEM DEFINITION

2.1. What are the problems?

Given the scale of the challenges ahead for achieving the European Green Deal in aviation, the current scientific, technological and economic positioning of Europe in the field, and the

overarching EU policy context, a set of problems have been identified where there is a need for EU research and innovation in the field of Clean Aviation.

2.1.1. Growing ecological footprint of aviation associated to unclear path to climate neutrality

The growing demand for air-transport of passengers and goods, expected to swiftly pick up again after COVID, is insufficiently offset by incremental technological and operational improvements, as well as market-based measures, to reduce the environmental externalities of aviation. This is not consistent with the EU's objective of climate neutrality by 2050 and EU citizens' expectations.

The technological path towards climate neutrality is not obvious in aviation, and established solutions in other sectors cannot simply be transferred, due to severe constraints like weight and/ or performance (e.g. batteries⁸¹), safety or scalability issues.

Some of the most interesting research paths identified so far – clean hydrogen (for which there are currently no established large green supplies) and electrification with batteries – will require huge investments not only for powering new aircraft but also for renewing airports and infrastructure worldwide to enabling this shift of technology.

All this has global consequences on climate change, serious health implications especially for people living near airports, and it puts the prosperity of the European aviation industry in danger. This could have wider effects on mobility and connectivity which are important for the European integration project.

A Clean Aviation initiative should concentrate on disruptive technologies with high potential to accelerate the development of climate neutral aviation technologies for the earliest possible deployment in view of the European Green Deal targets for 2030 and 2050. Within the context of the deadlines set by the European Green Deal, selecting the most promising technologies should include an assessment on how fast these could be brought to the market.

2.1.2. Insufficient deployment of EU R&I aviation solutions putting EU European industrial leadership & technological sovereignty at risk

The current incremental pace of innovation is largely set by the global context in which European aviation is operating. Europe is manufacturing roughly 50% of all civil aircraft worldwide and has a very good performance in terms of green patenting in aviation. Looking at the European aviation value chain as a whole, it is designing and manufacturing each significant part of a civil aircraft.

While the ability to design, prototype and patent every aspect of a radical innovative design in combination with the strong policy drive (and linked public support) puts Europe in an excellent position to contribute to clean aviation, it should not be forgotten that only a competitive European industry can put the necessary focus on the needed technological breakthroughs to achieve climate neutrality while upcoming international competitors are competing on price, not quality.

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⁸¹ With current technology, the weight of the batteries required for normal flight operations of an airliner would have the order of magnitude of 100+ tons and exceed the maximum take-off weight. (source: Airbus)

Potential clients weigh the purchase costs, performance advantages, operational and expected maintenance costs of the various aircraft on offer. This way, an innovative design may price itself out of the market compared to much cheaper, less advanced aircraft.

One technological challenge is to significantly accelerate technology development and tap into technologies emerging from other sectors with potential for adoption in aviation while ensuring that this does not lead to a higher sales price.

In fact, the "market" for breakthrough technologies has largely been created by the European Green Deal. Without this strong policy drive and support, it would be impossible, even with the resources of the combined European aviation industry, to justify developing civil aircraft using alternative energy sources such as hydrogen and/or through electrification with batteries.

In addition, there are no shortcuts on safety in aviation. Safety is a fundamental objective embedded in any aviation R&I effort. The prior indication that an innovative climate neutral solution has reasonable chances to be certified by the regulatory bodies is of major importance to drive research and innovation.

As an illustration, the two main demonstrators in terms of Clean Sky 2 achievements (the BLADE wing design, and the CROR open rotor) aiming at increasing the environment performance of aircraft have not been taken up by the market on the ground that they were not certified.

The aviation sector is a highly internationally regulated market, characterised by very long lifecycles. Emerging technological R&I solutions to reduce the environmental impact of the aviation industry (e.g. electrified aircraft, hydrogen), require long development and demonstration cycles compared to other modes of transports. Access to the global market for the European industry, and for very innovative products, is heavily dependent upon the corresponding standardisation efforts, and on ensuring world-wide regulatory convergence in the field of certification and common rule making. As with all global regulation and standardisation, this is often a complex and lengthy process.

In addition to the research, product development and related certification prohibiting cost, the huge investments required by airports to store hydrogen, or supply electricity to the aircrafts would prevent any such breakthrough technology from reaching the market.

The current certification regulatory framework does not sufficiently allow for the early certification of more promising climate neutral solutions. Certification – although its value and necessity is not questioned – tends to delay market introduction of innovations.

2.1.3. Fragmented R&I capacity of the European aviation value chains prevents to develop climate neutral technologies within the Green deal delays

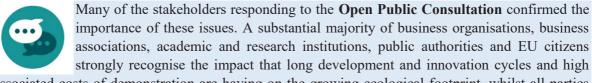
The European Green Deal deadlines of 2030 and 2050 pose a challenge on their own and introduce a sense of urgency in a sector used to work with very long life-cycles and carefully planned introduction of new technologies on the market.

The initiative will have to pay particular attention towards analysing options for the most promising technologies, to tap into the most knowledgeable sources for individual R&I issues and to define and continuously refine the most efficient critical path towards the delivery of the envisaged demonstrators.

Without such careful analysis, and sufficient attention for review, testing and certification throughout the R&I process to ensure that cleaner aviation remains safe, secure and efficient the introduction of the radically new technologies required to achieve the green deal targets could be impossible.

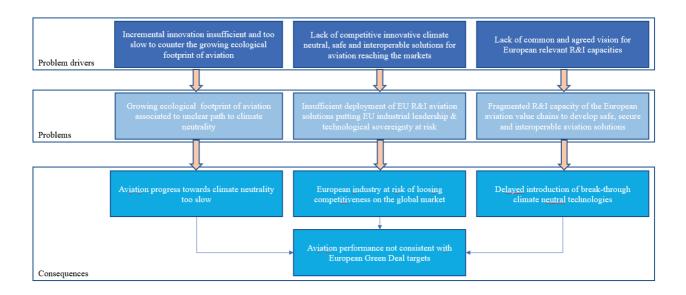
In view of the limited resources compared to the highly ambitious targets of the Clean Aviation initiative, synergies with national aviation R&I programmes will be key to achieving the objectives. The absence of systematic cooperation with these programmes reduces efficiency of aviation research overall, potentially with solutions to occurring problems hidden at a national level, only partially investigated, or investigated in parallel in different countries.

This fragmentation in aviation R&I actions could be addressed by policy actions seeking alignment of the national and European schemes for R&I.



associated costs of demonstration are having on the growing ecological footprint, whilst all parties also recognise that a future initiative in the area must also make significant contributions to EU global competitiveness.

These themes were echoed during the **interviews**, with several stakeholders (from across industry, Member States, academics and research institutes) also highlighting the long development and innovation cycles and high associated costs as contributing to the growing ecological footprint, and that a transformative change was required to achieve sustainability in the industry, despite the practicalities of this being unclear at this stage. Most stakeholders noted the importance of EU industrial leadership in the field, especially in the face of increasing competition from China and Russia. Many business stakeholders also expressed the need for the industry to deliver cost-efficient products that would be affordable for their airline customers.



2.2. What are the problem drivers?

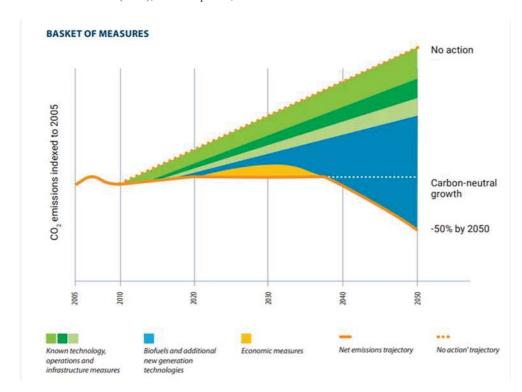
2.2.1. Incremental innovation insufficient and too slow to counter the growing ecological footprint of aviation

Whilst advancements in technology reduce the average fuel consumption and emissions per passenger by -1.5 % per annum, the 4.4% average annual passenger growth more than counteracts this, resulting in fuel consumption and emissions rising by approximately +2.9% per annum or doubling every 25 years 82 . Without transformative interventions in next generation aircraft, the aviation industry's CO_2 emissions will be approximately 136% higher in 2050 compared to 2020^{83} .

As shown in the Figure below, ICAO's schematic CO₂ emission reduction roadmap highlights the effects of different measures on the aviation industry from 2020. It shows (in green) that improvements to current aircraft technologies, infrastructure and operating procedures are not sufficient to achieve carbon-neutral growth in the context of growing levels of air traffic.

ICAO's schematic CO_2 emissions reduction roadmap for the aviation industry





http://publications.jrc.ec.europa.eu/repository/bitstream/JRC113446/kj1a29462enn geco2018.pdf

⁸² Source: European Commission, PRIMES scenario, https://ec.europa.eu/clima/policies/strategies/analysis/models_en
83 European Commission (2018), Global Energy and Climate Outlook 2018: Sectoral mitigation options towards a low-emissions economy – see:

Instead radically new technologies and sustainable aviation fuels are required (blue zone in the drawing below) to address the substantially increased level of EU aviation CO₂ emissions (+95% from 1990 to 2016)⁸⁴.

Economic measures could decrease the demand and thus control the growth of emissions. These would, however, also reduce airline profitability leading to reduced investments in new aircraft and technologies. If such activities were not coordinated at a global level, competitors from outside Europe who are less impacted by these measures would get a competitive advantage compared to European companies.

They would, therefore, need to be carefully designed to incentivise airlines to invest faster in greener technologies or accelerate the demand for sustainable aviation fuels for which there are, currently, no proper alternatives for long-haul flights.

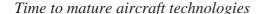
In light of the above graph, incremental technology gains will not lead to climate neutrality.

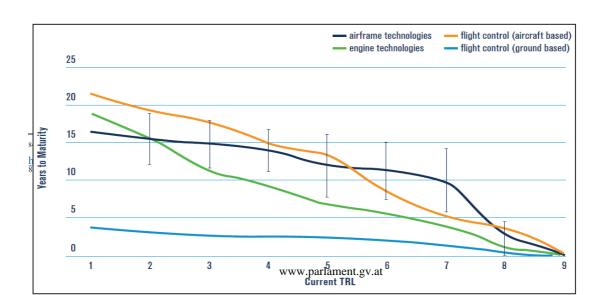
2.2.2. Lack of competitive innovative climate neutral, safe and interoperable solutions for aviation reaching the markets

Commercial aircraft combine a wide range of different, complex, and interacting components for aerodynamics, propulsion, navigation, and communication. The components' integration is crucial for safe and effective aircraft performance. As one example of this complexity, Airbus has more than 12,000 suppliers worldwide. The main parts of the popular A320 series⁸⁵ are constructed in seven countries with final assembly in three factories in three different countries one three different continents.

The complex interaction of components makes it very hard to predict if a new design will (under all possible) real-world circumstances behave exactly as predicted, based on theoretical and computational models. This is already true for the traditional civil aircraft configuration, and it certainly applies when moving into the uncharted territory of alternative propulsion (hydrogen, batteries) systems, innovative aerodynamic (blended wing) designs, and the accelerated introduction of digitalised systems. Testing of aircraft functionality and safety is therefore a crucial but timely and costly part of the R&I process.

From conception phase (TRL 1) through all the steps of maturing the technologies to "fit-to-fly" (TRL 9) typically takes between 10 and 20 years (see Figure below), including substantial financial investment. The consequences of bringing design errors to the market could include the loss of life, disruption of the aviation and tourist sector as a whole by grounded planes, economic disaster for the aeronautical supply chain, and potential bankruptcy of the integrator.





This is the reason why aircraft manufacturers are very careful when introducing new technologies and, more often than not, limit themselves to the gradual roll-out of incremental improvements.

The Commission Staff Working Document on better regulations for innovation-driven investment at EU level⁸⁶ underlines that cost, time and uncertainty related to certification are important factors in preparing new aviation products and services. Certification can indeed add three to five years of additional delay after an accumulated 10 years of investments costs (accumulating credit/debt) also postponing sales.

Due to high costs associated with the production process of aircraft, manufacturers seek to receive certification for their aircraft quickly and the early involvement of regulators in research and the deployment of emerging technologies can reduce time to market significantly.

An extra dimension is the long life-span of aircraft once on the market⁸⁷. Although the life-span of a commercial aircraft is declining, it is still fairly common for civil aircraft to be used for a period between 20 to 30 years or longer. It may be expected that the COVID-19 outbreak will lead to an increase in those average life spans of civil aircraft and slower replacement of older, less environmentally friendly aeroplanes by the newest models.

The European Union Aviation Safety Agency (EASA⁸⁸) benefits in the implementation of its tasks from early knowledge sharing between regulators and industry (while ensuring regulator independence), as aspects of the design, production, and servicing of aircraft become more dispersed⁸⁹. To be noticed though that acceleration of safety critical technologies (such as aircraft-based flight control) without timely, proper, and independent oversight can lead to fatal outcomes.

Unable to compete on price with upcoming new aircraft manufacturers, the maintenance of Europe's leadership position in the global aeronautical market in an increasingly competitive environment depends on R&I leading to technological excellence in turn leading to cost efficiency, offering a far better performance to airlines compared to cheaper products from upcoming manufacturers.

To sustain Europe's leadership position and thus make green aircraft globally available, the Clean Aviation initiative has to focus on those new technologies that brought to market could maintain the European competitive lead over the competing products from international competitors.

https://op.europa.eu/en/publication-detail/-/publication/404b82db-d08b-11e5-a4b5-01aa75ed71a1/language-en/format-PDF/source-79728021

⁸⁷ http://www.boeing.com/assets/pdf/commercial/aircraft economic life whitepaper.pdf

⁸⁸ A short contribution on the role of EASA in research and innovation is available in annex 6.6.

EASA (2019), Emerging Technologies and Aircraft Certification – accessible at http://congress.cimne.com/emus2019/frontal/doc/PL Abstract/PL Abstract Waite Expert.pdf

2.2.3. Lack of common and agreed vision for European relevant R&I capacities

The Flightpath 2050 (ACARE's Vision for Aviation) only provides a general umbrella but in practice, a coordinated roadmap and workload share are not available. In addition, Flightpath 2050 environmental ambitions have to be revised and made more ambitious in relation to the European Green Deal.

Under H2020 and on the European level, cooperation between the two aviation Joint Undertakings (Clean Sky and SESAR) is based upon a memorandum of understanding between the two Joint Undertakings. This cooperation is limited to an exchange of information and preventing overlapping research projects. Coordination is also limited between the European collaborative research programme for aviation, and the Clean Sky demonstrator programmes.

Next to the European aviation research and innovation programmes there are national aviation R&I programmes with significant budgets such as those of Germany (LuFo), France (CORAC) and the UK (ATI), with a budget of between EUR 2-3 billion for a period of five years.

However, an external study shows that these programmes were not sufficiently coordinated, neither at national level nor at European level. In some cases, national interest in local employment and technology, led to non-complementary policies, with a possible duplication of activities.

Under Horizon 2020, Clean Sky 2 made some limited efforts seeking better alignment with European Structural and Investment Funds. Results achieved indicate that a better alignment of the R&I efforts between European and national levels could lead to significant efficiency gains.

Some of the most promising technologies to achieve climate neutrality in aviation are the core business of other sectors. The obvious examples are hydrogen and batteries, but also digitalisation could have a significant impact on the environmental performance of the sector.

The insufficient tracking of technological developments in other sectors may lead to aviation being unaware of potentially interesting research or unable to transfer and take up potentially useful technologies developed elsewhere into its own R&I path.

In addition, those other sectors may be unaware of the specificities of aviation (such as limiting weight, be able to function under extreme heat/cold and at altitude, safety) to be taken into account in their own research. It should be carefully analysed how the experience and know-how of these sectors could be translated to aviation.



Responses to the **Open Public Consultation** widely agreed on the nature of the problem drivers. Most of stakeholders agreed strongly that innovation and development cycles in the industry are both too long and too costly and these views were held in similar proportions across all stakeholder groups. Stakeholders also noted the presence of

regulatory barriers in the context of standards and disruptive technology development, although these considerations were felt less strongly than those regarding the innovation cycles. A majority of stakeholders also noted that the lack of global integrated standards undermines the benefits of R&I activities developed at an EU level, thus affecting European competitiveness.

Similar views were also emphasised by most **interviewed stakeholders**, particularly supporting the views that the development cycles in the industry are both long and costly, and that regulatory barriers⁹⁰ need to be suitably addressed to not cause further delay to development cycles. There was a strong consensus, in the absence of policy intervention, that it would not be possible to achieve the long-term strategy and level of stakeholder participation required to achieve the goal of climate neutrality by 2050.

2.3. How will the problem(s) evolve?

The lack of a framework to secure the necessary long-term commitments, reduce the financial risks, and combine the R&I capacity in Europe may result in the delay or cancellation of expensive demonstrators or system integration projects based on decades of research at low and later high TRLs which would significantly reduce the impact of R&I in aviation, and delay achieving the green deal targets. The reshuffling of priorities in response to COVID-19 by the European Industry may have an additional negative influence.

Without policy intervention creating such frameworks, the gap between technological progress and the European Green Deal's ambitions will widen, leaving only market based measures such as additional taxes on fuel, expanding the ETS system etc. to achieve the European Green Deal's ambitions and reducing air traffic, with significant negative social and economic consequences, and reducing the competitive lead of the European industry. In this it should be taken into account that technology maturation requires an exponential increase in resources, rather than a linear one, because the more integration towards the final product/system is achieved, the more complexity needs to be addressed. The kind of demonstration and integration, projects needed before moving towards product development are very costly, and risky for the industry involved.

As explained above, without any policy action, it is anticipated that an increased gap will form between the demand for mobility and the achievement of the climate neutrality target.

The Figure below outlines the potential evolution of the problem if there is no intervention. It uses two sets of numbers, the first set based on the EC PRIMES Reference Scenario⁹¹ whilst the second comes from EC estimations⁹². Those forecasts have been produced before the COVID-19 crisis and may be now overestimated. However, aviation will most likely recover at some point and reconnect with the current trends.

Potential evolution of the problems if there is no intervention

Parameter	Position from 2022	Source	Commentary on starting point and evolution during period of Horizon Europe
Air passenger traffic growth	Ranges between +2.2% per annum	EC (PRIMES) EC (Inception	Different sources of traffic forecasts anticipate different rates of air passenger growth: the EC

⁹⁰ A brief explanation on these perceived regulatory barriers is annexed

https://ec.europa.eu/energy/sites/ener/files/documents/20160713%20draft_publication_REF2016_v13.pdf 92 https://ec.europa.eu/info/law/better-regulation/initiative/11904/publication/5722372/attachment/090166e5c639d431_en

⁹¹ The EU Reference Scenario is one of the European Commission's key analysis tools in the areas of energy, transport and climate action. It allows policy-makers to analyse the long-term economic, energy, climate and transport outlook based on the current policy framework.

	to +4.4% per annum	Impact Assessment)	PRIMES Reference scenario estimates that air passenger will grow an average of 2.2% per annum, whilst the EC IIA estimates that it will grow 4.4% per annum. External forces and/or regulation may alter demand for air travel.
Average evolution of fuel consumption per passenger	-1.5% per annum	EC (PRIMES)	Fuel consumption decreased at an average rate of 1.5% per annum. Without intervention, It is assumed that this trend will continue short term. Long term, disruptive new technologies will be required for when the current technologies reach their maximum performance.
CO ₂ emissions by 2050 compared to 2020	Ranges between +0.6% per annum to +2.8% per annum (depending on the air traffic forecast source)	Calculated from EC (PRIMES) and EC (Inception Impact Assessment)	The joint impacts of air passenger traffic growth and fuel consumption per passenger results in fuel consumption and emissions rising between 0.6% and 2.8% per annum. Taking the worst-case scenario, CO ₂ emissions will rise by a further 22% during Horizon Europe. If there is no intervention by 2050 this may rise to 137%
Funding of civil aeronautics research and development activities (outside of Clean Sky) by public and private stakeholders	EUR9 billion per annum	ASD	Currently approximately 7% of the civil aeronautics industry turnover is spent on research and development activities. Without intervention, no change is predicted
Years necessary to achieve TRL 1 to 9	Between 10 and 20 years	IATA	No change is predicted. However, a significant acceleration will be necessary to meet the Green Deal requirements and deadlines, for instance by earlier preparation of certification.

Source: Steer analysis

In summary, without policy intervention leading to transformative technology, traffic growth will offset CO_2 emissions reduction resulting in 22% increased consumption of kerosene by 2027. A worst-case extrapolation to 2050, results in a 136% increase in kerosene consumption, compared to 2020.

The European aviation sector will be at greater risk of losing competitiveness in the global market. In turn this could negatively affect investments in research and innovation for greener technologies, which would be detrimental to the achievement of the European Green Deal's objectives.

As the objective of the European Green Deal are global in nature, a slower path towards clean aviation in the EU could also reduce incentives for other manufacturers to develop greener technologies. ⁹³ Unless the European Green Deal's targets become, at least de facto, global industry standards.

The continued fragmented R&I capacity of the European aviation value chains will have to develop safe, secure and interoperable aviation solutions.

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⁹³ Indeed, upcoming non-EU manufacturers tend to primarily compete on costs and may place less emphasis on greening aviation.

The combined effects will mean that aviation performance will not be consistent with EU climate targets and that the contribution of European aviation to the growth of the economy and employment will be below potential.

The evolution of the problem will also be driven by the overall aviation strategies that will be put in place at the EU level and MS' level, and to a lesser extent at the international level, on the regulatory framework, and the provision of economic incentives or loans.



intervention

Stakeholders interviewed tended to support the view that intervention was required in order to bridge the gap between academic based innovations and their commercial application (the 'valley of death')⁹⁴, which was more prevalent before Horizon 2020. Stakeholders providing feedback to the inception impact assessment tended to support the view that problems would persist in the absence of policy

3. WHY SHOULD THE EU ACT?

3.1. Subsidiarity: Necessity of EU action

The rationale for EU intervention follows directly from the previous discussion of the problems. The primary justification for EU public intervention in aviation R&I is to harmonise, optimise and coordinate resources at ecosystem level from all European countries towards climate neutrality in aviation – an ambitious target that cannot be achieved by neither one aeronautics company nor single country alone. As underlined above, there is a need for a holistic R&I approach towards climate neutrality.

Furthermore, all research needs should be coherent with market measures, incentives as well as a robust and modern regulatory and standardisation framework, which can only be designed in the EU context and through international cooperation. This framework should be coherent and aligned with environment and climate policies, trade, defence, space, air traffic management, certification and standardisation schemes which are under the remit of the EU.

In addition, European research with open competitive calls allows participants to break away from their natural suppliers and develop new partnerships with different types of organisations (academia, research centres, industry etc.) including those from EU countries without traditional aviation industry but potentially bringing novel approaches.

The rationale for EU intervention includes risk sharing, considering the high costs of developing and demonstrating innovative technological solutions, which cannot be carried out by individual companies alone.

In the context of the specific characteristics of the aviation sector, the costs and risks of new developments depend on effective cooperation at European scale. Cooperation between different stakeholders is important, both in the development stages as well as during the maturing of innovative technologies.

⁹⁴ The 'Valley of Death' was referred to in several stakeholder interviews and is a metaphor often used to describe the gap between academic-based innovations and their commercial application in the marketplace.

3.2. Added value of EU action

With a clear climate policy and clear objectives for 2030 and for 2050, there is a strong need for directionality of European investments as well as additionality. EU action would complement the national schemes to provide a clearer policy approach, especially as innovations are urgently needed to realise the climate action plan and objectives.

The European Commission is ideally placed to strive towards cooperation between the national aviation R&I programmes and the Clean Aviation initiative, avoiding duplication of effort and combining resources towards achieving the European Green Deal's targets.

At the same time, it takes the initiative on many aviation related policy measures and can ensure that policy measures, legislation and R&I efforts are aligned.

Further, The European Commission is an ad-hoc observer in many ICAO⁹⁵ bodies (Assembly and other technical bodies) focusing on aviation safety, security, environment, air traffic management and air transportation.



Among stakeholders responding to the **Open Public Consultation** there was widespread recognition of the problem of fragmentation and lack of effective coordination of R&I activity, underpinning the case for intervention at the European level.

Stakeholders participating in the **interviews** and providing feedback on the **inception impact assessment** were also generally fully supportive of EU action to address these and other aspects of the problem. Member States and businesses agreed that the pan-European nature of the industry coupled with uncoordinated support for R&I at national level justified EU action.

4. OBJECTIVES: WHAT IS TO BE ACHIEVED?

4.1. General objectives of the initiative

Based on the identified problems, the initiative's main objective would be to contribute to reduce the ecological footprint by accelerating the development of climate neutral aviation⁹⁶ technologies for earliest possible deployment, therefore significantly contributing to the achievement of the general goals of the European Green Deal, i.e.: a 50% to 55% emissions reduction by 2030, and climate neutrality by 2050⁹⁷.

The focus on climate neutrality, in line with the Commission's top priority, is justified because other environmental aspects can be covered by the collaborative research programme (outside the partnership), and because a push towards climate neutrality requires a strong mobilisation of the whole community around the most promising technologies, which is less the case for other environmental aspects.

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⁹⁵ https://ec.europa.eu/transport/modes/air/international aviation/european community icao en

⁹⁶ Clean Aviation is complemented by a collaborative research effort that deals with other aviation research priorities.

⁹⁷ The main objective complements several of the Sustainable Development Goals (SDGs) supported by the Climate, Energy and Mobility Cluster, including SDG 3 (Good Health and Well-being), SDG 9 (Industry, Innovation and Infrastructure), SDG 11 (Sustainable Cities and Communities), SDG 12 (Responsible Consumption and Production) and SDG 13 (Climate Action).

The second general objective would be to ensure that aeronautics-related research and innovation activities **contribute to the global sustainable competitiveness** of EU aviation, while ensuring that remains a safe, secure, reliable, cost-effective, and efficient means of passenger and freight transportation. Without a strong European supply chain, Europe has no leverage to pursue to ambitious environmental policy.

The third objective would be to **further advance the European R&I capacity** to accelerate and optimise the R&I process. This objective is similarly aligned with several SDGs, especially SDG 9 (Industry, Innovation and Infrastructure).

It should be noted that addressing market and regulatory barriers is not in the research remit of any future initiative but remains vital for achieving the general objectives.



There was strong support from stakeholders responding to the open public consultation to making significant contributions towards achieving the EU's climate-related goals. The vast majority of business organisations (both large organisations and SMEs), business associations, academic and research institutions, public authorities and EU

citizens considered that any future European Partnership should respond effectively to achieving European policy goals and recognised that this is hindered by development cycles in the industry that were both lengthy and costly. Most of these groups also confirmed the importance of meeting societal needs and contributing to both EU climate related goals and UN Sustainable Development Goals through the effective deployment of new technology, whilst also maintaining European competitiveness in the market.

Stakeholders interviewed, whether from industry, research institutes, academics or other types of organisations were generally very supportive of the proposed objective of achieving climate neutrality by 2050. It was felt that that objective, whilst ambitious, was more encompassing of the effects of aviation and also allowed a more long-term solution to be realised.

Virtually all stakeholders providing feedback on the **inception impact assessment** also noted their support for the previous objective ⁹⁸ of achieving deep-decarbonisation in the industry.

4.2. Specific objectives of the initiative

The following specific objectives have been defined for the R&I efforts under the Clean Aviation initiative:

• to demonstrate disruptive aircraft technological innovations able to decrease net emissions of greenhouse gasses by no less than 30% by 2030, compared to 2020 state-of-the-art technology;

The primary objective is to achieve climate neutrality by 2050, with an intermediate step towards 2030. Together with the large-scale deployment and use of new, net-zero or fully decarbonised sustainable aviation fuels such as power-to-liquid synthetic fuels, methane and/or hydrogen, the operating fleet in 2050 could achieve a 90+% improvement in carbon efficiency compared to today's fleet. The sector can meet the Air Transport Action Group's (ATAG) goal to halve total CO₂ emissions in 2050 compared to 2005 levels, while maintaining its forecast growth.

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⁹⁸ The objective was changed from deep-decarbonisation to climate neutrality after the inception impact assessment was issued.

The Clean Aviation initiative should **focus on disruptive technologies** that also allow the earliest possible deployment with the greatest potential to contribute to the ambitious European Green Deal targets for 2030 and 2050.

Three key R&I 'thrusts' will drive the energy efficiency and the emissions reductions of future aircraft.

- **Hybrid electric and full electric architectures** driving research into novel (hybrid) electrical power architectures and their integration; and maturing technologies towards the demonstration of novel configurations, on-board energy concepts and flight control.
- Ultra- efficient aircraft architectures to address the short, medium and longrange needs with innovative aircraft architectures making use of highly integrated, ultra-efficient thermal propulsion systems and providing disruptive improvements in fuel efficiency. This will be essential for the transition to low/zero emission energy sources (synthetic fuels, non-drop in fuels such as hydrogen), which will be more energy intensive to produce, more expensive, and only available in limited quantities.
- **Disruptive technologies to enable hydrogen- powered aircraft** to enable aircraft and engines to exploit the potential of hydrogen as a *non-drop-in* alternative *zero carbon fuel*, in particular liquid hydrogen.

Exclusions:

• Other aspects of the aviation sector's comprehensive decarbonisation strategy (eg incremental improvements in energy efficiency of engines and aircraft design, drop-in sustainable aviation fuels) should be supported by industry's own R&D budgets, or by national resources. Operational measures, such as optimised green trajectories and air traffic management will also contribute in achieving climate neutrality and may be covered by another initiative following the current SESAR Joint Undertaking.

- Alternative energy sources that gradually complement or replace kerosene play a pivotal role in achieving climate neutrality in aviation. These energy sources include sustainable aviation fuels⁹⁹ (SAF), batteries and hydrogen. SAF are already available on the market and are therefore excluded from the research activities of a Clean Aviation initiative.
- Ensure the market readiness of innovative, climate neutral, safe and interoperable solutions for aviation

The second specific objective is to ensure that the technological innovations are available in time to permit the launch of disruptive new products and services by 2035 – with the aim of replacing 75% of the operating fleet by 2050 – and developing an innovative, reliable, safe and cost-effective European aviation system that is able to meet the objective of climate neutrality by 2050.

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Sustainable Aviation Fuel (SAF) is a clean substitute for fossil jet fuels. Rather than being refined from petroleum, SAF is produced from sustainable feedstocks such as waste oils from biological origin, agri residues or non-fossil CO₂

An independent Impact Monitor mechanism should ensure continuous strategic monitoring and steering, and ensure objectives are met.

The continuous assessment of intermediate project deliverables should guarantee that the developed technologies meet their full innovation potential, or allow re-orienting the research and innovation activities towards the most promising technologies.

Modelling, testing, evaluation, and assessment will play a vital role within the clean aviation initiative in validating technologies and increase their change to reach the market:

- O To select the most promising technologies with the highest potential to have significant impact on climate change and to assess the impact that the implementation of those technologies on the market would have.
- o To evaluate project progress and assess how practical research results confirm the impact forecasts, potentially leading top re-orienting the projects.
- To identify knowledge gaps and shortcomings and define targeted projects to tackle these.
- o To support safety certification in cooperation with an independent EASA to mitigate safety concerns and accelerate the research life cycle and the introduction of technologies in the market later on.

Thorough testing and demonstration (in-flight) of new technologies should guarantee that they are sufficiently matured, reliable and affordable to be integrated in novel aircraft designs and ensure that they are taken up by the market.

The impact monitor could play a role in preparing for international standards and certification of novel technologies.

• To expand and foster integration of the aviation research and innovations value chains, including academia, research organisations, industry, and small and medium sized enterprises, also by exploiting synergies with other, related, national and European programmes

The independent Impact Monitor will be used to support dialogue with internal and external counterparts regarding environmental aspects, policies, required infrastructures and critical success factors for the transition to a climate neutral aviation. The Impact Monitor mechanism could also be used to assess other parts of Horizon Europe relevant to the partnership, such as traditional calls.

Building upon the work done under Clean Sky 2, the initiative will increase efforts to exploit synergies with other initiatives and programmes with a special focus on areas offering a high potential such as hydrogen, batteries and digital that could bring new knowledge to the aviation sector.

Discussions on the best mechanisms for exploiting synergies with other partnerships, or with collaborative research in aviation are still on-going.



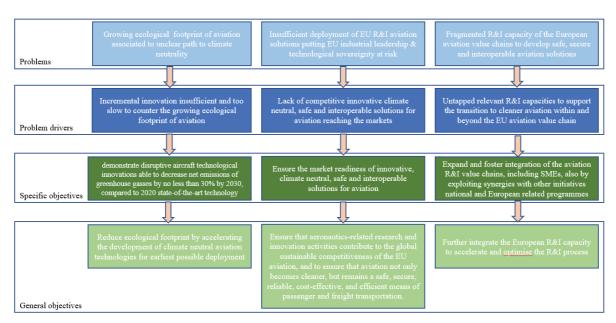
Respondents to the open public consultation – including business organisations of different sizes, business associations, academic and research institutions, public authorities, and EU citizens – largely endorsed the view that a European Partnership

should be responsive to societal needs and should make a significant contribution to achieving the UN SDGs and EU climate-related goals. The vast majority also agreed that more focus should be placed on bringing about a transformative change towards sustainability through the development and effective deployment of technology, whilst also making significant contributions towards EU global competitiveness.

Stakeholders interviewed supported to focus higher proportions of the budget on larger aircraft, as resultant developments have larger impacts versus other aircraft. All stakeholders interviewed supported the inclusion of regulators throughout the development process, albeit in an observational capacity, to assist in addressing market barriers to entry.

Stakeholders providing feedback to the **inception impact assessment** were generally very supportive of the objectives identified in the document, in particular the need to explore, mature and demonstrate new technologies, whilst also ensuring competitiveness of the European aeronautics industry.

4.3. Intervention logic for the initiative



How would success look like?

Should the initiative deliver on its specific objectives, it is expected that it would translate in practice into the following impacts:

Expected Scientific impacts

- Acceleration of the development of know-how and the process of maturing technologies and knowledge transfer for key new technologies and 'differentiators';
 - o Increased ability to theoretically model and compute the effects of new technologies.
 - o Increased scientific knowledge of climate impact and atmospheric effects and so enable optimised interventions in the aviation system.
- Increased diffusion of scientific excellence and high-quality knowledge in the field of aeronautics among research staff from universities, research institutes or private companies;
 - o New high-value skills and new engineering capacities for future generations of the European workforce.

- Increased collaboration with other sectors and integration of areas of fundamental research that are not traditionally within the aeronautical scientific ecosystem;
- > Strengthened innovation pipeline by creating better directionality of research;



All academic and research institutions responding to the **open public consultation** were highly in favour of the potential partnership being used for the advancement of science. This was supported by most businesses and other stakeholder groups too. The views on its role in development of new scientific knowledge and capabilities were similarly

highly positive among all stakeholder groups.

Similar opinions were expressed by stakeholders engaging in the **interviews**, particularly academic and research institutions. During these interviews many academic and research institutions mentioned that more research resulting from the partnership should be published.

Stakeholders responding to the **inception impact assessment** were generally supportive as well of the view that an initiative under Horizon Europe would have important scientific impacts.

Expected economic/ technological impacts

If successful, the proposed initiative has the potential to achieve direct and indirect economic and technological impacts affecting several areas of the EU economy and society, namely:

Direct impact

- New safe, climate neutral and efficient airborne transport modes such as regional aircraft that have the potential to reduce traffic congestion in highly populated areas, and connect remote regions;
- ➤ Increased competitiveness of European aeronautics industry through cost-efficiency improvements throughout the entire supply-chain;
 - This would also be a catalyst for a further reduction in environmental impacts. Together, these impacts would contribute to the achievement of SDG 11 (Sustainable Cities and Communities) and SDG 13 (Climate Action);
 - o Growth in aviation industry and wider employment;
- New sustainable business models for innovative aircraft technology for future aircraft and fleet retrofits, exploiting next generation digitalisation/automation technologies;
- The emergence of new branches of the aviation industry, such as new sources of propulsion, systems or airframes which will enhance European competitiveness.
 - Strategic partnerships with non-aviation sectors to make use of emerging technologies (e.g. drop-in and non-drop-in fuels, fuel cells, batteries, artificial intelligence, electronics, and materials).

Indirect impact

- A multitude of spin-offs that will benefit Europeans through exploitation iof critical areas such as disaster response, emergency interventions, space and security;
- ➤ International co-operation prowess, leadership and shared socio-cultural values.
- > Strengthened demand for sustainable forms of energy for aviation;
- > Increased demand and opportunity for sustainable air mobility leading to job creation:

Most stakeholders consulted as part of the open public consultation scored the resulting economic



and technological impacts from the partnership as being very relevant. The following impacts received high relevance scores: increased industrial leadership and uptake of new technologies; the acceleration of key technologies through selected demonstrators; as well as the creation of high-skilled jobs in the low-carbon economy.

In addition to supporting above views, several **interviewed stakeholders** highlighted the importance of encouraging participation from a wide group of stakeholders, including those outside the traditional aviation industry, to assist with the development of innovative technologies. As mentioned previously, there was a consensus that regulatory bodies (such as EASA) should also have early knowledge of all developments to ensure that the regulation process did not ultimately delay the introduction of new technologies.

Stakeholders responding to the **inception impact assessment** generally confirmed that an initiative under Horizon Europe could be expected to deliver substantial economic and technological benefits, whilst ensuring competitiveness of the European aeronautics industry.

Expected societal impacts

- ➤ Clean Aviation will significantly contribute to the delivery of Europe's climate neutrality by 2050 by pioneering new solutions in the aeronautics disciplines and readying them for market introduction.
 - Considerable impact on reducing climate change, considering that the European aeronautics industry is a world leader in the field and produces +/-50% of all civil aircraft (SDG 13 Climate Action).
 - Reduction of noise and improved air quality around airports with positive and immediate impact on the health of citizens in support of SDG 11 (Sustainable Cities and Communities).
 - o Positive impact on the health and well-being of EU citizens, starting with those living in the vicinity of airports (pollution and noise reduction) as well as for other part of the world. SDG 3 (Health and Well Being)
- > Further increase safety and security levels, in cooperation with the European Union Aviation Safety Agency (EASA) by deeply transforming present operations with the help of innovation;
- > Fulfil customers' and the general public's expectations of a globally competitive European industry;
- > Improving mobility and connectivity of European citizens with safe, reliable, affordable and resilient air travel options.



The majority of the respondents to the **open public consultation** have mentioned the importance of societal benefits and view the reduction in CO_2 emissions and the improvement in public health as being particularly relevant impacts associated with the future partnership.

The vast majority of **interviewees** maintained the view that safety in European aviation was of paramount importance, but also mentioned that developments from new technologies would ensure the longevity and relevance of the European aeronautics industry, whilst also resulting in reductions of gas and noise emissions, which in turn would contribute to improved societal impacts.

4.4. What is needed to achieve these objectives – Key Functionalities needed

Given the focus of the impact assessment on comparing different forms of implementation, the identification of "key functionalities needed" allows making the transition between the definition of the objectives and what would be crucial to achieve them in terms of implementation. These functionalities relate to the type and composition of actors that have to be involved, the type of range of activities that should be performed, the degree of directionality needed and the linkages needed with the external environment.

4.4.1. Type and composition of the actors to be involved 100

The inclusion¹⁰¹ of the largest possible number of stakeholders from across the value chain, from different sectors, backgrounds and disciplines, and EU Member States is essential for an initiative for Clean Aviation research and innovation to leverage all the relevant expertise and capabilities. In particular:

The European industry, including SMEs, to develop and ensure the uptake of the most promising climate neutral solutions.

Academic and research organisations to translate disruptive ideas, possibly coming from other sectors, to the aviation context.

The Commission and Member States to ensure alignment and synergies between the EU, national and regional priorities and funding programmes and for a broader political coordination of national and international policies to achieve impact.

An increased involvement of **Member States** in the deployment and uptake of the most promising climate neutral technologies at EU level will promote synergies and economy of scale with the national R&I programmes as well as increase the alignment of the national educational schemes to match the future needs for corresponding skills and jobs.

EASA to provide guidance on certification related matters, and in assessing the environmental impact of the proposed solutions.

The broader stakeholder community (e.g. airports) that will ultimately roll-out and implement the new aircraft at an early stage should allow anticipating practical considerations such as needed infrastructural works from an early stage.

Note: International participation should be considered in compliance with the Horizon Europe rules for associating countries to the Horizon Europe.

The Figure below summarises the stakeholders that need to be involved and indicates the capabilities that they can bring.

Type and composition of actors that need to be involved

Annex 6.9 shows the high interest of stakeholders from various backgrounds (industry, SME, academia, research organisations) for participating in the Clean Aviation initiative.

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This functionality relates to the criterion "Involvement of partners and stakeholders from across the entire value chain, from different sectors, backgrounds and disciplines, including international ones when relevant and not interfering with European competitiveness".

	Aeronautics Industry	Universities and research institutions	Member States	End-users (Airline and airports)	EASA	Technology- based organisations outside aviation
Long term perspective	✓	✓	✓	✓	✓	✓
Flexibility and disruptive thinking	✓	✓				✓
Expertise in aircraft operations		(✓)		✓	✓	
Understanding of passengers, aviation workers and citizens needs			✓	✓	✓	
Understanding of current R&I	✓	✓	✓			✓
In-kind support	✓	✓			✓	✓
Financial contribution	✓		(√)			✓

4.4.2. Type and range of activities needed

Given the very ambitious objectives, a **strategic vision** for the initiative is essential for the prioritisation and focus. It is important that the initiative sets out and maintains (reality checks) a comprehensive strategic research and innovation agenda including milestones and deliverables.

Increased focus on the most promising breakthrough technologies and a limited set of high TRL (4 to 6+), integration, demonstration and validation demonstrators. These high TRL activities may be supported on a case-by-case basis with limited low TRL (1-3) research activities that are directly linked to the demonstrators.

Increased **openness and transparency** through open calls and actively seeking for potential partners from outside the traditional aviation sector.

Reinforced **public involvement** in the governance of the initiative should avoid a tendency within the private sector for a 'share the cake' approach instead of a real strategic orientation towards higher performance and lower climate footprint. This includes a feedback to relevant policy initiatives.

Enhanced governance responsibility for the demonstrator and project progress.

Independent monitoring, progress and impact assessment directly reporting to the governing board. These assessments will also contain aspects related to the post-research stage, in verifying the feasibility of bringing technologies to the market considering the unequivocal deadlines (2030 and 2050) set out in the European Green Deal.

Actively **exploiting synergies** and coordination of R&I activities, especially with the proposed air-traffic management partnership under Horizon Europe (the current SESAR Joint Undertaking).

4.4.3. Priority setting system and level of directionality required

A common vision and a Strategic Research and Innovation Agenda is under development, taking into consideration the diverging business agendas and the post-covid-19 aviation crisis. To address the future challenges, Horizon Europe proposes a holistic approach that is based on two main sets of activities.

Firstly, a <u>Clean Aviation initiative</u> that will focus on the acceleration of the development, validation and integration of climate-neutral technologies, towards market uptake and with strong long-term commitment of industry but also academia and research organisations.

A Strategic Research and Innovation Agenda (SRIA) will focus on the activities foreseen in the context of the Clean Aviation initiative. The programme and its content will be clearly described and ring-fenced. Links to, and expected inputs from other research programmes (other partnerships, collaborative research or otherwise) shall be indicated in a summarised form for later elaboration and a close coordination between Clean Aviation, the Commission and these other areas/partnerships is envisaged.

Exclusions:

- Sustainable aviation fuels research is outside the scope of the Clean Aviation initiative (as it is dealt with in the energy-related partnerships, missions and other instruments). However, technological development needed for their use is within the scope. Technical and system level impacts for drop-in can be justified if an essential element of the demonstrator logic. Technology development and initial demonstration efforts for non-drop-in, notably liquid hydrogen, are in scope and of interest.
- Low-TRL research generally are out of the scope of the Clean Aviation initiative unless it concerns the accelerated development of essential low-TRL activities which are directly linked to development, integration and validation of the demonstrator elements and/or their future transition to a market offering.
- Critical enablers i.e. technologies that would lead to essential features of the demonstrator in terms of its successful transition to a viable product can be in scope if motivated properly.

Secondly, <u>collaborative research</u> will bring together all stakeholders, but primarily research establishments, academia and SMEs will mature low-TRL technologies (including climate neutral ones) which could benefit from subsequent acceleration and deployment in the second fifteen-year cycle.

- The bulk of low-TRL aviation research needs an adequate collaborative research programme in Cluster 5. Low-TRL R&I in the collaborative part of Cluster 5 of Horizon Europe will complement the Clean Aviation initiative's SRIA.
- A strong and effective mechanism will be developed together with the Commission for the effective and efficient transfer of knowledge and research outcomes in areas of relevance to the Clean Aviation initiative, and to enhance exploitation through the

- absorption in the demonstration programme areas within the <u>Clean Aviation</u> initiative.
- The Commission, through its presence in both the Clean Aviation initiative and in defining the work programmes for collaborative research, will ensure the complementarity between both.

A key added-value of Horizon Europe will be the increased synergies between EU, national and regional levels and the timely development of transformative and disruptive climate neutral aviation pathways. Lessons learned from the current Clean Sky 2 programme include:

- The European strategic R&I agenda needs to be well-focused and designate a few disruptive research paths, since targets cannot be achieved with purely evolutionary paths as it was in the two Clean Sky programmes;
- stronger synergies as well as coherent and timely alignment with national/regional R&I programs;
- better planning and better connection to Pillars I and III of Horizon Europe, as well as other relevant partnerships.

Public oversight, and regular reviews of projects, should ensure that focus on the green deal ambitions is not lost in favour of less disruptive approaches that could fit better the research and commercial agenda of the industry. This entails political commitment from both Member States' and the Commission to ensure that the work (such as infrastructure) needed to support the new technologies on the market is done.

4.4.4. Coherence needed with the external environment

Issues related to the policy, regulatory and financial inadequacies framework have to be addressed in parallel and/or factored in so that the initiative is enabled to achieve its objectives and effectively contribute to the climate policies and targets from a broader perspective. This could be addressed by future developments of the regulatory framework and aviation relevant policies and strategies.

Achieving climate neutrality will partly depend on adopting and integrating new, environmentally friendly energy sources such as sustainable aviation fuels, electricity (batteries) or hydrogen. Links to relevant R&I partnerships and programmes active in these areas will be very important.

The European Commission and Member States should ensure better synergies between the EU, national and regional funding programmes to allocate sufficient resources to the ambitious Clean Aviation projects.

In addition, ties with the broader policy initiatives is crucial to support the achievement of the objectives of an initiative on Clean Aviation by facilitating market uptake.

This could include building upon other European programmes such as:

• European Investment Bank (EIB) loans ¹⁰²: EIB loans and guarantees may provide funding for relevant market uptake of projects. One of the current priorities of the EIB is

¹⁰²https://www.eib.org/en/press/all/2019-313-eu-bank-launches-ambitious-new-climate-strategy-and-energy-lending-policy

climate and environment, including sustainable transport. Additional support should be in line with WTO rules.

- Cohesion Policy Funds: includes the European Regional Development Fund (ERDF) and Cohesion Fund (CF), which aim to increase economic and social cohesion and reduce imbalances and disparities between the regions of the European Union, may also provide support, including indirect, the further development of the aeronautics industry in certain Member States.
- Connecting Europe Facility¹⁰³ (CEF): CEF is an EU funding instrument to promote growth, jobs and competitiveness via targeted infrastructure investment at EU level. It is important for encouraging the deployment of these technologies, in particular airports' fuel/electrification infrastructure, and green door-to-door air transports corridors.
- As well as building upon national and regional funding such as the French research national programme (CORAC), as well as the German federal aeronautical research programme *Luftfahrtforschungsprogramm* (LuFo) underlining the need to an increased involvement of Member States in the aviation partnership.

The impact on airport and air traffic management infrastructure and operations will also need to be considered, as new aircraft technologies may result in new operational requirements for airlines, airports, and air traffic management providers.

5. WHAT ARE THE AVAILABLE POLICY OPTIONS?

This section describes the specific functionalities that could be provided under the baseline scenario of traditional calls and the different options of different types of European partnerships.

5.1. What is the baseline from which options are assessed

The baseline scenario used in this impact assessment is a situation without a Partnership and only traditional calls of Horizon Europe. Given that there is a predecessor Joint Undertaking as well as other funding sources in the area, these will continue generating effects even if there is no new Partnership. In particular it is expected that these already existing initiatives will still create effects on maturing technologies addressing environmental concerns up to TRL 6. This is taken into account in the effectiveness assessment.

In parallel, the baseline situation means that the current implementation structure of the Article 187 would be closed, which bears winding down and social discontinuation costs. There would also be financial cost-savings related to the closing of the structure, related to operations, staff and coordination costs in particular. This is taken into account in the efficiency assessment.

Table 1: Key characteristics of the baseline situation - Horizon Europe calls



¹⁰³ https://ec.europa.eu/transport/modes/air/airports_en

Enabling appropriate profile of participation	 The Commission would need to prepare the Strategic Research and Innovation Agenda (SRIA) by consulting a wide range of actors covering the complete aeronautics value and supply chain, and in addition consult key associations such as ACARE, ASD and so on, as well as the broader aviation community (airports, airlines) possibly through their federations. A well-defined process would be needed to ensure that the programme committees of Member States/ Associated Countries were properly informed about R&I priorities, including key demonstration programmes. The specification of calls over the period of the Framework Programme could reflect the need for an evolving profile of participation, with different consortia forming at different stages to take different types of activity forward.
Supporting implementation of R&I agenda	 Implementation would rely on standard infrastructure underpinning the open calls procedure, drawing on resources of relevant Commission Executive Agencies and systems, benefiting from economies of scale. Administrative costs for the European Commission would be significantly reduced. Calls for proposals would be published in the work programmes of Horizon Europe. Transparency and open publication of results would ensure their availability to interested parties. Dissemination of knowledge and share of practice would happen predominantly among partners within the calls consortia.
Ensuring alignment with R&I agenda	 Work programmes would need to reflect the requirement for R&I activity across TRLs, with input from representatives of all relevant stakeholders. Specification of calls for activity at higher TRLs, particularly demonstration programmes, would need input from industry. Calls would need to be compatible with CS 2 Joint Undertaking ITDs/ IATD¹⁰⁴ to ensure continuity where appropriate R&I activity would focus on the short to medium term needs of the industry. Commission input into specification and oversight of calls would help to ensure alignment with overarching policy objectives but integration with other programmes would require additional coordination. Selection of high TRL projects would require provision of external expert (and independent) advice to the Commission (as has been done in the past in FP5, FP6, etc.)
Securing effective leveraging of resources	 Progress of R&I effort would depend largely on EU funding, with no mechanisms to ensure binding industry commitment and additional contributions. However, depending on the R&I scope and co-financing rules, some contributions from industry support could be expected at project level. Demonstration programmes would require significant in-kind support and collaboration from industry, but there are some unknowns as to whether critical mass could be reached.
Key differences compared to the current situation	 The programme and project management tasks performed by the JU should be performed elsewhere and a separate Technology Evaluator and impact assessment mechanism has to be defined. Portfolio of individual projects with reduced strategic integration and demonstration leading to less maturation of the technologies.

5.2. Option 1 - Co-programmed European Partnership

developed.

leading to less maturation of the technologies.

Table 2: Key characteristics of Option 2 – Co-Programmed European Partnership

Potentially very promising Clean Sy 2 outcomes would not find a habitat to be further

Clean Sky 2 knowledge and experience pool disappears, and is not further exploited.

 $^{^{104}}$ ITD: Integrated Technology Demonstrator. IADP: Innovative Aircraft Demonstrator Platform

	What is feasible under this option - Functionalities of option
Enabling appropriate profile of participation	 The partnership would enable participation by key stakeholders as partners – to commit and contribute to the specification and delivery of the common strategic R&I agenda. The strategic R&I agenda is developed prior to the partnership to ensure that partners know what they sign up to and the wider community is aware of the ambitions. It would need to consult with a wide range of stakeholders to ensure that the R&I agenda, and ultimately the work programme, was aligned with industry and market needs. At the same time, it would offer the flexibility to change the profile of participation over time, with new partners joining to support new areas of activity in response to emerging results and changing priorities.
Supporting implementation of R&I agenda	 Implementation would rely on standard administrative infrastructure underpinning the open calls procedure, drawing on resources of relevant Commission executive agencies and IT systems. Calls for proposals would be published in the work programmes of Horizon Europe. Transparency and open publication of results would ensure their availability to interested parties. Partners are responsible for drafting input to the work programmes, and for implementing their additional activities, notably to support the take-up of results (these are agreed in the SRIA and annual work programmes)
Ensuring alignment with R&I agenda	 Work programmes would need to reflect the requirement for R&I activity across TRLs, with input from the various partners to achieve an appropriate balance of activity directed towards different markets. The partnership would be responsible for ensuring that priorities for calls were specified in line with R&I priorities, including demonstration programmes. Specification of calls would need to be informed by CS2 JU ITDs/IATDs to ensure continuity where appropriate R&I activity would be likely to focus on the medium to long-term needs of the industry. Commission co-steering role and Programme Committee responsible for mobility would need to ensure alignment with overarching policy objectives and coordination with related programmes.
Securing effective leveraging of resources	Aspirations for partner contributions would be clearly defined at the outset. Commitments from partners would be defined at the outset, with private sector partners expected to match at least half of partnership resources through in-kind contributions. Industry commitments would be best efforts, defined in the contractual arrangement. Expected in-kind contributions from the private sector would be identified in the work programme.

5.3. Option 2 – Institutionalised European Partnership

Table 3: Key characteristics of Option 2 – Institutionalised European Partnership (Article 187 TFEU)

	What is feasible under this option - Functionalities of option
Enabling appropriate profile of participation	 The partnership would enable participation of key stakeholders as partners – to commit and contribute to the specification and delivery of the SRIA. The strategic R&I agenda is developed prior to the partnership to ensure that partners know what they sign up to. The implementation of the agenda would not need further consultation, as the structure, thanks to its technical, economical and industrial knowledge and acquired expertise, allows self-management.

	What is feasible under this option - Functionalities of option
	 It would provide a forum or even a platform for consulting stakeholders on R&I priorities and the work programme, ensuring that they are aligned with industry, research and market needs and with the agenda of other partnerships and sectoral programmes. Participation would be less flexible than under other options, but it might nevertheless be possible to change the profile of participation over time, with new partners joining to support new areas of activity in response to emerging challenges and evolving priorities.
Supporting implementation of R&I agenda	 A dedicated administrative structure would be established to coordinate the specification of R&I activity, manage implementation and report on the results (with administrative expenditure limited to 4% of the budget and subject to an indicative 40:60 allocation between the Commission and private partners). Dissemination of knowledge and share of practices would happen among the stakeholders of the community, and through additional diffusion activities managed by the partnership structure. Calls for proposals would be published broadly by the administrative structure. Transparency and open publication of results would ensure their availability to interested parties.
Ensuring alignment with R&I agenda	 The partnership would be responsible for specifying a work programme fully in line with the R&I priorities identified by the industry to fulfil the European policy needs. The work programme would reflect the medium- and long-term needs of industry, the research organisations and society in adopting clean aviation solutions. The work programme can build on, but not be constrained by, the current CS 2 JU ITDs/IADPs to ensure continuity where appropriate. Commission participation in the partnership governance arrangements and approval of the work programme would help to ensure alignment with overarching policy objectives and enable integration with other programmes.
Securing effective leveraging of resources	 Funding requirements would be clearly defined at the outset, with private sector partners required to provide between 50% and up to 75% of partnership resources through in-kind and/or financial commitments. Given more limited funding than in the past, critical R&I priorities would need to be identified at the outset.

Options discarded at an early stage

For an initiative on Clean Aviation, industry involvement is vital to ensure that research results are further developed and reach the market as fast as possible. This requires an alignment of the Clean Aviation research agenda and the substantial research budgets of major market participants such as Airbus¹⁰⁵, Rolls-Royce¹⁰⁶, and SAFRAN¹⁰⁷ that spend respectively

EUR 3.2 billion, EUR 1.5 billion, and EUR 1.1 billion annually on research and product development¹⁰⁸.

Partnerships, created under Article 185 of the TFEU, do not include private partners, only Member States. A co-funded partnership relies on public bodies with research funders (or governmental research organisations) and other public organisations at the core of the

 $^{^{105}\} https://annualreport.airbus.com/pdf/Complete_Annual_Report.pdf$

https://www.rolls-royce.com/investors/annual-report-2016.aspx#group-at-a-glance https://www.safran-group.com/media/safran-2016-annual-results-20170224

Note that these figures include product development beyond TRL6

consortium. Co-funded partnerships rely on pooling and/ or coordinating national programmes and policies with EU policies and investments. Member States become the 'owners' of the priorities and take sole responsibility for its funding. The industry R&I can only be addressed without formal commitments and financial contributions.

For these reasons, these two options have been discarded at an early stage and are not considered suitable for a Clean Aviation initiative where a public-private cooperation is vital to achieving the intended objectives.

6. How do the different policy options compare

Based on the objectives pursued by the initiative and the key functionalities identified to be able to achieve them, each option for implementation is assessed in terms of effectiveness, efficiency and coherence compared to the baseline scenario of traditional calls. The analysis is primarily based on the degree to which the different options would cater for the key needed functionalities. All options are compared to the baseline situation of traditional calls, which is thus consistently scored 0 to serve as reference point.

6.1. Effectiveness

To be in line with the Horizon Europe impact framework, the fulfilment of the specific objectives of the initiative is translated into 'expected impacts' – what success would look like – differentiating between scientific, economic/ technological, and societal (including environmental) impacts. This section considers to which extent the different policy options would allow delivering these expected impacts – confronting what is needed (functionalities) with what each form of implementation can provide in practice.

Scientific impacts

The **baseline option** could easily manage fundamental R&I activities (and could be complementary to any type of partnership). It is more directed towards low TRL and academic research and is of less interest to industry players who focus on closer to market research.

It is however unlikely to contribute to the emergence of high TRL solutions and close to market integrated demonstrators that require large scale integration and a coordinated research effort involving many partners and combining the research results of many projects.

This option does not provide for a framework or ecosystem of actors. However, this option could deliver improvements for low and medium TRL applications by a large number of individual small projects if a clear work programme is established.

Option 1 could deliver more impact than the baseline option when it comes to higher TRL applications, where a strong community with all actors is needed in order for all potential partners to liaise on complex projects. It would therefore have a similar or good potential compared to the baseline with scores between 0 and + according to the different types of scientific impacts.

Its better structure would facilitate knowledge exchange between the academic and industrial world.

Option 2 is the most effective option for well-focused integration, demonstration and validation activities in aviation. This option should be complemented with additional collaborative research under Cluster 5, which will bring together all stakeholders, but primarily research establishments, academia and SMEs towards inventing and maturing low-TRL technologies (including climate neutral ones). The management structure can adapt and coordinate the programme orientation based on early individual research results. Its score would therefore be a high potential compared to the baseline with ++ on this aspect.

Economic/ technological impacts

The **baseline option** could contribute to achieve technological impacts but on a very long-term scale, following the current very long life cycle in aviation research. The lack of a community structure beyond the project consortia might limit the sharing and diffusion of experience among the key actors involved and thus limit the coordination and collaboration necessary to integrate the research outcomes.

This option will not significantly support the scaling up of ready-to-market applications as there is no mechanism to facilitate bridging from R&D to market deployment and it is assessed as more difficult for SMEs to access funding. Hence, it will have little impact on the development of new climate neutral transport modes or on creating, on the competitiveness of the industry or on creating new branches of that industry.

This option would probably be less efficient in creating new networks, or to align European, national and company research programmes. In addition, it may not achieve involving the larger aviation community in preparation of market uptake, or in defining priorities for a strategic research and innovation agenda.

Option 1 has a better impact as it provides elements of the governance structure, but does not yet offer the complete governance and management structure required to build large scale demonstrators. Its potential would therefore be between similar and good compared to the baseline (scores of 0/+).

In light of the above, **Option 2** appears as the most effective, provided a concrete commitment from industry not only to develop climate neutral technologies, but also to ensure that the most promising climate neutral solutions would subsequently benefit from a market uptake.

A strategic research and innovation agenda (SRIA) with a clear view on certification needs and implementation measures will be an essential part of the establishment of the Clean Aviation partnership.

A call of expression of interest under the forthcoming research and innovation programme would help identifying the few building blocks where this acceleration of the most promising climate neutral solutions and deployment should be concentrated under the future Partnership.

The future initiative shall have improved, simplified and well performing governance and monitoring capability able to swiftly re-orient the programme where needed. Option 2 would thus be scored as high compared to the baseline with ++.

Societal (including environmental) impacts

The **baseline option**, given the short-term perspective of the calls, and the focus on low TRL research without much attention for technology integration and demonstration, would mainly lead to individual technology improvements. This conflicts with the sense of urgency introduced by the Green Deal that requires a focus on demonstrating integrated solutions close to market and reach concrete impacts by already 2030. Compared to the usual very long development cycles in aviation this is a very short period.

While **option 1** offers some improvements (Scores 0/+) it will require the binding commitments that would be made by the industry in the **Option 2** to enable higher level of market-focused development and demonstration projects and hence a substantially higher level of market take-up, which is essential for meeting the requirements of the European Green Deal.

It would however miss the advanced programme and project management oversight offered by an institutionalised partnership office, making it much more difficult to ensure the correct level of involvement of EASA, and the early detection of risks and issues with projects and demonstrators. This would lead to a loss of effectiveness, and a risk for loss of focus on the most promising technologies and demonstrators. This would inevitably lead to a reduced capacity to reach the green deal climate targets by the deadlines set and would not fulfil the expectations of society.

Option 2 appears to be the only option focussing on the demonstration of the most promising climate neutral technologies with a concrete view (and industry commitment) on their further development into products on the market. Safety would be ensured by involving EASA in the initiative. This would have the envisaged impact on climate neutrality and improvement of citizens' health the initiative aims at.

As demonstrated by the CS and CS2 experience, and recognised in the CS2 mid-term evaluation, Option 2 benefits strongly from its Programme Office that coordinates and executes a very large range of tasks for which ad-hoc and case by case solutions would have to be found under Option 1. This leads to significant gains in effectiveness.

Option 2 is thus scored as having a high potential compared to the baseline with scores of ++.

The capacity to reduce emissions and achieve climate neutrality within the time limits set is directly dependent on the ability to accelerate the integration and demonstration of innovative technologies which requires an advanced programme management.

Table 5: Overview of the options' effectiveness compared to the baseline

	Baseline: Horizon Europe calls	Option 1: Co- programmed	Option 2: Institutionalised Article 187 TFEU
Scientific impac	t		
Acceleration of the development of know-how and the process of maturing technologies and knowledge transfer for key new technologies and 'differentiators	0	+	++
Increased diffusion of scientific excellence and high-quality knowledge in the field of aeronautics among research staff from universities, research institutes or private companies	0	+	+
Increased collaboration with other sectors and integration of areas of fundamental research that are not traditionally within the aeronautical scientific ecosystem	0	+	++

	Baseline: Horizon Europe calls	Option 1: Co- programmed	Option 2: Institutionalised Article 187 TFEU
Strengthened innovation pipeline by creating better directionality of research;	0	+	++
Economic/technologica	al impact		
New safe, climate neutral and efficient airborne transport modes such as commuter/regional aircraft that have the potential to reduce traffic congestion in highly populated areas, and connect remote regions	0	+	++
Increased competitiveness of European aeronautics industry through cost-efficiency improvements throughout the entire supply-chain	0	0	++
New sustainable business models for innovative aircraft technology for future aircraft and fleet retrofits, exploiting next generation digitalisation/automation technologies	0	0	++
The emergence of new branches of the aviation industry, such as new sources of propulsion, systems or airframes which will enhance European competitiveness	0	0	++
Societal impac	t		
Clean Aviation will significantly contribute to the delivery of Europe's climate neutrality by 2050 by pioneering new solutions in the aeronautics disciplines and readying them for market introduction.	0	+	++
Further increase safety and security levels, in cooperation with the European Union Aviation Safety Agency (EASA) by deeply transforming present operations with the help of innovation;	0	+	++
Fulfil customer and general public expectations of a globally competitive European industry	0	0	++
Improving mobility and connectivity of European citizens with safe, reliable, affordable and resilient air travel options	0	0	++

Notes: Score ++ : Option presenting a *high* potential compared to baseline; Score +: Option presenting a *good* potential compared to baseline; Score 0: Potential of the baseline.

6.2. Efficiency

In order to compare the policy options consistently in terms of their efficiency, a standard cost model was developed for the external study supporting the impact assessment for the set of candidate Institutionalised Partnerships. The model and the underlying assumptions and analyses are set out in the Common Part of this Impact Assessment, Section 2.3.2 and in the methodology, in Annex 4. A dedicated Annex 3 also provides more information on who is affected and how by this specific initiative in line with the Better Regulation framework. The scores related to the costs set out in this context allow for a "value for money" analysis (cost-effectiveness) in the final scorecard analysis in Section 6.4.

In addition, for this specific initiative under the baseline scenario of traditional calls, there would be winding down and social discontinuation costs for the existing implementation structure of the current Article 187 initiative.

There would also be longer term financial cost-savings related to the closing of the structure, related to operations, staff and coordination costs in particular. These can be estimated at EUR 6 million per year of operation. Overall, it is estimated that the overall longer term cost savings from using traditional calls instead of an Article 187 initiative would exceed the costs incurred for winding down operations. This overall situation is set as the starting point for the comparison of options. The score of this baseline scenario (traditional Horizon Europe calls) is set to 0 to be used as a reference point.

On this basis, the scores for the costs of the different options range from a value of 0, in case an option does not entail any additional costs compared to the baseline, to a score of (-) when an option introduces limited additional costs when compared to the baseline and a score of (-)(-) when substantial additional costs are expected in comparison with the baseline. In case the scores are lower than for the baseline scenario, (+) and (+) (+) are used.

It is considered that while there is a clear gradation in the overall costs of the policy options, the cost differentials are less marked when one takes into account the expected co-financing rates and the total budget available for each of the policy options, assuming a common Union contribution. From this perspective, there are only one or two percentage points that split the most cost-efficient policy options – the baseline (traditional calls) and the Co-Programmed policy options – and the least cost-efficient – the Institutionalised Partnership option. Indeed, in terms of cost-efficiency, the Co-Programmed Partnership (Option 1) is 2 percentage points more efficient than the baseline and an Article 187 Partnership is 2 percentage points less cost-efficient than the baseline. However, it should be taken into account that winding down the existing Joint Undertaking would have a negative impact on the finalisation of the research agenda of the CS2 programme with key staff leaving before programme finalisation. The objective of the CS2 research programme have a strong link with the European Green Deal's objectives of Clean Aviation independent of the implementation options chosen for the proposed future initiative.

A score of 0 is therefore assigned for **cost-efficiency** to the Co-Programmed options and a score of (-) for the Institutionalised Partnership policy option ¹⁰⁹.

Looking at cost-efficiency on the broader perspective of attracting higher level of investments from stakeholders, Option 2 may appear much more cost-efficient. The reason is a much higher total investment in European R&I by the private partners and a more concrete spin-off towards full product development by those private partners leading to new products on the market. This also ensures contribution of the initiative to the Green Deal.

In comparison with CS2, the administrative cost (hence the maximum saving possible when not taking this option) is limited to EUR 80 million compared to a total managed research budget of EUR 4 billion (including additional activities).

Looking at cost-efficiency within context of the effectiveness of achieving meaningful research results with the highest (and fastest) possible value for society and contribute timely to achieving the European Green Deal it should be noted that option 2 scores much higher than any other option.

Although difficult to quantity, a slight loss in effectiveness by choosing option 0 or 1 would lead to much higher costs, and more importantly reduced impact, than potential savings.

In addition, only Option 2 contains all the characteristics as regards partner composition, commitment, governance needed to manage a hugely complex and large research and innovation agenda on time.

M	atri	x c	on '	overall	costs'	and	`adjust	ted	cost	scoring	, '

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¹⁰⁹ The baseline (traditional calls) is scored 0, as explained above.

	Baseline: Horizon Europe calls	Option 1: Coprogrammed	Option 2: Institutionalised Article 187 TFEU
Administrative, operational and coordination costs	0	(-)	(-)(-)
Administrative, operational and coordination costs adjusted per expected co-funding (i.e. cost-efficiency)	0	0	(-)

Notes: Score 0 = same costs as for the baseline; score (-) = limited additional costs compared with the baseline; score (-)(-) = substantial additional costs compared with the baseline.

6.3. Coherence

6.3.1. Internal coherence

In this section we assess the extent to which the policy options show the potential of ensuring and maximising coherence with other actions, programmes and initiatives under Horizon Europe, in particular European Partnerships (internal coherence).

Strong synergies should be established between the two proposed aviation partnerships, Integrated Air Traffic Management¹¹⁰ and Clean Aviation, and several other proposed initiatives. This should ensure compatibility between the solutions developed by Clean Aviation, and the advanced ATM approaches developed under the Integrated Air Traffic Management initiative. For example, one of the main objectives is the environmental optimisation of air traffic operations in the European airspace. This optimisation requires optimisation in aircraft design and comprehensive meteorological data including different atmospheric parameters. Aligned roadmaps for new aircraft designs and operations, ATM and use of meteorological data will enable the instantaneous calculation of the climate impact caused by the engine emissions released at any point in the four-dimensional space (latitude, longitude, altitude, time).

Cooperation, and the alignment of research agendas, between partnerships is a key condition for success. For instance, the hydrogen initiative and the batteries initiative (potentially delivering alternative energy sources to aviation) could have a huge impact as enablers of zero-emission aviation, if their deliverables respond to the needs of the aviation sector (see Figure in Section 1.4).

Creating synergies would benefit all these initiatives. It is worth mentioning that moreelectric aircrafts will require advancements in high-voltage electric power systems, which at high altitudes pose additional safety risks that have to be addressed and technological solutions to be validated. That's why aircraft requirements have to be taken into consideration at initial stages of proposed solutions.

Depending on the selection of the most promising technologies, and the practical research and innovation requirements expressed in the strategic research and innovation agenda, closer cooperation with other initiatives may be envisaged. An overview is available in annex 2.6.

For the **baseline option**: synergies and coherence between Clean Aviation and other initiatives would require an additional level of coordination. Exploiting potential synergies would be hampered by the difference in focus (low TRL versus high TRL) and the more limited scope of lower TRL projects. The baseline option is more appropriate for

¹¹⁰ https://www.sesarju.eu/approach/environment

collaborative research/incremental improvements whereas the initiative would focus on disruptive technologies and high TRL demonstrators.

For **Option 1**: The Co-Programmed option would be able to provide this coherence, notably in the context of work programme preparation. The European Commission could ensure coordination at the level of research agendas. Option 1 is not considered optimum to address the complex R&I chains typical for aviation.

For **Option 2**: The institutionalised partnership would allow for greater internal coherence than the two other options, expanding the possibilities of coordination and exploitation of synergies offered by the Co-Programmed option by the existence of the central coordination level, managed by the programme office and supported by the European Commission. This would also enable the development of a shared vision and better exploitation of synergies from joint programmes and calls, in areas such as hydrogen and battery technology,

6.3.2. External coherence

In this section we assess the extent to which the policy options show the potential of ensuring and maximising coherence with their external environment, including EU-level programmes and initiatives beyond the Framework Programme and/or national and international programmes and initiatives, but as well as with overarching framework conditions, such as regulation, standardisation, etc. (external coherence).

The **baseline** option and **the co-programmed** partnership are assessed to be less effective than an institutionalised partnership in creating the required systemic effects. This is due to their weaknesses in addressing the international community, ensuring adequate coordination with other programmes, third countries and international organisations, aligning with their own R&D agendas and low carbon roadmaps, and for facilitating market uptake support to be put in place.

The **institutionalised partnership** option, through its programme office, has a dedicated structure that provides a large value in organising systematic links with stakeholders, for establishing a structured dialogue with MS (SRG) or to exploit synergies with ERDF. This is the more important because synergies and sequencing with other EU, national, and regional R&I programmes will help in creating a critical mass to support breakthrough technologies in clean aviation.

In case other initiatives with large potential for synergies (e.g. hydrogen) would become an Article 187 partnership, then there could be a fluent cooperation between the various programme offices.

In addition, it will promote economies of scales, non-duplication and best practices with and among national and regional programs; promote participation of less active countries; and bridge the gap between R&I and national policies on new skills and jobs.

This applies also for setting ambitious standards and performance targets. Working with Member States and international standardisation bodies, the European Commission identifies areas where standards and performance targets could have the greatest impact towards aviation climate neutrality and could propose the development of other standards if needed.

Research provides results, and in this case enables climate neutrality, only when it leads to innovations that enter the market. Trends in EU policies such as the review of the energy

taxation framework, aircraft certification processes, carbon taxation schemes, the Air Quality Directives, as well as the Emissions Directives may create barriers to innovation or on the contrary stimulate research and innovation towards climate neutral aviation by 2050.

For maximising results, research and innovation must be part of a much broader EU strategy encompassing EU programmes, national and international policies.

To ensure continued progress, barriers to innovation as well as accelerators need to be addressed holistically in all EU policies in close cooperation with stakeholders¹¹¹.

All the synergies should be aligned in a shared, integrated and comprehensive roadmap. Combining resources and funding will produce a substantial leverage effect and help reach the objective of climate neutral aviation.

Figure 6 Overview of the options' potential for ensuring and maximizing coherence

	Option 0: Horizon Europe calls		Option 2: Institutionalised Article 187 TFEU
Internal coherence	0	0/+	++
External coherence	0	+	++

Notes: Score ++ : Option presenting a *high* potential compared to baseline; Score +: Option presenting a *good* potential compared to baseline; Score 0: Potential of the baseline.

6.4. Tabular comparison of options and identification of preferred option

Figure 7 Overall scorecard of the policy options for all criteria

	Items	Baseline Traditional calls	Option 1: Co- programme d	Option 2: Article 187
	Scientific impact			
	Acceleration of the development of know-how and the process of maturing technologies and knowledge transfer for key new technologies and 'differentiators	0	+	++
	Increased diffusion of scientific excellence and high-quality knowledge in the field of aeronautics among research staff from universities, research institutes or private companies	0	+	+
	Increased collaboration with other sectors and integration of areas of fundamental research that are not traditionally within the aeronautical scientific ecosystem	0	+	++
	Strengthened innovation pipeline by creating better directionality of research;	0	+	++
	Economic/technological impact			
	New safe, climate neutral and efficient airborne transport modes such as commuter/regional aircraft that have the potential to reduce traffic congestion in highly populated areas, and connect remote regions	0	+	++
ıess	Increased competitiveness of European aeronautics industry through costefficiency improvements throughout the entire supply-chain	0	0	++
Effectiveness	New sustainable business models for innovative aircraft technology for future aircraft and fleet retrofits, exploiting next generation digitalisation/automation technologies	0	0	++

the Advisory Council for Aviation Research and Innovation in Europe (ACARE), and the Association of European Research Establishments in Aeronautics (EREA), as well as key national organisations, e.g. the *Direction Générale de l'aviation civile* in France, BMWi in Germany, CDTI in Spain, MISE in Italy, etc.

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	The emergence of new branches of the aviation industry, such as new sources of propulsion, systems or airframes which will enhance European competitiveness	0	0	++
	Societal impact			
	Clean Aviation will significantly contribute to the delivery of Europe's climate neutrality by 2050 by pioneering new solutions in the aeronautics disciplines and readying them for market introduction.	0	+	++
	Further increase safety and security levels, in cooperation with the European Union Aviation Safety Agency (EASA) by deeply transforming present operations with the help of innovation;	0	+	++
	Fulfil customer and general public expectations of a globally competitive European industry	0	0	++
	Improving mobility and connectivity of European citizens with safe, reliable, affordable and resilient air travel options	0	0	++
Coherence	Internal coherence	0	+	++
Cohe	External coherence	0	+	++
ncy	Overall cost	0	-	
Efficiency	Cost-efficiency	0	0	-

Notes: Scores for effectiveness and coherence: Score ++: Option presenting a *high* potential compared to baseline; Score +: Option presenting a *good* potential compared to baseline; Score 0: Potential of the baseline Scores for efficiency: Score 0 = same costs as for the baseline; score (-) = limited additional costs compared with the baseline; score (-)(-) = substantial additional costs compared with the baseline

Overall, the implementation of the Clean Aviation initiative through an institutionalised partnership established under Article 187 of TFEU is the preferred option as it would best ensure that private and public sectors remain fully engaged in the development and implementation of a long-term strategy for clean aviation R&I.

It is also consistent with the aim of leveraging industrial financial and in-kind resources, strive towards synergies with national programmes, and create ties with the broader policy initiatives to support to facilitate market uptake. This way, the impact of funding provided by the Commission is maximised.

This form of partnership would continue to provide a stable framework for encouraging the participation of organisations from all concerned sectors (including those outside the traditional aviation industry), securing and allocating resources, managing a wide range of RD&I projects favouring high TRL and creating synergies with other partnerships and initiatives within and outside the Climate, Energy and Mobility Cluster.

It is also considered appropriate to develop a strategy for Clean Aviation that is fully aligned with European Green Deal priorities, and especially the European climate commitment, and with several sustainable development goals.

As documented in the CS2 mid-term evaluation, elements of the CS2 procedural structure are constraining the R&I effort. One objective in Horizon Europe is to optimise the structure of the partnership, in reply to the mid-term evaluation recommendations. This is seen as a key condition for having an Art. 187 partnership. Without such optimisation, a coprogrammed partnership could become the better option.

Conclusion:

Three options have been considered under the Clean Aviation initiative: traditional calls, a co-programmed partnership and an Article 187 institutionalised partnership. The other

options, a co-funded partnership and an Article 185 partnership, were discarded at an early stage because Clean Aviation builds upon a strong and long-term commitment of industry.

The traditional calls (baseline option) would support a substantial effort for the **exploration of novel solutions**, but it would miss the long-term planning, and large long-term industry commitment, leading to high TRL technology demonstrators required for achieving the Green Deal. In addition, those novel solutions would take far too long to reach TRL 6 stage to be useful for achieving the European Green Deal's climate neutrality targets on time.

In order to achieve large-scale integrated demonstrators there is a need for a management structure providing in-house programme management capacities, which would allow for close monitoring and swift adaptation of the research and innovation priorities in the course of the programme implementation.

A **co-programmed partnership** would be an improvement compared to traditional calls but would require a very heavy programme management and would lack flexibility.

The dedicated programme office foreseen under the **Article 187 institutionalised partnership** is vital for programme management of large-scale integrated demonstrators. In fact, one of the perceived weaknesses of Clean Sky 2 is that the programme office should have even better governance and programme/project management capabilities.

In addition, the Article 187 institutionalised partnership ensures long-term commitment of the industry around the European Green Deal climate neutrality target as well as a precise timeline (up to 55% emission reduction by 2030, climate neutrality by 2050), which is vital for the envisaged research which is directly contributing to the European Green Deal climate neutrality target.

The following comparison between the preferred option and the current partnership existing in the area taking into account lessons from past evaluations.

What continues	What is different
Strategic research and innovation agenda as basis for research and innovation activities. Dedicated structure of programme office managed by executive director	The European Green Deal sets a very clear ambition with corresponding target dates. This gives a much stronger focus compared to CS 2. Focus on disruptive research instead of incremental changes. Commitment of industry beyond research and towards market introduction Selection of a very limited number of most promising technologies, with high potential for market introduction, and a business plan on how to get there. Much simplified programme structure with projects selected by open calls instead of pre-allocation of budgets. Better involvement of Member States and the Scientific Community.
	Strong focus on analysis, project progress monitoring and

impact assessment.

Annex 6.11 gives an overview of the weaknesses of the H2020 CS2 Joint Undertaking and how these could be addressed when establishing a new Article 187 Partnership.

7. THE PREFERRED OPTION

In the below table, the alignment of the preferred option of Institutionalised European Partnership under Article 187 TFEU with the selection criteria for European Partnerships defined in Annex III of the Horizon Europe Regulation is depicted.

Seeing that the design process of the candidate Institutionalised Partnerships is not yet concluded and several of the related topics are still under discussion, the criteria of additionality/directionality and long-term commitment are covered in terms of *expectations* rather than ex-ante demonstration.

Alignment with the selection criteria for European Partnerships

Criterion	Alignment of the preferred option
Higher level of	An institutionalised partnership would be more effective in achieving the objectives of the initiative within the timeframe set by the Green Deal.
effectiveness	This the more important considering the global impact of the European aviation industry, and the global environmental challenges to be addressed.
	An institutionalised partnership would be considerably more effective in addressing global challenges and delivering research and innovation objectives, in securing EU competitiveness and,
	The institutionalised partnership would also be effective in securing sustainability (the final goal of "clean aviation"), in strengthening the European Research and Innovation Area, in securing the competitiveness of our industry, and where relevant, in contributing to international commitments (e.g. on standards).
Coherence and synergies	A dedicated management structure similar to the Programme Office in current CS 2 would operate on basis of but with an optimised governance structure, bringing the CS 2 mid-term evaluation recommendations to practice.
	Projects would be selected by open calls, on the basis of the Strategic Research and Innovation Agenda.
	Under the supervision of the European Commission, the institutionalised partnership could ensure where possible synergies with relevant strategies and programmes developed by other partnerships and initiatives, in particular in areas such as Clean Hydrogen, Integrated Air Traffic Management and Battery Technology. It would strive towards active coordination and exploiting synergies with national aviation research programmes.
	This would enable the gradual development of a shared vision and better exploitation of synergies from joint programmes and calls.
Transparency and openness	An institutional partnership would ensure that the outputs of R&I programmes are transparent and available to stakeholders inside and outside the aeronautics industry. The framework governing participation would allow any organisation meeting defined criteria to participate, with a proportion of funded activity subject to open calls.
	An institutionalised partnership would be better placed to identify priorities and objectives in terms of expected results and impacts, in involving partners and stakeholders from across the entire aviation value chain, from different sectors, backgrounds and disciplines, including international ones when relevant and not interfering with European competitiveness.
	SMEs would have the most appropriate support from the partnership, similar to CS 2.

Criterion	Alignment of the preferred option
	An institutional partnership would ensure that the outputs of RD&I programmes are transparent and available to stakeholders inside and outside the aviation community.
	The approach of using open calls would allow any organisation meeting defined criteria to participate, in an open and transparent way. This framework could provide support and guidance, help networking and build up consortia when addressing complex projects throughout the whole value chain
Additionality and directionality	Only a partnership would be able to secure the necessary industry commitments. The partnership should start on basis of a strategic research and innovation agenda for aeronautical-related R&I and establish a set of common objectives governing the direction, outputs and timeframe of R&I activity under Horizon Europe. This SRIA should, at best, fit within a larger EU aviation policy and strategy.
	An institutionalised partnership would be very well placed to maintain an Strategic Research and innovation agenda, and adapt it on basis of research results and progressive insights.
	The active and long term involvement of private as well as public partners would ensure flexibility of implementation and permit to adjust to changing policy, societal and/or market needs, and increase policy coherence between regional, national and EU level.
Long-term commitment	In the case of institutionalised European Partnerships, established in accordance with article 187 TFEU, the financial and/or in-kind, contributions from partners other than the Union, will at least be equal to 50% and may reach up to 75% of the aggregated European Partnership budgetary commitments

7.1. Operational Objectives

Clean Aviation low and zero emissions technologies will allow fuel efficiency gains of one-third to one-half in 2050, compared to today's fleet.

To deliver on the identified objectives, an initiative in this area must enable aircraft, engines and systems to utilise the full potential of low or zero carbon fuels, including potential disruptive innovations such as hydrogen. Together these outcomes will accelerate the transition towards climate-neutrality.

The ambition of the Clean Aviation Partnership is to ensure that breakthrough technology advancements allow **new aircraft developments by 2030**, with maximum progress towards climate neutral aviation, while meeting socio-economic expectations and providing benefits for European society and businesses. It will go well beyond previous framework programme R&I, and will accelerate the transition towards a climate neutral system by enabling all-new aircraft platforms and configurations, and taking a system-wide approach. To deliver on its objectives, the initiative must aim to bring about decisive steps in new aircraft performance demonstrated and **on offer to airlines and operators by 2030 and available by 2035**. The focus will be on pursuing two pivotal aircraft demonstration efforts for the validation of selected technologies. **Ultra-efficient short-medium range aircraft** coupled with the use of sustainable aviation fuels, and **hybrid electric regional and short-range aircraft** will deliver major steps, together with optimised green trajectories and operations and with accelerated transition to low or zero carbon fuels. Clean Aviation will develop in parallel the technologies to deliver full climateneutrality by 2050, by bringing key technologies to a maturity that can allow appropriate scaling across the full spectrum of aircraft segments and flight operations, including long-haul travel.

The technical details are worked out in an (approved) Strategic Research and Innovation Agenda¹¹² (SRIA) prepared by the private sector in response to the Clean Aviation initiative.

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¹¹² http://clean-aviation.eu/files/Clean Aviation SRIA 16072020.pdf

The primary focus of the demonstration efforts will be on the hybrid electric regional and the ultra-efficient short-medium range aircraft concepts, with a stepwise development and demonstration strategy.

This allows for opportunities for technology spin-off to other aircraft categories (commuter and vertical lift applications, long range applications) and for a broad-based participation in the programme, and a much broader and deeper penetration of the overall air transport system with important additional environmental and climate-related benefits.

Note: The SRIA contains a table (page 20) indicating the targets set by the aviation sector for achieving impact linked to the Green Deal with 2030 and 2050 deadlines, confirming the ambition to reach climate neutrality by 2050.

An **Impact Monitor** mechanism and work programme will be included in the Partnership's work breakdown structure to ensure regular strategic monitoring and steering, and ensure objectives are met. The performance levels in targeted the aircraft types to be demonstrated in Clean Aviation are below.

7.2. Monitoring indicators

We have identified a number of short, medium and long-term monitoring indicators to enable the progress of the partnership towards meeting its objectives to be tracked. However, it is indicated that the development of technologies within EU-funded R&I is limited to TRL 6 activities and additional product development and integration is necessary before first flight and entry into service. Furthermore, the societal impact of the aviation R&I is apparent and quantifiable at least ten years after TRL 6. Having these in mind, the monitoring indicators are shown in the below table.

Monitoring indicators in addition to the Horizon Europe key impact pathway indicators

	Short-term (typically as of year 1+)	Medium-term (typically as of year 3+)	Long-term (typically as of year 5+)
Scientific impact	Alignment of European fundamental and collaborative aeronautics research with medium/long term industry objectives. Cross-fertilisation with other S&T initiatives from relevant areas in Pillar I and II of HE.	Number of times that journal citations generated by the partnership are cited in the global literature Number of occupied and advertised jobs in aeronautical-related R&I Number of PhD thesis, inventions and patents.	Number of patents registered by the aeronautical industry and research organisations located in Europe
Technological / economic impact	Number of programmed projects involving organisations outside the aeronautical industry Number of programmed projects with a documented strategy identifying the potential application of results	Number of programmed projects leading to validated demonstration of new applications of technology Number of years for programmed projects to reach TRL 6 Level and intensity of the	Performance of engine ground demonstrators and/or flying test beds for emissions and noise. Reliability and cost reduction achieved from manufacturing technologies and the projected integration.

	Short-term (typically as of year 1+)	Medium-term (typically as of year 3+)	Long-term (typically as of year 5+)
	to defined market needs	aeronautical-related R&I (in percentage of turn-over) Number of joint ventures or suppliers ready to invest further in the development and integration beyond TRL 5-6	Number of programmed projects with high potential for market take-up Projected value of exports generated by the European aeronautical sector (note this will be significantly beyond year 5+) Projected direct and indirect employment generated by the European aeronautical sector
Societal impact	Number of programmed projects developing technological solutions towards climate neutrality	Level and intensity of the aeronautical-related R&I (in percentage of turn-over) Education and training of students and staff in new technological field	Maintain and/or increase European competitiveness and employment. Level of matching funds from National or International funding mechanisms required to integrate, integrate and certify developed technologies. Changes in air quality and well-being (note this will be significantly beyond year 10+)
Incl. Environmental / sustainability impact	Number of programmed projects focusing on large civil aircraft Number of programmed projects focusing on sustainable aviation fuels integration	Number of programmed projects focusing on alternative energies or technologies. Potential and scalability successfully demonstrated and quantified	Changes in CO ₂ , non- CO ₂ emissions and noise generated by the aviation industry in Europe and globally (note this will be significantly beyond year 10+)

Source: Steer analysis

7.3. Evaluation framework

The evaluation of the Partnership will be done in full accordance with the provisions laid out in Horizon Europe Regulation Article 47 and Annex III, with external interim and ex-post evaluations feeding into the overall Horizon Europe evaluations. As set in the criteria for European Partnerships, the evaluations will include an assessment of the most effective policy intervention mode for any future action; and the positioning of any possible renewal of the partnership in the overall European Partnerships landscape and its policy priorities. In the absence of renewal, appropriate measures will be developed to ensure phasing-out of framework programme funding according to conditions and timeline agreed, ex-ante, with the legally committed partners.



Brussels, 23.2.2021 SWD(2021) 37 final

PART 15/19

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT REPORT Accompanying the document

Proposal for a COUNCIL REGULATION establishing the Joint Undertakings under Horizon Europe

European Partnership for Clean Aviation

{COM(2021) 87 final} - {SEC(2021) 100 final} - {SWD(2021) 38 final}

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Annex 1 Procedural information

1. LEAD DG, DECIDE PLANNING REFERENCES

Lead DG: Directorate-General Research and Innovation (RTD)

Decide number: PLAN/2019/5304

2. ORGANISATION AND TIMING

Institutionalised partnerships are foreseen in Articles 185 and 187 of the Treaty on the Functioning of the European Union (TFEU). The preliminary agreement on Horizon Europe contained a list of possible areas for institutionalised partnerships based on Articles 185 and 187. For these areas, the Commission considered 12 potential institutionalised partnerships. Their set up involves new EU legislation and the establishment of dedicated implementing structures and therefore an impact assessment for each of these initiatives.

Following political validation in June 2019, the impact assessment process started with the publication of inception impact assessments for each initiative in August 2019.

An inter-service steering group (ISSG) on research and innovation partnerships under Horizon Europe was set up in May 2019 and held four meetings before submission of the Staff Working Document to the Regulatory Scrutiny Board (7 May 2019, 19 June 2019, 5 December 2019, and 20 January 2020). The ISSG consisted of representatives of: the Secretariat-General; Directorate-General for Budget; Directorate-General for Research and Innovation; Directorate-General for Communications Networks, Content and Technology; Directorate-General for Mobility and Transport, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, Directorate-General for Energy; Directorate-General for Environment; Directorate-General for Climate Action; and the Legal Service.

An online public stakeholder consultation was launched between September and November 2019, receiving 1635 replies for all 12 initiatives.

3. CONSULTATION OF THE RSB

Two upstream meetings with the Regulatory Scrutiny Board were held on 10 July 2019 and 30 September 2019.

In accordance with the feedback received from the Regulatory Scrutiny Board on 12 June 2020 the Staff Working Document has been revised as presented in Figure 1. The impact assessment was endorsed by the Inter Service Steering Group on 20 January 2020.

4. EVIDENCE, SOURCES AND QUALITY

To ensure a high level of coherence and comparability of analysis for all candidate initiatives, an external study was procured to feed into the impact assessments of the 12 candidate institutionalised partnerships¹. It consisted of a horizontal analysis and individual thematic analyses for each of the initiatives under review.

For all initiatives, the evidence used includes desk research partly covering the main impacts and lessons learned from previous partnerships. A range of quantitative and qualitative data

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¹ Technopolis Group, 2020, forthcoming.

sources complement the evidence base, including evaluations; foresight studies; statistical analyses of framework programmes application and participation data and Community Innovation Survey data; analyses of science, technology and innovation indicators; reviews of academic literature; sectoral competitiveness studies and expert hearings. The analyses included a portfolio analysis, a stakeholder and social network analysis in order to profile the actors involved as well as their co-operation patterns, and an assessment of the partnerships' outputs (bibliometrics and patent analysis). A cost modelling exercise was performed in order to feed into the efficiency assessments of the partnership options. Public consultations (open and targeted) supported the comparative assessment of the policy options. For each initiative up to 50 relevant stakeholders were interviewed by the external contractor (policymakers, business including SMEs and business associations, research institutes and universities, and civil organisations, among others). In addition the analysis was informed by the results of the Public Consultation (Sept. – Nov. 2019), the consultation of the Member States through the Strategic Programme Committee and the online feedback received on the Inception Impact Assessments of the set of candidate Institutionalised European Partnerships.

A more detailed description of the methodology and evidence base used, completed by thematic specific methodologies, is provided in Annexes 4 and 6.

Figure 1 Modifications to the draft Staff Working Document based on comments received from the Regulatory Scrutiny Board

Comments from the Regulatory Scrutiny Board	Actions taken for the Staff Working Document
The report should be clearer about the differences between the new partnership and the current one and the underlying drivers (e.g. evaluation results, policy or market developments).	The report, mainly chapter 1, has been updated to better reflect the underlying drivers of the proposed initiative. A summary table, on page 67, compares the preferred option to the current partnership. In addition, an annex 6.11 has been added including a table indicating the changes to the Clean Aviation initiative to address the perceived shortcomings of Clean Sky 2 (source Clean Sky 2 mid-term evaluation and impact assessment study)
The report should clarify how the proposed two-pronged approach would work in practice. It should explain the links between the foreseen actions under the traditional calls for collaborative research and the institutionalised partnership. It should explain to what extent these approaches address different problems and have distinct objectives.	The problems addressed by the Clean Aviation initiative have been better explained in chapter 2 of the report. Point 4.4.3 on priority setting and the level of directionality, has been revised to clarify the distinction between the activities of the Clean Aviation initiative and collaborative research, and how these relate to each other.
The report could explain better the links with other EU policies and instruments in place to support aviation and to tackle its climate and environmental impacts	The revised report explains how activities are linked. Specifically, the revised report, mainly Chapters 1.3 and 4.4.4, address synergies

while Annex 6.10 contains an initial list of potential synergies.

Chapter 3.2 emphases the role of the Commission to ensure co-operation between various policy areas, and national programmes.

Note also that one of the specific objectives of the initiative is to expand and foster the integration of the aviation R&I value chains, including SMEs, also by exploiting synergies with other initiatives national and European related programmes.

The report should specify more precisely the environmental and climate impacts the initiative will address. It should discuss the extent to which the partnership would be able to deliver these ambitious objectives. In this regard, the report should better explain the foreseen sequencing and expected timing of the forthcoming disruptive technologies.

The environmental impact of aviation is better explained in Annex 6.3. A paragraph has been added to Point 4.1, explaining why the focus on climate neutrality by this initiative is justified.

The Clean Aviation initiative will primarily focus on the Green Deal's ambition to reduce net greenhouse gas emissions. This has been made clearer in the description of the objectives and specific objectives.

The report should explain how the new partnership would be better able to attract relevant stakeholders and Member States. It should discuss whether smaller companies with potential to provide disruptive solutions are likely to be interested in traditional calls, instead of applying for the partnership.

The two-pronged approach (a focussed Clean Aviation, and a complementary collaborative research programme) is explained on page 32 of the main report. This is further detailed in Chapter 4.4.3.

An Annex 6.9 has been added confirming the commitment and involvement of the private sector and stakeholders to the Clean Aviation initiative.

In addition, the private sector has finalised a Strategic Research and Innovation Agenda (SRIA).

The most recent public consultation (statistics also included in Annex 6.9), which was part of the SRIA's preparation process, received a remarkable high number of positive reactions from SMEs (16%) and private citizens (36%).

Overall, the feedback was very positive on the ambition and focus of the presented SRIA, and the stakeholders' interest in participating. The report should clarify the logic behind the intervention. It could better explain the links between problems and objectives, and between objectives, targeted impacts and functionalities. The intervention logic should focus on the part of the "two-pronged" approach that the Clean Aviation partnership would address.

The report has undergone various changes to improve the logic from problems to targeted impacts and functionalities; this effort was based on the replies given to the questions asked by the Regulatory Scrutiny Board before and during the hearing with the RSB.

The revised intervention logic is focusing on the Clean Aviation partnership activities. The collaborative research is not addressed as this is outside the scope of the partnership.

The report should integrate the latest realistic expectations on the effects of the Covid-19 crisis on the aviation sector. It should consider these in the analysis of the problems, baseline and impacts.

The COVID-19 crisis is still on-going and insights in the potential impact still evolving.

The text related to COVID-19 under Chapter 1 has been changed, adding the position of stakeholders that are involved in the preparations for the proposed initiative to protect the focus of the Clean Aviation initiative on its Green Deal-oriented objectives.

An Annex 6.2 has been added with a summary of the known information at the moment of writing.

Annex 2 Stakeholder Consultation

1. OVERVIEW FOR ALL CANDIDATE INSTITUTIONALISED EUROPEAN PARTNERSHIPS

1.1. Introduction

In line with the Better Regulation Guidelines,² stakeholders were widely consulted as part of the impact assessment process of the 12 candidates for institutionalised partnerships, including national authorities, the EU research community, industry, EU institutions and bodies, and others. These inputs were collected through different channels:

- A feedback phase on the inception impact assessments of the candidate initiatives in August 2019, gathering 350 replies for all 12 initiatives on the "Have your Say" web portal during a three-week period;
- A structured consultation of Member States performed by the EC services 2019 through the Shadow Strategic Configuration of the Programme Committee of Horizon Europe (in line with the Article 4a of the Specific Programme of Horizon Europe). This resulted in 44 possible candidates for European Partnerships identified as part of the first draft Orientations Document towards the Strategic Plan for Horizon Europe (2021-2024), taking into account the areas for possible institutionalised partnerships defined in the Regulation.
- An online public stakeholder consultation administered by the EC, based on a structured questionnaire, open between September and November 2019, gathering 1635 replies for all 12 initiatives;
- A targeted consultation run by the external study contractors with a total of 608 interviews performed as part of the thematic studies by the different study teams between August 2019 and January 2020.

1.2. Horizontal results of the Open Public Consultation

The consultation was open to everyone via the EU Survey online system.³ The survey contained two main parts to collect views on general issues related to European partnerships (in Part 1) and specific responses related to one or more of the 12 candidate initiatives (as selected by a participant). The survey was open from 11 September until 12 November 2019. The consultation was available in English, German and French, and was advertised widely through the European Commission's online channels as well as via various stakeholder organisations.

1.2.1. Profile of respondents

In total, 1635 respondents filled in the questionnaire of the open public consultation. Among them, 272 respondents (16.64%) were identified to have responded to the consultation as part of a campaign (coordinated responses). Based on the Better Regulation Guidelines, the groups of respondents where at least 10 respondents provided coordinated answers were labelled as 'campaigns', segregated and analysed separately and from other responses. In total 11 campaigns were identified, the largest of them included 57 respondents⁴. In addition, 162

² https://ec.europa.eu/info/files/better-regulation-guidelines-stakeholder-consultation_en

³ https://ec.europa.eu/eusurvey/runner/ConsultationPartnershipsHorizonEurope

⁴⁴ The candidate Institutionalised Partnership Clean Hydrogen has the highest number of campaigns, namely 5. A few initiatives, such as Innovative SMEs, Smart Networks and Systems, were not targeted by campaigns. Some campaign respondents decided to provide opinions about several partnerships.

respondents in the consultation also display similarities in responses but in groups smaller than 10 respondents. Hence, these respondents were not labelled as campaigns and therefore were not excluded from the general analysis.

Table 1: Country of origin of respondents (N=1635)

Country	Number of	Percentage of
Country	respondents	respondents
Germany	254	15.54%
Italy	221	13.52%
France	175	10.70%
Spain	173	10.58%
Belgium	140	8.56%
The Netherlands	86	5.26%
Austria; United Kingdom	61	3.73%
Finland	49	3.00%
Sweden	48	2.94%
Poland	45	2.75%
Portugal	32	1.96%
Switzerland	28	1.71%
Czechia	24	1.47%
Greece	23	1.41%
Norway; Romania	22	1.35%
Denmark	20	1.22%
Turkey	19	1.16%
Hungary	14	0.86%
Ireland	12	0.73%
United States	11	0.67%
Estonia; Slovakia; Slovenia	10	0.61%
Bulgaria; Latvia	9	0.55%
Bosnia and Herzegovina	7	0.43%
Lithuania	4	0.24%
Canada; Croatia; Israel	3	0.18%
China; Ghana; Iceland; Japan; Luxembourg; Morocco	2	0.12%
Bhutan; Botswana; Cyprus; Iran; Malta; Mexico; Moldova; Mongolia; Palestine; Russia; Serbia; South Africa; Tunisia; Ukraine; Uruguay	1	0.06%

As shown in Figure 2, the three biggest categories of respondents are representatives of companies and business organisations (522 respondents or 31.9%), academic and research institutions (486 respondents or 29.7%) and EU citizens (283 respondents or 17.3%). Among the group of respondents that are part of campaigns, most respondents are provided by the same groups of stakeholders, namely company and business organisations (121 respondents or 44.5%), academic and research institutions (54 respondents or 19.8%) and EU citizens (42 respondents or 15.4%).

522 486 283 99 97 78 53

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

Company/business organisation Academic/research institution EU citizen

Business association Public authority Other

Non-governmental organisation (NGO) Non-EU citizen Consumer organisation

Environmental organisation

Figure 2 Type of respondents (N=1635) - For all candidate initiatives

Among all consultation respondents, 1,303 (79.69%) have been **involved in the on-going research and innovation framework programme** Horizon 2020 or the preceding Seventh Framework Programme, while 332 respondents (20.31%) were not. In the group of campaign respondents, the share of those who were involved in these programmes is higher (245 respondents out of 272 or 90.07%) than in the group of non-campaign respondents (1058 out of 1,363 or 77.62%). When respondents that participated in the Horizon 2020 or in the preceding Seventh Framework Programme were asked to indicate in which capacity they were involved in these programmes, the majority stated they were a beneficiary (1,033 respondents) or applicant (852 respondents). The main stakeholder categories, e.g. companies/business organisation, academic/research institutions, etc., show a similar distribution across the capacities in which they 'have been involved in Horizon 2020 or in the Seventh Framework Programme' as the overall population of consultation respondents.

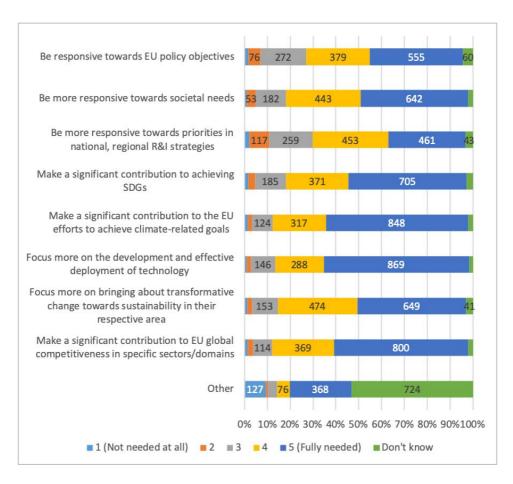
Among those who have been involved in Horizon 2020 or the preceding Seventh Framework Programme, 1,035 respondents (79.43%) are/were **involved in a partnership**. The share of respondents from campaigns that are/were involved in a partnership is higher than for non-campaign respondents, 89.80% versus 77.03% respectively.

1.2.2. Characteristics of future candidate European Partnerships

Respondents were asked to assess what areas, objectives, aspects need to be in the **focus of the future European Partnerships** under Horizon Europe and to what extent. According to Figure 6, a great number of respondents consider that a significant contribution by the future European Partnerships is 'fully needed' to achieve climate-related goals, to the development and effective deployment of technology and to EU global competitiveness in specific sectors/domains. Overall, respondents' views reflect that many aspects require attention of the Partnerships.

Overall, only minor differences can be found between the main stakeholder categories. Academic/research institutions value the responsiveness towards EU policy objectives and focus on development and effective deployment of technology a little less than other respondents. Business associations, however, found that the future European Partnerships under Horizon Europe should focus a little bit more on the development and effective deployment of technology than other respondents.

Figure 6: To what extent do you think that the future European Partnerships under Horizon Europe need to (N=1363) (non-campaign replies) For all candidate initiatives



1.2.3. Main advantages and disadvantages of Institutionalised European Partnerships

An open question asked respondents to outline the main advantages and disadvantages of participation in an Institutionalised European Partnership (as a partner) under Horizon Europe (1,551 respondents). The advantages mentioned focus on the development of technology, overall collaboration between industry and research institutions, and the long-term commitment. Disadvantages mentioned are mainly administrative burdens. An overview is provided below.

Advantages mentioned: Long term commitment, stability, and visibility in financial, legal, and strategic terms; Participation of wide range of relevant stakeholders in an ecosystem (large/small business, academics, researchers, experts, etc.); Complementarity with other (policy) initiatives at all levels EU, national, regional; Efficient and effective coordination and management; High leverage of (public) funds; Some innovative field require high levels of international coordination/standardisation (at EU/global level); Ability to scale up technology (in terms of TRL) through collaboration; Networking between members; Direct communication with EU and national authorities

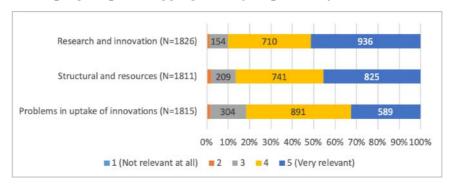
Disadvantages mentioned: Slow processes; System complexity; Continuous openness to new players should be better supported as new participants often bring in new ideas/technologies that are important for innovation; Lower funding percentage compared to regular Horizon Europe projects; Cash contributions; Administrative burdens; Potential for IPR constraints.

1.2.4. Relevance of EU level to address problems in Partnerships' areas

Respondents were asked to rate the relevance of research and innovation efforts at EU level efforts to address specific problems in the area of partnerships. Research and innovation related problems were rated as most relevant across all candidate initiatives, followed by structural and resources problems and problems in the uptake of innovations.

Overall, all three areas were deemed (very) relevant across the partnerships, as more than 80% of respondents found these challenges (very) relevant across the partnerships. Only minor differences were found between stakeholder categories. Research and innovation problems were found slightly more relevant by academic/research institutions, yet slight less relevant by large companies and SMEs. Structural and resource problems were indicated as slightly more relevant by NGOs, but slightly less by academic/research institutions. While both NGOs and public authorities found it slightly more relevant to address problems in uptake of innovation than other respondents. The views of citizens are not significantly different. Respondents that are/were directly involved in a current/preceding partnership find, however, the need to address problems related to the uptake of innovations was slightly more relevant than other respondents.

Figure 9: To what extent do you think this is relevant for research and innovation efforts at EU level to address the following problems in relation to the candidate partnership in question? (non-campaign replies) Aggregation of responses of all candidate initiatives



1.2.5. Horizon Europe mode of intervention to address problems

Respondents were asked to indicate how these challenges could be addressed through Horizon Europe intervention. Just over 50% of all respondents indicated that institutionalised partnerships were the best fitting intervention, with relatively strong differences between stakeholder categories. The use of Institutionalised Partnership was favoured more by business associations and large companies, but less by academic/research institutions and SMEs. While academic/research institutions valued traditional calls more often, this was not the case for business associations, large companies and public authorities. Public authorities indicated a co-programmed intervention more often than other respondents. Citizens indicated slightly less often that institutionalised partnerships were the best fitting intervention. Respondents that are/were directly involved in a current/preceding partnership, selected the institutionalised partnership intervention in far higher numbers (nearly 70%).

Figure 10: In your view, how should the specific challenges described above be addressed through Horizon Europe intervention? (non-campaign replies) For all candidate initiatives



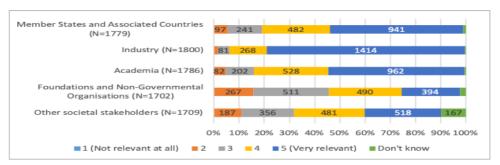
When asked to reflect on their answers, respondents that pointed to the need for using institutionalised partnerships mentioned the long-term commitment of collaboration, a common and ambitious R&I strategy as well as the overall collaboration between industry and research institutions. Others shared positive experiences with other modes of interventions:

- Traditional calls, because of their flexibility and integration of a wide range of actors, as long as the evaluation panels do not deviate from the policy focus. This was mentioned by 94 participants, including companies (25), academics (26) and EU citizens (25).
- Co-funded partnership, as a mechanism to ensure that all participants take the effort seriously, while allowing business partnerships to develop. This approach was deemed suitable based on previous experiences with ERANETs. This was raised by 84 participants, 36 of them academic respondents, 18 companies and 16 EU citizens.
- Co-programmed partnerships, to tackle the need to promote and engage more intensively with the private sector. This was mentioned by 97 participants, most of them companies (34), followed by academics (22), business associations (15) and EU citizens (11).
 - 1.2.6. Relevance of a set of elements and activities to ensure that the proposed European Partnership would meet its objectives

Setting joint long-term agendas

Respondents were asked how relevant it is for the proposed European Partnerships to meet their objectives to have a strong involvement of specific stakeholder groups in setting joint long-term agenda. All respondents see stakeholders from industry as the most relevant, followed by academia and governments. The involvement of foundations and NGOs as well as other societal stakeholders were, however, still found to be (very) relevant by more than 50% of the respondents. Most respondents indicated the stakeholder group they belong to themselves or that represent them as relevant to involve.

Figure 11: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives - Setting joint long-term agenda with strong involvement of: (non-campaign replies) For all candidate initiatives

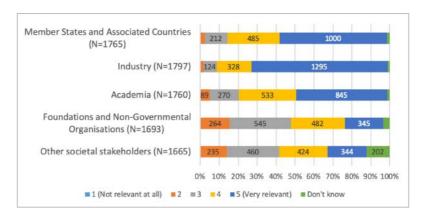


<u>Pooling and leveraging resources through coordination, alignment and integration with stakeholders</u>

Respondents were asked how relevant it is for the proposed European Partnership to meet its objectives to pool and leverage resources (financial, infrastructure, in-kind expertise, etc.) through coordination, alignment and integration with specific groups of stakeholders. Respondents see stakeholders from industry as the most relevant, followed by academia and governments (Member States and Associated Countries). The involvement of foundations and NGOs as well as other societal stakeholders are also still found to be (very) relevant for more

than 50% of the respondents. Similarly as described for the question on setting joint long-term agendas, most stakeholder categories valued their own involvement higher than other respondents – although also here differences between stakeholder categories were minor.

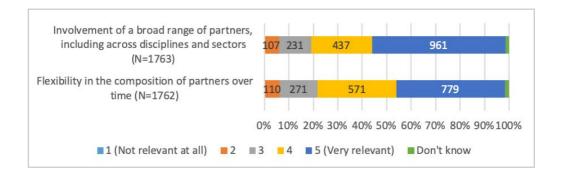
Figure 12: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives – Pooling and leveraging resources (financial, infrastructure, in-kind expertise, etc.) through coordination, alignment and integration with: (non-campaign replies) For all candidate initiatives



Composition of the partnerships

Regarding the composition of the partnership most respondents indicated that for the proposed European Partnership to meet its objectives the composition of partners needs to be flexible over time and that a broad range of partners, including across disciplines and sectors, should be involved (see Figure 13). When comparing stakeholder groups only minor differences were found. Academic/research institutions and public authorities found the involvement of a broad range of partners and flexibility in the composition of partners over time slightly more relevant than other respondents, while large companies found both less relevant. SMEs mainly found the flexibility in the composition of partners over time less relevant than other respondents, while no significant differences were found regarding the involvement of a broad range of partners. Citizens provided a similar response to non-citizens. Respondents that are/were directly involved in a current/preceding partnership, when compared to respondents not involved in a current/preceding partnership, indicated a slightly lower relevance of involving a broad range of partners and flexibility in the composition of partners over time.

Figure 13: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives — Partnership composition (non-campaign replies) Aggregation of responses of all candidate initiatives

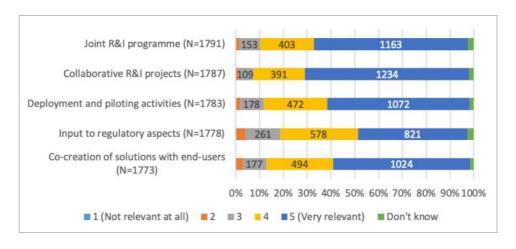


Implementation of activities

Most respondents indicated that implementing activities like a joint R&I programme, collaborative R&I projects, deployment and piloting activities, providing input to regulatory aspects and the co-creation of solutions with end-users are all (very) relevant for the partnerships to be able to meet its objectives. Minor differences were found between the main stakeholder categories, the differences found were in line with their profile. As such, academic/research institutions found joint R&I programme & collaborative R&I projects slightly more relevant and deployment and piloting activities, input to regulatory aspects and co-creation with end-users slightly less relevant than other respondents.

For SMEs an opposite pattern is shown. Large companies, however, also found collaborative R&I projects slightly more relevant than other respondents, as well as input to regulatory aspects. The views of citizens are similar to non-citizens. Respondents that are/were directly involved in a current/preceding partnership, when compared to respondents not involved in a current/preceding partnership, show a slightly higher relevance across all activities.

Figure 14: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives – Implementing the following activities (non-campaign replies) For all candidate initiatives

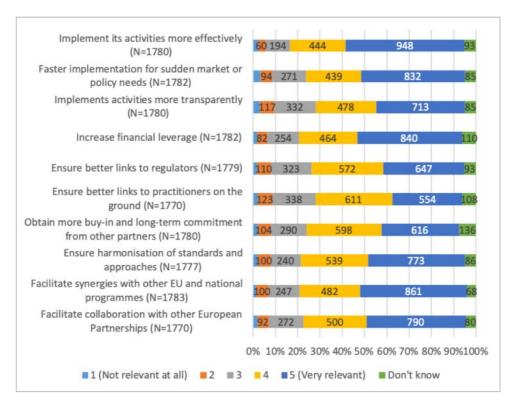


1.2.7. Relevance of setting up a legal structure (funding body) for the candidate European Partnerships to achieve improvements

Respondents were asked to reflect on the relevance of setting up a legal structure (funding body) for achieving a set of improvements, as shown in the below Figure. In general, 70%-80% of respondents found a legal structure (very) relevant for these activities. It was found

most relevant for implementing activities in a more effective way and least relevant for ensuring a better link to practitioners on the ground, however differences are small.

Figure 15: In your view, how relevant is to set up a specific legal structure (funding body) for the candidate European Partnership to achieve the following? (non-campaign replies) Aggregation of responses of all candidate initiatives



When comparing stakeholder categories there are only minor differences. Academic/research institutions indicated a slightly lower relevance for transparency, better links to regulators as well as obtaining the buy-in and long-term commitment of other partners. SMEs also indicated a lower relevance regarding obtaining the buy-in and long-term commitment of other partners. Large companies showed a slightly higher relevance for implementing activities effectively, ensure better links to regulators, obtaining the buy-in and long-term commitment of other partners, synergies with other EU/MS programmes and collaboration with other EU partnerships.

NGOs found it slightly more relevant to implement activities faster for sudden market or policy needs. Public authorities, however, find it slightly less relevant to facilitate collaboration with other European Partnerships than other respondents. The views of citizens show a slightly lower relevance for a legal structure in relation to implementing activities in an effective way. Respondents that are/were directly involved in a current/preceding partnership indicated a higher relevance across all elements presented.

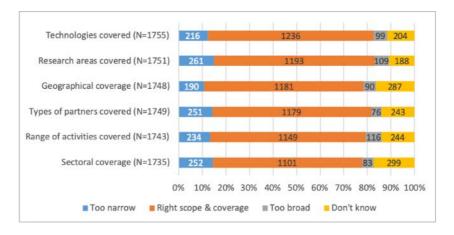
1.2.8. Scope and coverage of the candidate European Partnerships based on their inception impact assessments

Consulted on the scope and coverage for the partnerships, based on their inception impact assessments, the large majority considered that the scope and coverage initially proposed in the inception impact assessments is appropriate. However, about 11-15% of the respondents indicated the scope and coverage to be too narrow. About 11-17% of respondents answered "Don't know". Overall, differences between the main stakeholder categories were found to be

minor. Academic/research institutions indicated slightly more often that the research area was "too narrow" then other respondents. SMEs on the other hand indicated slightly more often that the research area and the geographical coverage were "too broad". NGOs and public authorities, however, found the geographical coverage slightly more often "too narrow".

Large companies found the range of activities slightly more often "too broad" and the sectoral focus slightly more often "too narrow" when compared to other respondents. The views of citizens are the same as for other respondents. Respondents that are/were directly involved in a current/preceding partnership more often indicated that the candidate institutionalised European Partnership have the "right scope & coverage".

Figure 16: What is your view on the scope and coverage proposed for this candidate institutionalised European Partnership, based on its inception impact assessment? (non-campaign replies) Aggregation of responses of all candidate initiatives



1.2.9. Scope for rationalisation and alignment of candidate European Partnerships with other initiatives

When asked whether it would be possible to rationalise a specific candidate European Institutionalised Partnership and its activities, and/or to better link with other comparable initiatives, nearly two thirds of respondents answered "Yes" (1,000, or 62%), while over one third answered "No" (609, or 39%). Nearly no differences were found between stakeholder categories, only large companies and SMEs indicated slightly more often "Yes" in comparison to other respondents. The views of citizens are the same as for other respondents. Respondents that are/were directly involved in a current/preceding partnership, indicated "No" more often, the balance is about 50/50 between "Yes" and "No" for this group.

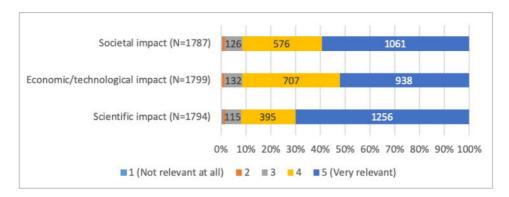
Relevance of European Partnerships to deliver targeted scientific, economic/technological and societal impacts

Finally, respondents were asked to rate the relevance of partnership specific impacts in three main areas: Societal; Economic/technological; and Scientific impacts. All three areas were deemed (very) relevant across the candidate partnerships. Scientific impact was indicated as the most relevant impact, more than 90% of respondents indicated that this as (very) relevant. Only minor difference between stakeholder groups were found.

Academic/research institutions found scientific impacts slightly more relevant, while large companies found economic and technological impacts slightly more relevant than other respondents. NGOs found societal impact slightly more relevant, while SMEs found this

slightly less important. Citizens did not a significantly different view when compared to other respondents. Respondents that are/were directly involved in a current/preceding partnership find all impacts slightly more relevant than other respondents.

Figure 17: In your view, how relevant is it for the candidate European Institutionalised Partnership to deliver on the following impacts? (non-campaign replies) Aggregation of responses of all candidate initiatives



Stakeholder consultation results for this specific initiative

1.2.10. Feedback to the inception impact assessment on candidate initiatives for Institutionalised Partnerships

Following the publication of the inception impact assessment, a feedback phase of three weeks allowed any citizen to provide feedback on the proposed initiatives on the "Have your say" web portal. In total, 350 feedback responses were collected for all initiatives.

For the initiative "Clean Aviation", 34 individual feedback responses were collected, mainly from businesses and business associations, academic/research institutions, non-governmental organisations and public authorities.⁵ These responses included the following topics:

- Overall support in achieving climate neutrality in aviation;
- Requirement for further collaboration between stakeholders to accomplish the innovation and impact required for achieving the objectives;
- Persistence of problems in absence of policy intervention;
- Support of EU action to address different aspects of the problem;
- The need to explore, mature and demonstrate new technologies, whilst maintaining competition;
- The potential of Horizon Europe to have significant scientific impacts, delivering economic, technological and societal benefits, while ensuring competitiveness in Europe;
- Support of the implementation of an institutionalised partnership to successfully deliver economic and technological impacts; and
- The need to cooperate with other initiatives to enable cutting-edge technologies to be incorporated into the aviation sector.

1.2.11. Structured consultation of the Member States on European partnerships

The structured consultation of Member States resulted in 44 possible candidates for European Partnerships identified as part of the first draft Orientations Document towards the Strategic Plan for Horizon Europe (2021-2024), taking into account the areas for possible institutionalised partnerships defined in the Regulation.

The thematic coverage for the Cluster Climate, Energy and Mobility is perceived as rather satisfying, with 62% being somewhat satisfied and 10% very satisfied, while 7% each are not very satisfied or not satisfied at all.

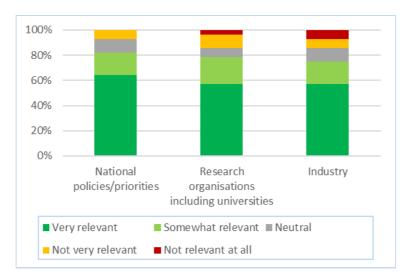
Many delegations comment on the **balance of topics and suggest a stronger focus on the environment and climate**, as well as energy topics. Mobility is considered too prominent and should be rationalised further. The area of transport in particular appears to have a disproportionate number of partnerships, which may result in an under-investment for open calls in this area.

For the initiative "Clean Aviation", the following overall feedback was received from Member States.

Relevance and positioning in a national context

⁵ Feedback on inception impact assessment to be found on https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2019-4972457/feedback_en?p_id=5722372

Overall, the results of the consultation confirm the relevance of the proposed European Partnership on Clean Aviation, with 78% considering it 'very relevant' or 'somewhat relevant' for their national policies and priorities.



Relevance of the European Partnership on Clean Aviation in the national context

On the question of existing national/regional R&I strategies, plans and programmes in support of the proposed partnership on Clean Aviation, 68% (19 out of 28) countries report that they relevant elements in place.

Feedback on aspects that could be reinforced in the proposal for this partnership in order to increase its relevance for national priorities⁶ underline support for the ambition of reducing the environmental footprint of aviation and achieving a carbon neutral aviation. But, there seems to be a divergence of views on the scope of the partnership and the pathway to achieve this goal. For instance, some delegations underline that **the focus should be on real world introduction of new technologies** (i.e. the next generation of commercial aircraft).

Other comments suggest broadening the scope to focus on short-range transport solutions within urban and developing small/ urban aircraft solutions, and thereby ensure bigger involvement of smaller suppliers for the air industry, and to strengthen the impact narrative beyond environmental (e.g. by including safety needs, international competitiveness goals, quicker in-service introduction).

The majority of countries (57%) are undecided regarding their interest in participating.

Feedback on objectives and impacts

Overall, there was a strong agreement (82%) on the use of a partnership approach in addressing challenges related to EU aviation and the development and demonstration of aircraft technologies. There was broad agreement (71%) that a partnership is more effective in achieving the objectives and delivering clear impacts for the EU and its citizens, and to lesser degree that (56%) it would contribute to improving coherence and synergies within the EU R&I landscape.

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⁶ Comments on scope and content have to be assessed in the context of the overall priority setting to ensure coherence.

Member States indicated strong agreement with the proposed objectives for the short, medium and long term (75%) and the expected scientific, economic and societal impacts at European level (75%), with the remaining ones remaining neutral. 71% of countries consider the impacts very or somewhat relevant in the national context. There was overall agreement with the envisaged duration of the proposed partnership with 82% of countries finding it adequate.

In addition, individual comments suggested considering the full life-cycle of the aircraft by including the means of production and disposal, as well as to include under objectives innovative flight design, and redesign of the entire aviation system. In terms of technologies, individual respondents highlighted the importance to cover also aeronautics advance manufacturing technologies and materials, and novel battery technologies.

Views on partners, contributions and implementation

The responses suggested that there is good agreement between countries (57%) on the type and composition of partners. In additional comments, several countries called for opening the proposed partnership to more industries involved in aeronautics, and ensuring broad participation of new and small players. There are some countries expressing support for a model with a core group of partners steering the European Partnership, whilst ensuring appropriate involvement of participants from other sectors.

The majority of countries (71%) found that there was insufficient information to assess the nature of contributions and level of commitment from the partners, notably on the introduction of financial contributions from industry.

The proposed mode of implementation in the form of Article 187 TFEU is supported by 46% of countries, whilst three countries Additional comments suggest considering a coprogrammed model for implementing the priority, to merge the proposed European Partnership on Integrated Air Traffic Management, and to move away from mode-specific implementation in mobility. Moreover, several delegations (notably from smaller countries) highlighted the need to ensure transparency and openness of the partnership, including the use of open competitive calls.

1.2.12. Targeted consultation of stakeholders

Approach to the targeted consultation

The stakeholder interviews underpin:

- The selection and description of the policy options for the intervention;
- The comparative assessment of options: and
- The assessment of the preferred option in terms of its effectiveness and coherence as well as in relation to the key criteria for European Partnerships (openness and transparency, additionality and directionality, Member States' involvement, and systemic approach and flexibility).

Accordingly, the consultation exercise covered a wide range of organisations in identifying stakeholders, the following criteria were applied:

- The need to discuss the role of a future partnership with key European bodies with a central role in the delivery of EU policy objectives, in particular the European Commission and the CS2 JU itself;
- The need to engage with stakeholders located in all Member States with an interest in the future direction of aviation-related R&I;

- The need to obtain views from both founding and associate members of the CS2 JU, including manufacturers and industry who can provide insights into the costs and benefits of a partnership approach to sponsorship and coordination of R&I;
- The importance of understanding key developments in research through dialogue with universities and other research institutions engaged in pre-competitive R&I in the aviation sector;
- The need to engage with organisations who have had little or no involvement in the existing JU but whose role in the delivery of clean aviation and in ensuring that the sector meets European economic, social and environmental targets is important;
- The importance of engaging with pan-European representative organisations who can provide an overview of the perspectives of specific stakeholder groups, including environmental representatives who can bring diverging views from the aeronautics industry;
- The need to obtain data to support an analysis of the costs and benefits of different policy options.

Overview of respondents to the targeted consultation

The table below describes the number of interviews undertaken by stakeholder category, as well as its proportion of the total.

Stakeholder category	Number	Share (%)
Key European bodies	7	14%
Member State transport authorities	3	6%
Industry and representatives	19	38%
Research organisations and universities	14	28%
Airlines and airports representatives	3	6%
Non-aviation technology organisations	2	4%
European environmental organisations	2	4%
TOTAL	50	100%

Representatives from all stakeholder groups were interviewed to ensure that all groups were represented in the impact assessment.

1.2.13. Key results/messages from the targeted consultation

Political and legal context: Emerging challenges in the field

All stakeholders interviewed were supportive of the proposed objective of achieving climate neutrality by 2050. It was felt that that objective, whilst extremely ambitious, was more encompassing of the effects of aviation and also allowed a more long-term solution to be realised in comparison with those presented under CS2. As well as mitigating the impacts of climate change there was also a consensus that striving towards climate neutrality would

support the longevity of the aviation industry in Europe. Many stakeholders noted that the European aviation industry was facing increased competition from Russia and China, and thus investing in new technologies could also reinforce Europe's position in the global market place.

Problem definition: What are the problems?

Many interviewed stakeholders highlighted the effect of long development and innovation cycles and high associated costs as a contributing factor to the growing ecological footprint, and that a transformative change was required to achieve sustainability in the industry, despite the actuals of this being unclear at this stage. There was recognition amongst stakeholders that investments would have to be made in both airframe and propulsion technologies as well as in alternative fuels to achieve the objective at hand. Most stakeholders noted the importance of EU industrial leadership in the field, especially in the face of increasing competition from China and Russia.

What are the problem drivers?

The development of the problem drivers also took the views of stakeholders into account and were fixed as follows:

- Demand for mobility increases faster than the deployment of technological improvements;
- Improving the environmental performance of the aviation industry is complex, lengthy, costly and risky;
- Economic incentives for greener aviation are not strong enough; and
- Ensuring strong competitiveness of the EU aeronautics industry is complex.

There was widespread recognition amongst stakeholders that current levels of traffic growth were not sustainable in the longer term, especially given this growth currently causes a net increase in emissions.

Stakeholders agreed in part that this was due to long and costly development cycles in the industry, especially when compared with non-aviation industries. At the same time there was also recognition that shifting the aviation industry to cleaner fuels is a more complicated and involved process than implementing changes to land-based transport modes. Some parties mentioned the effective duopoly in the commercial aircraft market as a reason for stifled development.

European environmental organisations and some other stakeholder also highlighted that the current state of the market permits this rapid growth and that this could be reduced through the implementation of taxes on fossil fuels. The implementation of taxes and/or market-based measures could have the effect of both reducing air transport demand and increasing the attractiveness of greener technologies as they become more cost effective.

Stakeholders also noted that presence of regulatory barriers in the context of standard and disruptive technology development, although these considerations were felt less strongly than those. It was noted by some stakeholders that the lack of global integrated standards undermines the benefits of R&I activities developed at an EU level, thus affecting European competitiveness.

How will the problem(s) evolve?

There was a strong consensus, in the absence of policy intervention, that it would not be possible to achieve the long-term strategy and level of stakeholder participation required to achieve the goal of climate neutrality by 2050. The vast majority of stakeholders recognised that the aviation industry has to be more environmentally friendly, if it wants to continue growing in Europe.

At the same time many stakeholders noted that the current regulation in place for CS2 was not always as efficient as required with the majority of stakeholder citing that it was too inflexible and should be reviewed for Horizon Europe. This would enable resources to be allocated more effectively throughout the programme dependent on levels of achievement rather than through pre-determined allocations.

Why should the EU act?

There was widespread recognition of the problem of fragmentation and lack of effective coordination of R&I activity underpinning the case for intervention at the European level. Many stakeholders described a lack of coordination in R&I activities at Member State level and national interests considerations rather than a united European approach. Stakeholders participating in the interview programme and providing feedback on the inception impact assessment were also generally fully supportive of EU action to address these and other aspects of the problem.

Objectives: What is to be achieved?

The vast majority agreed that more focus should be placed on bringing about a transformative change towards sustainability through the development and effective deployment of technology, whilst also making significant contributions towards EU global competitiveness.

There was general support to focus higher proportions of the budget on larger commercial aircraft as resulting developments would have larger impacts compared other airborne modes. The overwhelming majority of stakeholders interviewed supported inclusion of EASA in Clean Aviation, albeit in different roles, to assist in addressing product certification at an earlier stage. Ultimately this should assist in allowing new products to enter the market more quickly.

Likely scientific impacts

Virtually all stakeholders agreed that the objectives would be achieved through the development of airframe, propulsion and fuel technology, all of which would further the advancement of science in materials, aerodynamics, combustion and fuels. During the interview process many research organisations and universities mentioned however that more research results from the partnership should be published.

Likely economic/technological impacts

Most stakeholders regarded the resulting economic and technological impacts from the partnership as being very relevant and were supportive of ensuring increased European industrial leadership as well as the creation of more high-skilled jobs in a low-carbon economy.

Several stakeholders highlighted the importance of encouraging participation from a wide group of stakeholders, including those outside the traditional aviation-market, to assist with the development of innovative technologies. There was a general consensus that EASA

should also have oversight of all developments to ensure that the regulation process does not delay the introduction of new technologies.

Likely societal impacts

The vast majority of interviewees maintained the view that safety in the European aviation was of paramount importance, but also explained that developments from new technologies would ensure the longevity and relevance of the European aviation industry, whilst also resulting in reductions of gas and noise emissions, which in turn contribute to improved societal impact.

Comparative assessment of the policy options

Assessment of effectiveness

Scientific impacts

Most of stakeholders interviewed for this study supported the view that the scientific impact under Horizon Europe would be best achieved through and institutionalised partnership. Most stakeholders emphasised the importance of a long-term strategy and greater participation of a wider selection of stakeholders. At the same time some stakeholders were of the opinion that the budget should be focussed on higher TRL projects, i.e. levels 3-6, which would ultimately reduce the scientific impact realised from more innovative technologies. Stakeholders interviews also noted that the ability to have more flexibility with regards to programme composition and funding allocation during the partnership would enable resources to be better focussed on more promising technologies, ultimately improving scientific impact.

Economic/technological impacts

Virtually all interviewees considered that an institutionalised partnership was essential if EU sponsorship of aviation related R&I was to have a transformative economic and technological impact on the sector. In the absence of such a framework it transpired, particularly among many of the larger corporations, that their support for the partnership would be substantially reduced. The reason that was most often quoted by stakeholders for supporting a partnership was financial commitment of the industry in this option.

Societal impacts

The vast majority of stakeholders participating in the interview programme considered an institutionalised partnership to be offer the best range of societal benefits, whilst striving for climate neutrality.

Assessment of Coherence

Internal coherence

Stakeholders participating in the interview programme indicated that a future partnership would be able to cooperate more with other initiatives under Horizon Europe to leverage the benefits of technology that is not specific to the aviation sector.

External coherence

A significant proportion of stakeholders mentioned that links with external organisations, such as regulators or the bodies which define the standards, and the synergies drawn from these relationships, are considered as relevant or very relevant topics which need to be addressed by the type of partnerships which is put forwards and reflected in their legal

structure. The ability of each of the options, as described above, to deliver these impacts will be essential to achieve the expected outcomes.

1.3. Open Public Consultation

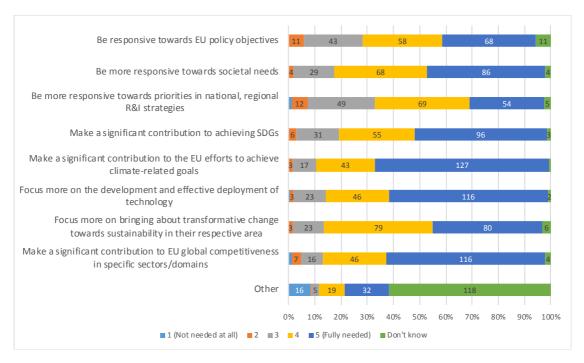
1.3.1. Characteristics of respondents

There are 191 respondents who have answered (part of) the consultation for the Clean Aviation Partnership. Of these respondents, 55 (29%) were citizens. The largest group of respondents were academic and research institutions (57, 30%) closely followed by businesses 55 respondents (28.80). There were five respondents from business associations (3%). The other respondents were eight representatives of public authorities (4%), three non-governmental organisations (1.57%), or seven others (4%). The overwhelming majority, namely 167 (87%) respondents, have been involved in the on-going research and innovation framework programme, of which 140 respondents (73%) were directly involved in a partnership under Horizon 2020 or its predecessor Seventh Framework Programme.

1.3.2. Characteristics of future candidate European Partnerships – as viewed by respondents to the Clean Aviation initiative

The respondents of this partnership were asked to indicate their views of the needs of the future European Partnerships under Horizon Europe. All 191 respondents answered and mainly indicated that many of these needs were required. The most valued option was making a significant contribution to the EU efforts to achieve climate-related goals (127, 66%).

Views of the respondents in regard to the needs of future European Partnerships under Horizon Europe (N=191)



Stakeholders also noted the presence of regulatory barriers in the context of standards and disruptive technology development and that the lack of global integrated standards

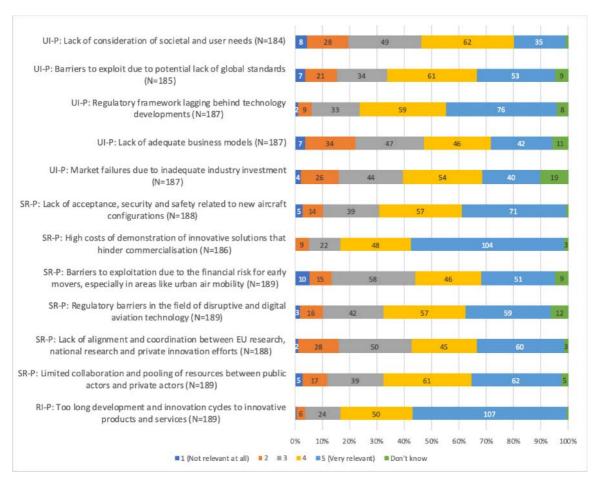
undermines the benefits of R&I activities developed at an EU level, thus affecting European competitiveness.

The Open Public Consultation responses pointed towards several factors that would contribute to a more effective delivery of scientific impacts under an institutionalised partnership.

1.3.3. Relevance of EU level efforts to address problems in relation to Clean Aviation

Respondents were asked to provide their view on the relevancy of research and innovation efforts at EU level to address three types of problems: problems in uptake of Clean Aviation innovations (UI-P), structural and resource problems (SR-P) and research and innovations problems (RI-P).

Views of respondents on relevance of research and innovation efforts at the EU level to address problems in relation to clean aviation



A substantial majority of business organisations, business associations, academic and research institutions, public authorities and EU citizens strongly recognise the impact that long development and innovation cycles and high associated costs of demonstration are having on the growing ecological footprint, whilst all parties also recognise that a future partnership must also make significant contributions to EU global competitiveness.

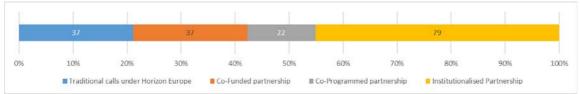
With regard to the uptake in innovation problems, 76 respondents have indicated that the regulatory framework lagging behind technology developments is very relevant (41%). The lack of consideration of societal and users' needs was considered as less relevant for research

and innovation efforts at EU level to address, with only 35 respondents indicating this was very relevant (19%)

1.3.4. Horizon Europe mode of intervention to address problems

Respondents were asked to indicate how these challenges could be addressed through Horizon Europe intervention. As shown in Figure 23, just over 45% of respondents indicated that institutionalised partnerships were the best fitting intervention.

Figure 23: Assessment of Horizon Europe intervention

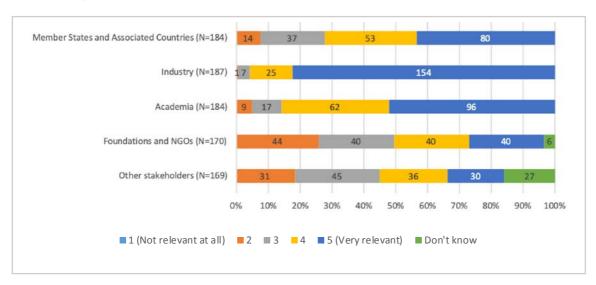


Long-term commitment, demonstration and development of new technology, relevant stakeholders and a common research roadmap were mentioned in support of an institutionalised partnerships

1.3.5. Relevance of a set of elements and activities to ensure that the proposed European Partnership would meet its objectives

Respondents were asked how relevant the involvement of actors is in setting a joint long-term agenda to ensure that the proposed European Partnership would meet its objectives. Most respondents indicated that the involvement of industry, (154 respondents; or 82.%) academia (96; 52.%) and Member States and Associated Countries (80; 43.%) is very relevant.

Views of respondents on relevance of actors in setting joint long-term agenda



The responses supported the view that the initiatives should enable the development of a long-term strategy, underpinned by a roadmap, that mainly draws on inputs from industry and academia, with additional inputs from Member States.

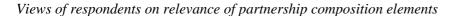
1.3.6. Relevance of elements and activities in pooling and leveraging resources

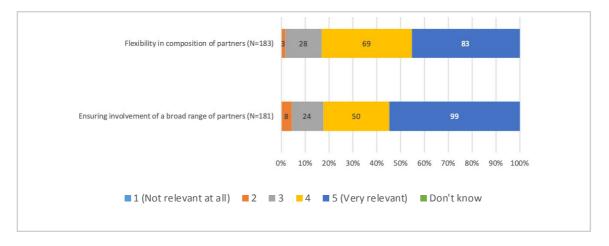
With respect to the relevance of actors in pooling and leveraging resources, such as financial, infrastructure, in-kind expertise etc.), to meet the partnership's objectives, the patterns are very similar. Most of the respondents (13.9; 75%) indicated that industry was very relevant. A large part of respondents also indicated that the involvement of Member States and Associated Countries (96; 52%) and academia (80; 43%) is very relevant.

Among stakeholders responding to the Open Public Consultation there was widespread recognition of the problem of fragmentation and lack of effective coordination of R&I activity, underpinning the case for intervention at the European level.

1.3.7. Relevance of elements and activities for the partnership composition

Respondents were asked about the relevance of Partnership composition, such as flexibility in the composition of partners over time, and involvement of a broad range of partners (including across disciplines and sectors), to reach the partnership's objectives. Ensuring involvement of a broad range of partners has more 'very relevant' answers (99; 55%) than the flexibility in the composition of partners (83; 45%). Overall, 83% of respondents have given flexibility either a score of 4 or 5 (very relevant) which is higher than the 82% who have given the broad range of partners a score of 4 or 5 (very relevant).



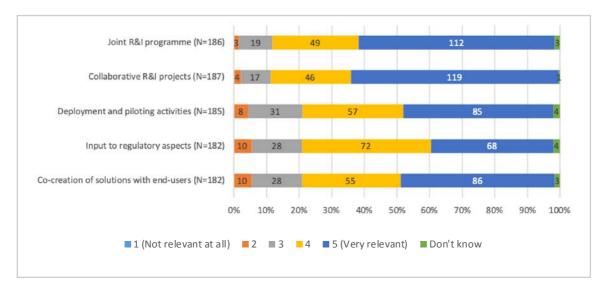


1.3.8. Relevance of implementation of activities

Respondents were asked to provide opinions on relevance of implementation of several activities for meeting objectives of the Clean Aviation. Among activities were listed – joint R&D programme, collaborative R&D projects, deployment and piloting activities, input to regulatory aspects and co-creation of solutions with end-users. Out of 187 respondents, 119 (64%) indicated that collaborative R&I projects are very relevant to ensure that the Partnership would meet its objectives. A Joint R&I programme has also been considered as very relevant by a large number of respondents (112 respondents or 60%). Input to regulatory aspects is seen by the least respondents as very relevant, with 37% (68) of the responses falling in this category, however 72 respondents (40%) have given it a score of 4 on the relevance scale, which indicates that it is still considered as relevant.

No statistical differences were found between the views of citizens and other respondents.

Views of respondents on relevance of implementation of the following activities

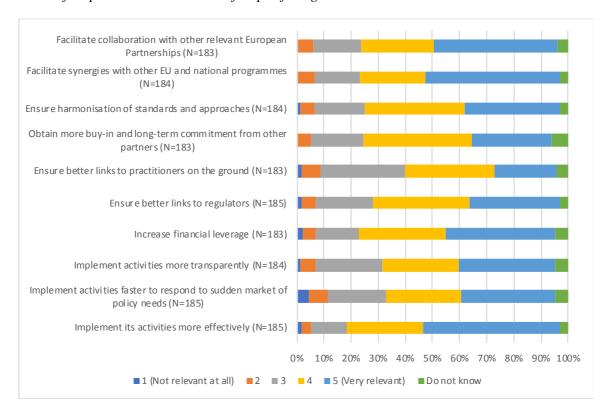


In addition, virtually all stakeholders consulted as part of the Open Public Consultation scored the following impacts with high relevance scores: increased industrial leadership and uptake of new technologies; the acceleration of key technologies through selected demonstrators; as well as the creation of high-skilled jobs in the low-carbon economy.

1.3.9. Relevance of setting up a legal structure (funding body) for the candidate European Partnerships to achieve improvements

Respondents were also asked to assess the relevance of a specific legal structure (funding body) for the candidate European Partnership to achieve several activities. According to Figure 29, the differences across the different categories are not incredibly large. For all but one measure (Implement activities more transparently), over 55% of respondents have selected either 4 or 5 (very relevant) for all the categories. The most respondents indicated that a specific legal structure was 'very relevant' to implement its activities more effectively (93 respondents; 50%).

Views of respondents on relevance of a specific legal structure



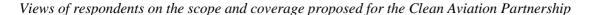
The Open Public Consultation responses provided further support for the view that a well-defined legal structure of the kind underpinning an institutional partnership could be expected to increase the economic and technological impacts of the initiative.

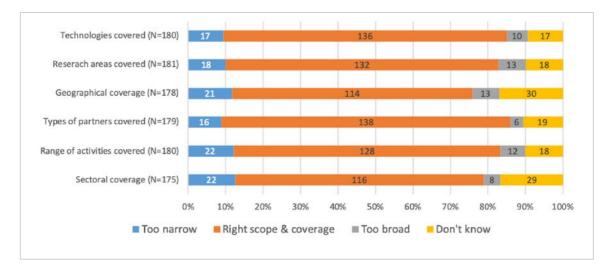
A substantial majority of business organisations of different sizes, business associations, academic institutions, public authorities and EU citizens considered that such a structure was either relevant or very relevant for achieving more effective and faster implementation of the initiative, increased financial leverage, better links to both regulators and practitioners on the ground, harmonised standards, facilitated synergies with EU/national programmes and facilitated collaboration with other partnerships.

1.3.10. Scope and coverage of the candidate European Partnerships based on their inception impact assessments

Respondents were asked to assess the scope and coverage of the Clean Aviation Partnership, based on its inception impact assessment. The clear majority of the respondents indicated that the partnership has the right scope and coverage across all areas, with over 60% of respondents choosing this option. Respondents were the most positive with regard to the type of partners covered (138; 77%), technologies covered (136; 76%) and research areas covered (132; 73%). Across all areas an average of 10% of the respondents indicated that the scope is too narrow.

No statistical differences were found between the views of citizens and other respondents.





Aside from this multiple choice question, the respondents were also asked to provide any comment that they may have on the proposed scope and coverage for this candidate Institutionalised Partnership. This analysis showed the respondents used this question to talk about low carbon fuel, hybrid electric batteries, impact assessment and the geographical coverage of new technology.

1.3.11. Scope for rationalisation and alignment of candidate European Partnerships with other initiatives

The respondents were also asked if it they thought it would be possible to rationalise the candidate European Institutionalised Partnership and its activities, and/or to better link it with other comparable initiatives. 111 respondents (67%) have indicated that they think this is the case.

No statistical differences were found between the views of citizens and other respondents.

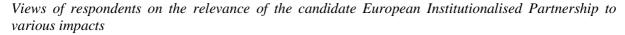
The respondents who answered affirmative, where asked which other comparable initiatives it could be linked with. The results show that respondents think the initiative could be linked with comparable initiatives at national level, other European partnerships, including clean hydrogen and traffic management.

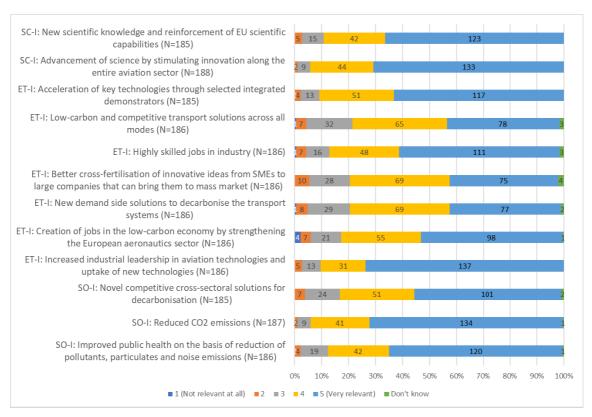
In responding to the Open Public Consultation, a majority of stakeholders stated that the legal structure underpinning an institutionalised partnership was either relevant or very relevant to the facilitation of collaboration with other partnerships under Horizon Europe. Support for this view was particularly strong among business organisations with fewer than 250 people, but it was also held by most SMEs, academic and research institutions, public authorities and EU citizens.

A substantial majority in each of the same stakeholder groups confirmed that there would be scope for rationalising the activities of the candidate partnership for Clean Aviation and to link it with other initiatives under Horizon Europe.

1.3.12. Relevance of European Partnerships to deliver targeted scientific, economic/technological and societal impacts

Respondents were asked to assess the relevance of the candidate European Institutionalised Partnership to deliver on listed impacts. Among societal impacts, a higher number of respondents, namely 134 out of 187 (72%), indicated that the partnership would be 'very relevant' for reducing CO₂ emissions. Figure 34 shows that among presented economic/technological impact categories, over 60% of respondents suggest that the partnership would be 'very relevant' for increasing industrial leadership in aviation technologies and in uptake of new technologies, for providing highly skilled jobs in industry, and for acceleration of key technologies through selected integrated demonstrators.





Respondents were highly in favour of the potential partnership being used for the advancement of science, to develop new scientific knowledge and capabilities. Impacts that received high relevance scores include increased industrial leadership and uptake of new technologies, the acceleration of key technologies through selected demonstrators and the creation of high-skilled jobs in the low-carbon economy. The reduction in CO₂ emissions and the improvement in public health were also considered as relevant impacts.

1.3.13. Summary of campaigns results for this specific initiative

Three campaigns were identified among respondents that provided answers for the current candidate Partnership. The first campaign includes 17 respondents (campaign #2), the second campaign consists of 19 respondents (campaign #6) and the third campaign consists of 13 respondents (campaign #8).

Question category	Summary of responses
Research and innovation problems	With exception of one respondent, all respondents from that campaign indicated that the research and innovation efforts at the EU level are 'very relevant' to address a listed problem.
Structural and resource problems	With exception of one respondent, all respondents gave a high score (5 'very relevant') for the following categories: "limited collaboration and pooling of resources between public actors and private actors" and "high costs of demonstration of innovative solutions that hinder commercialisation". Other answer categories received lower and more mixed scores.
Problems in uptake of digital innovations	Respondents views are very mixed across all answer categories. On average, each category received a score of 3.
Preferred Horizon Europe intervention	Institutionalised Partnership was selected by all respondents. When respondents were asked to explain their choice, all of them used the following quote: "Regular calls under Horizon Europe would not deliver the coordinated approach needed for aviation decarbonisation goals. A coprogrammed partnership would not have the legal status of an EU body to confer stability, legal certainty and clarity to the partnership. An
	Institutionalised Partnership has proven effective in ensuring broad participation & financial and legal commitment of all stakeholders, while delivering on ambitious technology Demonstration targets".
Relevance of actors for setting join long-term agenda	All respondents consider the involvement of industry and academia 'very relevant'. The involvement of Member States and Associated Countries, on average, scored four. Other answer categories have a lower score, on average.
Relevance of actors for pooling and leveraging resources	All respondents consider the involvement of industry and academia 'very relevant'. The involvement of Member States and Associated countries, on average, scored four. Other answer categories have a lower score, on average.
Partnership composition	Both categories are considered 'relevant' (score 4), on average. However, respondents gave a higher rating to the category "involvement of a broad range of partners, including across disciplines and sectors".
Implementation of activities	Most respondents gave the highest score to the following activities: "joint R&I programme" and "collaborative R&I projects". Other categories have more mixed views and a lower score, on average.
Relevance of the legal structure	On average, across all categories, respondents indicated that the legal structure would be 'relevant' (score 4). The lowest score (namely, 2.8) was given to the category "ensure better links to practitioners on the ground".
	Most respondents consider that listed components of the candidate Partnership have right scope and coverage. The greatest number of respondents that indicated that the scope and coverage are too narrow was for the category "technologies covered".
Scope and coverage of the candidate Partnership	Respondents were offered an opportunity to provide comments on the proposed scope and coverage of the Institutionalised Partnership. Several of them included the following quote: "Complexity of aviation products and the global-based market and regulations do require any EU effort in improving environmental impact is pursued in parallel and coherently with many other technologies allowing faster in-service introduction, affordability, modularity and simple upgrade of aeronautical products to answer to huge investments EU competitors are doing in those areas to challenge the EU leadership in the Sector".

Question category	Summary of responses
Rationalisation of the candidate Partnership and linking to other initiatives	Out of 17 respondents, 11 (64.71%) consider that it would be possible to rationalise the candidate Partnership and its activities, and/or to better link it with other comparable initiatives. Respondents were asked to explain their answer. Several of respondents that stated that the Partnership and its activities could be rationalised inserted a following quote: "Distinct partnerships needed as stakeholders and processes are different. Lowering emissions need links and synergies with other partnerships. Despite the aeronautical requirements, several building blocks technologies must be developed in common with other sectors and customized to aviation as of basic performances and potential assessed. Among them battery, materials, digitalization, software, big data, industry 4.0, automation, ATM. PPP-I has the strength and role to set-up such strong links". Almost all respondents that states that it is not possible to rationalise the candidate Partnership and its activities, and/or to better link it with other comparable initiatives inserted the following quote: "The initiatives have distinctly different technology challenges & objectives; while transport partnerships certainly are aligned with one another, the challenges that would be addressed within rail are distinctly."
Societal impact	All respondents consider that the candidate Partnership would be 'very relevant' to "reduce CO ₂ emissions". Other categories received a slightly
	lower score, but are considered 'relevant' by most respondents.
Economic/technological impact	Most respondents consider that the candidate Partnership would be 'very relevant' or 'relevant' for all suggested impacts.
Scientific impact	Both answer categories are considered 'very relevant' by all respondents.

Table 10: Overview of responses of the first campaign (campaign #6) (N=19)

Question category	Summary of responses
Research and innovation problems	All respondents indicated that the research and innovation efforts at the EU level are 'very relevant' to address a listed problem.
Structural and resource problems	Most respondents gave a high score (5 'very relevant') for the following categories: "limited collaboration and pooling of resources between public actors and private actors" and "high costs of demonstration of innovative solutions that hinder commercialisation". Other answer categories received lower and more mixed scores. The lowest score received the category "regulatory barriers in the field of disruptive and digital aviation technology".
Problems in uptake of digital innovations	The majority of respondents gave a low score (between 2 and 3) across all answer categories.
Preferred Horizon Europe intervention	Institutionalised Partnership was selected by all respondents. When respondents were asked to explain their choice, most of them used the following quote: "Timescales, risks, interdependencies between technologies, integration challenge at aircraft design level require strong coordination. JU = critical mass & strengthens EU aero-industry ecosystem, global leadership & competitiveness. Stable, long-term commitment & collaboration from the innovation chain gives visibility, overcomes inhibitors to increased investment in disruptive R&I & market failure risks. Roadmap aligned with public policy & synergies with national programs".
Relevance of actors for setting join long-term agenda	All respondents consider the involvement of industry is 'very relevant'. The involvement of Member States and Associated Countries, as well as, of academia, on average, received a score of 4. Other answer categories have a lower score, on average.

Question category	Summary of responses
Relevance of actors for pooling and leveraging resources	Most respondents consider the involvement of industry and academia is 'very relevant'. Other answer categories have a lower score, on average.
Partnership composition	Both categories are considered 'relevant' (score 4), on average.
Implementation of activities	All respondents gave a high score (either 4 or 5) for all activities, with exception of "co-creation of solutions with end users". This category received a lower score (3.16), on average.
Relevance of the legal structure	Almost all respondents considered that the legal structure would be 'very relevant' for implementation of Partnership activities more effectively, for ensuring better links to regulators, for obtaining more buy-in and long-term commitment from other partners, for facilitating synergies with other EU and national programmes and for facilitating collaboration with other relevant European Partnerships. Other answer categories received a lower score, but all of them are considered 'relevant', on average.
Scope and coverage of the candidate Partnership	With exception of one respondent, all listed components of the candidate Partnership are considered to be of right scope and coverage by all respondents. Respondents were offered an opportunity to provide comments on the proposed scope and coverage of the Institutionalised Partnership. Almost all respondents included the following quote: "The Clean Aviation shall serve the green deal policy objectives and contribute to carbon neutrality. Research areas: the Partnership in itself covers the right research areas, but other issues must be tackled in other partnerships: e.g. batteries for aviation in the Battery partnership. Geographical coverage: excellence shall remain the only criterion for the selection of partners".
Rationalisation of the candidate Partnership and linking to other initiatives	Most respondents (17, 89.47%) consider that it would be possible to rationalise the candidate Partnership and its activities, and/or to better link it with other comparable initiatives. Respondents were asked to explain their answer. Those who stated that it would be possible to rationalise the candidate Partnership included the following quote: "No rationalisation but build bridges with other initiatives. Air transport decarbonisation is too complex for solutions to be developed in CA alone. Upstream cooperation is needed for solutions developed in different sectors to be integrated into aircraft/to ensure new fleets & transport modes can be integrated into ATM. EC should coordinate & support implementation of synergies with ATM, Key Digital Technologies, Batteries, Clean Hydrogen, cybersecurity, AI, 5G, Made in Europe". Those respondents that considered that it would not be possible to rationalise the candidate Partnership and its activities inserted the following statement: "A dedicated, strong and stable partnership embracing all relevant research and innovation actors not only from within the aeronautics sector, but where appropriate newcomers with key technologies from other sectors joining in the effort is a condition precedent for success. This partnership must maximize synergies with other partnerships such as ECSEL, SESAR and FOF to ensure coordination and increase impact".
Societal impact	All respondents consider that all listed categories are 'very relevant'.
Economic/technological impact	With exception of one answer in one category, all respondents consider that the candidate Partnership would be 'very relevant' for all suggested impacts.
Scientific impact	All respondents consider that all listed categories are 'very relevant'.

Annex 3 Who Is Affected And How?

1. PRACTICAL IMPLICATIONS OF THE INITIATIVE

The proposed European Partnership on Clean Aviation focuses on areas where there is a demonstrable advantage in acting at the EU-level due to complexity and size of the industry, the significant societal impact, and scope of the efforts needed for the EU as a whole to achieve the intended objectives.

The partnership will aim at contributing significantly to meeting the intermediate Green Deal targets for 2030 and achieving climate neutrality for aviation by 2050. It will bring together the public, academic and private sectors around this common goal.

The coordinated involvement of the private sector in this context is crucial in designing a strategic research and innovation agenda with concrete targets, milestones and deliverables in line with Green Deal requirements. The private sector, by having a central role in the proposed Clean Aviation Partnership, will benefit from the long-term vision and financial certainty required for its businesses and industries to grow and to strengthen the competitiveness of the EU Clean Aviation value chain (notably SMEs);

The public sector involvement in the partnership needs to ensure adequate policy support to facilitate the market uptake of the partnership's technical achievements.

Academia and the scientific community play a pivotal role in strengthening and integrating scientific capacity to accelerate the development and improvement of advanced clean aviation technologies and create a pipeline of innovative solutions to be picked up by the partnership.

Civil society as a whole is mainly affected by the climate change issue. The proposed Clean Aviation Partnership provides the right framework to accelerate the greening of aviation.

Finally, in an increasingly globalized and interlinked world, governments are required to enhance their role in the fight against climate change. New evidence on this issue should be incorporated in every level of policy-making and in every sector. Governments are responsible for the development, implementation and enforcement of environmental clean energy and climate change regulation.

2. SUMMARY OF COSTS AND BENEFITS

For the preferred option

	I. Overview of Benefits (total for all provisions) – Preferred Option								
Description				Estimation (quantitative or qualitative)	Comments				
	Direct benefits								
Impliment aviation	Green	Deal	for		Considering the world-wide impact of the European aeronautics industry, the benefits would have world-wide effects				

	Reduction of noise around airports	
Increased competitiveness of the European aeronautics industry		The technological advancements would significantly increase the quality of the European aircraft helping to maintain the European leadership position in this sector.
The alignment of European, national and company research efforts on basis of a single Strategic Research and Innovation Agenda would significantly increase the impact of aviation research	Increased effectiveness and efficiency of the European research in aviation.	
Better integrated research and innovation landscape	Early involvement of EASA reducing the long research and innovation life cycle in the sector Establish structural links with other sectors (such as batteries and hydrogen) leading to cross sectoral benefits	
	Increased cooperation between European companies across the whole value chain in aviation.	
	Indirect benefits	

II. Overview of direct and indirect costs – Preferred option								
		Citizens/Consumers Businesses		Admi	nistrations			
		One- off	Recurrent	One-off	Recurrent	One-off	Recurrent	
Management/ Administrative costs	Direct costs				170		170	
	Indirect costs			4	790	4	790	
Personnel costs	Direct costs			0	2200	0	2200	
	Indirect costs			4	105	4	105	
Coordination costs (or transaction costs)					110		110	

Budget expenditure/investment costs		45	45	
, 050 00505				

TOTAL (kEUR)

6,854.96

The table assumes a similar Office size for the Horizon Europe Clean Aviation partnership as the current Horizon 2020 Clean Sky 2 Joint Undertaking. The table is filled on basis of the actual 2019 administrative budgetary payments of the Clean Sky 2 Joint Undertaking. Since according to the Clean Sky 2 basic act 50% of the admin cost are covered by the private members, the figures were equally split between the "Businesses" and "Administrations" columns.

Thus the "business" part represents what's paid by industry and the "administration" part what's paid by EC funds.

In particular please find here after examples of categories of costs included:

Under the personnel category:

- Direct: salaries (interim and SNEs included)
- Indirect (recruitment, training fees, health insurance, transport)

coordination:

- Direct (meetings organisation; SCICOM experts)
- Indirect: N/A

Investment:

- Indirect: audio-visual equipment for meeting rooms, photocopier, laptop

Management:

- Direct: missions, experts reviewers
- Indirect: building, external consultants, communication (publications, events), telecommunications, IT operational expenses (external IT support, connections, systems etc)

REFIT Cost savings table

Not applicable for the proposed Clean Aviation Partnership. The initiative will benefit from the existing organisation/structure (e.g. the Programme Office) already in place for the CS2 JU. There are no additional regulatory costs associated, and no specific simplification measures apply in this case.

Annex 4 Analytical Methods

The methodology for each impact assessment is based on the Commission Better Regulation Guidelines⁷ to evaluate and compare options with regards to their **efficiency**, **effectiveness** and **coherence**. This is complemented by integrating the **conditions and selection criteria** for European Partnerships, as well as requirements for setting up Institutionalised Partnerships.⁸

1. OVERVIEW OF THE METHODOLOGIES EMPLOYED

In terms of **methods and evidence used**, the set of impact assessments for all candidate Institutionalised European Partnerships draw on an external study covering all initiatives in parallel to ensure a high level of coherence and comparability of analysis.⁹

All impact assessment mobilised a mix of qualitative and quantitative data collection and analysis methods. These methods range from desk research and interviews to the analysis of the responses to the Open Consultation, stakeholder analysis and composition/portfolio analysis, bibliometric/patent analysis and social network analysis, and a cost-effectiveness analysis.

The first step in the impact assessment studies consisted in the definition of the context and the problems that the candidate partnerships are expected to solve in the medium term or long run. The main data source in this respect was desk research. This includes grey and academic literature to identify the main challenges in the scientific and technologic fields and in the economic sectors relevant for the candidate partnerships, as well as the review of official documentations on the policy context for each initiative.

In the assessment of the problems to address, the lessons to be learned from past and ongoing partnerships were taken into account, especially from relevant midterm or ex-post evaluations.

The description of the context of the candidate institutionalised European Partnerships required a good understanding of the corresponding research and innovation systems and their outputs already measured. Data on past and ongoing Horizon 2020 projects, including the ones implemented through Partnerships, served as basis for descriptive statistic of the numbers of projects and their respective levels of funding, the type of organisations participating (e.g. universities, RTOs, large companies, SMEs, public administrations, NGOs, etc.) and how the funding was distributed across them. Special attention was given to analysing the participating countries (and groups of countries, such as EU, Associated Countries, EU13 or EU15) and industrial sectors, where relevant. The sectoral analysis required enriching the eCORDA data received from the European Commission services with sector information extracted from ORBIS, using the NACE codification up to level 2. These data enabled the identification of the main and, where possible, emerging actors in the

⁸ A pivotal element of the present analysis is the so-called two-step 'necessity test' for European Partnerships, used to establish: step 1) the need for a partnership approach in the first place, followed by step 2) a justification for the form of Institutionalised Partnership. The necessity test is described in Annex 6. This impact assessment focuses on the second step of the test.

⁷ European Commission (2017), Better Regulation Guidelines (SWD (2017) 350)

⁹ Technopolis Group (2020), Impact Assessment Study for Institutionalised European Partnerships under Horizon Europe

relevant systems, i.e. the organisations, countries and sectors that would need to be involved (further) in a new initiative.

A Social Network Analysis was performed by the contractors using the same data. It consisted in mapping the collaboration between the participants in the projects funded under the ongoing R&I partnerships. This analysis revealed which actors – broken down per type of stakeholders or per industrial sector – collaborate the most often together, and those that are therefore the most central to the relevant research and innovation systems.

The data provided finally served a bibliometric analysis run by the contractor aimed at measuring the outputs (patents and scientific publications) of the currently EU-funded research and innovation projects. A complementary analysis of the Scopus data enabled to determine the position and excellence of the European Union on the international scene, and identify who its main competitors are, and whether the European research and innovation is leading, following or lagging behind.

A cost modelling exercise was performed in order to feed into the efficiency assessments of the partnership options.

The conclusions drawn from the data analysis were confronted to the views of experts and stakeholders collected via three means:

- The comments to the inception impact assessments of the individual candidate institutionalised European Partnerships;
- The open public consultation organised by the European Commission from September to November 2019;
- The interviews (up to 50) conducted by each impact assessment study team conducted between August 2019 and January 2020 (policymakers, business including SMEs and business associations, research institutes and universities, and civil organisations, among others).

The views of stakeholders (and experts) were particularly important for determining the basic functionalities (see further below) that the future partnerships need to demonstrate to achieve their objectives as well as their most anticipated scientific, economic and technological, and societal impacts. The interviews allowed more flexibility to ask the respondents to reflect about the different types of European Partnerships. Furthermore, as a method for targeted consultation, it was used to get insights from the actors that both the study teams and the European Commission deemed the most relevant. For the comparative assessment of impacts, the external contractors confronted the outcomes of the different stakeholder consultation exercises to each other with a view of increasing the validity of their conclusions, in line with the principles of triangulation.

Annex 2 includes also the main outcomes of the stakeholder consultation exercises.

2. METHOD FOR ASSESSING THE EFFECTIVENESS, EFFICIENCY AND COHERENCE OF EACH OPTION - THE USE OF FUNCTIONALITIES

Given the focus of the impact assessment on comparing different forms of implementation, the Better Regulation framework has been adapted to introduce "key functionalities needed"

– so as to link the intended objectives of the candidate European Partnerships and what would be crucial to achieve them *in terms of implementation*. The identification of "key functionalities needed" for each initiative as an additional step in the impact assessment is based on the distinguishing factors between the different options (see Section 2.2.1 in the main body of the impact assessment). In practical terms, each option is assessed on the basis of the degree to which it would allow for the key needed functionalities to be covered, as regards e.g. the type and composition of actors that can be involved ('openness'), the range of activities that can be performed (including additionality and level of integration), the level of directionality and integration of R&I strategies; the possibilities offered for coherence and synergies with other components of Horizon Europe, including other Partnerships (internal coherence), and the coherence with the wider policy environments, including with the relevant regulatory and standardisation framework (external coherence). This approach guides the identification of discarded options. It also allows for a structured comparison of the options as regards their effectiveness, efficiency and coherence, and also against a set of other key selection criteria for European Partnerships (openness, transparency, directionality)¹⁰.

Figure 3 Overview of key functionalities of each form of implementation of European Partnerships

Baseline: Horizon Europe calls	Option 1: Co- programmed	Option 2: Co- funded	Option 3.1: Institutionalised Article 185	Option 3.2: Institutionalised Article 187					
Type and compositi	Type and composition of actors (including openness and roles)								
Partners: N.A., no common set of actors that engage in planning and implementation Priority setting: open to all, part of Horizon Europe strategic planning Participation in R&I activities: fully open in line with standard Horizon Europe rules	Partners: Suitable for all types: private and/or public partners, foundations Priority setting: Driven by partners, open stakeholder consultation, MS in comitology Participation in R&I activities: fully open in line with standard Horizon Europe rules	Partners: core of national funding bodies or governmental research organisations Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: limited, according to national rules of partner countries	Partners: National funding bodies or governmental research organisation Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: fully open in line with standard Horizon Europe rules, but possible derogations	Partners: Suitable for all types: private and/or public partners, foundations Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: fully open in line with standard Horizon Europe rules, but possible derogations					
Type and range of a	ctivities (including add	itionality and level of	integration)						
Activities: Horizon Europe standards that allow broad range of individual actions Additionality: no additional activities and investments outside the funded projects Limitations: No systemic approach beyond individual actions	Activities: Horizon Europe standard actions that allow broad range of individual actions, support to market, regulatory or policy/ societal uptake Additionality: Activities/investment s of partners, national funding Limitations: Limited systemic approach beyond individual	Activities: Broad, according to rules/programmes of participating States, State-aid rules, support to regulatory or policy/ societal uptake Additionality: National funding Limitations: Scale and scope depend on the participating programmes, often	Activities: Horizon Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to systemic approach Additionality: National funding	Activities: Horizon Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to systemic approach (portfolios of projects, scaling up of results, synergies with other funds. Additionality: Activities/investments of partners/ national					

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¹⁰ The criterion on the ex-ante demonstration of partners' long term commitment depends on a series of factors that are unknown at this stage, and thus fall outside the scope of the analysis.

Baseline: Horizon Europe calls	Option 1: Co- programmed	Option 2: Co- funded	Option 3.1: Institutionalised Article 185	Option 3.2: Institutionalised Article 187	
	actions.	smaller in scale		funding	
Directionality					
Priority setting: Strategic Plan and annual work programmes, covering max. 4 years. Limitations: Fully taking into account existing or to be developed SRIA/roadmap	Priority setting: Strategic R&I agenda/ roadmap agreed between partners and COM, covering usually 7 years, including allocation of Union contribution Input to FP annual work programme drafted by partners, finalised by COM (comitology) Objectives and commitments are set in the contractual arrangement.	Priority setting: Strategic R&I agenda/ roadmap agreed between partners and COM, covering usually 7 years, including allocation of Union contribution Annual work programme drafted by partners, approved by COM Objectives and commitments are set in the Grant Agreement.	Priority setting: Strategic R&I agenda/ roadmap agreed between partners and COM, covering usually 7 years, including allocation of Union contribution Annual work programme drafted by partners, approved by COM Objectives and commitments are set in the legal base.	Priority setting: Strategic R&I agenda/ roadmap agreed between partners and COM, covering usually 7 years, including allocation of Union contribution Annual work programme drafted by partners, approved by COM (veto-right in governance) Objectives and commitments are set in the legal base.	
industrial strategies	l (Horizon Europe) and	external (other Union	i programmes, nationai	programmes,	
Internal: Between different parts of the Annual Work programme can be ensured by COM External: Limited for other Union programmes, no synergies with national/regional programmes and	Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Limited synergies with other Union programmes and industrial	Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Synergies with national/regional	Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Synergies with national/regional programmes	Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Synergies with other Union programmes and	
activities	strategies If MS participate, with national/ regional programmes and activities	programmes and activities	and activities	industrial strategies If MS participate, with national/ regional programmes and activities	

In line with the Better Regulation Framework, the assessment of the effectiveness, efficiency and coherence of each option is made in comparison to the baseline. Therefore, for each of the above criteria, the performance of using traditional calls under Horizon Europe is first estimated and scored 0 to serve as a reference point. When relevant, this estimation also includes the costs/benefits of discontinuing existing implementation structures. The policy options are then scored compared to the baseline with a + and – system along a two-point scale, to indicate limited (+ or -) or high (++ or --) additional/lower performance compared to the baseline. When a policy option is scored 0, this means that its impact is expected to be roughly equal to the baseline option.

On the basis of the evidence collected, the intervention logic of each initiative and the key functionalities needed, the impact assessments first evaluate the **effectiveness** of the various policy options to deliver on their objectives. To be in line with the Horizon Europe impact framework, the fulfilment of the specific objectives of the initiative is translated into 'expected impacts' - how success would look like -, differentiating between scientific,

economic/ technological, and societal (including environmental) impacts. Each impact assessment considers to which extent the different policy options provides the 'key functionalities needed' to achieve the intended objectives. The effectiveness assessment does not use a compound score but shows how the options would deliver on the different types of expected impacts. This is done to increase transparency and accuracy in the assessment of options¹¹.

A similar approach is followed to evaluate the coherence of options with the overarching objectives of the EU's R&I policy, and distinguishes between **internal** and **external coherence**. Specifically, internal coherence covers the consistency of the activities that could be implemented with the rest of Horizon Europe, including European Partnerships (any type). External coherence refers to the potential for synergies and/or complementarities (including risks of overlaps/gaps) of the initiative with its external environment, including with other programmes under the MFF 2021-27, but also the framework conditions at European, national or regional level (incl. regulatory aspects, standardisation).

To compare the expected costs and benefits of each option (efficiency), the thematic impact assessments broadly follow a cost-effectiveness approach 12 to establish to which extent the intended objectives can be achieved for a given cost. A preliminary step in this process is to obtain a measure of the expected costs of the policy options, to be used in the thematic assessments. As the options correspond to different implementation modes, relevant cost categories generally include the costs of setting-up and running an initiative. For instance, setup costs includes items such as the preparation of a European Partnership proposal and the preparation of an implementation structure. The running costs include the annual work programme preparation costs. Where a Partnership already exists, discontinuation costs and cost-savings are also taken into account 13. The table below provides an overview of the cost categories used in the impact assessment and a qualitative scoring of their intensity when compared to the baseline option (traditional calls). Providing a monetised value for these average static costs would have been misleading, because of the different features and needs of each candidate initiative. 14 The table shows the overall administrative, operational and coordination costs of the various options. These costs are then put into context in the impact assessments to reflect the expected co-financing rates and the total budget available for each of the policy options, assuming a common Union contribution (cost-efficiency):

- The costs related to the baseline scenario (traditional calls under Horizon Europe) are pre-dominantly the costs of implementing the respective Union contribution via calls and project, managed by the executive agencies (around 4%, efficiency of 96% for the overall investment).
- For a Co-Programmed partnership the costs of preparation and implementation

¹¹ In the thematic impact assessments, scores are justified in a detailed manner to avoid arbitrariness and spurious accuracy. A qualitative or even quantitative explanation is provided of why certain scores were given to specific impacts, and why one option scores better or worse than others.

¹² For further details, see Better Regulation Toolbox # 57.

¹³ Discontinuation costs will bear winding down and social discontinuation costs and vary depending on e.g. the number of full-time-equivalent (FTEs) staff concerned, the type of contract (staff category and duration) and applicable rules on termination (e.g. contracts under Belgian law or other). If buildings are being rented, the cost of rental termination also apply. As rental contracts are normally tied to the expected duration of the current initiatives, these termination costs are likely to be very limited. In parallel, there would also be financial cost-savings related to the closing of the structure, related to operations, staff and coordination costs in particular. This is developed further in the individual efficiency assessments.

¹⁴ A complete presentation of the methodology developed to assess costs as well as the sources used is described in the external study supporting this impact assessment (Technopolis Group, 2020).

increase only marginally compared to the baseline (<1%),¹⁵ but lead to an additional R&I investment of at least the same amount than the Union contribution¹⁶ (efficiency of 98% for the overall investment).

- For a Co-Funded partnership the additional R&I investment by Member States accounts for 2-3 times the Union contribution¹⁷. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the national programmes, can be estimated at 6% of the Union contribution (efficiency of 98% related to the overall investment).¹⁸
- For an Article 185 initiative the additional R&I investment by Member States is equal to the Union contribution¹⁹. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the dedicated implementation structure, can be estimated at 7% of the Union contribution (efficiency of 96% related to the overall investment).
- For an Article 187 initiative the additional R&I investment by partners is equal to the Union contribution²⁰. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the dedicated implementation structure, can be estimated at 9% of the Union contribution (efficiency of 94% related to the overall investment).

Figure 4 - Intensity of additional costs compared with Horizon Europe Calls (for Partners, stakeholders, public and EU)

Cost items	Baseline: traditional calls	Option 1: Coprogrammed	Option 2 Co-funded	Option 3a - Art. 185	Option 3b -Art. 187	
Preparation and set-up costs						
Preparation of a partnership proposal (partners and EC)	0		↑ ↑			
Set-up of a dedicated implementation structure		0		Existing: ↑ New: ↑↑	Existing: ↑↑ New: ↑↑↑	
Preparation of the SRIA/ roadmap	0		$\uparrow \uparrow$			
Ex-ante Impact Assessment for partnership		0			$\uparrow \uparrow \uparrow$	
Preparation of EC proposal and negotiation		0		$\uparrow \uparrow \uparrow$		
Running costs (annual cycle of implementa	tion)					
Annual Work Programme preparation	0		1			
Call and project implementation	0	0 In case of MS contributions: ↑	↑	↑	1	
Cost to applicants	Comparable, unless there are strong arguments of major different oversubscription				fferences in	
Partners costs not covered by the above	0	↑	0	↑	↑	

¹⁵ Specifically, some additional set-up costs linked for example to the creation of a strategic research and innovation agenda (SRIA) and additional running costs linked with the partners role in the creation of the annual work programmes and the Commission's additional supervisory responsibilities. A CPP will have lower overall costs than each of the other types of European Partnership, as it will function with a smaller governance and implementation structure than will be required for a Co-Funded Partnership or an Institutionalised Partnership and – related to this – its calls will be operated through the existing Horizon Europe agencies and RDI infrastructure and systems.

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¹⁶ Minimum contributions from partners equal to the Union contribution.

¹⁷ Based on the default funding rate for programme co-fund actions of 30%, partners contribute with 70% of the total investment.

¹⁸ These costs reflect set-up costs and additional running costs for partners, and the Commission, of the distributed, multi-agency implementation model.

¹⁹ Based on the minimum requirement in the legal basis that partners contribute at least 50% of the budget.

²⁰ Based on the minimum requirement in the legal basis that partners contribute at least 50% of the budget.

Cost items	Baseline: traditional calls	Option 1: Coprogrammed	Option 2 Co-funded	Option 3a - Art. 185	Option 3b -Art. 187
Additional EC costs (e.g. supervision)	0	↑	↑	↑	$\uparrow \uparrow$
Winding down costs					
EC	0				$\uparrow\uparrow\uparrow$
Partners	0	\uparrow	0	\uparrow	↑

Notes: 0: no additional costs, as compared with the baseline; \uparrow : minor additional costs, as compared with the baseline; $\uparrow \uparrow$: medium additional costs, as compared with the baseline; $\uparrow \uparrow \uparrow$: higher costs, as compared with the baseline.

The cost categories estimated for the common model are then used to develop a scorecard analysis and further refine the assessment of options for each of the 12 candidate Institutionalised Partnerships. Specifically, the scores related to the set-up and implementation costs are used in the thematic impact assessments to consider the scale of the expected benefits and thereby allow a simple "value for money" analysis (**cost-effectiveness**). In carrying out the scoring of options, the results of fieldwork, desk research and stakeholder consultation undertaken and taken into account.

3. METHOD FOR IDENTIFYING THE PREFERRED OPTION – THE SCORECARD ANALYSIS

For the **identification of the preferred option**, a scorecard analysis is used to build a hierarchy of the options by individual criterion and overall in order to identify a single preferred policy option or in case of an inconclusive comparison of options, a number of 'retained' options or hybrid. This exercise supports the systematic appraisal of alternative options across multiple types of monetary, non-monetary and qualitative dimensions. It also allows for easy visualisation of the pros and cons of each option. Each option is attributed a score of the adjudged performance against each criterion with the three broad appraisal dimensions of effectiveness, efficiency and coherence.

This scorecard approach also relies on a standard cost model developed for the external study supporting the impact assessment, as illustrated in **Error! Reference source not found.**. Specifically, the scores related to the set-up and implementation costs are used in the thematic impact assessments to consider the scale of the expected benefits and thereby allow a simple "value for money" analysis (**cost-effectiveness**). In carrying out the scoring of options, the results of fieldwork, desk research and stakeholder consultation undertaken and taken into account.

These costs essentially refer to the administrative, operational and coordination costs of the various options. The figure shows how the scoring of costs range from a value of 0, in case an option does not entail any additional costs compared to the baseline (traditional calls), to a score of (-) for options introducing limited additional costs relative to the baseline and a score of (-) when substantial additional costs are expected in comparison with the baseline. Should the costs of a policy option be lower than those of the baseline, (+) and (++) are used.

It is considered that while there is a clear gradation in the overall costs of the policy options, the cost differentials are less marked when one takes into account the expected co-financing rates and the total budget available for each of the policy options, assuming a common Union contribution. From this perspective, there are only one or two percentage points that split the most cost-efficient policy options – the baseline (traditional calls) and the Co-Programmed policy options – and the least cost-efficient – the Institutionalised Partnership option. A score of + is therefore assigned for **cost-efficiency** to the Co-Programmed and Co-Funded options,

a score of zero to the Article 185 option and a score of (-) for the Article 187 Institutionalised Partnership policy option²¹.

Figure 5: Matrix on 'overall costs' and 'adjusted cost scoring'

	Baseline: Horizon Europe calls	Option 1: Co- programmed	Option 2: Co- funded	Option 3a: Institutionalised 185	Option 3b: Institutionalised 187
Administrative, operational and coordination costs	0	(0)	(-)	()	()
Administrative, operational and coordination costs adjusted per expected co-funding (i.e. cost- efficiency)	0	(+)	(+)	(0)	(-)

Notes: Score 0 = same costs as for the baseline; score (-) = limited additional costs compared to baseline; score (-) = substantial additional costs compared to baseline.; score (+) = lower costs compared to baseline

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 $^{^{21}}$ The baseline (traditional calls) is scored 0, as explained above.

Annex 5 Subsidiarity Grid

1. Can the Union act? What is the legal basis and competence of the Unions' intended action?

1.1 Which article(s) of the Treaty are used to support the legislative proposal or policy initiative?

This proposal is based on (1) Article 185 TFEU which stipulates that in implementing the multiannual framework programme, the EU may make provision, in agreement with the Member States concerned, for participation in research and development programmes undertaken by several Member States, including participation in the structures created for the execution of those programmes; and (2) Article 187 TFEU according to which the EU may set up joint undertakings or any other structure necessary for the efficient execution of Union research, technological development and demonstration programmes (both articles are under Title XIX of the TFEU - Research and Technological Development and Space).

The proposal aims to implement Article 8 of the Commission proposal for Horizon Europe the future EU research and innovation (R&I) programme for 2021-2027, according to which, "European Partnerships shall be established for addressing European or global challenges only in cases where they will more effectively achieve objectives of Horizon Europe than the Union alone and when compared to other forms of support of the Framework programme". The Horizon Europe proposal has received the political agreement of the Council and the European Parliament.

1.2 Is the Union competence represented by this Treaty article exclusive, shared or supporting in nature?

Research is a shared competence between the EU and its Member States according to the TFEU. Article 4 (3) specifies that in the areas of research, technological development and space, the European Union can carry out specific activities, including defining and implementing programmes, without prejudice to the Member States' freedom to act in the same areas.

Subsidiarity does not apply for policy areas where the EU has **exclusive** competence as defined in Article 3 TFEU²². It is the specific legal basis which determines whether the proposal falls under the subsidiarity control mechanism. Article 4 TFEU²³ sets out the areas where competence is shared between the Union and the Member States. Article 6 TFEU²⁴ sets out the areas for which the EU has competence only to support the actions of the Member States.

https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12008E004&from=EN

https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12008E006:EN:HTML

2. Subsidiarity Principle: Why should the EU act?

2.1 Does the proposal fulfil the procedural requirements of Protocol No 2^{25} :

- Has there been a wide consultation before proposing the act?
- Is there a detailed statement with qualitative and, where possible, quantitative indicators allowing an appraisal of whether the action can best be achieved at Union level?

This proposal and the accompanying impact assessment were supported by a wide consultation of stakeholders, both during the preparation of the Horizon Europe proposal and - later on, all the candidates for European Partnerships. Member States were consulted via the Shadow Strategic configuration of the Horizon Europe Programme Committee. On candidates for institutionalised Partnerships based on Article 185/187 of the TFEU, an Open Public Consultation (OPC) was held between 11 September and 6 November 2019. Over 1 600 replies were received. In addition, targeted consultation activities were undertaken to prepare the present impact assessment. In particular, for each of the candidate partnerships, an external consultant interviewed a representative sample of stakeholders. The need for EU action as well as its added value were covered in those interviews.

The explanatory memorandum and the impact assessment (horizontal part, Section 3) contain a dedicated section on the principle of subsidiarity, as explained in question 2.2 below.

2.2 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the conformity with the principle of subsidiarity?

The impact assessment accompanying the proposal features a horizontal part on relevant common elements to all the candidate partnerships, including the conformity of the proposed initiative with the principle of subsidiarity (Section 3). Moreover, the individual assessments of each candidate partnership include additional details on subsidiarity, touching in particular on the specificities of a candidate partnership that could not be adequately reflected in the horizontal part of the impact assessment. This will also be reflected in the explanatory memorandum.

2.3 Based on the answers to the questions below, can the objectives of the proposed action be achieved sufficiently by the Member States acting alone (necessity for EU action)?

National action alone cannot achieve the scale, speed and scope of support to R&I needed for the EU to meet its long-term treaty objectives, to deliver on the EU's strategic policy priorities (including the climate and energy goals set out in the Paris Agreement, and the European Green Deal), and to contribute to tackling global challenges and meeting the Sustainable Development Goals (SDGs).

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²⁵ https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12016E/PRO/02&from=EN

(a) Are there significant/appreciable transnational/cross-border aspects to the problems being tackled? Have these been quantified?

The thematic areas covered by the candidate partnerships feature a series of challenges in terms of cross-border/transnational aspects, need to pool resources, need for a critical mass to meet intended policy objectives, need to coordinate different types of actors (e.g. academia, industry, national and regional authorities) across different sectors of the economy and society, which cannot be tackled to the same degree by Member States alone. This is particularly true for the research and innovation (R&I) dimension of the proposed initiative: the importance of a multi-centre and interdisciplinary approach, cross-country data collection and research, and the need to develop and share new knowledge in a timely and coordinated manner to avoid duplication of efforts are key to achieve high quality results and impact. The Interim Evaluation of Horizon 2020 and the impact assessment of Horizon Europe provide extensive qualitative and quantitative evidence on the above points. In addition, Sections 1 and 2 of the individual impact assessments on the candidate partnerships include more detail on the necessity to act at EU-level in specific thematic areas. Finally, it is worth noting that not all Member States have the same capacity or R&I intensity to act on these challenges. As the desired policy objectives can be fully achieved only if the intended benefits are widespread across the Member States, this requires action at the EU-level.

(b) Would national action or the absence of the EU level action conflict with core objectives of the Treaty²⁶ or significantly damage the interests of other Member States?

As per Article 4(3) TFEU, national action does not conflict with core objectives of the Treaty in the area of R&I. The absence of EU level action in this area would however prevent the achievement of core objectives of the Treaty. Indeed, national action alone cannot achieve the scale, speed and scope of support to R&I needed for the EU to meet its long-term Treaty objectives on e.g. competitiveness, to deliver on the EU's strategic policy priorities, and to contribute to tackling global challenges and meet the Sustainable Development Goals (SDGs).

(c) To what extent do Member States have the ability or possibility to enact appropriate measures?

As foreseen by Article 4(3) TFEU, this proposal does not hamper Member States' ability to enact appropriate measures in the field of R&I. However, the scale and complexity of the policy objectives pursued by the present initiative cannot be fully addressed by acting at national level alone.

(d) How does the problem and its causes (e.g. negative externalities, spill-over effects) vary across the national, regional and local levels of the EU?

As described in the horizontal part of the impact assessment accompanying the present proposal, several problems (e.g. on competitiveness, global challenges, demographic change) and their underlying causes affect the EU as a whole rather than individual Member States.

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²⁶ https://europa.eu/european-union/about-eu/eu-in-brief en

Where important differences between Member States are present, these are described in Sections 1 and 2 of the individual impact assessments.

(e) Is the problem widespread across the EU or limited to a few Member States?

The problem of coordinating R&I efforts in the thematic areas covered by the candidate partnerships affects all Member States, albeit to different degrees. However, from a general EU perspective, available evidence shows that the EU as a whole needs to step up efforts and investments in thematic areas that are crucial to tackle present and future policy challenges on several fronts, e.g. ageing population, global technological trends, and climate change to name a few. The way these problems affect the EU and its Member States is described in the horizontal part of the impact assessment and in Sections 1 and 2 of the individual impact assessments.

(f) Are Member States overstretched in achieving the objectives of the planned measure?

As indicated in the horizontal part of the impact assessment and in Sections 1 and 2 of the individual assessments, the sheer scale, speed and scope of the needed support to R&I would overstretch national resources, without guaranteeing the achievement of the intended objectives. Acting at EU-level would achieve greater impact in a more effective and efficient manner.

(g) How do the views/preferred courses of action of national, regional and local authorities differ across the EU?

No specific differences between the views of national, regional and local authorities emerged from the stakeholder consultation.

2.4 Based on the answer to the questions below, can the objectives of the proposed action be better achieved at Union level by reason of scale or effects of that action (EU added value)?

EU funded R&I activities, including those covered by the present proposal, produce demonstrable benefits compared to the corresponding national and regional initiatives, due to the scale, speed and scope achievable by acting at the EU level. In addition, the proposed initiatives should be seen as complementary and reinforcing national and sub-national initiatives in the same area.

(a) Are there clear benefits from EU level action?

Quantitative and qualitative evidence of the benefits of EU level action are available in the interim evaluation of Horizon 2020 and in the impact assessment of Horizon Europe, among others. An analysis of the emerging challenges in each thematic areas, of the EU's competitive positioning, as well as feedback gathered from different types of stakeholders for the present impact assessment indicate that EU level action remains appropriate also for the

present proposal. In addition, the benefits of acting at EU level have been illustrated by the success and the impact achieved by the predecessors to the proposed initiative.

(b) Are there economies of scale? Can the objectives be met more efficiently at EU level (larger benefits per unit cost)? Will the functioning of the internal market be improved?

EU funded R&I activities, including those covered by the present proposal, produce demonstrable benefits compared to the corresponding national and regional initiatives, due to the scale, speed and scope achievable by acting at the EU level. This is the case both in terms of effectiveness in achieving intended policy objectives, but also in terms of efficiency. Positive impact is also visible in terms of competitiveness: recent data on EU funded R&I activities indicate that EU-funded teams grow 11.8% faster and are around 40% more likely to be granted patents or produce patents applications than non-EU funded teams. Efficiency gains are also visible in terms of dissemination of results to users beyond national borders, including SMEs, and citizens. EU funded R&I is more effective in leveraging private investment. Finally, there are clear additionality benefits (i.e. EU R&I funding does not displace or replace national funding), as the EU focuses on projects that are unlikely to be funded at national or regional level. Overall, this is beneficial to the functioning of the internal market in several respects, including human capital reinforcement through mobility and training, the removal of barriers to cross-border activity for economic players including SMEs, easier access to finance and to relevant knowledge and research, and increased competition in the area of R&I.

(c) What are the benefits in replacing different national policies and rules with a more homogenous policy approach?

A homogeneous policy approach in the various thematic areas covered by the present proposal would reduce fragmentation and increase efficiency and effectiveness in meeting the intended policy objectives. Indeed fragmentation, persisting barriers in the internal market and differences in the resources available to Member States are some of the key problems that stand in the way of fully achieving the intended policy objectives and reaching the required critical mass to obtain tangible results. Specific detail on how these issues differ in each thematic area are illustrated in Sections 1 and 2 of the individual impact assessments, so as to reflect the specificities of each case.

(d) Do the benefits of EU-level action outweigh the loss of competence of the Member States and the local and regional authorities (beyond the costs and benefits of acting at national, regional and local levels)?

The proposed initiative does not lead to a loss of competence of the Member States. In fact, the proposed initiative should be seen as complementary and reinforcing national and subnational initiatives in the same area. Previous quantitative and qualitative assessments of Horizon Europe and Horizon 2020 have shown that the proposed EU-level action do not displace national ones and tend to concentrate on initiatives that would not have been funded by the Member States themselves, or would not have reached the same scale and ambition without EU-level intervention, due to their complexity and trans-national nature.

(e) Will there be improved legal clarity for those having to implement the legislation?

Yes. The proposed initiatives will be implemented in line with the Horizon Europe single set of rules for participation; this will ensure increased clarity and legal certainty for end beneficiaries, other stakeholders and programme administrators. It will also reduce the administrative burden for beneficiaries, and for the Commission services. In addition, the accessibility and attractiveness of the broader Horizon Europe programme, in particular for applicants with limited resources, would be sustained.

3. Proportionality: How the EU should act

3.1 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the proportionality of the proposal and a statement allowing appraisal of the compliance of the proposal with the principle of proportionality?

The principle of proportionality underpins the entire analysis of the candidate partnerships. Specifically, the analysis included in the accompanying impact assessment is structured along the following logic: 1. Justification of the use of a partnership approach in a given area (including considerations on additionality, directionality, link with strategic priorities) instead of other forms of intervention available under Horizon Europe; 2. If the partnership approach is deemed appropriate, proportionality considerations guide the assessment of which type of partnership intervention (collaborative calls, co-programmed, co-funded or institutionalised partnership) is most effective in achieving the objectives. This will also be reflected in the explanatory memorandum.

3.2 Based on the answers to the questions below and information available from any impact assessment, the explanatory memorandum or other sources, is the proposed action an appropriate way to achieve the intended objectives?

The proposed initiative only focuses on areas where there is a demonstrable advantage in acting at the EU-level due to the scale, speed and scope of the efforts needed for the EU to meet its long-term Treaty objectives and deliver on its strategic policy priorities and commitments. In addition, the present proposal leaves full freedom to the Member States to pursue their own actions in the policy areas concerned. This will also be reflected in the explanatory memorandum.

(a) Is the initiative limited to those aspects that Member States cannot achieve satisfactorily on their own, and where the Union can do better?

The proposed initiative only focuses on areas where there is a demonstrable advantage in acting at the EU-level due to the scale, speed and scope of the efforts needed for the EU to meet its long-term Treaty objectives and deliver on its strategic policy priorities and commitments.

(b) Is the form of Union action (choice of instrument) justified, as simple as possible, and

coherent with the satisfactory achievement of, and ensuring compliance with the objectives pursued (e.g. choice between regulation, (framework) directive, recommendation, or alternative regulatory methods such as co-legislation, etc.)?

For each of the candidate partnerships, the analysis carried out in the accompanying impact assessment has explored several options for implementation. A comparative assessment of the merits of each option also included an analysis of the simplicity of the intervention, its proportionality and effectiveness in achieving the intended objectives. This is reflected in the fact that a tailored approach has been suggested for each candidate partnership, ranging from looser forms of cooperation to more institutionalised ones, depending on the intended policy objectives, specific challenges, and desired outcome identified in each case.

(c) Does the Union action leave as much scope for national decision as possible while achieving satisfactorily the objectives set? (e.g. is it possible to limit the European action to minimum standards or use a less stringent policy instrument or approach?)

The proposed approach leaves full freedom to the Member States to pursue their own actions in the policy areas covered by the present proposal.

(d) Does the initiative create financial or administrative cost for the Union, national governments, regional or local authorities, economic operators or citizens? Are these costs commensurate with the objective to be achieved?

The proposed initiatives create financial and administrative costs for the Union, national governments and, depending on the chosen mode of implementation, for regional and local authorities. In addition, economic operators and other stakeholders potentially involved in the candidate partnerships will also incur some costs linked to implementation. The financial cost of the proposed initiative is covered under the Horizon Europe programme. Its exact amount is still subject to political decision. As regards the candidate partnerships and the different modes of implementation (co-programmed, co-funded, institutionalised), the relevant costs and benefits are assessed in the individual impact assessments covering each candidate partnership. The additional administrative costs of implementation via partnerships are limited, when compared to the administrative costs of implementation through traditional calls. As indicated by comparable experience with previous initiatives and in feedback provided by a variety of stakeholders, these costs are expected to be fully justified by the benefits expected from the proposed initiative. Where available, additional details on costs are provided in Annex 3 of the impact assessment.

(e) While respecting the Union law, have special circumstances applying in individual Member States been taken into account?

Where relevant, differences between Member States in capacity and stage of advancement of R&I in specific thematic areas have been taken into account in the individual impact assessments.

Annex 6 Additional background information

1. BACKGROUND INFORMATION FOR ALL INITIATIVES

1.1. Selection criteria of European Partnerships

Partnerships based on Article 185 and 187 TFEU shall be implemented only where other parts of the Horizon Europe programme, including other forms of European Partnerships would not achieve the objectives or would not generate the necessary expected impacts, and if justified by a long-term perspective and high degree of integration. At the core of this impact assessment is therefore the need to demonstrate that the impacts generated through a Partnership approach go beyond what could be achieved with traditional calls under the Framework Programme – the Baseline Option. Secondly, it needs to assess if using the Institutionalised form of a Partnership is justified for addressing the priority.

The necessity test for a European Partnership (as set out in the Horizon Europe regulation) has two levels:

- 1. The justification for implementing a priority with a European Partnership to address Horizon Europe and EU priorities. This is linked to demonstrating that a European Partnership can produce added value beyond what can be achieved through other framework programme modalities, notably traditional calls in the work programmes (Option 0 Baseline).
- 2. The justification for the use of the form of Institutionalised Partnership: Once it has been demonstrated that a partnerships approach is justified, co-programmed and/or co-funded forms are considered for addressing the priorities as they are administratively lighter, more agile and easier to set-up (Options 1 and/or 2). As Institutionalised Partnerships require setting up a legal framework and the creation of a dedicated implementation structure, they have to justify higher set-up efforts by demonstrating that it will deliver the expected impacts in a more effective and efficient way, and that a long-term perspective and high degree of integration is required (Option 3).

The outcomes of the 'necessity test' is presented together with the preferred option.

Figure 5 Horizon Europe selection criteria for the European Partnerships

Common selection criteria & principles	Specifications
1. More effective (Union added value) clear	Delivering on global challenges and research and innovation objectives
impacts for the EU and	Securing EU competitiveness
its citizens	Securing sustainability
	Contributing to the strengthening of the European Research and Innovation Area
	Where relevant, contributing to international commitments
2. Coherence and	Within the EU research and innovation landscape
synergies	Coordination and complementarity with Union, local, regional, national and,

Common selection criteria & principles	Specifications
	where relevant, international initiatives or other partnerships and missions
3. Transparency and openness	Identification of priorities and objectives in terms of expected results and impacts
	Involvement of partners and stakeholders from across the entire value chain, from different sectors, backgrounds and disciplines, including international ones when relevant and not interfering with European competitiveness
	Clear modalities for promoting participation of SMEs and for disseminating and exploiting results, notably by SMEs, including through intermediary organisations
4. Additionality	Common strategic vision of the purpose of the European Partnership
and directionality	Approaches to ensure flexibility of implementation and to adjust to changing policy, societal and/or market needs, or scientific advances, to increase policy coherence between regional, national and EU level
	Demonstration of expected qualitative and significant quantitative leverage effects, including a method for the measurement of key performance indicators
	Exit-strategy and measures for phasing-out of the programme
5. Long-term	A minimum share of public and/or private investments
commitment of all the involved parties	In the case of institutionalised European Partnerships, established in accordance with article 185 or 187 TFEU, the financial and/or in-kind, contributions from partners other than the Union, will at least be equal to 50% and may reach up to 75% of the aggregated European Partnership budgetary commitments

1.2. Overview of potential functions for a common back office among Joint Undertakings

Functions	Current situation	Option of common back office	Comments
Organising calls for grant and proposal evaluations	Each JU organises this independently.	A central organisation of evaluation, logistics, contracting evaluators, managing the data of the evaluation results Central database of potential evaluators with domain expertise in thematic areas of partnerships	The evaluations would still need to be supervised by the Scientific staff of the individual Joint Undertakings (consensus meetings of expert evaluators etc)
Human Resources related matters	Each JU has own HR policy and resources Substantial resources spent on recruitment in some JUs Some HR facilities are procured from external contractors Some JUs have a Service Level Agreement with EC for HR	More generic resources and expertise for HR matters More consistency in HR policy Shared HR investment for specialised expertise (IP and legal)	Ensuring consistency with EC HR policies is already in place
Financial	Each JU conducts own financial	Financial management	Simplifies the harmonisation of

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management	contract management;	•	financial management across
	differences between JUs	financial staff	JUs in line with Horizon
	Each JU is audited separately.	Would reduce the	Europe
	Auditing at project level more frequent than in other Horizon 2020 parts and outsourced by JUs thus differences ECA: too many audits on JUs	number of interfaces for audits and simplifies the auditing of the all JUs Harmonisation of project auditing	
	•	1 1 00	
Communication	Each JU has a separate	A common back-office	A considerable share of
(internal and	communication strategies, team	can support activities such as event	communication activity is
external)	and resources		partnership specific (addressing particular target groups,
		organisation, dissemination of results,	particular target groups, synthesising project results)
		setting up website	however there are generic
		communication	communication activities that
		Can help create a more	can be shared
		visible European	Needs to avoid duplication of
		Partnership brand	efforts
Data	Most JUs but not all use e-	Harmonised data	This will need to happen
management on	Corda for project data	management	regardless of the common back
calls, project portfolios, information on project results	Overall IT integration of JUs still difficult	Reduction of IT systems and support that is procured	office but will likely be more smooth if managed centrally
projectionals			

2. COVID-19 IMPACT ON AVIATION AND AVIATION RESEARCH

2.1. The overall impact

At European level, and before the COVID-19 outbreak, Eurocontrol estimated that Europe would see 16.2 million flights in 2040, 53% more than 2017 – that is 1.9% average annual growth per year over the 2017-2040 period, a rather slower growth rate than before 2008.

On 22 March 2020, the European traffic was 75% less than on the same day last year. The current and post COVID-19 economic situation, with the connected national restrictions on travel has led to a situation where the air traffic is about 10% in comparison to before the crisis.

Initial reports suggest that coronavirus could wipe out up to USD 113 billion in worldwide airline revenues in 2020. This figure is nearly half of the five-year (2015-2019) cumulative profit of the airline industry, estimated at USD 269 billion – the best in airline history. The US government approved USD 2 trillion coronavirus stimulus and part of it will go to US airlines and US aircraft manufacturers (i.e. Boeing).

While previous pandemic outbreaks have demonstrated the resilience of the sector to bounce back relatively swiftly²⁷ it must be recognised that the COVID-19 crisis is of unprecedented scale and magnitude. The consequences of the COVID-19 pandemic may be felt strongly and long term in aviation, with reduced customer demand, shrinking civil

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https://www.iata.org/en/iata-repository/publications/economic-reports/what-can-we-learn-from-past-pandemic-episodes/

aircraft fleets and the manufacturing industry confronted with cancelled orders instead of overflowing order-books.

The industrial sector is not expecting a full recovery²⁸ before 2025-30.

2.2. Impact on research and innovation

The impact of coronavirus to the economy will also be felt in EU aviation R&I – hopefully in the short-term only. Many companies, in view of the expected downturn in aviation, have already announced plans to cut costs (including research activities). Research and market decisions, as well as the financial investments, have long-term impact in aviation. Preparation of new transformative R&I programmes entails big financial and technological risk, without any immediate market reward.

The Clean Sky 2 JU and main private partners reported during the Clean Sky 2 Governing Board meeting that COVID-19 and related health measures, already caused a 4-6 months delay across the board for the on-going research projects. It is foreseen that cuts in research and innovation (R&I) investments in the private sector will range from 25% to 40% in 2020.

2.3. Impact on deployment of research results

The COVID-19 crisis may delay the market entry of green technologies.

For airlines to invest in cleaner and more efficient aircrafts, four elements should be timely aligned: healthy air-traffic demand (high regional and/or global growth, limited geopolitical instabilities), high airlines profitability (over a number of years), low interest rates and high fuel prices. At times of high uncertainty (i.e. coronavirus, trade wars, increased geopolitical instabilities), these four parts of the "invest-in-more-efficient-aircrafts" equation do not add up. As a consequence, aircraft makers do not easily decide to invest EUR 20-40 billion for developing a new aircraft.

In addition to the nearly complete halt of air traffic, the recent (March 2020) drop in oil-prices due to coronavirus, exposed airlines to billions of euro of fuel hedging losses. These hundreds of billions of euro in total losses for airlines due to coronavirus will have a direct impact to ongoing as well as future orders and decisions. This makes the investment in aviation R&I even more urgent and more financially demanding. That's why the limited available European R&I investments should have clear ambitious and achievable objectives.

2.4. Research focus on health

Aviation, climate and economy are all inherently global. It contributes to European prosperity, national security, European social integration, single market and provides EU leaders the financial strength to absorb external shocks (e.g. financial crisis, coronavirus) and invest in climate neutrality and social challenges.

However, aviation has contributed as a carrier for the fast spread of the coronavirus from Asia to the rest of the world – as happened in the past with other infectious diseases (avian flu, SARS, etc). The COVID-19 crisis may thus also lead to new research efforts

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²⁸ https://www.icao.int/sustainability/Pages/Economic-Impacts-of-COVID-19.aspx

in turning civil aircraft into early warning systems and for collecting health data on planes. This area can however be tackled by collaborative research outside the initiative.

This priority should follow a holistic approach between technologies and operations, at airport and aircraft levels. While, it will build on existing WHO, ICAO, and ACI recommendations on airport preparedness guidelines for outbreaks of communicable diseases, it will also focus on a clean-sheet technological approach to air cabin quality.

The objectives may include:

- breakthrough cost-effective air-cabin circulation technologies that will increase the effectiveness of cabin air circulation, before being filtered by HEPA filters;
- Real-time measurement technologies for pathogens should be developed, validated and tested in real aircraft environment;
- Air-circulation-altering devices for specific rows in the aircraft cabin, or for the whole aircraft should be explored as mitigating measures, especially for longhaul flights;
- Technologies already used in hospitals, based on ultraviolet light UV-C to sterilize rooms against viruses, including superbugs, should be further exploited and become cost-effective at airport and aircraft levels;

Aircraft technologies can act as early warning systems rather than virus spreading vehicles, if post-examination procedures for pathogens in the cabin and lavatories are in place.

2.5. Risks for the Clean Aviation initiative

When the Clean Sky 1 programme started in 2009, the coverage of its activities included nearly all commercial aviation segments and aircraft types (i.e. large passenger aeroplanes, regional aircraft, business jets, and helicopters). The post-2008 financial crisis shifted the centre of attention from the environmental challenges to include a broader focus on competitiveness issues. The result was, however, a less focused, more diverse and less impactful portfolio of technologies (both geographically and in terms of aircraft segments).

For Clean Aviation, the temptations of short-term solutions in response to the present crisis should be resisted as they risk locking the EU into a fossil fuel economy for the longer term. The limited research and innovation funds should not be subsumed into a wider COVID-19 recovery effort, for which there are better-suited instruments at EU and national level.

It should therefore be clear that the EU funding for the proposed Clean Aviation initiative does not aim to contribute to the aviation sector's cash flow balance nor will be able to resolve their post-COVID-19 financial difficulties, especially given that other EU and national programmes will be available for that purpose.

The added-value of the Clean Aviation initiative lies, rather, in providing a clear strategic direction for the aviation sector and its efforts to decarbonise.

3. ENVIRONMENTAL IMPACT OF AVIATION

3.1. Magnitude and trends

The civil aviation market has grown – as flying became much more accessible with the appearance of low-cost carriers and increased competition – combined with rising levels of disposable income, mobile student populations and few equivalent alternatives from other transport modes. While flying has become accessible to a wide audience, aviation is increasingly criticised for its perceived insufficient ambition to decarbonise.

The total impact of global aviation to greenhouse gasses (GHG) emissions in 2005 was estimated to represent 4.9% of total anthropogenic forcing, where 1.6% was attributed to CO₂ and 3.3% was attributed to non-CO₂ emissions. There are significant contributions, to better understanding the non-CO₂ emissions, which have both positive and negative radiative forcing effects and are not directly proportional to CO₂ emissions.

At European level, in 2016, aviation contributed to 3.6% of the total EU28 greenhouse gas emissions and to 13.4% of the total transport emissions. In absolute numbers, European aviation CO₂ emissions in 2016 were 171 million tonnes, while the total anthropogenic CO₂ emissions the same year were estimated to 36,000 million tonnes (or 0.4%). This shows that European aviation CO₂ emissions is not the only driving force of anthropogenic CO₂ emissions.

In 2017, Europe recorded strong and broad-based traffic growth taking flight totals to a record 10.6 million. In Europe, passenger traffic grew at an average rate of 4.4% per year between 2011 and 2018.

In 2018, over 1.2 billion passengers flew to and from over 500 airports in Europe. More than 3,500 intra-EU routes now provide access to both large cities as well as peripheral regions.

It is expected that flights in Europe will, post COVID-19, increase by 1.9% per year²⁹ to 2040, while at the global level flights may increase at 3.7% per annum.

Efficiency improvements are constantly being incorporated into newer generation aircraft, reducing fuel consumption and in turn reducing CO₂ and ufPM emissions, while improvements are also incorporated to reduce NOx and noise but these are insufficient to counter the growing air traffic.

3.2. Scientific

Aviation has significant impacts on the environment: it contributes to climate change through the emission of carbon dioxide (CO₂) and nitrogen oxides (NO_X), but also through the emission of contrails, sulphur dioxide (SO₂), carbon monoxide (CO), hydrocarbons, ultra-fine particulate matter (ufPM) and soot. All are a product of kerosene (fossil fuel) combustion.

The impact of aviation on the environment and climate is driven by long-term effects (several years to hundreds of years) from CO₂ emissions and shorter-term ones (several hours, days, weeks or years), also from non-CO₂ emissions.

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²⁹ https://www.eurocontrol.int/sites/default/files/2019-07/challenges-of-growth-2018-annex1_0.pdf

The CO₂ effects are well understood and emissions are proportional to the fuel used in aviation. The non-CO₂ (mainly water, nitrogen oxides, sulphur oxides, soot, contrails and contrail cirrus) effects emissions relating to aviation are still poorly understood and their effect on climate change largely unknown.

Additional key environmental issues are the generation of noise and particulate matter, specifically in the vicinity of airports where it has impacts on the population living close to the airport area as well as under the main flight paths for take offs and landings. More than 4,2 million people are exposed to harmful noise levels leading to cardiovascular diseases and stress, and more than 1 million people have their sleep disturbed.

The total impact of global aviation on greenhouse gas emissions in 2005 (the most recent complete and reliable available measurements) was estimated to represent 4.9% of the total, where 1.6% was attributed to CO₂ and 3.3% was attributed to non-CO₂ emissions.

There are no quick-fix solutions, but there are aviation research and innovations paths leading towards climate neutrality by 2050. Evolutionary and disruptive technological research, together with accelerated deployment of sustainable aviation fuels (biofuels and e-fuels) and operational optimisations (mostly related to air traffic management) are the key directions for aviation research to be supported under Horizon Europe.

3.3. Mitigation Measures

Airlines' operating business models are still driven by the cost per seat. Environmental issues have not been the central focus or have been considered as a side effect/objective: for instance, the reduction in CO₂ emissions over the years has been driven by the incentive to reduce fuel costs (circa 25-35% of total operating costs) rather than reducing the environmental footprint. The full environmental costs of aviation are born by society rather than airlines and manufacturers, leading to sub-optimal investment in, and deployment of, new environmentally-friendly technologies.

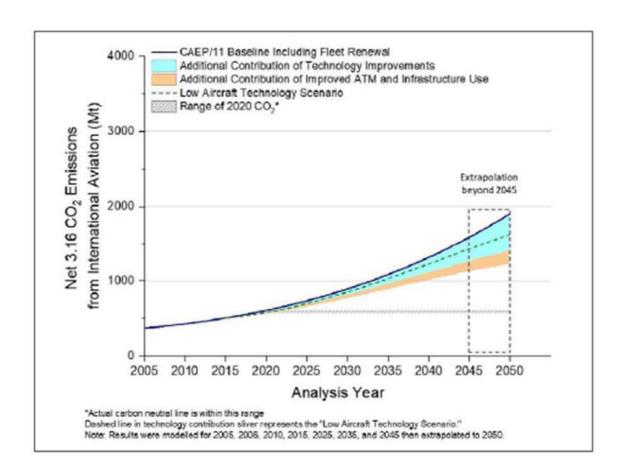
The ICAO environmental report³⁰ (2019), based on extensive analysis and data, suggests that even under the most optimistic scenario, the projected long-term fuel efficiency of 1.37% per annum falls short of ICAO's aspirational goal of 2% per annum.

ICAO, in the 39th Assembly, recognised that despite the environmental benefits from aircraft technologies, operational improvements and sustainable alternative fuels, sufficient CO₂ emissions reductions to address the growth of international air traffic, will not be achieved in time (CNG2020). ICAO CORSIA - a global market-based measure was therefore designed to offset international aviation CO₂ emissions in order to stabilize the levels of such emissions. Provided that growth in passenger numbers and reductions in fuel consumptions continue at current rates, the overall effect is that emissions from the air transport industry will still continue to rise.

Figure Below: CO₂ Emissions from International Aviation - 2005 to 2050, (ICAO, 2019)

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³⁰https://www.icao.int/environmental-protection/pages/envrep2019.aspx



The response of the aviation sector needs to go far beyond the incremental efficiency improvements that are constantly being incorporated into newer aircraft generations, reducing fuel consumption and in turn reducing emissions but at a much smaller rate (+/-1.5% annually) than traffic growth, thus leading to a growing environmental impact from aviation.

In doing that, it would continue to fulfil its economic and societal role as the safest mode of transport³¹ & ³² and by far the most convenient one for medium and long-range distances.

POSITIONING OF THE EUROPEAN INDUSTRY IN AVIATION

Europe has become the global leader in the supply of large civil aircraft, as one half of the Airbus-Boeing duopoly. Two main European OEMs, Rolls Royce (UK/D) and Safran (F), hold almost 40% of the world market for engines, and Safran and GE (USA) run a very successful joint venture (CFM) that dominates the global market for large civil aircraft engines. Europe is by far the international leader in the supply of civilian helicopters. Europe also plays a significant role in the market for maintenance, repair and overhaul of aircraft.

³¹ The number of accidents in the EU-28 in 2013 for three transport modes were: 16 aviation accidents, 1 982 railway accidents and 144 inland water transportation accidents (data for Bulgaria, the Czech Republic, Croatia, Hungary, Austria, Poland, Romania and Slovakia). The total number of fatalities amounts to eight from aeroplane accidents (fatalities from accidents on national territory regardless of the nationality of the aircraft operator); 1 130 from railway accidents, and 16 932 from road accidents (data for 20 out of the 28 EU Member States).

³² https://ec.europa.eu/eurostat/statistics-explained/index.php/Archive:Transport accident statistics

Four of the top ten aeronautical manufacturing companies by revenue are European; the others are US-based. The European industry also plays a key role in civil helicopters (Airbus Helicopters and Leonardo), engine manufacturing (Rolls-Royce-ITP, Safran, GE-AVIO, and MTU), and manufacturing, repairs and overhaul (MRO).

Through its direct, indirect and induced economic impact, aviation represents 3.3% of all employment and spurs 4.1% of the EU GDP in 2016³³.





Source: aviationbenefits.org/around-the-world/europe

The industry provides a positive contribution to the EU trade balance (EUR 96 billion in EU exports). In total, aviation supports 12.2 million European jobs and EUR 730 billion in European economic activity.

Compared to its key competitor, the USA, the European aeronautics industry has fewer companies of sufficient size and capability for large risk sharing projects, and crucially does not benefit to the same extent as US companies (such as Boeing, Lockheed Martin, and GE) from government-funded military and space research spill-over effects. R&D investments in the USA (from industry and government) are generally higher than in Europe³⁴. Lastly, the European industry is more exposed to currency exchange risks with sales and revenues expressed in USD (the preferred currency of the global aviation market) and costs made in Europe calculated in EUR³⁵.

Other aircraft manufacturers – such as UAC in Russia and COMAC in China – may in the future weaken the EU and US positions with very price competitive products, backed up by their large and expanding home markets³⁶. For example, in 2018 it was reported that the COMAC C919 aircraft, an A320neo and Boeing 737 competitor, has over 1,000 domestic

³³ https://aviationbenefits.org/around-the-world/europe

³⁴ https://ec.europa.eu/eurostat/statistics-explained/index.php/R %26 D expenditure

³⁵ https://bizfluent.com/facts-6818189-exchange-rate-affects-business.html

³⁶ https://www.rand.org/content/dam/rand/pubs/research_reports/RR200/RR245/RAND_RR245.pdf

orders³⁷ and is due to enter service in 2021. The aircraft's reported list price is USD 50 million, i.e. about half the cost of the equivalent Airbus and Boeing aircraft³⁸. Russia and China are also collaborating on a new wide-body aircraft, the CR929, to be ready for 2027. Additionally, aeronautics companies are setting up engineering offices in India to access cheaper labour and be active in promising markets. MRO companies are moving to the Middle East, pulled by the growing airlines in that region. Potential risks also arise from off shoring, including possible forced technology or intellectual property transfers. Airbus has final assembly lines in China and the USA and Rolls-Royce in Singapore³⁹.

Table 2: International competitiveness of the global aeronautics industry

1	2 Large Civil aircraft	3 Re gional aircraft	4 Business /general aviation	5 Heli copter	6 En gines	7 M RO
8 Marke t Situation	9 Airbus/ Boeing Duopoly	10 All dominant players linked with Airbus/Boein g	11 Dominan ce of North American players	12 Dom inant European and US players	13 Ro Ils Royce and Safran (CFM) are significant players	14 M any independe nt and dependent players
15 Develo pment	16 China and Russia entering the market	17 Chi na, Russia and Japan entering the market	18	19	20	21
22 Europ ean Aeronautics Industry	23 Airbus has grown to compete for the market 50:50 with Boeing	bus purchased the C-Series from Bombardier. Airbus own a stake in ATR	25 Dassault and some smaller players	26 Civil market leader and technology leader	27 Ro Ils-Royce and Safran (through CFM) are major world players	28 S trong European position

Source: Competitiveness of the EU Aerospace Industry, Ecorys, 2009, updated by Steer to reflect market developments since (Technopolis, Steer, 2020).

The European aviation industry appears to be in a comfortable position. However, the EU aviation value chain is exposed to increasing international competition (from traditional competitors such as the USA, and from emerging countries like China and Russia) in a complex and global political environment.

In the US, the civil aeronautical industry benefits strongly from defence related research and development activities. The US Department of Defense 40,41 and China 42 are investing huge

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³⁷ https://www.bizjournals.com/seattle/news/2018/03/21/chinas-rival-to-boeing-737-nowhas-nearly-1-000.html

³⁸ It must be underlined though that the entry into market of this aircraft has been delayed several times

https://www.rolls-royce.com/country-sites/sea/our-locations/singapore.aspx https://www.sbir.gov/content/high-temperature-materials-and-sensors-propulsion-systems

⁴¹ https://www.nap.edu/read/10056/chapter/6

⁴² https://www.sciencedirect.com/science/article/pii/S100093611730273X

sums on research and innovation for all the underlying technologies relevant to aircraft engines. The US Department of Defense R&D budget in Y2020 amounts to a total of USD 92.3 billion⁴³.

In China, the government has identified the development of a national civil aeronautics industry as a key priority and sponsored⁴⁴ domestic aircraft purchases by Chinese airlines. Over the last decade the patents filled by China have multiplied tenfold. A recent analysis, performed by the UK's Aerospace Technology Institute, on global aerospace patents shows that China's patent quota system, employed since 1999, encouraged vast volumes of patent applications that seem largely superficial as few are converted to publications. Western aerospace companies are increasing their patent⁴⁵ activity in China, recognising the significance of the aviation market there but also the competitive threat posed by a rapidly maturing homegrown industry.

Aircraft engines is also one of the very few advanced technologies that Asian industries have not yet succeeded in developing – therefore relying on European and American engines. Made in China 2025⁴⁶ pays particular attention to that. Because of the synergies between civil and defence, the level-playing field is difficult to achieve.

5. AERONAUTICAL SCIENTIFIC AND TECHNOLOGICAL RESEARCH IN EUROPE

5.1. Scientific and technological achievements

Aeronautical scientific and technological research in Europe, with a transformational impact to air transport and humanity, started more than 100 years ago⁴⁷. Over a century, European aviation research led to scientific and technological advancements in new innovative aerostructures, engines and equipment. Today these innovations are found not only in aircrafts from European integrators (i.e. Airbus, Leonardo, Dassault, Saab). During the last three years, Boeing alone purchased European systems and equipment valued over EUR 25 billion from European suppliers providing employment to 190,000 Europeans⁴⁸.

The impact of **2,073 collaborative European aviation research projects** from FP2 to H2020 and the **demonstration and integration activities in two Clean Sky programmes** (under FP7 and H2020) has been particularly significant. Representative examples that have pronounced impact on clean aviation technologies include:

→ Lightweight composite aerostructures R&I has peaked in FP7, where European research funding (330 ME total cost) enabled the development of new materials, new manufacturing technologies and new integration methodologies. Research efforts in FP6-ALCAS⁴⁹, FP7-MAAXIMUS⁵⁰, FP7-SARISTU⁵¹ and FP7-LOCOMACHS⁵² matured

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⁴³https://www.aia-aerospace.org/report/2019-facts-figures/

^{44 &}lt;u>https://ustr.gov/sites/default/files/Section%20301%20FINAL.PDF</u> Page 33 onwards

⁴⁵ In aerospace, where long term technology maturity is often the case, patent filing numbers in isolation may not be conclusive and may not give a useful insight into technology strategies.

⁴⁶ https://www.merics.org/sites/default/files/2017-09/MPOC No.2 MadeinChina2025.pdf

The Rijks-Studiendienst voor de Luchtvaart, the predecessor of today's Royal National Aerospace Laboratory (NLR) in the Netherlands, was established in 1919 in the north part of Amsterdam.

⁴⁸ Communication from Boeing to Commissioner Gabriel – dated 02 December 2019.

⁴⁹ https://cordis.europa.eu/project/id/516092

⁵⁰ https://cordis.europa.eu/project/id/213371

composite and adaptive wing technologies. These technologies were developed further by the private industries and finally integrated in the Bombardier C Series, in Belfast⁵³ (now the Airbus A220) and in the Airbus A350 (fuselage and wing).

Research in H2020 further developed innovative concepts and will be demonstrated in the Adapted Wing Integrated Demonstrator Flying test bed⁵⁴ under Clean Sky 2 in 2022. These lightweight composite wings, fuselage and nacelles account for 53% of the empty weight for the A350⁵⁵ and contributed to 25% greater fuel efficiency⁵⁶ than the competition. Such performance gains are attributed to focused R&I activities over three decades⁵⁷ and contribute to environmental gains and European supply chain leadership.

→ Ultra-efficient engines contribute more than anything else in the reduction of the environmental footprint of aviation. They also embed classified (confidential) and patented innovations. In addition, they often share technologies (e.g. internal aerodynamics, high temperature materials and thermal barrier coatings) between civil, defence and even space applications.

The European engine manufacturers (i.e. Safran, Rolls-Royce, MTU and GE-AVIO) together with their American counterparts (GE and P&W) have established joint ventures and deliver propulsion units for all market segments.

Aircraft engines is also one of the very few advanced technologies that Asian industries have not yet succeeded in developing – therefore relying on European and American engines. Made in China 2025⁵⁸ pays particular attention to that. Because of the synergies between civil and defence, the level-playing field is difficult to achieve. The US Department of Defense⁵⁹ &60 and China⁶¹ are investing huge sums on research and innovation for all the underlying technologies relevant to aircraft engines. The US Department of Defense R&D budget in Y2020 amounts to a total of \$92.3 billion⁶².

Research efforts in FP7-ENOVAL⁶³, FP7-LEMCOTEC⁶⁴, FP7-E-BREAK⁶⁵, FP7-NEWAC and an array of smaller low TRL R&I collaborative projects matured further low and high

⁵¹ https://cordis.europa.eu/project/id/284562

⁵² https://cordis.europa.eu/project/id/314003

^{53 &}lt;a href="https://www.materialstoday.com/composite-applications/features/bombardier-throws-down-the-gauntlet-with-cseries/">https://www.materialstoday.com/composite-applications/features/bombardier-throws-down-the-gauntlet-with-cseries/

⁵⁴https://www.cleansky.eu/sites/default/files/inline-files/CS-GB-2019-11-21%20Decision%20CS2DP%20adoption 0.pdf

⁵⁵ https://www.flightglobal.com/airbus-urged-to-rethink-composite-material-choice-for-a350-xwb/83560.article

https://www.airbus.com/content/dam/corporate-topics/publications/backgrounders/Backgrounder-Airbus-Commercial-Aircraft-A350-XWB-Facts-and-Figures-EN.pdf

⁵⁷ While European R&I on composite aerostructures started in the early 80s, the A350 programme started in 2007 with entry into service in 2013.

⁵⁸ https://www.merics.org/sites/default/files/2017-09/MPOC No.2 MadeinChina2025.pdf

⁵⁹ https://www.sbir.gov/content/high-temperature-materials-and-sensors-propulsion-systems

⁶⁰ https://www.nap.edu/read/10056/chapter/6

⁶¹ https://www.sciencedirect.com/science/article/pii/S100093611730273X

⁶²https://www.aia-aerospace.org/report/2019-facts-figures/

⁶³ https://cordis.europa.eu/project/id/604999

⁶⁴ https://cordis.europa.eu/project/id/283216

pressure compressor and turbine parts as well as their combustion cycles towards ultra-high by-pass ratio propulsion systems.

These technologies were developed further by the engine manufacturers and integrated in engines that propel single-aisle and long-haul aircrafts (from Airbus and Boeing). In addition to the collaborative research within FP6, FP7 and H2020, Clean Sky 2 is contributing to the validation and demonstration of Very High Bypass Ratio Large turbofan (TRL 6 in 2023), Ultrahigh Propulsive Efficiency (TRL 5+ by mid-2022) and Advanced Geared Engine Configuration (TRL 5 by 2023).

Examples demonstrating the contribution of the EU-funded research to clean aircraft engines have been documented in the open access deliverables (e.g. FP7-NEWAC⁶⁶, and E-BREAK⁶⁷, Clean Sky⁶⁸) among other scientific publications. The success of the A320neo (New Engine Option) and possibly of B737max (after recertification) is/will attributed mainly to new engines from GE-SAFRAN and P&W-MTU.

Finally, the impact of aircraft engines R&I to the environmental footprint of aviation can be easily quantified. In 2019, civil aviation consumed 380 billion litres of jet fuel. Aircraft engines contribute on the average around 1% of jet fuel efficiency per annum (i.e. 3.8 billion litres of aviation fuel saved per annum, because of new engine technologies), which is 12 million tonnes of CO₂ less in the atmosphere.

By increasing the research and development in those technologies and accelerating the development of even cleaner gas turbines, combined with other breakthrough technologies (e.g. hybrid-electric), the European Commission aims to have **250-300 million tonnes less CO₂ over the next 10 years, from aircraft engines alone**. There are no other technologies in the world today (apart from renewable energy) that can achieve such impressive CO₂ reductions. The renewal of the aircraft fleet can also contribute to even more accelerated impact. It is estimated⁶⁹ that yearly emissions equivalent to CO₂ released by 3 million cars could be avoided if half of the global aircraft fleet was equipped with new efficient engines.

5.2. patents and scientific publications

In terms of aviation R&I performance and in particular on **patents and scientific publications**, Europe shows strong leadership, especially in peer-reviewed publications and references with high impact factor. Out of the 50 journals on aerospace engineering⁷⁰ worldwide, 26 are based in Europe, including a clear lead in the total cites over the last three years. The EU-based journal, Progress in Aerospace Sciences, has one of the highest impact factors (9.27), while the EU-based journal Aerospace Science and Technology has one of the highest citation indexes over the last three years (4,113).

⁶⁵ https://cordis.europa.eu/project/id/314366/reporting

⁶⁶https://trimis.ec.europa.eu/sites/default/files/project/documents/20121029_130736_70767_Publishable_Final_ Activity_Report.pdf

⁶⁷ https://cordis.europa.eu/docs/results/314/314366/final1-e-break-project-summary-handbook.pdf

⁶⁸ https://www.cleansky.eu/the-uhbr-engine-flight-testing-programme-gathers-momentum

⁶⁹ https://www.eco-business.com/news/how-the-aviation-industry-is-lowering-its-carbon-footprint/

⁷⁰ https://www.scimagojr.com/journalrank.php?category=2202&area=2200&type=all

In terms of patents, leading European aeronautics companies hold an extensive portfolio (Airbus⁷¹: 37,000, Safran⁷²: 38,000, Thales⁷³: 15,000). In the EU-funded aviation R&I a considerable number of patents is requested – often after the end of the project (e.g in FP7-SARISTU and FP7-AFLONEXT). In the first Clean Sky programme⁷⁴ a significant number of requests for patent (196) were registered and most of them (166) have been granted.

However, over the last decade the patents filled by China have multiplied tenfold. A recent analysis, performed by the UK's Aerospace Technology Institute, on global aerospace patents⁷⁵ shows that China's patent quota system, employed since 1999, encouraged vast volumes of patent applications that seem largely superficial as few are converted to publications.

Western aerospace companies are increasing their patent activity in China, recognising the significance of the aviation market there but also the competitive threat posed by a rapidly maturing indigenous industry. In aerospace, where long term technology maturity is often the case, patent filing numbers in isolation may not be conclusive and may not give a useful insight into technology strategies.

Finally, additional anecdotal evidence on the relative scientific and technological performance of Europe in aviation and related clean technologies can be obtained by assessments performed outside of Europe. The government of Canada⁷⁶ assessed that the EU is a key partner in science, technology and innovation for Canada and a major source of new technologies, in particular in the areas of health and aeronautics.

5.3. 2019 Industrial R&D Scoreboard

As regards the R&D investment in the field, EU companies are well positioned compared to the rest of the world according to the 2019 Industrial R&D Scoreboard⁷⁷. The 39 top companies of the Aerospace & Defence sector in terms of R&D investment invested close to EUR 20bn in R&D in 2018 worldwide, where EU companies represent 46% of the investments, slightly more than the USA. This followed a slight decrease over the last 10 years, whereas global R&D growth in 2018-19 was driven by the ICT and the health sector. The table below lists the key indicators for the top 20 companies investing in R&D categorised in this sector, highlighting the ones located in the EU.

Figure Top 2500 companies investing in R&D worldwide – Focus on Aerospace and Defence 20 top companies

Morld				R&D	R&D	one-	Net	sales	R&D	
World rank	Company	Country	Region	2018/19	year	growth	one-y	ear	intensity	Employees
Idlik				(€million)	(%)		growt	h (%)	(%)	

⁷¹ https://www.airbus.com/careers/working-for-airbus/innovations-of-tomorrow.html

⁷⁶ https://www.tradecommissioner.gc.ca/european-union-europeenne.aspx?lang=eng&wbdisable=true

https://www.safran-group.com/media/safran-third-ranked-patent-filings-france-7th-year-row-20180406

https://www.thalesgroup.com/en/group/journalist/press-release/thales-once-again-amongst-top-100-global-innovators-clarivate

⁷⁴ https://www.cleansky.eu/sites/default/files/inline-files/CS-GB-2018-06-29-AAR-2017 20180706.pdf

⁷⁵ https://www.ati.org.uk/media/o5zjy32j/insight 11-global-aerospace-patents-1.pdf

⁷⁷ European Commission, JRC/DG RTD, The 2019 EU Industrial R&D Investment Scoreboard, computing data on the top 2500 companies investing the largest sums in R&D in the world in 2018/19

48	AIRBUS	Netherlands	EU	3308,0	9,3	7,9	5,2	133671
56	BOEING	US	US	2650,7	5,0	7,6	3,0	153000
65	UNITED TECHNOLOGIES	US	US	2150,2	3,1	11,1	3,7	240000
107	LEONARDO	Italy	EU	1401,0	-7,5	6,2	11,4	46462
115	ROLLS-ROYCE	UK	EU	1269,5	16,0	6,7	7,3	54500
134	LOCKHEED MARTIN	US	US	1135,4	8,3	7,6	2,4	105000
141	SAFRAN	France	EU	1075,0	17,7	22,8	5,1	92639
161	BOMBARDIER	Canada	RoW	992,1	-8,0	0,2	7,0	64010
209	THALES	France	EU	714,9	13,2	4,1	4,5	66135
254	TEXTRON	US	US	561,6	1,4	-1,6	4,6	35000
309	GENERAL DYNAMICS	US	US	438,4	-3,6	16,9	1,4	105600
310	ROCKWELL COLLINS	US	US	438,4	53,5	27,0	5,8	31200
367	DASSAULT AVIATION	France	EU	359,3	28,4	4,5	7,0	11395
438	L3 TECHNOLOGIES	US	US	284,7	13,6	7,0	3,2	31000
477	EMBRAER	Brazil	RoW	262,7	-32,5	0,0	6,2	18520
489	ELBIT SYSTEMS	Israel	RoW	251,0	8,4	9,1	7,8	16149
496	BAE SYSTEMS	UK	EU	247,3	-21,2	-2,3	1,3	78000
543	SAAB	Sweden	EU	216,8	8,0	5,6	6,7	17096
715	TELEDYNE TECHNOLOGIES	US	US	162,1	4,4	11,4	6,4	10850

Source: The 2019 EU Industrial R&D Investment Scoreboard, European Commission, JRC/DG RTD. The UK was classified as a EU country at the time of the computation and publication of the Scoreboard.

50.0% 40.0% 30.0% 20.0% 10.0% 0.0% 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 - Aerospace & Defence - - - Automobiles & other transport - -- - Chemicals

- - ICT producers

- -- - Others

- - Health industries

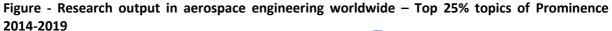
- - Industrials

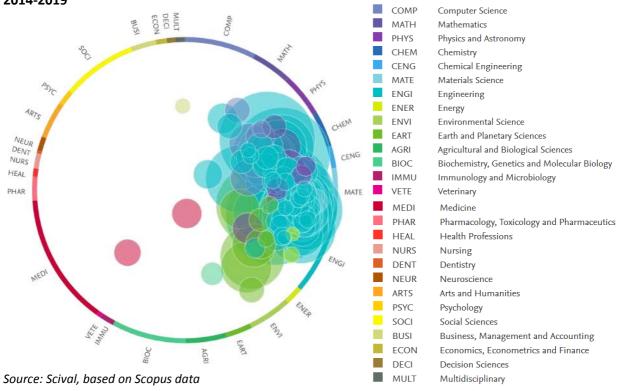
Figure 2.13 – Evolution of the global R&D share of EU companies for the main industrial sectors

Note: Figures displayed refer only to the 386 out of the 551 EU companies with R&D data available for the all period 2009-2018. These companies represent 86.6% of R&D whole sample in 2018. Source: The 2019 EU Industrial R&D Investment Scoreboard. European Commission, JRC/DG RTD.

- ICT services

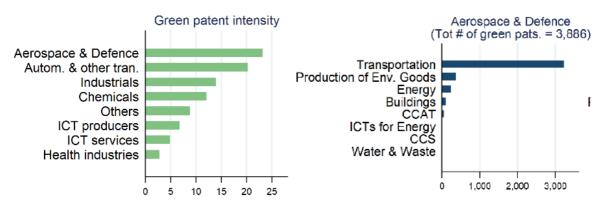
In terms of scientific performance, the EU28 shows a good performance compared to the rest of the world based on scientific publications in the field of aerospace engineering. Based on Scopus data, EU28 publications represents 23 % of all publications in the field with close to 40,000 publications between 2014 and 2019, involving close to 60,000 authors. Worldwide the most prolific country is China with more than 50,000 publications, followed by the United States (40,000). Publications from authors with affiliations in Germany, the UK, Italy, and France are the best positioned in the EU. The Field Weighted citation Index shows that EU28 publications in the field are cited 23% more than the world average whereas the ones from China show a lower performance than the average. Looking at trends in the field, during the period 2014-2019, the main topics of prominence worldwide ("hot topic") in terms of publications appeared related to physics, chemistry, chemical engineering, materials sciences and engineering but also energy and environmental sciences.





In terms of technological performance, between 2010 and 2016 the EU overall maintains a stable higher performance compared to the USA (details in the Figure below per specific technologies). When looking in the EU industrial R&D Scoreboard at the share of green patenting with respect to the total technological inventions of the biggest R&D investors worldwide, the highest share of green over total patents is revealed by companies operating in transport-related industries, including aerospace & defence (23.2%), totalising almost 3,900 green over more than 17,000 patents in the period 2012-2015, and automobiles and other transports (20.1%). These companies concentrate their green inventions in green transportation technologies. From the top 25 green inventors among the top R&D investors, green patents represent 28% of the patents of the company United Technologies (USA), 20% of the patents filed by Airbus (EU), and 34% of the patents filed by Rolls Royce (UK-DE).

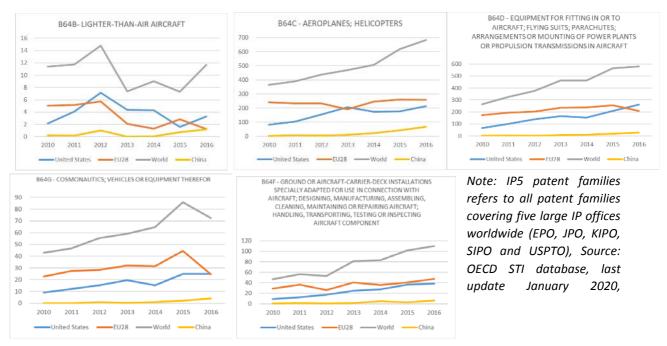
Figure - Green patent intensities of top R&D investors by industry and industry green-tech breakdown



Note: Share (left panel) and number of green patents (right panel) by industry (ICB) and environmental technology (CPC), 2012-2015. Caption: CCS = "Carbon Capture and Storage", ICT = "Information and Communication Technologies" CCAT =

"Climate Change Adaptation Technologies", ICB = "Industry Classification Benchmark". Source: The 2019 EU Industrial R&D Investment Scoreboard, European Commission, JRC/DG RTD

Figure: IP5 patent families in the IPC class AIRCRAFT; AVIATION; COSMONAUTICS (B64) by priority date, based on inventor's country of residence, for EU28, United Stes, China and the World



https://stats.oecd.org/OECDStat_Metadata/ShowMetadata.ashx?Dataset=PATS_IPC

6. ROLE OF EASA IN RESEARCH AND INNOVATION

For new aircraft products, operations and services certification is the gateway from research and development to market uptake, as a compulsory guarantee of safety and environmental compliance. The cost, time and uncertainty related to certification are important factors in preparing new products and services.

The European Union Aviation Safety Agency (EASA) is in charge of certification in Europe, including for technologies developed in EU programmes. However, EASA participation in early R&D activities has been hindered due to the lack of dedicated resources. The solution has been addressed in the context of the revision of the EASA Regulation currently adopted by the Commission that aims – amongst other things – to strengthen the Agency's work in the field of certification.

It is important to shorten time-to-market and to decrease costs of the development and operation of new air transport products and services, notably for market-creating innovations. This would help increase the European share in the fast-growing global market despite increasing global competition.

The cycle from preparation to completion of certification tests for large aircraft can take more than five years. A six-month delay in delivery to an airline can lead to penalties for the manufacturer of up to 2% of the price of each aircraft, or cancellation of orders to the benefit of competitors. Development costs exceed EUR 10 billion for a new large aircraft. If a design issue is detected at a late stage of the certification process, the development costs can increase by 10%. The cycle design-build-test-redesign drives up costs and leads to delays.

Following the R&D stage, all new aviation products and services need to be certified for safety and environmental compliance before market uptake. Therefore, EASA participation is needed in early R&D stages to avoid issues and delays later at the certification level.

Early preparation of certification is particularly important in EU programmes supporting aviation research & innovation, deployment and investment e.g. Horizon 2020 (including Clean Sky 2 and SESAR 2020 JTIs), Connecting Europe Facility (including Single European Sky Deployment) and Structural Funds (at least 20 EU regions include aeronautics among the targeted sectors).

Research underpins the new certification processes and the new regulations, including those adopted internationally by the United Nations International Civil Aviation Organisation (ICAO), where EASA is called upon to play a more active role. The supporting technical evidence put forward firstly by one country (typically USA) is influential in the final decision. The act setting up the US Federal Aviation Administration includes provisions not only for safety regulation but also for the promotion of aeronautics and air-transportation in such a manner as to best foster their development adapted to US commercial needs.

The improvement of certification with EASA participation in early R&D activities can also contribute to three other policy objectives of the Commission, namely: strengthening Europe's role as a global actor, notably at ICAO, where global regulations are discussed among aviation authorities on the basis of evidence collected e.g. from R&D programmes. Timely involvement of EASA in R&D activities could accelerate the pace of setting European regulations and standards, which could then become a reference at global level.

The main issue relates to uncertainties in the timely and cost-efficient development and certification of innovative air transport products, operations and services if EASA is not involved at early stages of the R&I process. Certification issues increase costs and delays, put orders at risk, endanger market penetration, and reduce returns on investments for European companies. In a global market worth an estimated EUR 5000 billion over the next 20 years, drop of 1% market share equates potential each in to loss EUR 2.5 billion per year to the European industry.

7. CLEAN SKY BACKGROUND

7.1. The first Clean Sky programme:

The Clean Sky Joint Undertaking (JU)⁷⁸ was created in 2008 as a public-private partnership (PPP) between the European Union (EU) and the aeronautics industry. The first research programme, Clean Sky, had a value of EUR 1.6 billion and was launched under the Seventh Framework Programme, FP7. The EU and industry each contributed 50% of this budget. Clean Sky aimed to demonstrate and validate the technology breakthroughs that are necessary to make major steps towards the environmental goals sets by Advisory Council for Aeronautics Research in Europe (ACARE), the European Technology Platform for aeronautics and air transport, and to be reached in 2020:

- 50% reduction of CO₂ emissions through drastic reduction of fuel consumption.
- 80% reduction of NOx (nitrogen oxide) emissions.
- 50% reduction of external noise.

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⁷⁸ http://www.cleansky.eu/

• A green product life cycle: design, manufacturing, maintenance and disposal/recycling.

Clean Sky consisted of six Integrated Technology Demonstrators (ITDs):

- 1. Smart Fixed-Wing Aircraft.
- 2. Green Regional Aircraft.
- 3. Green Rotorcraft.
- 4. Sustainable and Green Engines.
- **5.** Systems for Green Operations.
- 6. Eco-Design.

Clean Sky (FP7) had different levels of membership:

- Leaders the 12 Leaders received 50% of the funding. Two key industry players were appointed to lead each of the six ITDs for the duration of the programme. The Leaders were listed in the Annex to the JU's founding Regulation⁷⁹;
- Associates the 71 Associates received 25% of the funding. They were private or public organisations, selected through open calls, as permanent members of the Clean Sky JU. They committed to perform, and complete, certain essential work packages in one or more of the ITDs for the duration of the programme.
- Partners the over 500 Partners received 25% of the funding. They were private or public organisations, selected via Calls for Proposals, that participated for certain specific tasks over a limited period in the programme.



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⁷⁹ Council Regulation (EC) No 71/2008 of 20 December 2007 setting up the Clean Sky Joint Undertaking

7.2. The Clean Sky 2 programme

For the second programme under Horizon 2020, Clean Sky 2, a new Clean Sky 2 Joint Undertaking was established in 2014. It was responsible for carrying out the activities of both Clean Sky programmes until the first programme ended in 2017. The new Clean Sky 2 programme has a budget of approximately EUR 4 billion. The EU contributes EUR 1.755 billion and private members EUR 2.2 billion. Clean Sky 2 retains the three tiers of membership:

- Leaders now 16 rather than 12. They receive 40% of funds.
- Core Partners Associates have been re-named as Core Partners, of which 256 have been selected. They receive 30% of the funding.
- **Partners** Selected via Calls for Partners and are not members of the JU, but contribute to a specific, time-limited, task. Over 730 organisations have been selected from the 10 calls. They receive 30% of the funding.

Clean Sky 2 aims to integrate, demonstrate and validate the most promising technologies capable of:

- increasing aircraft fuel efficiency and reducing CO₂ emissions by 20 to 30% compared to state-of-the-art aircraft entering into service as from 2014.
- reducing aircraft NOx emissions by 20 to 30% compared to 'state-of-the-art' aircraft entering into service as from 2014.
- reducing aircraft noise emissions levels by up to 5dB using the recognised effective perceived noise levels decibel (EPNdB) standard per operation compared to 'state-of-the-art' aircraft entering into service as from 2014.

These objectives follow-on from those of the Clean Sky programme but are however more ambitious as they use a more up-to-date reference year, i.e. 2014 rather than 2000. In particular, the fuel efficiency and CO₂ emissions reduction of up to 30% will overtake the average 10-15% reduction for a new generation of aircraft. This will accelerate twice the rate of improvement otherwise achievable and could result in 'skipping a generation' of nominal development.

An additional aim of the Clean Sky 2 programme is industrial competitiveness; it aims at global leadership for European aeronautics, with a competitive supply chain, which includes academia, research bodies and SMEs.

7.3. Interim Evaluation of the CS2 Joint Undertaking

The Interim Evaluation Report⁸⁰ of CS2 JU, published in 2017, noted that the scope of activity identified is still considered relevant. It observed that the scope of CS2 was expanded compared to that of CS1 and also highlighted that recent political developments (such as the 2015 Paris Agreement) underscore even further the need to do everything possible to accelerate the development and introduction of environmentally friendly products and services. The Interim Evaluation and stakeholder discussions held for this study highlighted a number of issues, include the following observations:

Governance: Technology Evaluator: its limited scope (i.e. only technology and only inside Clean Sky 2) is not ideal. It is also dependent on the goodwill of the CS2 SPDs to provide it with input and information. The fact that the Technology Evaluator is within

75

⁸⁰ Interim Evaluation of the Clean Sky 2 Joint Undertaking (2014-2016) operating under Horizon 2020, Experts Group Report https://ec.europa.eu/research/evaluations/pdf/cs2.pdf

Clean Sky 2 may also raise questions regarding its objectivity in assessing CS2's technological achievements;

Scientific Committee: This could have greater focus on technological challenges than on Clean Sky 2 internal management;

States' Representative Group (SRG): there is a need for stronger interaction between Governing Boards and its advisory bodies (States' Representatives Group and Scientific Committee). Efficient collaboration between these bodies is of critical importance to the purposeful functioning and successful outcome of the JUs. A concern expressed related to the low impact of the advisory bodies on the Governing Boards' strategic decisions. For example, the SRG did not seem to have fulfilled its full potential in ensuring a close relationship with Member States in order to influence the Clean Sky programme or to develop synergies with their national research strategies. The Commission needs to stimulate the States' Representative Group to contribute to maximising the leverage effect of research programme synchronisation. The statutory SRG is not actively contributing to Clean Sky coordination with aeronautics research funded by the Member States.

Openness: A more integrative programmatic approach to managing work would be more effective and that there should be greater transparency regarding accomplishments and funding. In particular, the Interim Evaluation highlighted:

- Easier and more proactive disclosure of the parties and their funding;
- The economic impact of the programme should be better promoted, even if this may take years to be realised;
- As a scientific programme, some questioned whether CS2 should not have been able to contribute to more research publications.

Research: Call topics should be less prescriptive and funds should be allocated to create opportunities in areas that CS2 does currently not operate;

• The evaluation suggested to optimise 'complementarity and synergy' with the demonstrator projects while nurturing the bottom-up inspired 'innovation pipeline'.

Technical: Relationships between research activity and the demonstrator objectives in the broad framework should be clearer. Alternative views of research are needed to create visibility in the intended application of each technology development, whilst alternative views of accomplishments are needed to provide an overview of technology maturity – increased insight.

Management and communications: Current administrative processes are not always suitable and add much complexity and rigidity to the management process. The following points were identified:

- Options aim at reducing administrative workload (including grant administration) should be considered.
- Concerns were raised regarding the suitability of the Delegation Agreement.
- Greater use should be made of subcontracting in high TRL projects;
- CS2 currently operates with a top-down structure. A mechanism could be in place to foster more bottom-up working.

7.4. Clean Sky 2 Interim Evaluation Recommendations

The report provided ten points regarding the operation and its environment as elements to take into consideration for the Clean Sky 2 programme, applicable for the design and implementation of large-scale aeronautics research projects, such as Clean Sky 2 at the same time it could apply for the proposed European Partnership on Clean Aviation. The solutions will depend on the combined talents of all the Clean Sky stakeholders to take the right steps for the short and long-term continuity of this programme.

The Delegation Agreement

It is clearly not in the best interests of the CS2 JU to implement the Delegation Agreement that was made with the Commission under its Establishing Regulation just for the sake of it. The Commission should motivate the JU on each point, with reference to their specific needs and the available support for these transitions. The management of the grant agreements for members and research product archive system are two areas that could be considered inappropriate to migrate but the CS2 JU is the best judge of what will best meet their needs and responsibilities.

The framework, rules and suitable derogations should be considered well in advance of the drafting of a Basic Act for future programmes.

Administrative Simplification

Other options for meeting financial controlling requirements in grant administration, at reduced administrative workload, for future large-scale projects should be explored. The governance structure and the dedicated Programme Office of the JU are unique JTI feature that should permit a higher level of trust based operation than would apply to grant management by an Executive Agency.

The Horizon 2020 Aeronautics Innovation Pipeline

The CS2JU's best efforts should be made to convert appropriate parts of the Clean Sky 2 research agenda into call topics that are much less prescriptive than their current practice. Thus, funds could be allocated – where feasible without negative impact on demonstrators objectives – to create opportunities for research in areas that Clean Sky 2 does not currently address, the gaps.

Stimulate Subcontracting

It seems obvious now that the call topics in high TRL development work are small, of short duration, and highly-specified work packages that are valued at less than a few million Euros in value. They are probably not worth the effort of the call for proposal and grant management process. There are adequate mechanisms in place for transparency of subcontracting and increased use of that approach to 'outsourcing' seems preferable. A substantial increase of efficiency should be realised.

A Holistic Approach for Aeronautics Research

The maturity of collaborative, cross border research in the aeronautics research community and the close supply chain integration of the participating entities would suggest that a more integrative programmatic approach to managing this research area would be very effective. An additional responsibility of the CSJU for a collaborative

research work programme would optimise complementarities and synergies' with the demonstrator projects while nurturing the bottom-up inspired innovation pipeline.

Increased Transparency

Finding the recipients of public funding is for Clean Sky can be found but not very easily. The accomplishments of Clean Sky 1 and the objectives of Clean Sky 2 merit substantial respect. The best place for disclosure of the parties and their funding is right next to the accomplishments of each element of the research programme as these are achievements, or goals, to be proud of. The dedicated followers of the Clean Sky electronic newsletter would be pleased to be the first to know about new grant awards.

Increase Insight

The relationships between research activity and the demonstrators' objectives in the broad Clean Sky framework are not always clear and this will not be solved by putting more detail in the breakdown of work based descriptions or the progress reports. Alternative views of research are needed to create visibility in the intended application of each technology development, to ensure that the baseline is indeed state-of-the-art and to prevent research from being duplicated. Alternative views of the *accomplishments* are needed for an overview of the technology maturity that was realised in the programme, the application (or not) of the research outcomes in the realisation of the demonstrators and the contribution of the research to a marketable product. These measurements of the ability of the partners to both choose targets and accomplish them are much stronger performance indicators than milestones and deliverables currently being monitored.

Synergies with National Research

The statutory SRG is not actively contributing to Clean Sky coordination with aeronautics research funded by the Member States. Although synergies are being created by the wake effect of Clean Sky's visibility, and the Clean Sky insights that the SRG members acquire, the Commission needs to further stimulate the SRG to contribute to maximising the leverage effect of research programme synchronisation.

Promote Economic Impact

In the end, the Clean Sky programmes will be judged on the basis of their real world impact and – although that will sometimes take decades to materialise in a new, green air transport fleet – there are still methods by which the predicted benefits of the Clean Sky programmes can be made more substantial. Improved monitoring of industrial uptake, both intended and actual, combined with the elaboration of the scope of the Technology Evaluator to include socio economic impact all promote the need for the programme.

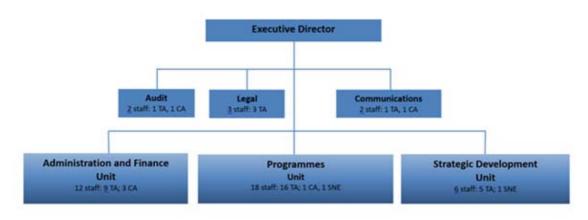
Energise and Enable Academic Participation

Academic participation in demonstrator work tends to focus on established aeronautic research partners that have the facilities and experience to support 'high TRL' development work. Herein lies an opportunity to expand the aeronautics research support base for Clean Sky. The main avenues to exploit could be:

• Enable students to contribute in an industrial environment, particularly in SMEs, which would not otherwise have that luxury, as a subject for PhD research. The "Initial Training Network" approach of the Marie Skłodowska-Curie Actions (MSCA) is a good basis from which to develop a unique 'Clean Sky' approach.

- Engage with universities to explore the unexplained outcomes of Clear Sky research that the ITD/ IAPDs do not prioritise in their own scope of work.
- Import new knowledge, solutions and innovation potential by finding ideas in other sciences and sectors.
- Reward excellent academic performance in the area of transition from fundamental to applied research thru grants, awards, prizes that energize and enable the academic community.

7.5. Clean Sky 2 Joint Undertaking Organisational chart



The Establishment Plan foresees 44 staff in total, out of which 42 staff members [36 Temporary Agents (TA) + 6 Contractual Agents (CA)] and 2 Seconded National Experts (SNE).

Source: CS 2 JU

The governance of the CS2 JU comprises:

- A Governing Board, including representatives of the founding members, Core Partners and the Commission (with 50% of the voting rights); Observers of the Governing Board include the Chairs of the States' Representative Group, and Scientific Committee.
- An Executive Director, supported by three Heads of Unit (Strategy and Horizontal Affairs, Programmes, and Administration and Finance), responsible for day-to-day management.
- A series of Steering Committees responsible for the technical decisions taken within each Integrated Technology Demonstrators (ITD)/ Innovative Aircraft Demonstration Platforms (IADP) and in the Technology Evaluator as set out below.
- A Scientific Committee providing advice to the Governing Board.
- A States' Representative Group (SRG) acting as an advisory body to the Governing Board.
- Various Working Groups.

7.6. Clean Sky 2 Stakeholder analysis

Up to 40% of CS2's available funding is allocated to its 16 Leaders (and their affiliates), and up to 30% to Core Partners, leaving only 30% of the funding to be distributed through calls for proposals and calls for tenders for which industry, SMEs, research organisations and academia are all eligible.

A key objective for the CS2 JU, as defined in Council Regulation 558/2014, is the active promotion of the participation and close involvement of all relevant stakeholders from the full aviation value chain, including from outside the traditional aviation industry in aeronautics-related R&I. The Impact Assessment study analysed this, by NACE industry sector and type of entity Note that this mapping of the partnership network is based on an identification of the participants in the partnership projects, derived from CORDA.

The results lead to a number of conclusions concerning participation in CS2:

The majority of funding went to private companies, specifically equipment manufacturers. On SMEs participation, information from stakeholders differs with ASD stating that 420 SMEs participated (with a SMEs Call for Partners funding share of 34% (of the 30% of funding reserved for Calls) with the SME average size of topics at EUR 600,000), and European Aerospace Cluster Partnership (EACP) noting that the current small allocation of funding to SMEs stifles innovation and that more funding should be allocated to foster innovation. Note that the 70% of budget that was pre-allocated to the Leaders and Core Partners included very few SMEs.

The JU has involved participation from organisations throughout the value chain, including aircraft manufactures, engine manufactures and avionic manufacturers, as well as research and educational institutions: ASD⁸¹ indicates 373 research centres, 350 universities were involved in addition to 334 bigger industrial organisations.

The weightings of the participating organisations imply a relatively even spread in participation among the organisations, however it should be noted that if the constituent parts of Airbus were to be grouped into one entity it would clearly dominate.

Educational and scientific and research institutions are well represented although, participation is concentrated on a relatively limited number of organisations with NLR, Onera, CIRA, DLR, and *Fraunhofer Gesellschaft* (FhG) being the dominant research organisation, and the University of Nottingham and *Technische Universiteit Delft* being the dominant higher education institutions.

8. THE H2020 EUROPEAN AVIATION RESEARCH LANDSCAPE

Under H2020, two Joint Undertakings are active in the aviation research area. Both these Joint Undertakings have their own specific objectives.

8.1. SESAR

SESAR is dedicated to optimising air traffic management in Europe – in particular in terms of capacity, cost, and safety. This means air traffic management infrastructure, ground and air operations, and to a limited extent aircraft system functionalities. It is strongly linked to the Single European Sky policy.

Most of the industrial partners involved in SESAR have also a prominent role in Clean Sky 2, but SESAR has other important partners, such as Eurocontrol and representatives of airports who are not in Clean Sky 2.

For the future, air traffic management (ATM) has great room for efficiency improvements by progressing with the implementation of the Single European Sky

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⁸¹ ASD, 2019

(SES) and further R&I on the Digital European Sky. The fragmented, national organisation of ATM, and the ineffective regulatory framework hinder the technical solutions to be deployed. The legislative process for improving SES has been blocked at Council level for over six years. The proposed European Partnership on Integrated ATM would continue the work of the current SESAR Joint Undertaking. An optimised ATM could lead to a 5 to 10% reduction of emissions if deployed.

8.2. Clean Sky 2

Clean Sky 2 is about optimising the aircraft performance, in particular with regards to environment, [fuel] efficiency and emissions. Clean Sky 2 can be considered to be the predecessor of the Clean Aviation initiative.

The Clean Sky 2 Joint Undertaking has the following objectives:

- to contribute to the finalisation of research activities initiated under Regulation (EC) No 71/2008 and to the implementation of Regulation (EU) No 1291/2013, and in particular the Smart, Green and Integrated Transport.
- to contribute to improving the environmental impact of aeronautical technologies, including those relating to small aviation, as well as to developing a strong and globally competitive aeronautical industry and supply chain in Europe. This can be realised through speeding up the development of cleaner air transport technologies for earliest possible deployment, and in particular the integration, demonstration and validation of technologies capable of:
 - increasing aircraft fuel efficiency, thus reducing CO2 emissions by 20 to 30% compared to 'state-of-the-art' aircraft entering into service as from 2014;
 - reducing aircraft NOx and noise emissions by 20 to 30 % compared to 'state-of-the-art' aircraft entering into service as from 2014.

8.3. Cooperation

A memorandum of understanding between the two current H2020 partnerships was signed in December 2015 to exploit areas of mutual interest. The cooperation is leading to:

- coordinating call topics and check if parallel activity is underway, and if needed adapt or even drop the topic in preparation of the Annual Work Plans
- Information exchanges from projects where the analysis of topics shows a benefit to coordinate
- joint communications and coordination of messages
- Extra technical reviews to ensure the complementarity and avoid duplication.
- The two Scientific Committees are 'connected' and exchanges are encouraged
- Experts and reviewers are shared

For the future, some initial discussions between the two JUs including a number of private stakeholders have taken place to analyse possible areas of shared/joint interest between the proposed Integrated Air Traffic Management and Clean Aviation partnerships under Horizon Europe.

A number of areas of possible joint demonstration were identified. The cooperation between the two future programmes could be intensified to ensure that progress in aircraft technology is matched by and is in step with the evolution of ATM and infrastructure capabilities. This is particularly relevant given the evolution in the objectives of the ATM partnership towards 'Digital Skies' including areas of automation and autonomy in aircraft and/or ground systems.

The implementation of these joint demonstration activities can be clarified and more areas of cooperation can be defined, once the two programmes are up and running under Horizon Europe. A new memorandum of co-operation between the two new partnerships would then be established.

8.4. Collaborative research

Collaborative research in aviation and aeronautics has been funded by the EU since the fourth framework programme that started in 1994. Since the establishment of Clean Sky, collaborative research projects on aviation have continued to be funded under FP7 and then H202082. This is mainly because the projects' focus did not fall under the scope of the Joint Undertakings. For example, projects dealing with issues not covered by Clean Sky – for example, safety, international co-operation83, aviation within multimodal transport, or providing a snapshot of EU aviation research infrastructure – or because they concentrated on more fundamental research at a lower TRL. Under H2020, apart from a few Coordination and Support Actions (CSA), the Commission has delegated the projects' management to its Innovation and Networks Executive Agency (INEA)⁸⁴.

8.5. Note: National research programmes

Next to the European aviation research and innovation programmes there are national aviation R&I programmes with significant budgets such as those of Germany (LuFo), France (CORAC) and the UK (ATI), with a budget of between EUR 2-3 billion for a period of five years.

However, an external study shows that these programmes were not sufficiently coordinated, neither at national level nor at European level. In some cases, national interest in local employment and technology, led to non-complementary policies, with a possible duplication of activities. The consultation showed that the situation has improved, however stakeholders recognised that there is room for further improvement.

9. STAKEHOLDER REACTION TO THE CLEAN AVIATION INITIATIVE

9.1. Joint Declaration of European Aviation Research Stakeholders

The earliest official recognition of the value of the Clean Aviation initiative by the private sector came under form of a "Joint Declaration of European Aviation Research

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⁸² https://ec.europa.eu/inea/sites/inea/files/aviation brochure 2019-web.pdf

⁸³ Thirteen non-EU countries have been involved in international co-operation during H2020, including .Japan, China, Canada, United States, Russia and Brazil. https://ec.europa.eu/inea/sites/inea/files/aviation_brochure_2019-web.pdf, p36

⁸⁴ https://ec.europa.eu/inea/

Stakeholders"⁸⁵ handed over to Jean-Eric Paquet, Director-General for Research and Innovation, European Commission at the 2019 Le Bourget Airshow.

It was signed by twenty-three Aeronautics Industry leaders, Research Organisations and University Associations from across Europe to express their strong commitment to a future European partnership leading to a deep decarbonisation of aviation by 2050.

9.2. Shared vision

This Joint Declaration was further developed into a "shared vision", published in January 2020, that recognised that the sector the sector has a duty to act and the power to lead, given support of the European Union, in bringing aviation in line with the European Green Deal.

This shared vision was signed by a broad spectrum of industrial parties, universities, research and technology organisations, EASA, and several associations such as Pegasus, EREA and EASN.

This shared vision already underlined several of the key success factors that have also been addressed in this Impact Assessment.

- The importance of establishing an eco-system for aviation and actively seek and develop synergies with other European Partnerships, EU research programmes, national research and innovation programmes.
- The focus on integration, demonstration and validation of technology.
- The need to involve the wider aviation community to raise awareness, and instil the necessary confidence for long-term investments needed for product development, and to build confidence among airlines and operators.
- The need to align the technical research effort with policy and legislative elements and new infrastructure provisions required for early market acceptance efforts.
- Strong pro-active European Union support on global regulation, standards for and certification of future products, supported through a strong and strategic alignment with EASA.

It also contained a first brief description of the technical dimension of the Clean Aviation initiative including an integrated roadmap comprises four key thrusts aiming at the selection of best approaches and solutions for maturation:

- Full Electric Aircraft and Rotorcraft maturing technologies towards demonstration of novel configurations, on-board energy concepts and flight control in the small/commuter segment.
- Hybrid Electric Aircraft driving research into ultra-efficient aircraft structures, configurations, novel power sources and management, and their integration; aiming predominantly at regional and short-range applications.

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⁸⁵ https://www.cleansky.eu/news/aviation-industry-declares-commitment-to-future-clean-aviation-partnership

- Ultra-efficient Aircraft and Gas Turbines to address the short, medium and long-range needs with highly integrated, ultra-efficient gas turbines.
- Sustainable Aviation Fuels-enabled Aircraft driving the capability of aircraft and engines to fully exploit the potential of both drop-in and non-drop-in alternative low and zero carbon fuels.

9.3. Strategic Research and Innovation Agenda

The Shared Vision was intensely debated between private stakeholders, and with the Commission.

The private sector formed a working group, called CS3PG, responsible to deliver in a timely, open and transparent manner an aligned position from the European aviation stakeholders of an ambitious programme, in support of the Commission's strategic planning and preparatory work towards a legislative proposal on a potential European Institutionalised Partnership on Clean Aviation under Article 187 Treaty on the Functioning of the European Union.

CS3PG members include industrial companies, both large and small; academia; research organisations from across the EU; seven⁸⁶ of the 34 stakeholders preparing the SRIA are not members of the current partnership, including three associations from academia; and Member States.

This significant and sustained effort led to a Strategic Research and Innovation agenda that was released on 1 July 2020.

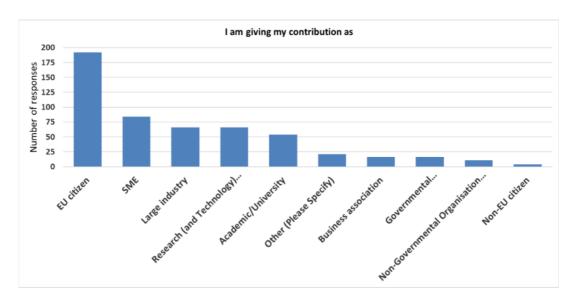
9.4. Public consultation

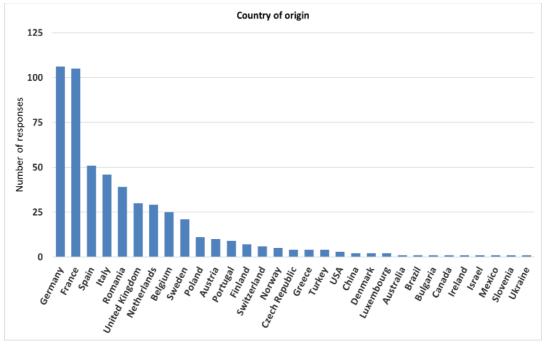
The CS3PG organised a public consultation on the SRIA from 15 May -11 June 2020. The 530 respondents from 31 different countries provided more than 1500 comments contributed to the CS3PG analyses of the SRIA leading in some cases to new lines of approach.

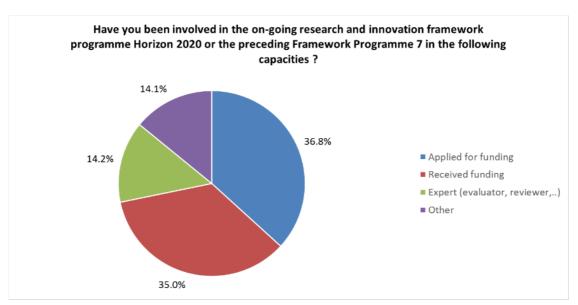
Remarkable the high number of SMEs (16%) and private citizens (36%) that provided their feedback and showed interest in the potential European Partnership for Clean Aviation. This indicates that the survey was broadly communicated and reached also the general public and shows that the general public gives importance to the subject.

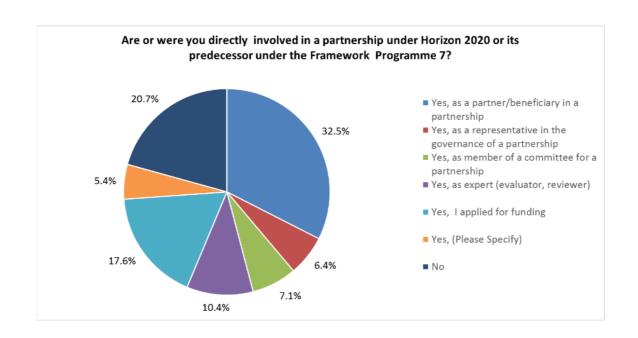
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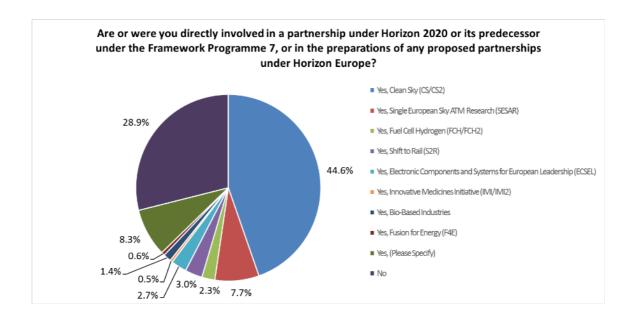
Association of European Research Establishments in Aeronautics (EREA); European Aeronautics Science Network (EASN); European Union Aviation Safety Agency (EASA); KU Leuven; Lufthansa Technik; Pegasus (Partnership of the European aerospace universities); Pipistrel (an SME)

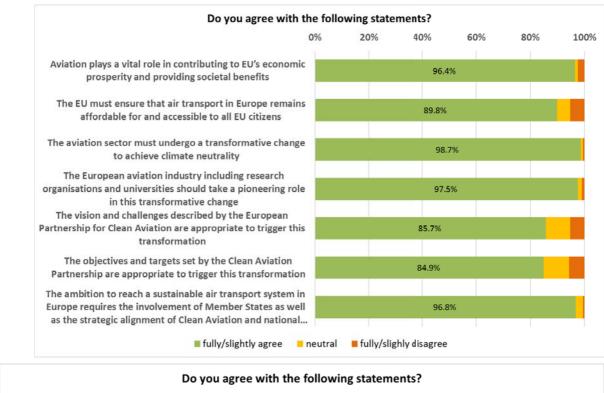


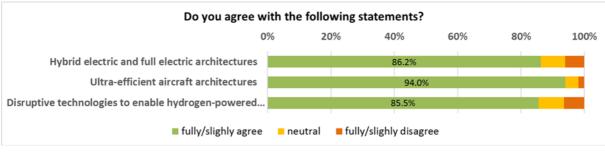


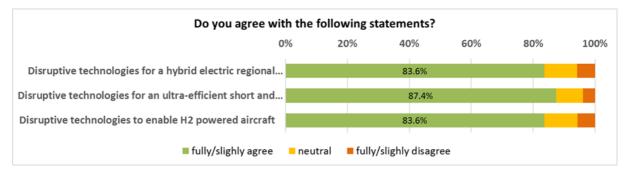












10. POTENTIAL LINKS AND SYNERGIES WITH OTHER PARTNERSHIPS AND EU PROGRAMMES AND INITIATIVES

The Clean Aviation Partnership will work towards establishing strategic synergies with other European Partnerships and Horizon Europe cross-cutting initiatives:

Sustainable Aviation Fuels

Sustainable aviation fuels (SAF) will make a crucial contribution to mitigating the current and expected future environmental impacts of aviation. Thus, it is important that EU initiatives related to sustainable [bio]-fuels include a dedicated area to address the development, production and deployment of bio- or synthetic aviation fuels as well as the logistics and required adaptations of the airport infrastructure.

Clean Hydrogen

Fuel cells represent a unique opportunity to reduce CO_2 emissions thanks to their high system efficiency of about 50% and their higher power density compared to batteries, as well as not releasing NO_x or particulates. They have also a very low noise footprint. It is necessary, to prepare the next generation of innovations, products and services, in close alignment with the Clean Hydrogen and Fuel Cell Initiative, to ensure a European technology breakthrough of this value chain in air transportation.

European battery research

Batteries are a valuable solution for full or partial electrification through hybridisation, mixing electric engines with on-board electricity production. As fundamental battery research cannot be addressed in the Clean Aviation programme, European battery research should include a dedicated area to accelerate towards the very high requirements for aviation to contribute their potential towards climate neutral aviation.

Integrated Air Traffic Management

As autonomous operations are expected to be key drivers for the next generation of aircraft, the research programme activities dealing with the flight management of the vehicle need to be well aligned with research aspects and activities regarding air traffic management as tackled in the SESAR 2020 Programme and the Integrated Air Traffic Management Partnership proposed under Horizon Europe.

Artificial Intelligence

Artificial intelligence will be required to contribute to achieve the ambitious goals of Clean Aviation, starting from design, manufacturing, testing and certification, operation and maintenance of aircraft as well as efficient and secure passenger management.

Electronics / Semi-conductors

The proposed Clean Aviation Partnership agenda relies on several complementary research activities proposed under the Electronic Components and Systems for European Leadership Joint Undertaking (ECSEL JU) regarding electronic components and systems and semiconductor manufacturing.

Advanced Materials and Structures

New materials, their future production processes and assembly techniques are key complementary contributors to improved performance and reduced environmental footprint. An effective systemic approach between Clean Aviation and several Horizon Europe initiatives, such as Made by Europe, Climate Neutral and Circular Industry and the European Institute of Innovation and Technology (EIT) Manufacturing and EIT Raw Material is key to maximise the results.

Security

As in many other sectors, increased automation and autonomy in systems of aircraft are expected to significantly increase the competitiveness. Security and increasingly cybersecurity are prerequisites for making use of the fast-increasing potential of new automated functions in aviation. Large-scale use of digital data/ data transfer e.g. wideband data link between aircraft and ground will require an increased focus of cybersecurity. Here the inherent safety and security of the on-board systems is at stake. Therefore, the fundamental issues of cyber resilience will be tackled in the Global Challenges Digital Europe and dedicated Horizon Europe initiatives, but it needs to be

ensured that their respective work programmes will assign appropriate topics and that their resources will cover the challenging aviation specific requirements.

11. CLEAN AVIATION RESPONSES TO CLEAN SKY 2 PERCEIVED SHORTCOMINGS

As explained in the impact assessment, the H2020 CS2 Joint Undertaking has a number of weaknesses that should be addressed when establishing a new Article 187 Partnership.

The most prominent weaknesses are:

- The scope of the Clean Sky 2 Joint Undertaking research and innovation programme has demonstrated being **too broad**; lacking the focus needed for achieving strategic disruptive results and for making a substantial contribution to the objectives described in the Clean Sky 2 Basic Regulation. The research effort revolves around incremental improvements to existing technologies and not on new technologies with potential step change capabilities.
- Further shortcomings are its **governance** with a Governing Board overloaded with administrative issues, a scientific body and a state representatives group with purely advisory functions, and a technology evaluator embedded in the Joint Undertaking and dependent on the goodwill of the private partners for information.
- It lacks **openness** with 70% of the Clean Sky 2 budget pre-allocated to the leaders (40%) and core partners (30%), leaving only 30% of the budget for open calls. This strongly limits flexibility and the possibility for new parties (including SMEs) to join the partnership.
- The funding imbalance between traditional calls (20%) and Joint Undertaking funding allocation (80%).

The analysis shows that the institutionalised European Partnership option would be the best-suited, provided it takes into account all lessons from the experiences with Clean Sky and Clean Sky 2 – both positive and negative. In particular:

- The dedicated programme office providing in-house programme management capacities would allow **closer monitoring and swift adaptation** of the research effort.
- Demonstrator selection will be based upon **open calls** (no pre-allocated budget), including criteria to assess real-world impact and providing a business case for market uptake. This should also lead to new Clean Aviation **partners outside the core players** (academia, SMEs, countries without a strong aviation industry) to bring technologies that are not common knowledge for aviation.
- In addition, much more attention will be paid to embedding supporting functions such as **environmental and safety certification**, (close collaboration with the European Union Aviation Safety Agency is envisaged) also on an international level, into the research effort. Managing these aspects in parallel to the research effort, instead of the current sequential approach, would ensure that all conditions are met for swift market introduction at the end of the programme.
- A strong governance is envisaged under the JU basic act to monitor progress with the help of an independent assessment instrument and steer the research effort on basis of achieved results, and to maximise synergies with other initiatives such as the initiatives on batteries or hydrogen, and with national research programmes.

• The strong involvement of the EC services will ensure alignment with EC priorities and policies.

A list of the perceived shortcomings of Clean Sky 2, as outcome of the mid term evaluation, is included in the impact assessment. This list is copied below with a brief description of how these shortcomings could be prevented in future by the Clean Aviation partnership.

Clean Sky 2

Project participation rates are distributed in favour of a relatively limited number of organisations. A large share of the funding is reserved to Leaders and Core Partners. There is a risk that SMEs or EU-13 Member States participants may find it difficult to join it, as project participation in the CS 2 JU is concentrated among a relatively limited number of players reflecting the composition of leaders and core partners

collaborative aviation R&I, over the last decade, compared to the large budget for demonstration, has adversely affected the availability and spectrum of lower technology readiness levels

Aspects of the design and implementation of the CS 2 JU have limited effectiveness: certain aspects of its governance arrangements such as the role of the States Representative Group

the assessment of potential safety risks and environmental standards related to certification of new products and technologies. Safety topics and procedural infrastructure are constraining the R&I effort. There is arguably a need for greater flexibility and for reduction in the administrative burden. There are also some communication improvements that could be made.

It is not always easy to establish what the precise outcomes CS1 and CS2 have been

There is a lack of multi-level policy coordination, whilst horizontal coordination between research, technology and innovation policies is good in the European aviation sector programmes, one of the Weaknesses of the European research landscape is that there is no systematic alignment, and no single roadmap, of the initiatives that could contribute to Clean Aviation. Overall, the CS2 programme has not contributed to the alignment of national and EU aviation research programmes – apart from creating Annual Activity Report. In addition, efforts to develop more electric properts with EU regional funds as outlined in the CS2 2018 demonstrator projects while collaborative research will demonstrator projects while opportunities for synergies were not exploited demonstrator projects while opportunities for synergies were not exploited demonstrators. All other groups such as Impact assessment group, states representatives group, stakeholders group to report directly to the Governing Board. EASA STRUCTURING TO THE INITIATIVE TOR monitoring and impact assessment group, states representatives group, stakeholders group to report directly to the Governing Board. EASA STRUCTURING TO THE INITIATIVE TOR monitoring and impact assessment group, states representatives group, stakeholders group to report directly to the Governing Board. EASA STRUCTURING TO THE INITIATIVE TOR monitoring and impact assessment group, states representatives group, stakeholders group to report directly to the Governing Board. EASA STRUCTURING TO THE MONITORING TO THE INITIATIVE TOR monitoring and impact assessment group, states representatives group, stakeholders group to report directly to the Governing Board. EASA STRUCTURING TO THE INITIATIVE TOR monitoring and impact assessment group, states representatives group to report directly to the Governing Board. EASA STRUCTURING TO THE INITIATIVE TOR monitoring and impact assessment group, states represented to the Governing Board. EASA STRUCTURING TO THE INITIATIVE TOR MONITORING TO THE INITIATIV		
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could be expected to introduce realistic roadmaps for bringing

their technologies to market.

Clean Aviation proposal

Increased involvement of the Commission to ensure the link between European policy initiatives and research.

Development of a European strategic research and Innovation roadmap. Involvement of ACARE as stakeholders group in identifying opportunities for synergies and cooperation.

States Representatives Group with dedicated mandate to ensure the alignment of the European research effort with the national research programmes. Dedicated related communication effort describing European research needs which could be met by national research activities.



Brussels, 23.2.2021 SWD(2021) 37 final

PART 16/19

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT REPORT Accompanying the document

Proposal for a Council Regulation establishing the Joint Undertakings under Horizon Europe

European Partnership for a Circular Bio-based Europe

{COM(2021) 87 final} - {SEC(2021) 100 final} - {SWD(2021) 38 final}

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Glossary

Term or acronym	Meaning or definition
EIT	European Institute of Innovation & Technology
R&I	Research and Innovation
SDGs	United Nations Sustainable Development Goals
SMEs	Small and Medium-sized Enterprises
TFEU	Treaty on the Functioning of the European Union
ERA	European Research Area
P2P	public-to-public cooperation
PPP	Public-Private Partnership
cPPPs	contractual PPPs
KPI	Key Performance Indicators
OPC	Open Public Consultation
RIA	Research and Innovation Action
CSA	Coordination and Support Action
BBI JU	Bio-based Industries Joint Undertaking
BIC	Bio-based Industries Consortium
TRL	Technology Readiness Level
CAP	Common Agricultural Policy
ESIF	European Structural and Investment Fund
ERDF	European Regional Development Fund
EAFRD	European Agricultural Fund for Rural Development

EMFF	European Maritime and Fisheries Fund
SRIA	Strategic Research and Innovation Agenda
MFF	Multiannual Financial Framework

PART 1 - COMMON FOR ALL CANDIDATE INSTITUTIONALISED EUROPEAN PARTNERSHIPS

1. BACKGROUND AND CONTEXT TO EUROPEAN PARTNERSHIPS IN HORIZON EUROPE AND FOCUS OF THE IMPACT ASSESSMENT—WHAT IS DECIDED

1.1 Focus and objectives of the impact assessment

This impact assessment accompanies the Commission proposal for Institutionalised European Partnerships to be funded under Horizon Europe, the 2021-2027 Framework Programme for EU Research and Innovation (R&I). It sets out to help decide in a coordinated manner the right form of implementation for specific candidate initiatives based on a common approach and methodology to individual assessments². It also provides an horizontal perspective on the portfolio of candidate European Partnerships to identify further efficiency and coherence gains for more impact.

European Partnerships are initiatives where the Union, together with private and/or public partners (such as industry, public bodies or foundations) commit to support jointly the development and implementation of an integrated programme of R&I activities. The rationale for establishing such initiatives is to achieve the objectives of Horizon Europe more effectively than what can be attained by other activities of the programme.³

Based on the Horizon Europe Regulation, European Partnerships may be set up using **three different forms**: "Co-funded", "Co-programmed" and "Institutionalised". The setting-up of **Institutionalised Partnerships** involves new EU legislation and the establishment of dedicated implementing structures based on Article 185 or 187 of the Treaty on the Functioning of the EU (TFEU). This requires an impact assessment to be performed.

The Horizon Europe Regulation defines **eight priority areas**, scoping the domains in which Institutionalised Partnerships could be proposed⁴. Across these priority areas, **13 initiatives** have been identified **as suitable candidate initiatives** for Institutionalised Partnerships because of their objectives and scope. This impact assessment aims to identify whether 12 of these initiatives⁵ need to be implemented through this form of implementation and would not deliver equally well with traditional calls of Horizon Europe or other lighter forms of European Partnerships under Horizon Europe. This means assessing whether each of these initiatives meets the necessity test set in the **selection criteria** for European Partnerships in the Horizon Europe Regulation, Annex III.

This assessment is done **without any budgetary consideration**, as the overall budget of the Multiannual Financial Framework of the EU – and hence of Horizon Europe – for the next financing period is not known at this stage.⁶

⁴ Set out in the Annex Va of the Horizon Europe Regulation (common understandates://data.consilium.europa.eu/doc/document/ST-7942-2019-INIT/en/pdf

¹ Horizon Europe Regulation (common understanding), https://data.consilium.europa.eu/doc/document/ST-7942-2019-INIT/en/pdf

² Based on the European Commission Better Regulation framework (SWD (2017) 350) and supported by an external study coordinated by Technopolis Group (to be published in 2020).

³ For further details on these points, see below Section 1.2.2.

⁵ Only 12 are subject to this impact assessment, as one initiative on High Performance Computing has already been subject to an impact assessment in 2017 (SEC(2018) 47).

⁶ EU budget commitments to the European Partnership candidates can only be discussed and decided following the political agreement on the overall Multiannual Financial Framework and Horizon Europe budgetary envelopes. The level of EU contribution for individual partnerships should be determined once there are agreed objectives, and clear commitments

1.2 The political and legal context

1.2.1 Shift in EU priorities and Horizon Europe framework

European priorities have evolved in the last decades, and reflect the social, economic, and environmental challenges for the EU in the face of global developments. In her Political Guidelines for the new European Commission $2019 - 2024^7$, the new Commission President put forward six overarching priorities, which reach well beyond 2024 in scope⁸. Together with the Sustainable Development Goals (SDGs), these priorities will shape future EU policy responses to the challenges Europe faces, and thus also give direction to EU research and innovation.

As part of the Multi-annual Financial Framework (MFF) 2021-27 the new EU Framework Programme for Research and Innovation Horizon Europe will play a pivotal role for Europe to lead the social, economic, and environmental transitions needed to achieve these European policy priorities. It will be more impact driven with a strong focus on delivering European added value, but also be more effective and efficient in its implementation. Horizon Europe finds its rationale in the daunting challenges that the EU is facing, which call for "a radical new approach to developing and deploying new technologies and innovative solutions for citizens and the planet on a scale and at a speed never achieved before, and to adapting our policy and economic framework to turn global threats into new opportunities for our society and economy, citizens and businesses." While Horizon Europe continues the efforts of strengthening the scientific and technological bases of the Union and foster competitiveness, a more strategic and impact-based approach to EU R&I investment is taken. Consequently, the objectives of Horizon Europe highlight the need to deliver on the Union strategic priorities and contribute to the realisation of EU objectives and policies, contribute to tackling global challenges, including the Sustainable Development Goals by following the principles of the Agenda 2030 and the Paris Agreement. 10

In this context, at least 35 % of the expenditure from actions under the Horizon Europe Programme will have to contribute to climate action. Furthermore, a Strategic Plan is co-designed with stakeholders to identify key strategic orientations for R&I support for 2021-2024 in line with the EU priorities. In the Orientations towards the first Strategic Plan for Horizon Europe, the need to strategically prioritise and "direct a substantial part of the funds towards the areas where we believe they will matter the most" is emphasised. The Orientations specify, that actions under Pillar II of Horizon Europe "Global Challenges and European Industrial Competitiveness" will target only selected themes of especially high impact that significantly contribute to delivering on the political priorities of the Union. Most of the candidate European Partnerships fall under this Pillar.

from partners. Importantly, there is a ceiling to the partnership budgets in Pillar II of Horizon Europe (the legal proposal specifies that the majority of the budget in pillar II shall be allocated to actions outside of European Partnerships).

https://ec.europa.eu/info/strategy/priorities-2019-2024_en

⁸ 1.A European Green Deal; An economy that works for people; A Europe fit for the Digital Age; Promoting our European way of life; A Stronger Europe in the World; and 6.A New push for European Democracy

⁹ EC (2018) A Modern Budget for a Union that Protects, Empowers and Defends. The Multiannual Financial Framework for 2021-2027. Communication from the Commission to the European Parliament, the European Council, the European Economic and Social Committee and the Committee of the Regions, COM(2018) 321 final

¹⁰ Article 3, Common understanding regarding the proposal for Horizon Europe Framework Programme.

1.2.2 Key evolutions in the approach to partnerships in Horizon Europe

Since their start in 1984 the successive set of Framework Programmes uses a variety of instruments and approaches to support R&I activities, address global challenges and industrial competitiveness. Collaborative, competition-based and excellence-driven R&I projects funded through Work Programmes are the most traditional and long-standing approach for implementation. Since 2002, available tools also include **partnerships**, whereby the Union together with private and/or public partners commit to jointly support the development and implementation of a R&I programme. These were introduced as part of creating the European Research Area (ERA) to align national strategies and overcome fragmentation of research effort towards an increased scientific, managerial and financial integration of European research and innovation. Interoperable and integrated national research systems would allow for better flows of knowledge, technology and people. Since then, the core activities of the partnerships consist of building critical mass mainly through collaborative projects, jointly developing visions, and setting strategic agendas.

As analysed in the **interim evaluation of Horizon 2020**¹¹, a considerable repertoire of partnership initiatives have been introduced over time, with 8 forms of implementation ¹² and close to 120 partnership initiatives running under Horizon 2020 - without clear exit strategies and concerns about their degree of coherence, openness and transparency. Even if it is recognised that these initiatives allow setting long-term agendas, structuring R&I cooperation between otherwise dispersed actors, and leveraging additional investments, the evaluation points to the complexity generated by the proliferation of instruments and initiatives, and their insufficient contribution to policies at EU and national level.

Box 1 Key lessons from the interim evaluation of Horizon 2020 and R&I partnerships

- The **Horizon 2020 Interim Evaluation** concludes that the overall partnership landscape has become overly complex and fragmented. It identifies the need for rationalisation, improve their openness and transparency, and link them with future EU R&I missions and strategic priorities.
- The **Article 185 evaluation** finds that these public-public partnerships have scientific quality, global visibility and networking/structuring effects, but should in the future focus more on the achievement of policy impacts. From a systemic point of view, it found that the EU public-to-public cooperation (P2P) landscape has become crowded, with insufficient coherence.
- The **Article 187 evaluation** points out that Public-Private Partnership (PPP) activities need to be brought more in line with EU, national and regional policies, and calls for a revision of the Key Performance Indicators. As regards the **contractual PPPs (cPPPs)** their reviews identified challenges of coherence among cPPPs and the need to develop collaborations and synergies with other relevant initiatives and programmes at EU, national and regional level.

Over 80% of respondents to the Open Public Consultation (OPC) indicated that a significant contribution by future European Partnerships is 'fully needed' to achieve climate-related goals, to develop and effectively deploy technology, and for EU global competitiveness in specific sectors/domains. Views converged across all categories of respondents, including citizens, industry and academia.

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¹¹ Interim evaluation of Horizon 2020, Commission Staff Working Document, SWD(2017)221 and 222 Interim evaluation of the Joint Undertakings operating under Horizon 2020 (Commission Staff Working Document, SWD(2017) 339); Evaluation of the Participation of the EU in research and development programmes undertaken by several Morekon States based on Article 185 of the TEEU Commission Staff Working Document, SWD (2017) 240)

several Member States based on Article 185 of the TFEU, Commission Staff Working Document, SWD (2017)340)

12 E.g. initiatives based on Article 187 (Joint Technology Initiatives), Article 185 TFEU, Contractual Public-Private Partnerships (cPPPs), Knowledge & Innovation Communities of the European Institute of Innovation & Technology (EIT-KICs), ERA-NETs, European Joint Programmes, Joint Programming Initiatives.

The impact assessment of Horizon Europe identifies therefore the need to rationalise the EU R&I funding landscape, in particular with respect to partnerships, as well as to reorient partnerships towards more impact and delivery on EU priorities. To address these concerns and to realise the higher ambition for European investments, Horizon Europe puts forward a major simplification and reform for the Commission's policy on R&I partnerships¹³. Reflecting its pronounced systemic nature aimed at contributing to EU-wide 'transformations' towards the sustainability objectives, Horizon Europe indeed intends to make a more effective use of these partnerships with a more strategic, coherent and impact-driven approach. Key related changes that apply to all forms of European Partnerships encapsulated in Horizon Regulation are summarised in the Box below.

Box 2 Key features of the revised policy approach to R&I partnerships under Horizon Europe based on its impact assessment

- ✓ **Simpler architecture & toolbox** by streamlining 8 partnership instruments into 3 implementation forms (Co-Funded, Co-Programmed, Institutionalised), under the umbrella 'European Partnerships'
- ✓ More systematic and transparent approach to selecting, implementing, monitoring, evaluating and phasing out all forms of partnerships (criteria for European Partnerships):
 - The selection of Partnerships is embedded in the strategic planning of Horizon Europe, thereby ensuring coherence with the EU priorities. The selection criteria require that partnerships are established with stronger ex-ante commitment and higher ambition.
 - The implementation criteria stipulate that initiatives adopt a systemic approach in achieving impacts, including broad engagement of stakeholders in agenda-setting and synergies with other relevant initiatives to promote the take-up of R&I results.
 - A harmonised monitoring & evaluation system will be implemented, and ensures that progress is analysed in the wider context of achieving Horizon Europe objectives and EU priorities.
 - All partnerships need to develop an exit strategy from Framework Programme funding. This new approach is underpinned by principles of openness, coherence and EU added value.

✓ Reinforced impact orientation:

- Partnerships are established only if there is evidence they support achieving EU policy objectives
 more effectively than other Horizon Europe actions, by demonstrating a clear vision and targets
 (directionality) and corresponding long-term commitments from partners (additionality).
- European Partnerships are expected to provide mechanisms based on a concrete roadmap to join
 up R&I efforts between a broad range of actors towards the development and uptake of innovative
 solutions in line with EU priorities, serving the economy and society, as well as scientific progress.
- They are expected to develop close synergies with national and regional initiatives, acting as dynamic change agents, strengthening linkages within their respective ecosystems and along the value chains, as well as pooling resources and efforts towards the common EU objectives.

Under Horizon Europe, a 'European Partnership' is defined as "an initiative where the Union, prepared with early involvement of Member States and/or Associated Countries, together with private and/or public partners (such as industry, universities, research organisations, bodies with a public service mission at local, regional, national or international level or civil society organisations including foundations and NGOs), commit to jointly support the development and implementation of a programme of research and innovation activities, including those related to market, regulatory or policy uptake."

The Regulation further specifies that European Partnerships shall adhere to the "principles of Union added value, transparency, openness, impact within and for Europe, strong leverage effect on sufficient scale, long-term commitments of all the involved parties, flexibility in implementation, coherence, coordination and complementarity with Union, local, regional, national and, where relevant, international initiatives or other partnerships and missions."

¹⁴ Article 8 and Annex III of the Horizon Europe Regulation (common understanding))

¹³ Impact assessment of Horizon Europe, Commission Staff Working Document, SWD(2018)307.

1.3 Why should the EU act

1.3.1 Legal basis

Proposals for Institutionalised European Partnerships are based on:

- 1) Article 185 TFEU which allows the Union to make provision, in agreement with the Member States concerned, for participation in research and development programmes undertaken by several Member States, including participation in the structures created for the execution of those programmes; or
- 2) Article 187 TFEU according to which the Union may set up joint undertakings or any other structure necessary for the efficient execution of Union research, technological development and demonstration programmes.¹⁵

1.3.2 Subsidiarity

The EU should act only in areas where there is demonstrable advantage that the action at EU level is more effective than action taken at national, regional or local level. Research is a shared competence between the EU and its Member States according to the TFEU. Article 4 (3) specifies that in the areas of research, technological development and space, the EU can carry out specific activities, including defining and implementing programmes, without prejudice to the Member States' freedom to act in the same areas. The candidate initiatives focus on areas where there is a demonstrable value added in acting at the EU level due to the scale, speed and scope of the efforts needed for the EU to meet its long-term Treaty objectives and deliver on its strategic policy priorities and commitments. In addition, the proposed initiatives should be seen as complementary and reinforcing national and subnational activities in the same area. Overall European Partnerships find their **rationale in addressing a set of systemic failures**¹⁶:

- Their primary function is to create a platform for a strengthened **collaboration** and knowledge exchange between various actors in the European R&I system and an enhanced **coordination** of strategic research agendas and/or R&I funding programmes. They aim to address **transformational failures** to better align agendas and policies of public and private funders, pool available resources, create critical mass, avoid unnecessary duplication of efforts, and leverage sufficiently large investments where needed but hardly achievable by single countries.
- The concentration of efforts and pooling of knowledge on common priorities to solve multi-faceted societal and economic challenges is at the core of these initiatives. Specifically, enhanced cross-disciplinary and cross-sectoral collaboration and an improved integration of value chains and ecosystems are among the key objectives of these instruments. In the light of Horizon Europe, the aim is to **drive system transitions and transformations towards EU priorities**.
- Especially in fast-growing technologies and sectors such as ICT, there is a need to **react to emerging opportunities** and address systemic failures such as shortage in skills or critical mass or cross-sectoral cooperation along the value chains that would hamper attainment of future European leadership and/or strategic autonomy.
- They also aim to address **market failures** predominantly to enhancing industry investments thanks to the sharing of risks.

¹⁵ Both Articles are under Title XIX of the TFEU - Research and Technological Development and Space.

¹⁶ The Interim Evaluation of Horizon 2020 and the impact assessment of Horizon Europe provide qualitative and quantitative evidence on these points. Sections 1 and 2 of each impact assessment on candidate European Partnerships include more detail on the necessity to act at EU level in specific thematic areas.

2. THE CANDIDATE EUROPEAN PARTNERSHIPS – WHAT NEEDS TO BE DECIDED

2.1 Portfolio of candidates for Institutionalised European Partnerships

The new approach for more objective-driven and impactful European Partnerships is reflected in the way candidate Partnerships have been identified. It involved a co-design exercise aiming to better align these initiatives with societal needs and policy priorities, while broadening the range of actors involved. Taking into account the 8 areas for Institutionalised European Partnerships set out in the Horizon Europe Regulation 17, a co-design exercise as part of the Strategic Planning process of Horizon Europe lead to the identification of 49 candidates for Co-funded, Co-programmed or Institutionalised European Partnerships 18. Out of these, 13 were identified as suitable candidate Institutionalised Partnerships because of their objectives and scope 19. Whilst the Co-Funded and Co-Programmed Partnerships are linked to the comitology procedure (including the adoption of the Strategic Plan and the Horizon Europe Work Programmes), Institutionalised Partnerships require the adoption of legislation and are subject to an impact assessment. The Figure below gives an overview of all candidate European Partnerships according to their primary relevance to Commission priorities for 2019-2024.

Figure 1 - Overview of the candidates for Co-Funded, Co-Programmed and Institutionalised European Partnerships according to Horizon Europe structure

Cluster 1: Health	Cluster 4: Digital, Industry &	Cluster. 5: Climate, Energy &	Cluster 6: Food, Bioeconomy, Agriculture,	
	Space	Mobility		
Innovative	Key digital technologies	Clean Hydrogen	Circular Bio-based Europe	
Health Initiative	Smart networks & services	Safe & automated road transport	Safe & sustainable food	
EU-Africa Global Health	High-Performance Computing	Transforming EU's rail system	system	
Large-scale	European Metrology	Clean Aviation	Climate-neutral, sustainable & productive blue bio-	
innovation & transformation of	AI-Data-Robotics	Integrated Air Traffic Management	economy	
health systems	Photonics	European industrial battery value	Animal Health	
Personalised	Made in Europe	chain	Water4All	
Medicine	Clean steel – low-carbon	Zero-emission waterborne	Accelerating farming systems transitions	
ERA for Health	steelmaking	transport		
Rare diseases	Carbon neutral & circular industry	Zero-emission road transport	Environmental observations	
One-Health Anti	Global competitive space	Built environment & construction	for sustainable agriculture	
Microbial Resistance	systems	Clean energy transition	Rescuing biodiversity	
Chemicals risk	Geological Service for Europe	Sustainable, smart & inclusive cities & communities	EIT Food	
assessment	EIT Digital	EIT Climate	Cluster 2: Culture, Creativity & Inclusive Society	
EIT Health	EIT Manufacturing	EIT InnoEnergy		
	EIT Raw Materials	EIT Urban Mobility	EIT Cultural and Creative Industries	
Horizon Europe Innovative Europ	Cross_Villa	rs		
Innovative SMEs	European Op	oen Science Cloud		

Source: Technpolis group (2020)

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¹⁷ Horizon Europe Regulation (common understanding), Annex Va.

¹⁸ Shadow configuration of Strategic Programme Committee for Horizon Europe. The list of candidate European Partnerships is described in "Orientations towards the Strategic Plan of Horizon Europe" - Annex 7

¹⁹ Only 12 are subject to this impact assessment, as one initiative on High Performance Computing has already been subject to an impact assessment in 2017 (SEC(2018) 47)

There are only three partnerships for which implementation as an Institutionalised Partnership under Article 185 is an option, i.e. European Metrology, the EU-Africa Global Health partnership, and Innovative SMEs. Ten partnerships are candidates for Institutionalised Partnerships under Article 187. Overall the initiatives can be categorised into 'horizontal' partnerships and 'vertical' partnerships.

The 'horizontal' partnerships have a central position in the overall portfolio, as they are expected to develop methodologies and technologies for application in the other priority areas, ultimately supporting European strategic autonomy in these areas as well as technological sovereignty. These 'horizontal' partnerships are typically proposed as Institutionalised or Co-programmed Partnerships, in addition to a number of EIT KICs, they cover mainly the digital field in addition to space, creative industries and manufacturing, but also the initiative related to Innovative SMEs. 'Vertical' partnerships are focused on the needs and development of specific application areas, and are primarily expected to support enhanced environmental sustainability thereby addressing Green Deal related objectives. They also deliver on policies for more people centred economy, through improved wellbeing of EU citizen and the economy, like health related candidate European Partnerships.

2.2 Assessing the necessity of a European Partnership and possible options for implementation

Horizon Europe Regulation Article 8 stipulates that Institutionalised European Partnerships based on Article 185 and 187 TFEU shall be implemented only where other parts of the Horizon Europe programme, including other forms of European Partnerships would not achieve the objectives or would not generate the necessary expected impacts, and if justified by a long-term perspective and high degree of integration. At the core of this impact assessment is therefore the need to demonstrate that the impacts generated through a Partnership approach go beyond what could be achieved with traditional calls under the Framework Programme – the Baseline Option. Secondly, it needs to assess if using the Institutionalised form of a Partnership is justified for addressing the priority.

For all candidate Institutionalised European Partnerships the options considered in this impact assessment are the same, i.e.:

- Option 0 Baseline option Traditional calls under the Framework Programme
- Option 1 Co-programmed European Partnership
- Option 2 Co-funded European Partnership
- Option 3 Institutionalised Partnership
 - o Sub-option 3a Institutionalised Partnerships based on Art 185 TFEU
 - o Sub-option 3b Institutionalised Partnerships based on Art 187 TFEU

2.2.1 Option 0 - Baseline option – Traditional calls

Under this option, strategic programming for R&I in the priority area will be done through the mainstream channels of Horizon Europe. The related priorities will be implemented through **traditional calls** of Horizon Europe covering a range of actions, mainly R&I and/or innovation actions but also coordination and support actions, prizes or procurement. Most actions involve consortia of public and/or private actors in ad hoc combinations, while some actions are single actor (mono-beneficiary). There will be no dedicated implementation structure and no support other than what is foreseen in the related Horizon Europe Work Programme. This means that discontinuation costs/benefits of predecessor initiatives should be factored in for capturing the baseline situation when relevant.

Under this option, strategic planning mechanisms in the Framework Programme will allow for a high level of flexibility in the ability of traditional calls to respond to particular needs over time, building upon additional input in co-creation from stakeholders and programme committees involving Member States. The Union contribution to addressing the priority covers the full duration of the initiative, during the lifetime of Horizon Europe. Without a formal EU partnership mechanism, it is less likely that the stakeholders will develop a joint Strategic Research Agenda and commit to its implementation or agree on mutual commitments and contributions outside their participation in funded projects.

2.2.2 European Partnerships

Under this set of options, three different forms of implementation are assessed: Co-funded, Co-Programmed, Institutionalised European Partnerships. These have **commonalities that cannot serve as a distinguishing factor in the impact assessment process**. They are all based on agreed objectives and expected impacts and underpinned by Strategic Research and Innovation Agendas / roadmaps that are shared and committed to by all partners in the partnership. They all have to follow the same set of criteria along their lifecycle, as defined in the Horizon Europe Regulation (Annex III), including ex ante commitment from partners to mobilise and contribute resources and investments. The Union contribution is defined for the full duration of the initiative for all European Partnerships. The Horizon Europe legal act introduces few additional requirements for Institutionalised Partnerships, e.g. the need for long-term perspective, strong integration of R&I agendas, and financial contributions.

Figure 2 - Key differences in preparation and implementation of European Partnerships

Type	Legal form	Implementation	
Co-Programmed	Contractual arrangement / MoU	Division of labour , whereby Union contribution implemented through Framework rogramme a partners' contributions under their responsibility.	
Co-Funded	Grant Agreement	Union provides co-funding for an integrated programme with distributed implementation by entities managing and/or funding national research and innovation programmes	
Institutionalised based on Article 185/187 TFEU	Basic act (Council regulation, Decision by European Parliament and Council)	Integrated programme with centralised implementation	

The main differences between the different forms of European Partnerships are in their preparation and in the way they function, as well as in the overall impact they can trigger. The Co-Programmed form is assessed as the simplest, and the Institutionalised the most complex to prepare and implement. The functionalities of the different form of Partnerships – compared to the baseline option – are presented in Figure 3. They relate to the types of actors Partnerships can involve and their degree of openness, the types of activities they can perform and their degree of flexibility, the degree of commitment of partners and the priority setting system, and their ability to work with their external environment (coherence), etc. These key distinguishing factors will be at the basis of the comparison of each option to determine their overall capacity to deliver what is needed at a minimised cost.

Figure 3 Overview of the functionalities provided by each form of European Partnerships, compared to the traditional calls of Horizon Europe (baseline)

Baseline: Horizon	Option 1: Co-	Option 2: Co-Funded		Option 3b:				
Europe calls Type and composition	Programmed		nalised Art 185	Institutionalised Art 187				
Type and composition of actors (including openness and roles) Partners: N.A., Partners: Suitable for all Partners: core of Partners: National Partners: Suitable for all								
no common set of actors that engage in planning and	types: private and/or public partners, foundations	national funding bodies or govern-mental research organisations		types: private and/or public partners, foundations				
implementation Priority setting: open to all, part of Horizon	Priority setting: Driven by partners, open stakeholder consultation, MS in comitology	Priority setting: Driven by partners, open stakeholder consultation	Priority setting: Driven by partners, open stakeholder consultation	Priority setting: Driven by partners, open stakeholder consultation				
Europe Strategic planning Participation in R&I activities: fully open in line with Horizon Europe rules	Participation in R&I activities: fully open in line with Horizon Europe rules	Participation in R&I activities: limited, according to national rules of partner countries	Participation in R&I activities: fully open in line with Horizon Europe rules, but possible derogations	Participation in R&I activities: fully open in line with Horizon Europe rules, but possible derogations				
Type and range of activ	vities (including additiona	lity and level of integrat	ion)	<u> </u>				
Activities: Horizon Europe standards that allow broad range of individual actions Additionality: no additional activities and investments outside the funded projects Limitations: No systemic approach beyond individual actions	Activities: Horizon Europe standard actions that allow broad range of individual actions, support to market, regulatory or policy/ societal uptake Additionality: Activities/investments of partners, National funding Limitations: Limited systemic approach	Activities: Broad, according to rules/programmes of participating States, State-aid rules, support to regulatory or policy/societal uptake Additionality: National funding Limitations: Scale & scope depend on participating programmes, often	Activities: Horizon Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to systemic approach Additionality: National funding	Activities: Horizon Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to systemic approach (portfolios of projects, scaling up of results, synergies with other funds. Additionality: Activities/investments of partners/ national funding				
Priority-setting process	*	smaller in scale						
Priority setting: Strategic Plan and annual work programmes, covering max. 4 years. Limitations: Fully taking into account existing or to be developed SRIA/ roadmap	Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Input to FP annual work programme drafted by partners, finalised by EC (comitology) Objectives &	Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Annual work programme drafted by partners, approved by EC	Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Annual work programme drafted by partners, approved	Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Annual work programme drafted by partners, approved by EC (vetoright in governance) Objectives &				
	commitments set in contractual arrangement	Objectives & commitments set in Grant Agreement	by EC Objectives & commitments set in legal act	commitments set in legal act				
	- 1			imes, industrial strategies)				
Internal: Coherence between different parts of the FP Annual Work programme can be ensured by EC External: Limited for other Union programmes, no synergies with national/regional	Internal: Coherence among partnerships & with parts of the FP Annual Work programme can be ensured by partners & EC External: Limited synergies with other Union programmes & industrial strategies. If	Internal: Coherence among partnerships & with parts of the FP Annual Work programme can be ensured by partners & EC External: Synergies with national/ regional programmes &	Internal: Coherence among partnerships & with parts of the FP Annual Work programme can be ensured by partners & EC External: Synergies with national/regional programmes	Internal: Coherence among partnerships & with parts of the FP Annual Work programme can be ensured by partners & EC External: Synergies with other Union programmes and industrial strategies If MS participate, with				
programmes & activities	MS participate, with national/ regional programmes & activities	activities	& activities	national/ regional programmes & activities				

2.2.2.1 Option 1 - Co-programmed European Partnership

This form of European Partnership is **based upon a Memorandum of Understanding or a Contractual Arrangement** signed by the Commission and the private and/or public partners. Private partners are represented by industry associations, which also support the daily management of the partnership. This type of partnership would allow for a large degree of flexibility for the activities, partners and priorities to continuously evolve. The commitments of partners are political efforts described in the contractual arrangement and the contributions from partners are provided in kind more than financially. The priorities for the calls, proposed by the Partnership's members for integration in the Horizon Europe's Work Programmes, are subject to further input from Member States (comitology) and Commission services. The Union contribution is implemented within the executive agency managing Horizon Europe calls for research and innovation projects proposals. The full array of Horizon Europe instruments can be used, ranging from research and innovation (RIA) types of actions to coordination and support actions (CSA) and including grants, prizes, and procurement.

2.2.2.2 Option 2 – Co-funded European Partnership

The Co-funded European Partnership is **based on a Grant Agreement** between the Commission and a consortium of partners, resulting from a specific call in the Horizon Europe Work Programme. This form of implementation only allows to address public partners at its core. Typically these provide co-funding to a common programme of activities established and/or implemented by entities managing and/or funding national R&I programmes. The recipients of the EU co-funding implement the initiative under their responsibility, with national funding/resources pooled to implement the programme with co-funding from the Union. The expectation is that these entities would cover most if not all EU Member States. Calls and evaluations would be organised centrally, beneficiaries in selected projects would be funded at national level, following national funding rules.

2.2.2.3 Option 3 – Institutionalised European Partnership

This type of Partnership is the most complex and high-effort arrangement, and requires meeting additional requirements. Institutionalised European Partnership are based on a Council Regulation (Article 187 TFEU or a Decision by the European Parliament and Council (Article 185 TFEU) and are implemented by dedicated structures created for that purpose. These regulatory needs limit the flexibility for a change in the core objectives, partners, and/or commitments as these would require amending legislation. The basic rationale for this type of partnership is the need for a strong integration of R&I agendas in the private and/or public sectors in the EU in order to address a strategic challenge. It is therefore necessary to demonstrate that other forms of implementation would not achieve the objectives or would not generate the necessary expected impacts, and that a long-term perspective and high degree of integration is needed. For both Article 187 and 185 initiatives, contributions from partners can be in the form of financial and in-kind contributions. Eligibility for participation and funding follows by default the rules of Horizon Europe, unless a derogation is introduced in the basic act.

Option 3a - Institutionalised Partnerships based on Article 185 TFEU

Article 185 of the TFEU allows the Union to participate in programmes jointly undertaken by Member States and limits therefore the scope to **public partners** which are Member States and Associated Third Countries. This type of Institutionalised Partnership aims

therefore at reaching the greatest possible impact through the integration of national and EU funding, aligning national strategies in order to optimise the use of public resources and overcome fragmentation of the public research effort. It brings together R&I governance bodies of most if not all EU Member States (legal requirement: at least 40% of Member States) as well as Associated Third Countries that designate a legal entity (Dedicated Implementation Structure) of their choice for the implementation. By default, participation of non-associated Third Countries is not foreseen. Such participation is possible only if it is foreseen in the basic act and subject to conclusion of an international agreement.

Option 3b - Institutionalised Partnerships based on Article 187 TFEU

Article 187 of the TFEU allows the Union to set up joint undertakings or any other structure necessary for the efficient execution of EU research, technological development and demonstration programmes. This type of Institutionalised Partnership brings together a stable set of **public and private partners** with a strong commitment to taking a more integrated approach and requires the set-up of a dedicated legal entity (Union body, Joint Undertaking (JU)) that carries full responsibility for the management of the Partnership and implementation of the calls. Different configurations are possible:

- Partnerships focused on creating strategic industrial partnerships where, most often, the partner organisations are represented by one or more industry associations, or in some cases individual private partners;
- Partnerships coordinating national ministries, public funding agencies, and governmental research organisations in the Member States and Associated Countries;
- Or a combination of the two: the so-called tripartite model.

Participation of non-associated Third Countries is only possible if foreseen in the basic act and subject to conclusion of an international agreement.

2.3 Overview of the methodology adopted for the impact assessment

The methodology for each impact assessment is based on the Commission Better Regulation Guidelines²⁰ to evaluate and compare options with regards to their **efficiency**, **effectiveness** and coherence. This also integrates key selection criteria for European Partnerships.

Box 2 Summary of European Partnerships selection criteria²¹

- Effectiveness in achieving the related objectives and impacts of the Programme;
- Coherence and synergies of the European Partnership within the EU R&I landscape;
- *Transparency* & *openness* as regards the identification of priorities and objectives and the involvement of partners & stakeholders from the entire value chain, backgrounds & disciplines;
- Ex-ante demonstration of *additionality* and *directionality*;
- Ex-ante demonstration of the partners' *long term commitment*.

2.3.1 Overview of the methodologies employed

In terms of **methods and evidence used**, the impact assessments draw on an external study covering all candidate Institutionalised European Partnerships in parallel to ensure a high level of coherence and comparability of analysis, in addition to an horizontal analysis.²² For

²¹ For a comprehensive overview of the selection criteria for European Partnerships, see Annex 6.

²⁰ European Commission (2017), Better Regulation Guidelines (SWD (2017) 350)

²² Technopolis Group (2020), Impact Assessment Study for Institutionalised European Partnerships under Horizon Europe, Final Report, Study for the European Commission, DG Research & Innovation

all initiatives, the understanding of the overall context of the candidate institutionalised European Partnerships relied on desk research, including among others the lessons learned from previous partnerships. This was complemented by the analysis of a range of quantitative and qualitative evidence, including evaluations of past and ongoing initiatives; foresight studies; statistical analyses of Framework Programmes application and participation data, and Community Innovation Survey data; analyses of science, technology and innovation indicators; reviews of academic literature; sectoral competitiveness studies and expert hearings. The analyses included a portfolio analysis, a stakeholder and social network analysis in order to profile the actors involved as well as their co-operation patterns, and an assessment of the partnerships' outputs (bibliometrics and patent analysis). A cost modelling exercise was performed in order to feed into the efficiency assessments of the partnership options, as described below. Public consultations (both open and targeted) supported the comparative assessment of the policy options. For each initiative, up to 50 relevant stakeholders were interviewed by the external contractor (policymakers, business including SMEs and business associations, research institutes and universities, and civil organisations, among others). In addition, the analysis was informed by the results of the Open Public Consultation run between September and November 2019, the consultation of Member States through the Strategic Programme Committee and the online feedback received on the Inception Impact Assessments of the set of initiatives.

A more detailed description of the methodology and evidence base that were mobilised, completed by thematic specific methodologies, is provided in Annexes 4 and 6.

2.3.2 Method for identifying the preferred option

The first step of the assessments consisted in scoping the problems that the initiatives are expected to solve given the overall economic, technological, scientific and social context, including the lessons to be learned from past and ongoing partnerships on what worked well and less well. This supported the identification of the objectives of the initiative in the medium and long term with the underlying intervention logic – showing how to get there.

Given the focus of the impact assessment on comparing different forms of implementation, the Better Regulation framework has then been adapted to introduce "key functionalities **needed**" - making the transition between the definition of the objectives and what would be crucial to achieve them in terms of implementation. The identification of "key functionalities needed" for each initiative as an additional step in the impact assessment is based on the distinguishing factors between the different options (see Section 2.2.1). In practical terms, each option is assessed on the basis of the degree to which it would allow for the key needed functionalities to be covered, as regards e.g. the type and composition of actors that can be involved ('openness'), the range of activities that can be performed (including additionality and level of integration), the level of directionality and integration of R&I strategies; the possibilities offered for coherence and synergies with other components of Horizon Europe, including other Partnerships (internal coherence), and the coherence with the wider policy environments, including with the relevant regulatory and standardisation framework (external coherence). This approach guides the identification of discarded options while allowing at the same time a structured comparison of the options not only as regards their effectiveness, efficiency and coherence, but also against a set of other key selection criteria for European Partnerships (openness, transparency, directionality)²³.

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²³ The criterion on the ex-ante demonstration of partners' long term commitment depends on a series of factors that are unknown at this stage, and thus fall outside the scope of the analysis.

In line with the Better Regulation Framework, the assessment of the effectiveness, efficiency and coherence of each option is made compared to the baseline. Therefore, for each of these aspects the performance of using traditional calls under Horizon Europe is first estimated and scored 0 to serve as a reference point. This includes the discontinuation costs/benefits of existing implementation structures when relevant. The policy options are then scored compared to the baseline with a + and – system with a two-point scale, to show a slightly or highly additional/lower performance compared to the baseline. A scoring of 0 of a policy option means that it would deliver as much as the baseline option.

On the basis of the evidence collected, the intervention logic of each initiative and the key functionalities needed, the impact assessments first evaluate the **effectiveness** of the various policy options to deliver on their objectives. To be in line with the Horizon Europe impact framework, the fulfilment of the specific objectives of the initiative is translated into 'expected impacts' - how success would look like -, differentiating between scientific, economic/ technological, and societal (including environmental) impacts. Each impact assessment considers to which extent the different policy options provides the 'key functionalities needed' to achieve the intended objectives. The effectiveness assessment does not use a compound score but shows how the options would deliver on the different types of expected impacts. This is done to increase transparency and accuracy in the assessment of options²⁴.

A similar approach is followed to evaluate the coherence of options with the overarching objectives of the EU's R&I policy, and distinguishes between **internal** and **external coherence**. Specifically, internal coherence covers the consistency of the activities that could be implemented with the rest of Horizon Europe, including European Partnerships (any type). External coherence refers to the potential for synergies and/or complementarities (including risks of overlaps/gaps) of the initiative with its external environment, including with other programmes under the MFF 2021-27, but also the framework conditions at European, national or regional level (incl. regulatory aspects, standardisation).

To compare the expected costs and benefits of each option (efficiency), the thematic impact assessments broadly follow a cost-effectiveness approach²⁵ to establish to which extent the intended objectives can be achieved for a given cost. A preliminary step in this process is to obtain a measure of the expected costs of the policy options, to be used in the thematic assessments. As the options correspond to different implementation modes, relevant cost categories generally include the costs of setting-up and running an initiative. For instance, set-up costs includes items such as the preparation of a European Partnership proposal and the preparation of an implementation structure. The running costs include the annual work programme preparation costs. Where a Partnership already exists, discontinuation costs and cost-savings are also taken into account²⁶. The table below provides an overview of the cost categories used in the impact assessment and a qualitative scoring of their intensity when compared to the baseline option (traditional calls). Providing a monetised value for these average static costs would have been misleading, because of the different features and needs

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²⁴ In the thematic impact assessments, scores are justified in a detailed manner to avoid arbitrariness and spurious accuracy. A qualitative or even quantitative explanation is provided of why certain scores were given to specific impacts, and why one option scores better or worse than others.

²⁵ For further details, see Better Regulation Toolbox # 57.

²⁶ Discontinuation costs will bear winding down and social discontinuation costs and vary depending on e.g. the number of full-time-equivalent (FTEs) staff concerned, the type of contract (staff category and duration) and applicable rules on termination (e.g. contracts under Belgian law or other). If buildings are being rented, the cost of rental termination also apply. As rental contracts are normally tied to the expected duration of the current initiatives, these termination costs are likely to be very limited. In parallel, there would also be financial cost-savings related to the closing of the structure, related to operations, staff and coordination costs in particular. This is developed further in the individual efficiency assessments.

of each candidate initiative.²⁷ The table shows the overall administrative, operational and coordination costs of the various options. These costs are then put into context in the impact assessments to reflect the expected co-financing rates and the total budget available for each of the policy options, assuming a common Union contribution (cost-efficiency):

- The costs related to the baseline scenario (traditional calls under Horizon Europe) are pre-dominantly the costs of implementing the respective Union contribution via calls and project, managed by the executive agencies (around 4%, efficiency of 96% for the overall investment).
- For a Co-Programmed partnership the costs of preparation and implementation increase only marginally compared to the baseline (<1%), but lead to an additional R&I investment of at least the same amount than the Union contribution²⁸ (efficiency of 98% for the overall investment).
- For a Co-Funded partnership the additional R&I investment by Member States accounts for 2,3 times the Union contribution²⁹. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the national programmes, can be estimated at 6% of the Union contribution (efficiency of 98% related to the overall investment).
- For an Article 185 initiative the additional R&I investment by Member States is equal to the Union contribution³⁰. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the dedicated implementation structure, can be estimated at 7% of the Union contribution (efficiency of 96% related to the overall investment).
- For an Article 187 initiative the additional R&I investment by partners is equal to the Union contribution³¹. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the dedicated implementation structure, can be estimated at 9% of the Union contribution (efficiency of 94% related to the overall investment).

Figure 4 - Intensity of additional costs compared with Horizon Europe Calls (for Partners, stakeholders, public and EU)

Cost items	Baseline: traditional calls	Option 1: Coprogrammed	Option 2 Co-funded	Option 3a - Art. 185	Option 3b -Art. 187	
Preparation and set-up costs						
Preparation of a partnership proposal (partners and EC)	0		↑ ↑			
Set-up of a dedicated implementation structure		0		Existing: ↑ New: ↑↑	Existing: ↑↑ New: ↑↑↑	
Preparation of the SRIA / roadmap	0		$\uparrow \uparrow$			
Ex-ante Impact Assessment for partnership		0		↑ ↑	↑	
Preparation of EC proposal and negotiation		0		↑ ↑	↑	
Running costs (Annual cycle of implementation)						
Annual Work Programme preparation	0		↑			

²⁷ A complete presentation of the methodology developed to assess costs as well as the sources used is described in the external study supporting this impact assessment (Technopolis Group, 2020).

²⁹ Based on the default funding rate for programme co-fund actions of 30%, partners contribute with 70% of the total investment.

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²⁸ Minimum contributions from partners equal to the Union contribution

³⁰ Based on the minimum requirement in the legal basis that partners contribute at least 50% of the budget.

³¹ Based on the minimum requirement in the legal basis that partners contribute at least 50% of the budget.

Cost items	Baseline: traditional calls	Option 1: Coprogrammed	Option 2 Co-funded	Option 3a - Art. 185	Option 3b -Art. 187	
Call and project implementation	0	0 In case of MS contributions: ↑	↑	1	1	
Cost to applicants	Comparable, unless there are strong arguments of major differences in oversubscription				fferences in	
Partners costs not covered by the above	0	↑	0	↑	↑	
Additional EC costs (e.g. supervision)	0	↑	↑	↑	$\uparrow \uparrow$	
Winding down costs						
EC		0			$\uparrow\uparrow\uparrow$	
Partners	0	↑	0	↑	↑	

Notes: 0: no additional costs, as compared with the baseline; \uparrow : minor additional costs, as compared with the baseline; $\uparrow \uparrow$: medium additional costs, as compared with the baseline; $\uparrow \uparrow \uparrow$: higher costs, as compared with the baseline.

The cost categories estimated for the common model are then used to develop a scorecard analysis and further refine the assessment of options for each of the 12 candidate Institutionalised Partnerships. Specifically, the scores related to the set-up and implementation costs are used in the thematic impact assessments to consider the scale of the expected benefits and thereby allow a simple "value for money" analysis (cost-effectiveness)³². In carrying out the scoring of options, the results of fieldwork, desk research and stakeholder consultation undertaken and taken into account.

For the **identification of the preferred option**, the scorecard analysis builds a hierarchy of the options by individual criterion and overall in order to identify a single preferred policy option or in case of an inconclusive comparison of options, a number of 'retained' options or hybrid. This exercise supports the systematic appraisal of alternative options across multiple types of monetary, non-monetary and qualitative dimensions. It also allows for easy visualisation of the pros and cons of each option. Each option is attributed a score of the adjudged performance against each criterion with the three broad appraisal dimensions of effectiveness, efficiency and coherence.

As a last step, the alignment of the preferred option with key criteria for the selection of European Partnerships is described, reflecting the outcomes of the 'necessity test'.³³ The monitoring and evaluation arrangements are concluding the assessment, with an identification of the key indicators to track progress towards the objectives over time.

2.4 Horizontal perspective on candidate Institutionalised European Partnerships

2.4.1 Overall impact orientation, coherence and efficiency needs

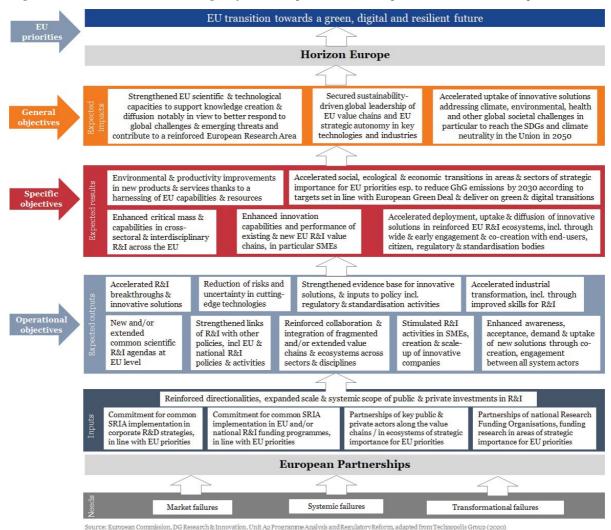
The consolidated **intervention logic** for the set of candidate Institutionalised European Partnerships in the Figure below builds upon the objectives as reported in the individual impact assessments.

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³² More details on the methodology can be found in Annex 4.

³³Certain aspects of the selection criteria will be further addressed/ developed at later stages, notably in the context of preparing basic acts (e.g. Openness and Transparency; Coherence and Synergies), in the Strategic Research and Innovation Agendas (e.g. Directionality and Additionality), and by collecting formal commitments (Ex-ante demonstration of partners' long-term commitment).

Figure 5 – Overall intervention logic of the European Partnerships under Horizon Europe



When analysed as a package the 12 candidate Institutionalised European Partnerships are expected to support the achievement of the European policy priorities targeted by Horizon Europe by pursuing the following joint general objectives:

- a) Strengthening and integrating EU scientific and technological capacities to support knowledge creation and diffusion notably in view to better respond to global challenges and emerging threats and contribute to a reinforced European Research Area:
- b) Securing sustainability-driven global leadership of EU value chains and EU strategic autonomy in key technologies and industries; and
- c) Accelerate the uptake of innovative solutions addressing climate, environmental, health and other global societal challenges contributing to Union strategic priorities, in particular to reach the Sustainable Development Goals and climate neutrality in the Union in 2050.

In terms of specific objectives, they jointly aim to:

- a) Enhance the critical mass and scientific capabilities in cross-sectoral and interdisciplinary research and innovation across the Union;
- b) Accelerate the social, ecological and economic transitions in areas and sectors of strategic importance for Union priorities, in particular to reduce greenhouse gas

- emissions by 2030 according to the targets set in line with the European Green Deal, and deliver on the green and digital transition;
- c) Enhance the innovation capabilities and performance of existing and new European research and innovation value chains, in particular SMEs;
- d) Accelerate the deployment, uptake and diffusion of innovative solutions in reinforced European R&I ecosystems, including through wide and early engagement and co-creation with end-users, citizen and regulatory and standardisation bodies;
- e) Deliver environmental and productivity improvements in new products and services thanks to a harnessing of EU capabilities and resources.

In terms of their operations, taking an horizontal perspective on all initiatives allows for the identification of further possible collective efficiency and coherence gains for more impact:

- Coherence for impact: The extent and speed by which the expected results and impacts will be reached, will depend on the scale of the R&I efforts triggered, the profile of the partners involved, the strength of their commitments, and the scope of the R&I activities funded. To be fully effective it comes out clearly that future partnerships need to operate over their whole life cycle in full coherence with their environment, including potential end users, regulators and standardisation bodies. This relates also to the alignment with relevant EU, national or regional policies and synergies with R&I programmes. This needs to be factored in as of the design stage to ensure a wide take-up and/or deployment of the solutions developed, including their interoperability.
- Collaboration for impact: Effectiveness could also be improved collectively through enhanced cross-disciplinary and cross-sectoral collaboration and an improved integration of value chains and ecosystems. An adequate governance structure appears in particular necessary to ensure cross-fertilisation between all European Partnerships. This applies not only to initiatives where similar R&I topics are covered and/or the same stakeholders involved or targeted, but also to the interconnections needed between the 'thematic' and the 'vertical' Partnerships, as these are expected to develop methodologies and technologies for application in EU priority areas. Already at very early stages of preparing new initiatives, Strategic Research and Innovation Agendas and roadmaps need to be aligned, particularly for partnerships that develop enabling technologies that are needed in other Partnerships. The goal should be to achieve greater impacts jointly in light of common challenges.
- Efficiency for impact: Potential efficiency gains could also be achieved by joining up the operational functions of Joint Undertakings that do not have a strong context dependency and providing them through a common back-office³⁴. A number of operational activities of the Joint Undertakings are of a technical or administrative nature (e.g. financial management of contracts), or procured from external service providers (e.g. IT, communication activities, recruitment services, auditing) by each Joint Undertaking separately. If better streamlined this could create a win-win situation for all partners leading to better harmonization, economies of scales, and less complexity in supervision and support by the Commission services.
 - 2.4.2 Analysis of coherence of the overall portfolio of candidate initiatives at the thematic level

Looking at the coherence of the set of initiatives at the thematic level, the "digital centric"

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³⁴ See Annex 6 for an overview of key functions/roles that could be provided by a common back office.

initiatives have a strong focus on supporting the digital competitiveness of the EU ecosystem. Their activities are expected to improve alignment and coordination with Member States and industry for the development of world-competitive EU strategic digital technology value chains and associated expertise. Addressing the Key Digital Technologies, the 5G and 6G connectivity needs as part of a Smart Networks and Services initiative and the underlying supercomputing capacities through a European High Performance Computing initiative present potential for synergies that can be addressed through cooperative actions (e.g. joint calls, coordinated support activities, etc.). They may as well profit from and contribute to Partnerships envisaged for Photonics, AI, data, robotics, Global competitive space system and Made in Europe, together with the EIT Digital. Synergies between these initiatives and several programmes (Digital Europe and Connecting Europe as well as cohesion programmes) are needed in areas where EU industry has to develop leadership and competitiveness in the global digital economy. They are expected to impact critical value chains including on sectors where digital is a strong enabler of transformation (health, industrial manufacturing, mobility/transport, etc.).

The transport sector face systemic changes linked to decarbonisation and digitalisation. Large scale R&I actions are needed to prepare the transition of these complex sectors to provide clean, safer, digital and economically viable services for citizens and businesses. Past decades have shown that developing and implementing change is difficult in transport due to its systemic nature, many stakeholders involved, long planning cycles and large investments needed. A systemic change of the air traffic network through an Integrated Air Traffic Management initiative should ensure safety and sustainability of aviation, while a Clean Aviation initiative should focus on the competitiveness of tomorrow's clean aircrafts made in Europe. The initiative for Transforming Europe's rail system would comprehensively address the rail sector to make it a cornerstone in tomorrow's clean and efficient door-to-door transport services, affordable for every citizen as well as the most climate-friendly mode of transport for freight. Connected and Automated Mobility is the future of road transport, but Europe is threatened to fall behind other global regions with strong players and large harmonised markets. The initiative Safe and Automated Road Transport would bring stakeholders together, creating joint momentum in digitalising road transport and developing new user-based services. Stronger links and joint actions will be established between initiatives to enable common progress wherever possible. The Clean Hydrogen initiative would be fundamental to that regard. Synergies would also be sought with partnerships driving the digital technological developments.

To deliver a deep decarbonisation of highly emitting industrial sectors such as the steel, transport and chemical industries would require the production, distribution and storage of **hydrogen** at scale. The candidate hydrogen initiative would have a central positioning in terms of providing solutions to the challenges for sustainable mobility and energy, but also is expected to operate in synergies with other industry related initiatives. The initiative would interact in particular with initiatives on the zero emission road and water transport, transforming Europe's railway system, clean aviation, batteries, circular industry, clean steel and built environment partnerships. There are many opportunities for collaboration for the delivery and end-use of hydrogen. However, the Clean Hydrogen initiative would be the only partnership focused on addressing hydrogen production technologies.

Metrology, the science of measurement, is an enabler across all domains of R&I. It supports the monitoring of the Emissions Trading System, smart grids and pollution, but also contributes to meeting demands for measurement techniques from emerging digital technologies and applications. More generally, emerging technologies across a wide range

of fields from biotechnologies, new materials, health diagnostics or low carbon technologies are giving rise to demands requiring a world-leading EU metrology system.

The initiative for a **Circular Bio-based Europe** is intended to solve a shortage of industry investments in the development of bio-based products whose markets do not have yet certain long-term prospects. The **Innovative Health Initiative** and **EU-Africa Global Health** address the lack of investments in the development of solutions to specific health challenges. The initiative on **Innovative SMEs** supports innovation-driven SMEs in participating in international, collaborative R&I projects with other innovative firms and research-intensive partners. As a horizontal initiative it is expected to help innovative SMEs to grow and to be successfully embedded in global value chains by developing methodologies and technologies for potential application in the other partnership areas or further development by the instruments of the European Innovation Council.

The description of the interconnections between all initiatives for each Horizon Europe cluster is provided in the policy context of each impact assessment and further assessed in the coherence assessment for each option.

PART 2 - THE CANDIDATE EUROPEAN PARTNERSHIP ON A CIRCULAR BIO-BASED EUROPE

INTRODUCTION: POLITICAL AND LEGAL CONTEXT

Europe embarked on its course to become the first climate neutral continent by 2050. The roadmap and series of measures and initiatives to lead this green transition are set out in the European Green Deal³⁵, the Commission's new growth strategy to boost the green economy and protect the environment.

The climate and environmental challenges that Europe is facing are interlinked with and reinforced by unsustainable production and consumption patterns, overexploitation of natural resources, ecosystem degradation, biodiversity loss and dwindling availability of critical raw materials³⁶. Research and innovation are fundamental drivers that can turn these complex and multi-faceted challenges into economic and environmental opportunities that are also inclusive and just. They can provide for disruptive innovations that trigger societal transitions, breakthrough technologies that open new market opportunities, as well as sustainable and circular solutions that address environmental challenges.

The bioeconomy – and notably its industrial part 'the bio-based industry' - have a strong role to play in delivering environmental and climate neutral solutions through bio-based innovation. Beyond decreasing EU dependency on and accelerating the substitution of nonrenewable fossil raw materials and mineral resources, and providing low-toxicity bio-based alternatives, the bio-based industry has the potential to create value from local feedstock and deliver jobs, economic growth and development not only in urban areas but also in rural and coastal territories where biomass is produced.

Definition of the bioeconomy³⁷

"The bioeconomy covers all sectors and systems that rely on biological resources (animals, plants, micro-organisms and derived biomass, including organic waste), their functions and principles. It includes and interlinks: land and marine ecosystems and the services they provide; all primary production sectors that use and produce biological resources (agriculture, forestry, fisheries and aquaculture); and all economic and industrial sectors that use biological resources and processes to produce food, feed, bio-based products, energy and services. 38,,

Definition of bio-based industry³⁹

The bio-based industry is the part of economy formed by companies that use biological input (feedstock) to produce material, products and services. The biological input can be the biomass extracted from natural environment and purpose grown biomass (e.g. from agriculture and forestry, marine, fisheries and aquaculture), as well as different forms of biological waste, side streams and residues (e.g. by-products, rejects and waste from agriculture, wood processing, food production, industrial biological waste or municipal biological waste). Bio-based industry can produce bulk materials (continuous industry) or

³⁵ COM(2019) 640 final, The European Green Deal.

³⁶ COM(2017) 490 final, 2017 list of Critical Raw Materials for the EU

³⁷ COM(2018) 673 final, EU Bioeconomy Strategy (2018).

³⁸ Biomedicines and health biotechnology are excluded.

³⁹ In this impact assessment biomedicines and health biotechnology is excluded from the definition of the bio-based industry in line with the EU Bioeconomy Strategy,

specific products⁴⁰ (discrete industries). Bio-based industries operate in many manufacturing sectors⁴¹.

Definition of bio-based innovation

Bio-based innovation is a novel concept, technology, process, material or product based on the use and transformation of biological input. The benefits of bio-based innovation include one or more of the following: increased energy or material efficiency of production process, new properties of produced material or product, ability to use and valorise waste, and elimination of pollution.

Building on the scientific advances in life-sciences and biotechnology, the area of bio-based innovation is growing fast. This is particularly the case in certain areas of application, such as health, agriculture, nutrition and specialty materials and consumer products, where there are expectations of high economic returns for the industry. However, the scientific advance in biology can be applied more broadly and introduce bio-based innovative solutions in most manufacturing sectors and thus contribute to the needed climate and environmental transition. The bio-based industry is now expected to invent and bring further to the market a wide set of climate- and environment-friendly circular and sustainable bio-based solutions for the production of basic chemicals and materials, plastics, packaging, construction products, textile and other goods with high material use.

To exploit the full potential of the bio-based industry, improved technologies and new transformation processes still need to be developed, tested in the real-life environment and brought to the market. Life sciences and biotechnologies, including industrial biotechnology and engineering (or synthetic) biology as well as digital, chemical, microbial, enzymatic and electrochemical technologies offer new opportunities for improvement of technologies and processes used by the bio-based industry⁴². These technologies are often platform technologies that can be applied in a number of sectors such as agriculture, foods and feed, pharmaceuticals⁴³, chemicals and materials, energy etc. Some segments of biotechnology are still in their infancy (e.g. marine biotechnology), while others (e.g. industrial biotechnology) are far more advanced and already at the heart of the bio-based industry (e.g. use of enzymes in biomass processing in biorefineries). Yet even in the latter case, the focus on new types of feedstock for processing requires intensive R&I effort to develop more efficient biotechnological processes (e.g. specific enzymatic mixtures or pre-treatment of biomass).

⁴⁰ Bio-fuels are bio-based products and in a broader sense, bio-fuel production is a segment of the bio-based industry. However, the bio-fuel production is excluded from the scope of the proposed R&I initiative as this segment operates in a very different policy and market context from the rest of the industry. The biofuel sector is highly regulated and markets are strongly affected by economic incentives. R&I in biofuel is facing a different set of issues as there are separate R&I and investment programmes and instruments for research in biofuels. From the technological point of view, bio-fuel innovation is still implicitly included in the scope of the proposed initiative, as the technology for production of biofuel is similar to the technology to produce many other bio-based materials. An example is the production of ethanol from agricultural residues through biorefining. This ethanol can be used as bio-additive to fuel or as a feedstock for the chemical industry. Also, the sustainability aspects of the bio-based industry are applicable for biofuels. As a result, the biofuel segment will benefit from this initiative.

⁴¹ In this impact assessment report the term 'sector' is interpreted as a part of economy that is defined by the product or service provided. For example there is the "manufacturing of chemicals and chemical products" sector (NACE code C20) which covers all industrial manufacture of chemicals. Within this sector there are companies that use abiotic materials as an input for production of chemicals as well as companies using biological input. The companies using the biological input will be considered as the bio-based industry within the chemicals sector. There is no single NACE code that would be assigned to the bio-based industry.

⁴² OECD, Meeting Policy Challenges for a Sustainable Bioeconomy, Paris, 2018.

While biotechnology is at the heart of bio-based processes, health biotechnology and biological medicines are not included in the European Union's (EU) bioeconomy definition.

The bio-based industry is a capital intensive, high-risk investment area that is facing technological, regulatory and market challenges that cannot be tackled by any Member State alone. It requires concerted action by a wide range of stakeholders and the mobilisation of public and private funding to create a supportive ecosystem that can trigger a green transition. Therefore, since 2014, the European Union supports the 'Bio-based Industries Joint Technology Initiative' (BBI Joint Undertaking or BBI JU) -- a public-private partnership between the EU and the Bio-based Industries Consortium⁴⁴. It is aimed at increasing research and innovation investment in the development of a sustainable bio-based industry in Europe. The interim evaluation of the BBI JU⁴⁵ underlined its structuring and mobilising effect on the bio-based industry, but also made recommendations for improvement as regards the scope of its activities, the synergies with other initiatives, and the involvement of stakeholders (e.g. NGOs, brand owners, citizens) and actors such as Member States, regions and municipalities. Since then, the socio-economic, scientific, technological, and political contexts have further evolved putting new demands on these types of partnerships. In particular, the analysis of participation highlighted the need to increase engagement of key actors (e.g. primary biomass producers in bio-based value chains, investors, regions). Furthermore, following the COVID-19 crisis, the bio-based industry is considered a strong catalyst and enabler to drive the green transition to a more resilient and environmentally sustainable EU economy, which is a critical opportunity for the Green Deal and the European recovery plan Next Generation EU⁴⁶ - and therefore this has to be reflected in any future initiative.

Based on lessons learned from past experience⁴⁷ and new and emerging needs, this Impact Assessment document assesses which of the available instruments under Horizon Europe would be the most effective and efficient to focus, structure and align joint European research and innovation activities in bio-based industrial systems to deliver on EU priorities.

Stakeholder opinion

Some 67% of the 1755 respondents (including industry, academic and research institutions, public authorities and NGOs) to the Open Public Consultation consider that the scope and coverage proposed for this candidate Circular Bio-based Europe partnership are right and appropriate in terms of technologies and research areas covered, geographical and sectoral scope, proposed types of partners and range of activities.

1.1 Emerging challenges in the field

Global challenges like climate change, land and ecosystem degradation, coupled with a growing population are forcing us to seek new ways of producing and consuming that respect the ecological boundaries of the planet 4849.

Unsustainable production and consumption patterns are on the rise including the use of fossils, minerals and metals with high climate and environmental footprint⁵⁰. The

⁴⁴ https://biconsortium.eu/bio-based-industries-consortium

⁴⁵ Interim evaluation of the Bio-based Industries Joint Undertaking (2014-2016) operating under Horizon 2020 (2017)

 $^{^{46}}$ COM/2020/456 final and SWD(2020) 98 final

⁴⁷ Importantly, additional sources of evidence since the BBI JU interim evaluation (2017), such as BBI JU Annual Activity Reports 2018 and 2019.

⁴⁸ COM(2018) 673 final, EU Bioeconomy Strategy (2018).

⁴⁹ COM(2019) 22 final, Reflection paper towards a sustainable Europe.

⁵⁰ Approximately one quarter of global GHG emissions is caused by material production (from: Material Economics (2019) Industrial Transformation 2050)

McKinsey Global Institute⁵¹ estimates that 60% of global material input can be made using biological means. Yet this is not happening. There is thus an enormous but not fully tapped potential for substitution of abiotic fossil materials with bio-based material which can offer the same functionality, or even have novel properties unachievable by conventional materials and products, such as lower toxicity or better functional characteristics.

This feedstock availability is not constant and quality is not homogenous by default. It can be affected among others by geography, climate and soil conditions, seasonality, logistical issues, competing uses of biomass for other applications such as energy production, certification requirements and type of feedstock (primary produce or secondary resources: biowaste, residues, etc.). These elements can lead to large price fluctuations and even unavailability of feedstock, which is an important constraint for the functioning of European bio-based industry. In such cases, if the bio-based industry cannot use alternative feedstock or increase feedstock efficiency, price increases or volatility end up reducing competitiveness and demand for bio-based products compared to fossil-based industry alternatives. As a result, bio-based products may become more expensive than their fossil-based substitutes, which is a significant structural competitive disadvantage for bio-based industry.

In addition, biomass is the most wasted material – more than one quarter or about 600 megatons of biomass ends up as waste every year, out of which 60 megatons is food waste⁵³ and 88 megatons is municipal waste⁵⁴. **Only about 25% of this resource is collected and recycled**, showing the high level of opportunities for capturing the economic value and reducing environmental impact of biological waste. Higher utilisation of biological waste as a feedstock would make the bio-based industries more circular⁵⁵ and contribute to the EU circular economy transition. However, low grade, non-homogenous waste with impurities is difficult to process with the current technologies so the ability of the bio-based industry to use bio-waste feedstock, especially in higher value products accepted by consumers, is a persisting R&I challenge for the future.

Climate change puts pressure on the need to decrease carbon emissions from industry, and bio-based industrial systems are intrinsically carbon efficient. Living organisms and in particular plants bind carbon from the air, soil or water, and turn it into biomass. If this biomass is converted into materials, the carbon stocks contained therein is sequestered for the time until the material is combusted or degraded so that carbon is released back to the atmosphere. However, the overall carbon efficiency of bio-based industrial production systems depends on the amount and form of energy they use in the whole production system including production of biomass, transport, processing, and so on, and can be measured by a whole 'life cycle assessment' (LCA). This is why some industrial systems can be demonstrably very carbon efficient and contribute to climate mitigation while others may even emit more carbon than they bind. For instance, in the biofuel sector some older

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⁵¹ McKinsey Global Institute: The Bio Revolution, May 2020.

⁵² EIB (2017): Access-to-finance conditions for Investments in Bio-Based Industries and the Blue Economy

⁵³ Bio-based Industry Consortium and Zero Waste Europe (2020): Bio-waste generation in the EU: Current capture levels and future potential

⁵⁴ COM (2010) 235 Communication from the Commission to the Council and the European Parliament on future steps in bio-waste management in the European Union

According to the EC Expert Group on Circular Economy F EIB (2017): Access-to-finance conditions for Investments in Bio-Based Industries and the Blue Economy, the bio-based industry can become circular by: using sustainably sourced renewable biomass as the feedstock, using the biological waste as the feedstock, or by producing materials/products that can be used in circular way (EC Expert Group on Circular Economy Finance (2020): Categorisation System for Circular Economy)

biorefineries in the EU do not meet the current legal requirement for GHG reduction and can actually emit more carbon emissions than equivalent fossil based operations⁵⁶. The scientific community agrees that the carbon efficiency of certain bio-based industrial systems can be improved significantly.

Socio-economic and environmental pressures push for more resilient, circular and local industrial processes. The bio-based industry can make the EU economy more circular and locally sourced. Bio-based technology can use domestic sustainably produced biomass or use local biological waste or residues from agriculture and forestry, industrial processes and municipal waste.

The **recovery from the economic crisis** caused by the Covid-19 pandemic further demonstrates the need for structural changes that will make the EU economy more resilient to future shocks. The bio-based industry can contribute to the economic recovery and maintain high growth for an extended period. As the bio-based industry uses domestic resources, e.g. the biological waste, it makes this industry more resilient to external crises and fluctuation in availability and cost of raw materials. It can bring jobs to economically depressed areas that may be affected by the crisis disproportionately without leaving certain groups or regions behind⁵⁷ by providing additional income to those who produce biomass in rural and depressed regions that typically do not benefit from industrial development. This **potential can however be undermined by the unequal capacity for bio-industrial activity in different regions**. The challenge is to ensure the development of bio-industrial activity in those parts of Europe where there are suitable conditions for bio-based industrial activities but insufficient capacity, e.g. in Central and Eastern Europe⁵⁸. This particular issue correlates with the policy support given by some EU Member States, demonstrated by the presence or absence of national Bioeconomy strategies⁵⁹.

The overall challenge for the EU bio-based industry to grow in an environmentally sustainable way and deliver jobs and income to rural and low-income regions is not only a concern for the economic actors involved. It is in the public interest that the bio-based industry delivers on its potential to address the societal problems of climate change, resource efficiency and socially fair transition. As research and innovation are fundamental enablers for the bio-based industry, R&I investment in bio-based industrial systems is both in the private and public interest, provided that there are effective safeguards that public policy goals will be pursued by joint activities.

The current state and pace of development is however insufficient for the bio-based industry to play its potential role in the immediate future. The bio-based industry is not yet ready for radically increased investment in the next decade as there are persistent technology, market and policy risks preventing the bankability of bio-based projects. In the context of the post-Covid-19 economic recovery, there is also a risk that unprepared sectors or market players will not be in a position to absorb the investment that could be made available through recovery policies. As a result, this investment is likely go into the conventional industries, thus cementing the unsustainable situation.

⁵⁶ Vera I. et al. (2019): A carbon footprint assessment of multi-output biorefineries with international biomass supply.

⁵⁷ OECD (2020) Policy implications of Coronavirus crisis for rural development

⁵⁸ Issue confirmed by the BBI JU Interim Evaluation (2017)

⁵⁹ Issue identified by the BBI JU Interim Evaluation (2017). See Section 1.2 below for further details on national strategies.

1.2 EU relative positioning in the field⁶⁰

The relative positioning of the bio-based industry and bio-based innovation can be analysed from different perspectives: the recent development and the current performance of the bio-based industry that indicates how well the EU exploits the potential of the industry based on past innovation; and the level of investment in bio-based industry, the intensity of R&I activities and the development of supporting policies that indicate how the bio-based industry will grow and exploit the potential in the future. This chapter will take both perspectives (within the limits of data availability) comparing the EU to global competitors as well as comparing the situation between different EU Member States.

The EU bio-based industry claims the leadership position in the world⁶¹. The industry has the annual turnover of 700 billion Euro and employs 3.6 million employees (based on 2016 data that do not reflect the impact of Covid-19 crisis)⁶². This is the result of 17% growth over the period 2008-2016 including the economic slowdown in 2009 and 2010. The fastest growing segments of bio-based industry were pharmaceuticals and chemicals. For example the production of bio-based chemicals grew by 33% in volume (from 15 to 20 megatons) and 40% in value (from 20 to 28 BEUR) in the same period. The bio-based industry also improves its position within traditional sectors, i.e. it grows faster than the rest of the industry. For example the share of bio-based industry in the chemicals sector grew from 5% in 2008 to 7% in 2016.

Within the EU, four Member States – Germany, Italy, France and Spain – represent more than half of the bio-based industrial activity, both from the turnover and employment perspective⁶³. In terms of labour productivity Belgium, Sweden, Denmark, Finland and the Netherlands are the leading Member States⁶⁴. There are 2,362 biorefineries⁶⁵ (facilities processing biomass for product manufacturing) in Europe. The Member States where biorefineries are most present are Germany (close to 600), France, Italy, Sweden and Finland. The Central and Eastern European EU Member States lag behind in terms of turnover, jobs, labour productivity and the number of industrial facilities. Figure 7 below shows specifically the distribution in Europe of bio-based facilities identified as smaller size plants which did not yet reach the commercial phase, including pilot, demo and R&D facilities, based on the distribution in terms of product categories.

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⁶³ Nova-Institute and Bio-based Industries Consortium (2019): European Bioeconomy in Figures 2008 – 2016

⁶⁰ The relative position of the bio-based industry and bio-based innovation is not yet well described due to the lack of detailed data. The bio-based industry cut across the sectoral taxonomy and other statistical categories. Methodologies in different studies differ and provide incomparable results. Also the international comparison is affected by different definitions of bio-based industry applied in national statistical systems.

⁶¹ Bio-based Industry Consortium (2018): A new EU bioeconomy strategy and action plan: Calling for tangible action to scale up the circular bioeconomy

⁶² Nova-Institute and Bio-based Industries Consortium (2019): European Bioeconomy in Figures 2008 – 2016

⁶⁴ Ronzon T. et al. (2020): Developments of Economic Growth and Employment in Bioeconomy Sectors across the EU, Sustainability 2020 vol. 12

European Commission Joint Research Centre, DataM dashboard on Bio-based industry and biorefineries, https://datam.jrc.ec.europa.eu/datam/perm/news/666

of facilities 100 80 60 32 ż 20 2 liquid biofuels composites and biomethane pulp&paper chemicals fibres Facilities by scale pilot/demo 92.59 commercial

Figure 7 Pilot, demo and R&D bio-based plants across the EU

Source: European Commission Joint Research Centre (2020)⁶⁶,

At global level the main competitor to the EU bio-based industry is the bio-based industry in the USA, China and Brazil⁶⁷. The bio-based industry generated added value of 400 billion USD and employed 4 million employees in 2013⁶⁸ and the industry was expected to grow fast due to market drivers and proactive policies (tax credits, public procurement, etc.) with expected employment of 5.3 million in 2020. The direct comparison is impossible due to statistical categorisation difference but the most comparable segment – bio-based chemicals – seems to similar dynamics than the EU one with annual growth of 12% in 2014⁶⁹ compared to 11% growth in the EU in 2015.

In the fast growing bio-based industry it is important to understand those factors that will affect the growth in the future. These factors include investment in bio-based industry infrastructure (e.g. biorefineries), intensity of research and innovation activities and the development of policies driving the growth (e.g. economic incentives).

Concerning the level of **investment** the total investment in bio-based industry is not available but one of its representative segment – the bio-based chemicals – attracted 9.2

⁶⁶ Parisi, C., Distribution of the bio-based industry in the EU, Publications Office of the European Union, 2020, ISBN 978-92-76-16408-1, doi:10.2760/745867, JRC119288

⁶⁹ Grand View research (2020): Bio-based Platform Chemicals Market Size, Share & Trends Analysis Report

⁶⁷ The comparison will be limited to comparison with the US as the industrial structure and statistical systems seems to be most comparable to the EU one.

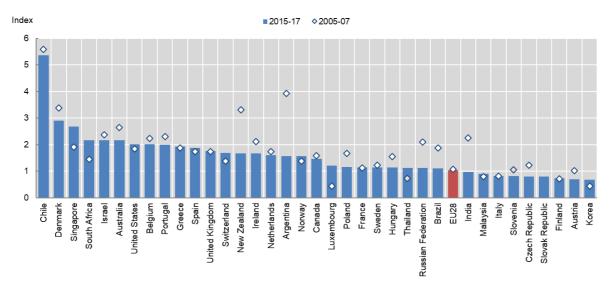
⁶⁸ US Department of Agriculture (2015): An Economic Impact Analysis of the U.S. Biobased Products Industry

billion USD globally from 2010 to 2015⁷⁰. The distribution of this investment is approximately equal for the four global regions (Europe, North America, South America and Asia) with the specific focus in Europe and the US on R&I and pilot facilities, while in Asia and South America investment goes more into commercial production plants. The recent investment in all four regions resulted in a comparable production capacity. The remarkable difference is the investment of venture capital funds that is predominantly attracted (82%) by the US market.

The intensity of R&I activities in the bio-based innovation area can be measured by proxy indicators including R&I spending, scientific publications and patents. The **private investment** in biotechnology – the key R&I area for the bio-based innovation – is dominated by the US with more than 50 billion USD in 2017 compared to estimated 15 billion in the EU⁷¹. As a percentage of biotech R&I on the total private R&I expenditure the US leads before all EU Member States except Belgium (13% in the US and 32% in Belgium). The **public expenditure** in biotech R&I in the EU Member States is estimated to 3.1 billion Euro.

In **scientific publications** in the bio-based area, cumulative statistics for EU countries show EU leadership at global level followed by the US and China⁷². However the US leads on the **number of patents** in the biotechnology area (37% compared to 24% of the EU). The EU is losing its position in patenting also to countries like China and Korea.

Figure 8 Revealed EU28 technological advantage in biotechnologies based on patents, 2005-07 and 2015-17



Source: OECD, STI Micro-data Lab: Intellectual Property Database, Index based on IP5 patent families, fractional counts http://oe.cd/ipstats, October 2019. The revealed technological advantage index is calculated as the share of country (or economy) in biotechnology patents relative to the share of country (or economy) in total patents. Only countries and economies with more than 100 patents per period are included in the figure.

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⁷⁰ Dammer L. et al., Current situation and trends of the bio-based industries in Europe. Pilot study by nova-Institute for BBI-JU, 2017.

⁷¹ OECD (2020): Key biotechnology indicators

⁷² Technopolis (2020), the analysis of the bio-based sector performed for the impact assessment study.

Concerning the **favourable policies** that facilitate the uptake of bio-based innovation and growth in the bio-based industry the EU Bioeconomy Strategy encourages Member States to develop their national Bioeconomy Strategies and other policies to stimulate bio-based industries. Currently, nine EU Member States (Austria, Finland, France, Germany, Ireland, Italy, Latvia, Spain, the Netherlands) have a national strategy while other Member States are involved in macro-regional bioeconomy initiatives (e.g. Denmark, Sweden) or have subnational/regional strategies (e.g. Belgium)⁷³. Despite their large biomass potential most Central and Eastern European (CEE) countries lag behind in the development of dedicated national Bioeconomy Strategies⁷⁴.

The national and regional Bio-economy Strategies provide an important stimulus for bio-based industry, especially if they include synergies with regional development and agriculture policy, including the utilisation of the EU Regional Development Fund and the Common Agricultural Policy funding to incentivise bio-based industrial development. However, this policy is fragmented as there are national and regional difference in the approach and in some regions such stimuli are missing completely.

Compared to the EU fragmented approach the US has developed a comprehensive approach with effective policy at federal level complemented by policy initiatives at states and regional levels. This policy includes tax incentives (15% tax rebate for bio-based industries), public procurement and labelling policy (BioPreferred Programme), subsidies (USDA Biorefinery Assistance Program) and public investment in R&I activities (e.g. USDA/DoE Biomass research and Development Programme) ⁷⁵.

The only policy initiative at the EU level specifically focused on bio-based industry is the 'Bio-based Industries Joint Technology Initiative' (BBI Joint Undertaking). Since 2014 the European Union supports this public-private partnership aiming at increasing research and innovation investment in the development of a sustainable bio-based industry in Europe (see the box below).

Box 3 Support for the field in the previous Framework Programmes – key strengths & weaknesses identified

What was/is being done with EU research and innovation funding until now

Dedicated R&I activities related to the bioeconomy have been supported through the Framework Programmes, notably via Horizon 2020 Societal Challenge 2 "Food Security, sustainable agriculture, and forestry, marine and maritime and inland water research and the bioeconomy". In the years 2014 - 2019 there were 807 grants signed under this Societal Challenge, which received 2,7 billion EUR of EU contribution (4,93% of Horizon 2020), with total cost of 3,6 billion EUR (5,1% Horizon 2020). This covers traditional (collaborative) projects but also support provided through the 'Bio-based Industries Joint Technology Initiative' (BBI Joint Undertaking) under Horizon 2020, which in the same period and under the same Societal Challenge funded 104 projects with 602 million EUR of EU contribution, and 909 million EUR of total costs. Thus, 22% of the EU funding (contribution) in Horizon 2020 Societal Challenge 2 was provided through the BBI JU, and 25% of total costs. In total, the BBI JU EU contribution represented 1,07% of Horizon 2020

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⁷³ https://ec.europa.eu/knowledge4policy/visualisation/bioeconomy-different-countries_en

⁷⁴ https://publications.jrc.ec.europa.eu/repository/bitstream/JRC120324/how-big-is-the-economy.pdf

⁷⁵ USDA (2015): An Economic Impact Analysis of the U.S. Biobased Products Industry

⁷⁶ Horizon 2020 Dashboard (data accessed on 20 July 2020).

EU contribution (amounting to 56,28 billion EUR), and 1,29% of total costs of Horizon 2020 (amounting to 70,52 billion EUR).

The Bio-based Industries Joint Undertaking (BBI JU) was initiated in 2014⁷⁷ with the aims to attract consistent private investment, promote R&I along whole values chains, to avoid fragmentation and duplication of efforts, and improve coordination in innovation activities of bio-based industries. It has originally been allocated EUR 975 million from Horizon 2020, and this sum is planned to be matched by EUR 2.73 billion by industries engaged in the partnership.

In terms of **activities**, the BBI JU partnership focuses on sustainable resource use, especially in resource-intensive and high-impact sectors such as agriculture, textiles, manufacturing and construction, in particular also aiming at local operators, manufacturers, plants and factories. It creates awareness, capacities and appropriate structures in a systemic approach. In addition, it focuses on market-oriented measures, such as engagement of consumers and local communities, cost-competitiveness via enlarging the market volume of bio-based innovation, and social innovation for inclusiveness and reducing overconsumption of resources⁷⁸.

In terms of **participants**, it extends beyond industry actors, and mobilises producers of biological resources from land and sea, public authorities managing local development and environmental protection, scientific communities, and end users. The private partner of the BBI JU is the Bio-based Industries Consortium (BIC), which originally included 35 bio-based companies. Since the setup of the BBI JU, the group of BIC members has been growing to over 250 (of which 150 associated members) entities from across different value chains (⁷⁹). Over 80% of them are SMEs – mostly in BIC via regional SME clusters. The members cover the whole value chain, from primary production to the market, across multiple and diverse sectors. BIC associated members include research and technology organisations, universities, European associations and organisations, European technology platforms, public institutions, regional organisations and private banks.

What has or is being achieved so far

One of the unique features of the BBI JU initiative has been to foster the closer collaboration between the scientific community and industry, ascending the scale of Technology Readiness Level (TRL) and thus enabling a swifter move towards innovation mentioned in the Strategic Innovation Research Agenda 2017⁸⁰. The scientific community mobilisation is evidenced by the 28.4% participation level of universities and research centres in the BBI JU projects. It is further confirmed by the annual survey directed to the BBI JU project coordinators⁸¹: according to the projects' reports, 80% of them contribute to knowledge creation, 79% contribute to increasing the academia-industry cooperation, and more than half contribute to the building of scientific community networks and to technology transfer. With regard to the mobilization of the SME community, the BBI JU has been very successful, with 41% of beneficiaries of BBI JU projects being SMEs, and 35% of funding

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⁷⁷ Council Regulation (EU) 560/2014 amended by Council Regulation (EU) 2018/121 https://www.bbi-europe.eu/

⁷⁸ https://www.bbi-europe.eu/

An overview of BIC's current membership, including information about the type of membership (industry or associate, the industrial sector, large or SME, and so on) is available at https://biconsortium.eu/sites/biconsortium.eu/files/documents/BIC%20members%20list%20January%202020.pdf.

⁸⁰ KPI 8 (Technology Readiness Level gain) https://www.bbi-europe.eu/sites/default/files/sira-2017.pdf

⁸¹ BBI JU Annual Activity Report 2018; https://www.bbi-europe.eu/sites/default/files/bbi-ju-aar-2018.pdf

dedicated to SMEs. This represents significantly higher level as compared to the 20% target for Horizon 2020.

The expected environmental impact from the projects other than flagships is large as two thirds of them report producing bio-based products with lower GHG emissions⁸². More than half of them expect to contribute to waste reduction, reuse, valorisation or recycling and a decrease of their energy consumption. Finally, 40% of the projects report they expect to improve land use and seven projects report a positive impact on biodiversity, e.g. by developing a sustainable agro-forestry biomass cultivation practice⁸³.

What are the key areas for improvement & unmet challenges?

However, several issues have come up and many lessons were learnt during the implementation of the BBI JU⁸⁴, which have to be taken into account when setting up a new initiative in the area.

Areas for improvement / challenges to overcome:

- Better synergies with national and regional developments are needed to develop interconnections between primary producers⁸⁵, regional authorities and biorefinery plants, as well private operators such as brand owners⁸⁶, and taking into account the need for higher circularity and digitalisation⁸⁷, inter-sectorial cooperation⁸⁸, as well as improved participation of EU-13 actors⁸⁹, and integration of territories in need of revitalisation⁹⁰.
- National and regional authorities should be aware of the economic and environmental potential of bio-based solutions and supported in the deployment of bio-based solutions, and an improved exchange of best practices should be put in place⁹¹.
- Programming of the initiative should take into account the public interest, especially critical for long-term impact, and avoiding the risk of industry capture⁹², while considering win-win scenarios for international cooperation⁹³.

83 BBI JU Annual Activity Report 2018; https://www.bbi-europe.eu/sites/default/files/bbi-ju-aar-2018.pdf. As mentioned, an independent study is ongoing to further assess the Key Performance Indicators for the current JU..

84 Commission Staff Working Document - Interim Evaluation of the Joint Undertakings operating under Horizon 2020,

⁸² As self-evaluated by the projects. A dedicated evaluation of the Key Performance Indicators and validation of impacts is underway (results expected by 1Q2021).

⁸⁴ Commission Staff Working Document - Interim Evaluation of the Joint Undertakings operating under Horizon 2020, {SWD (2017) 339 final}

⁸⁵ Addressing their low participation, as found by the BBI JU 2018 study on agricultural primary biomass producers, and following its specific recommendations.

⁸⁶ BBI JU interim evaluation, recommendation "To include increasingly brand owners and sectors at the interface with consumers with synergies with the existing ones".

⁸⁷ BBI JU interim evaluation, recommendations "To respond to important emerging trends through future calls that could consider conversion of biogenic CO2 into chemicals and materials as well as digitalization (including big-data analysis and exploitation) as one aspect in Bioeconomy value chains" and "To cover emerging trends, such as synthetic biology and platform technologies (e.g. bioinformatics), in the future BBI work programmes".

⁸⁸ BBI JU interim evaluation, recommendations "To strengthen the whole value chain approach by a greater participation of end users and customers" and "Efforts should be made to support development of completely new value chains and cross-value chains products and processes".

⁸⁹ BBI JU interim evaluation, recommendation "To improve the participation of EU-13 MS and Third Countries through a more open programming strategy, which should take into account potentials for growth at macro regional level, also in synergy with other EU initiatives (e.g. Smart Specialisation Strategies, S3)."

⁹⁰ BBI JU interim evaluation, recommendation "To reach out to EU member states and regions with rural or deindustrialized areas for catalysing revitalisation through bio-based industries".

⁹¹ BBI JU interim evaluation, recommendation "To analyse cases of success in terms of national participation and deliver 'best practices' for Member States, offering also mentoring support".

- At this stage of the current BBI JU initiative, for most BBI-specific KPIs, BBI JU projects are expected to largely exceed the key performance (KPI) targets set for 2020. On one hand, this shows that the BBI JU has contributed to the systemic evolution of the bio-based industry in bridging the gap between innovation and market. On the other, it also hints at the possibility that the **KPIs were not assessed accurately** beforehand, or lacked sufficient ambition⁹⁴.
- The **low focus on biodiversity preservation and enhancement** as part of the pursued biomass value chains has to be improved⁹⁵.
- The private partner of BBI JU, BIC, did not follow up on its **commitment on the financial contribution**⁹⁶ for the operational costs; this led to the need to amend the establishing Regulation (thus generating also additional administrative burden). The amended Model Financial Regulation ensures that the private partner will have to follow up its official financial commitment.
- The way of **reporting** the private partner's in-kind contributions⁹⁷ to operational and additional costs has proven to be complicated and costly. Based on the lessons drawn from current experience, it is possible to mitigate this risk by following the draft legal guidelines on financial commitments, and improving on the measuring the impact⁹⁸.
- The BBI JU Regulation under Horizon 2020 specified that the Union and BIC were to share the JU administrative costs equally. However, a contribution of the grant amount (4%) was asked from beneficiaries that were not members of the JU to cover the private share of these costs. With the adoption of the revised model Financial Regulation and the relevant BBI JU Financial Rules, this practice was put to an end.

Recently, the Corporate Europe Observatory (CEO), a corporate NGO, criticised the existing BBI JU initiative for being captured by private interests⁹⁹. It is legitimate for the public to demand that the public investment in a partnership with the private industry delivers benefits for the society at large. The CEO report also reiterated some of the lessons learned during the implementation of the BBI JU. At the time the BBI JU was established in 2014, it was not subject to an impact assessment process as it is the case for institutionalised partnerships under Horizon Europe. In addition the policy context has changed over the years. Firstly a solid basis was formed based on the interim evaluation report of the BBI JU that covered the years 2014 up to 2016. This was supplemented by information and experience drawn from the publicly available Annual Activity Reports covering the periods

⁹² BBI JU interim evaluation, recommendation "To avoid programming strategies aiming at short term benefit of BIC's specific sectors but rather invest resources in topics able to create wider and long lasting benefits both at multi-sectorial and macro-regional levels".

⁹³ BBI JU interim evaluation, recommendation "To identify win-win strategies for a larger involvement of Third Countries while ensuring the protection of EU industry's interests".

⁹⁴ BBI JU interim evaluation, recommendation "To monitor further progress of BBI JU by an annual comparison between BBI-specific KPIs projected, achieved and accumulated in the corresponding year".

⁹⁵ Issues identified in BBI JU Annual Activity Report 2018 and 2019.

⁹⁶ BBI JU interim evaluation, recommendations "To monitor the effectiveness of the measures implemented for solving the problems related to industrial financial contributions to operational costs and consider possible complementary measures to assure a balanced contribution of the Public and Private members to BBI JU" and "To deliver reports that provide comprehensive description of the actual private and public contributions to BBI JU delivered so far as well as the detailed plan for the delivery of the contribution of the two Partners over the next years"

⁹⁷ BBI JU interim evaluation, recommendations "To monitor the effectiveness of the guidelines for reporting and certification of IKOP and IKAA" and "To deliver reports that provide comprehensive description of the actual private and public contributions to BBI JU delivered so far as well as the detailed plan for the delivery of the contribution of the two Partners over the next years"

⁹⁸ BBI JU interim evaluation, recommendation "To build up metrics and statistical data on the bio-based industries in the EU with annual reporting on economic growth"

⁹⁹ https://corporateeurope.org/en/BBI-research-and-destroy

from 2014 to 2019, experience from managing the BBI JU for the past six years and the continuous interaction with stakeholders from the various sectors of the bioeconomy. Combining the changing policy landscape, the learnings from the mid-term evaluation and experience from the BBI JU programme have allowed to adjust the course during the implementation of the programme but also frame from the outset the design of the proposed successor and its governance structure. This is why any future initiative in the area needs to be based on a sound assessment of policy options from the perspective of governance, including in particular the possibility to set adequate safeguards to ensure that the public interests are duly respected in all operations. This is fully in line with the recommendations from the BBI JU interim evaluation referenced above ¹⁰⁰. CBE initiative will build on the success of BBI but will have evolved by learning from BBI JU shortfalls.

To conclude the EU comparative positioning, the EU is still a leader, together with the USA, in the field of bio-based industry, with strong growth and increasing share in the economy. However, these traditional leaders are being caught up by China, Brazil and other emerging economies of Asia and South America. Pro-growth initiatives, necessary for ensuring the continuing leadership, including the R&I and proactive policies tend to be fragmented and uneven across the EU.

1.3 EU policy context beyond 2021

The policy related to the bio-based industry has evolved in the last two years to provide a comprehensive frame and define what constitutes the public interest in the development of this industry in the near future. It also gives a sense of directionality for incentives, including for public R&I funding focused on sustainability issues.

The Green Deal communication¹⁰¹ creates the overarching framework for sustainable economic transition and sets the objective of carbon neutrality, resource efficiency and zero pollution. The Green Deal calls for mobilisation of R&I instruments in support of its objectives. It foresees the creation of partnership with the private sector to support R&I on circular bio-based industry¹⁰².

The Clean Planet for All communication¹⁰³ considers the circular economy and bioeconomy as key transition pathways to climate neutrality. It foresees the increased use of sustainable biomass in the form of biofuels and bio-based materials and calls for safeguards that increased demand for biomass will not lead to reduction of natural carbon sinks.

In the Circular Economy Action Plan¹⁰⁴ the Commission commits itself to support the sustainable and circular bio-based industry. The New Industrial Strategy¹⁰⁵ announces the EU support to key enabling technologies including industrial biotechnology. The Sustainable Finance Regulation foresees the development of the taxonomy for circular economy in the near future. In the preparatory work for the taxonomy, the Expert Group on Circular Economy Finance Support categorised bio-based industrial activity as a part of circular economy and proposed a set of performance criteria for substantial contribution to circular economy objectives.

102 COM(2019)640 final, p18

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¹⁰⁰ Especially the recommendation "To avoid programming strategies aiming at short term benefit of BIC's specific sectors but rather invest resources in topics able to create wider and long lasting benefits both at multi-sectorial and macroregional levels".

¹⁰¹ COM(2019)640 final

¹⁰³ COM(2018)773 final, p12, p13

¹⁰⁴ COM(2020)98 final, p6

¹⁰⁵ COM(2020)102 final

The Farm to Fork communication¹⁰⁶ refers to the bio-based economy as the opportunity for farmers and the Commission commits itself to actions to speed up market adoption of bio-based solutions. The Common Agricultural Policy is a powerful instrument for Member States to promote and incentivise the bio-based industry if they consider it as a strategic priority for rural development. The new Biodiversity Strategy¹⁰⁷ announced a plan to assess the availability of biomass for bio-fuel and review the legislative framework¹⁰⁸ as well as set sustainability criteria for use of forest biomass.

The updated EU Bioeconomy Strategy¹⁰⁹ and it Action Plan¹¹⁰, provides the most detailed operational guidelines on the development of the bio-based industry. Its first action area focusses on the strengthening and scaling up the bio-based industry, unlocking investment and markets. It commits the Commission to the following five actions: (1) to mobilise public and private stakeholders in research, demonstration and deployment of sustainable, inclusive and circular bio-based solutions; (2) to launch a Circular Bioeconomy Investment Fund; (3) to study enablers and bottlenecks for the deployment of bio-based innovations; (4) to promote and develop standards, labels and market uptake of bio-based products; (5) to facilitate the development of new sustainable biorefineries; and (6) to develop substitutes to fossil based materials that are bio-based, recyclable and marine biodegradable.

All the above policy objectives and actions have been reflected in the programming documents for the EU R&I programme for the period 2021-2027 – Horizon Europe. The Specific Programme¹¹¹ identifies the priority areas for R&I and indicates the plan to establish an initiative with private partners representing the bio-based industry. The priority agreed between the EU institutions in the Specific Programme are now operationalised in lower level planning documents including the Strategic Plan for 2021-2024 and Work Programme 2021-2022.

The overall policy framework is clear about the strategic role of the bio-based industry in contributing to achieving the EU sustainability objectives and about the direction in which the EU support will be oriented in the coming decade. The R&I programme is charged with the task of facilitating the development and deployment of bio-based innovations that contributes to climate neutrality, resource efficiency, biodiversity, and zero pollution objectives while ensuring also the bio-based industry's contribution to economic growth and regional development. In light of the above, the relevant policy question is thus not whether support in this area is justified but rather what form this support should take to deliver the greatest positive impact for EU investments.

The proposed initiative is among the activities envisaged to implement the Commission's vision for the period beyond 2020 under the Horizon Europe Pillar II, specifically Cluster 6 (Food, Bioeconomy, Natural Resources, Agriculture and Environment). It is one of the European Partnerships foreseen in the Partnership Area of 'sustainable, inclusive and circular bio-based solutions'. As shown below, an initiative for a Circular bio-based Europe would have potential interconnections with other candidate European partnerships such as Safe and Sustainable Food Systems, Accelerating Farming Systems Transition, Rescuing Biodiversity and more.

¹⁰⁷ COM(2020)380 final, p6, p9

¹⁰⁶ COM(2020)381 final

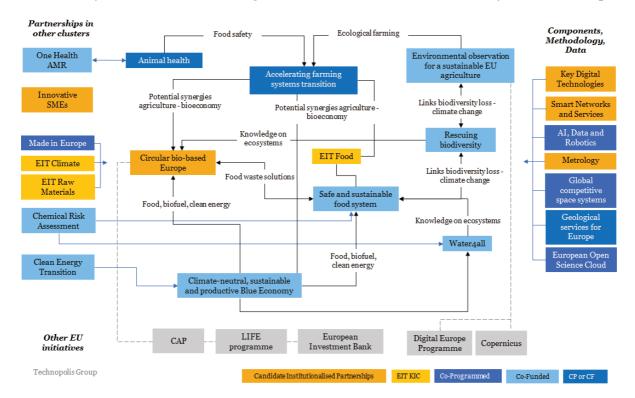
The Renewable Energy Directive II, the Emissions Trading Scheme, and the Regulation on land use, land use change and forestry (LULUCF)

¹⁰⁹ COM(2018)673/2 final

¹¹⁰ SWD(2018) 431

¹¹¹ COM(2018)436 final

Figure 9: Potential interconnections between partnership initiatives in the Food, Bioeconomy, Natural Resources, Agriculture and Environment cluster of Horizon Europe

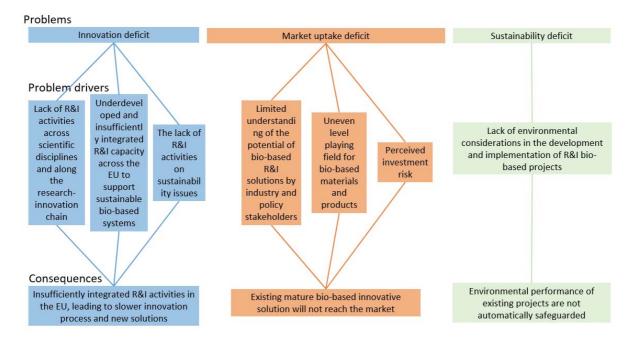


2. PROBLEM DEFINITION

Given the scale of the challenges ahead for the bio-based industry, the current scientific, technological and economic positioning of Europe in the field, and the overarching EU policy context, a set of problems have been identified where EU research and innovation in the circular bio-based industry would have a specific role to play.

The Figure below provides an overview of the problems and problem drivers that will be discussed in this section.

Figure 10: Problem tree for the initiative on Circular Bio-based Europe



2.1. What are the problems?

In general, the EU economy does not exploit bio-based innovation to the full potential and the bio-based industry does not contribute sufficiently to the societal objectives of sustainable and fair growth in the medium and long term. Despite the EU being a world leader in bio-based industry, there are still forgone economic and environmental benefits. As a result, at the moment, the bio-based industry brings a sub-optimal contribution to the carbon neutrality objective of the Green Deal and to the resilient economic recovery objective of the Next Generation EU.

This overarching problem can best be illustrated by focusing on three different strands – insufficient innovation, market failures that prevent mature bio-based innovations from entering markets, and a sustainability challenge to ensure that economically viable bio-based solutions deliver on environmental objectives.

2.1.1. Deficit of cutting-edge science and innovation serving the EU bio-based industry (Innovation deficit)

The bio-based industry is driven by innovation. Although bio-based solutions have been used throughout human history (e.g. food production and preservation, textile, tannery, paper, adhesives, etc.), the modern bio-based industry is based on innovative solutions that enhance the efficacy of natural biological processes. For example, new enzymatic processes or entire bio-based production systems – known as bioroutes – can do one or more of the following: radically improve the efficiency of production processes; enable the use of alternative (more available or cheaper) raw material input; and result in different products with new properties, and increased utility and value.

The biological science is undergoing a revolution that is enabled by advances in molecular biology and computing. The production of biological data is exploding, which is visible in

the accelerating rates of DNA sequencing and the development of "omics" ¹¹². This accelerating production of scientific results is a consequence of an acceleration of research using applied biological sciences. The biology science is then combined with physics, chemistry, medical, engineering and IT research to turn the theoretical bio-science concepts into innovative solutions in many areas ranging from medicine to i.a. pharmaceuticals, nutrition, industrial production based on biomachines, and IT based on bio-computing. The scientific community considers as scientifically plausible what used to be inconceivable a short time ago¹¹³.

These advances in biological science can also revolutionise more traditional industrial sectors. Specifically, they can make the existing use of biological resources radically more efficient. An example is squalene, a substance used in vaccines and cosmetics that was traditionally produced from shark liver. Squalene is now produced at industrial scale by an engineered yeast. Bio-based solutions can produce materials that are currently derived from non-renewable abiotic resources, e.g. microorganisms are already being used to produce plastics or bio-based alternatives to cement. Completely new materials or products can be produced by microorganisms as a bio-based optical films to be used in computer displays and flexible electronic circuits.

Stakeholder opinion

57.8% of respondents to the OPC (including industry, academic and research institutions, public authorities and NGOs) indicated that the innovation gap in the EU in translating research results into the development of innovative circular/bio-based products is very relevant. Collaborative R&I projects were also considered as very relevant by a large number of respondents (120 respondents or 59.11%). In particular, a large majority of academics, business associations and EU citizens, and all respondents from public authorities, described collaborative R&I projects as relevant.

Despite the theoretical potential of applying cutting-edge bio-science for radically increased use of biological resources as an input into the material and product economy, innovation in this area is trailing behind innovation in medical, pharmaceutical, nutrition and bioengineering areas. Out of 400 innovation pipelines in bio-science that are considered as scientifically feasible and economically plausible ¹¹⁴, the majority of applications is in the areas of health and nutrition. In terms of prospective economic impact of the innovation in the pipeline, these sectors also dominate with 33% of the total bio-based economic impact in the health and 36% in the nutrition sectors respectively. Conversely, innovation in material production represents only 8% of the estimated potential of the emerging innovation. The time of bringing innovation to the market also tends to be shorter for health innovation (5-15) years compared to material innovation (10-25 years), which indicates less intensive activities in testing and demonstration. This innovation deficit problem ultimately results in missing innovation pipelines that could be a basis for future radically improved industrial processes and products and suited to many economic sectors and areas of application.

¹¹² These include for example genomic, epigenomics, proteomics, glycomics, lipidomics, transcriptomic, metabolomics.

Examples of such breaktrough innovations enabled by the biological revolution include individualised gene therapies for genetic diseases, 3D printing of living tissues or organs, neuroprosthetics or Biocomputing (in McKinsey(2020) The Bio revolution)

¹¹⁴ McKinsey 2020: The Bio Revolution

2.1.2. Deficit in uptake of bio-based innovative processes in EU industrial value chains (Market uptake deficit)

In addition to the above, the bio-based industry also faces a problem of limited market uptake for current innovation. Existing and technically and economically viable solutions are not penetrating market at sufficient speed. The potential of biomass produced in the EU remains untapped and a large part of it is wasted ¹¹⁵. An indicator of this situation is that in the EU only 10% of the biomass is used in products and only a small part of it enters long lasting material stocks, such as durable and high-performance materials used in construction or automotive sector (e.g. insulation materials, composites). In contrast, more than half of all biomass is used for energy and one quarter of biomass is wasted.

An illustrative example of market uptake deficit is the use of waste from the food industry. This waste is an ideal input in the bio-based industry due to its relative homogeneity¹¹⁶. There is abundance of food waste (30 MT a year) as it is unavoidable in the food production process. With growing food production in the EU, this potential feedstock also grows at a compound annual growth rate of 4.3% from 2019 to 2024^{117,118}. There are a number of food waste processing bio-based technologies that are mature enough for industrial application. These technologies can also produce a wide range of materials and products for which markets exist (see Figure 11). In some cases, the produced chemicals or materials are very valuable, e.g. lycopene (a natural carotenoid with antioxidant and anti-cancer properties) extracted from tomato waste has a market value of 40 000 EUR per kg. The JRC studied the techno-economic feasibility of industrial installations - biorefineries - focusing on the optimisation of the use of this type of feedstock. The JRC study concludes that for four traditional waste streams (orange, potato, tomato and olive) and a limited scope of technologies and produced materials, there is already potential for profitable investment in 189 biorefineries with payback period up to 15 years and in some cases with a return on investment of 9%119. These biorefineries, however, have yet to be constructed and meanwhile this valuable resource – food waste -- is mainly used in low value applications such as combustion or composting and continues to emit methane and/or CO2 in the atmosphere.

A similar deficit in market uptake of technically and economically feasible bio-based applications exists in other biomass streams, including wood-based and aquatic biomass, and municipal biological waste and wastewater. The EU Bioeconomy Strategy estimated that 300 biorefineries should be constructed in the next decade to tap the existing potential of bio-based systems. This would require a total investment at the level of 50 billion EUR. This estimation does not include the potential of innovation in the low technology readiness stage that can further enlarge the economic opportunities of the bio-based industry.

The picture below illustrates how different kinds of food waste can be processed in a number of value added materials and products that can be used in diverse economic sectors.

¹¹⁵ The European Innovation Partnership on Raw Materials: Raw Material Scoreboard 2018.

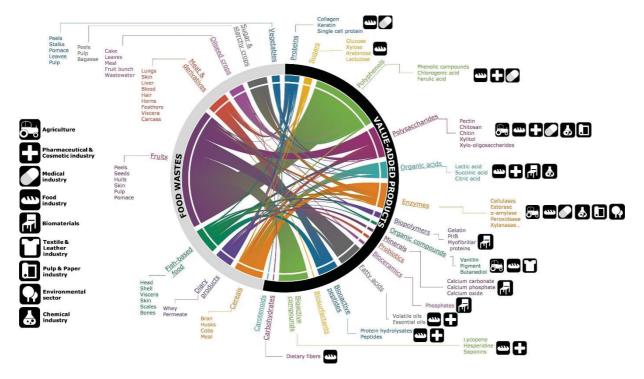
Caldeira C. et al. (2020) Sustainability of food waste biorefinery: A review on valorisation pathways, techno-economic constraints, and environmental assessment, Bioresource Technology, vol 312

¹¹⁷ Caldeira C. et al. (2020) Sustainability of food waste biorefinery: A review on valorisation pathways, techno-economic constraints, and environmental assessment, Bioresource Technology, vol 312

Research and Markets, 2019. Food Processing Market Report: Trends, Forecast and Competitive Analysis. Report.

¹¹⁹ Cristobal J. et al. (2018) Techno-economic and profitability analysis of food waste biorefineries at European level, Bioresource Technology, vol. 259

Figure 11 Food waste valorisation pathways



Source: Cristobal J. et al. (2018)

Stakeholder opinion

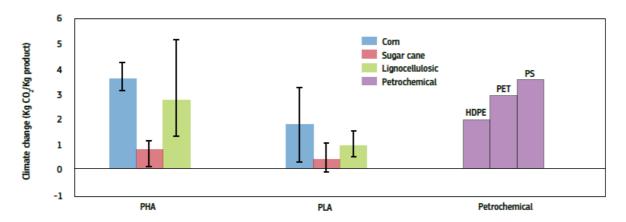
89% of the 206 respondents to the Open Public Consultation stated that it is either relevant or very relevant to maximise the valorisation of organic waste, agriculture and forestry residues. There were no notable differences of views on this point between different respondents categories.

2.1.3. Sustainability deficit of EU industrial production processes (Sustainability deficit)

As explained, the bio-based industrial systems have the potential to improve the environmental performance of industrial production. An example is the production of polyactic acid (PLA), a bio-based thermoplastic polyester that can replace polyethylene or polystyrene in many applications including packaging. The life cycle environmental performance of PLA can be significantly better than polystyrene ¹²⁰, HDPE or PET (see Figure 12).

¹²⁰ Vera I. et al. (2020) A carbon footprint assessment of multi- output biorefineries with international biomass supply: a case study for the Netherlands, Biofuels, Bioproducts, and Biorefining vol. 14(2)

Figure 12: Climate efficiency of bio-based and fossil based plastics



Source: Ronzon T. et al. (2017): Bioeconomy report 2016. JRC Scientific and Policy Report.

This improved environmental performance is mainly due to the intrinsic carbon efficiency of bio-based materials and due to the potential to utilise abundant biological waste, thus reducing the pressure on ecosystems. Many bio-based processes and products are also less polluting or less toxic. However, the overall environmental performance of bio-based systems depends on many factors, including the environmental performance of associated activities upstream and downstream. In this respect, the environmental impact of primary biomass production may have the dominant effect on the overall performance of the whole production system. For example, if the biomass is produced in an intensive agriculture system with high energy and chemical input, and/or biomass must be transported to distant processing facilities, the overall life-cycle negative impact can be significant. Bio-based industrial activity can also be seen as causing biodiversity loss and ecosystem degradation if too much biomass is extracted from valuable natural ecosystems or when excessive biomass demands lead to land use change and conversion of natural area into low biodiversity agricultural land. For bio-based production systems to be sustainable, they have to be designed and implemented with this objective in mind and their performance has to be assessed from a whole life-cycle perspective. This is not always the case, and a number of real life applications have dubious environmental performance.

For instance, in the past, the bio-fuel segment of the bio-based industry faced the criticism that the overall environmental impact of bio-fuel production can be negative due to energy intensive production of biomass used in the first generation bio-fuel refineries, long transport routes and indirect carbon emissions from land use change. As a consequence, sustainability conditions have been set for this sector at EU level¹²¹ in 2018. A number of older bio-fuel refineries fail to meet these sustainability criteria ¹²² and therefore need to upgrade. All new biofuel facilities have to meet the strict conditions concerning their overall carbon efficiency, e.g. 65% greenhouse gas savings by 2021.

In contrast to the above example, the rest of the bio-based industry operates in an incomplete regulatory environment. Industrial facilities have to comply with the applicable environmental legislation such as the Industrial Emissions Directive¹²³ or the regulation

¹²³ Directive 2010/75/EU

¹²¹ Renewable Energy Directive 2018/2001/EU

¹²² Vera I. (2019): A carbon footprint assessment of multi-output biorefineries with international biomass supply

concerning the use of GMOs¹²⁴ but the issue of sourcing of biomass, potential indirect land use change and biodiversity impact, and the overall carbon efficiency of bio-based systems are not regulated. In the absence of a comprehensive regulatory system, the environmental performance is thus a matter of voluntary commitments in the context of corporate social responsibility. The weakness of voluntary commitments is further exacerbated by the absence of robust methodologies to assess certain environmental impacts and generally accepted sustainability criteria. Uncertainties about the environmental performance of commercial bio-based installations, materials and products deter investors and undermine the public trust in bio-based solutions.

Stakeholder opinion

The majority of the respondents to the Open Public Consultation across all stakeholder groups (industry, academic and research institutions, public authorities and NGOs etc.) considered the proposed initiative Circular Bio-based Europe to be either very relevant (76%) or relevant (14%) for reducing greenhouse emissions. No respondents from different stakeholder groups stated that this target was 'Not relevant at all'.

2.2. What are the problem drivers?

2.2.1. Innovation deficit drivers

The innovation deficit of the bio-based European industry is underpinned by three drivers:

(a) Lack of R&I activities across scientific disciplines and along the research-innovation chain

This is linked to the lack of collaboration between scientific disciplines with the objective to develop bio-based materials and product innovation. The intensity of cross-fertilisation between relevant scientific developments tends to be lower for bio-based materials than for health and nutrition applications. Moreover there is less experimenting, testing and demonstrating of bio-based innovative technologies than in other biotech sectors, therefore it takes longer time for the material innovation to reach the market. The bio-based materials and products research competes for talents with sectors that provide more opportunities for revolutionary breakthrough, scientific prestige and profitability. As a result, in recent years there was an insufficient number of radical innovations in bio-based materials and products, compared to what would have been possible thanks to advances in basic research in life sciences or IT (e.g. artificial intelligence). In addition, increase in new products or value chains resulting from cross-disciplinary research remained limited.

Stakeholder opinion

With regard to the uptake in innovation problems, about 64% of the respondents to the OPC (industry, academic and research institutions, public authorities and NGOs etc.) have indicated that the research and innovation efforts at EU level address the issue of lack of competitiveness with traditional products/materials.

(b) Underdeveloped and insufficiently integrated R&I capacity across the EU to support sustainable bio-based systems

¹²⁴ E.g. Directive 2009/41/EC on contained use of genetically modified microorganisms and Regulation (EC) 1946/2003 on transboundary movement of GMOs.

¹²⁵ McKinsey (2020): The Bio Revolution.

There is an underdeveloped capacity for R&I in bio-based systems in some parts of the EU, in particular the Eastern and Southern European regions. The research efforts in bio-based material and products R&I are concentrated in Belgium, the Netherlands, Nordic countries and some regions of Germany, France, Italy and Spain. In other regions, the capacity for R&I has not been sufficiently developed, even though there would be great regional/local potential for bio-based industry due to availability of biomass, or presence of human skills. This missing capacity results in less intensive research and innovation development and commercialisation in those regions.

(c) Lack of R&I activities on sustainability issues

In parallel, there is an insufficient focus of R&I activities on sustainability issues. Due to limited regulatory pressure, R&I on sustainability aspects has not been of the highest priority, especially for corporate R&I. For example, the technological challenge to efficiently process non-homogenous mixtures of biological waste, such as municipal waste, remains untackled. Insufficient scientific effort has been devoted to studying the environmental impact of the bio-based industry; and as result there is still no full understanding of all impacts and their scale. Methods and tools for assessing this impact, including the life-cycle assessment (LCA), LCA databases and sectoral specifications, have not yet been developed at a level comparable to those for other industrial sectors. Consequently, there is insufficient scientific guidance for decision-makers on how to set sustainability conditions for bio-based industry operations in real life.

2.2.2. Market uptake deficit drivers

The market uptake deficit is caused by the following three drivers:

(d) Limited understanding of the potential of bio-based R&I solutions by industry and policy stakeholders

There is an information asymmetry between scientific actors who understand the potential of scientific advances in the bio-based systems without a full grasp of business models and the market situation, as opposed to market and policy actors who are not fully aware of the fast development in science and innovation and may thus not entirely understand the opportunities created by scientific inventions.

For companies that did not develop sufficient R&I capacity, especially for SMEs, it takes a longer time to integrate new bio-based technology in their business strategy and models. As a result, companies are not sufficiently engaged in experimentation and demonstration activities that are critical for maturing of technology or miss the opportunity to become part of emerging value chains and markets.

For policy makers at EU, national and local level, especially in less economically developed Member States and regions, it is still difficult to assess the potential of the bio-based industry and integrate it in national and regional development strategies. Indeed, there are a number of countries that have not yet developed their national bioeconomy strategies and only a limited number of regions have developed such strategies at their level. The barriers to market uptake of bio-based solutions are not well understood by policy makers and consequently policies do not necessary create favourable conditions, e.g. through incentives. Existing EU instruments such as the Common Agriculture Policy or the European Regional Development Fund are not adequately deployed in support of bio-based industries in many Member States.

(e) Uneven playing field for bio-based materials and products

There is an uneven playing field for conventional and bio-based industries in markets where bio-based materials compete with conventional materials, e.g. bio-based plastics versus plastics made from fossil raw material. Markets with conventional products tend to be consolidated with established supply chains and business relations. Companies may be locked-in into technologies and capital investment that has not yet been repaid. This results in inertia and slow adoption of bio-based solutions if the economic premium is not high enough. This in turn prevents economies of scale from taking effect. A special case of uneven playing field occurs when bio-based products compete with conventional products whose price is distorted by economic incentives or where price does not integrate negative externalities (e.g. CO2 emissions, or impact on biodiversity), especially if markets do not reward positive externalities of bio-based products (e.g. no price premium for carbon efficiency). The latter problem occurs for instance in the competition between bio-based and petrochemical-based products, where the economic viability of bio-based product depends on the price of oil. Without active governmental policies to address this market failure, some beneficial bio-based solutions will not be economically viable in the foreseeable future.

Stakeholder opinion

178 respondents believe that there is a lack of competitiveness, when compared to traditional products and materials.

The uneven playing field is an important driver of the market uptake deficit, however this R&I initiative is not able to address it. This driver is provided as contextual information in the impact assessment, for the sake of completeness and to highlight relevant elements that can impact the proposed initiative.

(f) Perceived investment risk

Perceived investment risk reduces access to finance possibilities for bio-based projects, particularly with regard to necessary capital expenditure¹²⁶. Investors perceive the bio-based industry as excessively risky due to technological, market¹²⁷ and policy uncertainties. Indeed, novel technologies have not yet proven on the market that they can deliver the expected economic performance. Additional market uncertainties are related to e.g. the instability in supply of biomass, or its price volatility¹²⁸, consumer demand, but also to the market failures described above. The policy uncertainty often stems from the fact that the bio-based industry is young and dynamic and it is thus not clear whether it will be subjected to environmental or other regulations and what policies and incentives affecting its economic performance will be developed in the future. The shift in public perception of biobased solutions both in a positive and negative direction can further increase the uncertainty levels.

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128 EIB (2017): Access to finance conditions for Investments in Bio-Based Industries and the Blue Economy

Commission Expert Group on Bio-based Products - Final Report, Commission Expert Group, 2017 https://ec.europa.eu/growth/content/commission-expert-group-bio-based-products-calls-alignment-bioeconomy-strategy-eu-policy en

Innovation Ecosystems in the Bio-economy, OECD, 2019, https://www.oecd-ilibrary.org/docserver/e2e3d8a1-en.pdf?expires=1594641236&id=id&accname=oid031827&checksum=C630B83C3B49E92A37A01241DE4D9C8D

As a result, many bio-based projects are not yet considered bankable. In the general absence of venture capital for technological innovation in Europe, these projects will only be financed if there is an active public policy on de-risking the bio-based investment 129.

Stakeholder opinion

A high number of stakeholders who responded to the public consultation believe that there is a lack of public (162) and private (133) investments in the bio-based industry.

Another consultation targeting the bio-based industry stakeholders was carried out by the European Investment Bank in the context of the study on Access to Finance in the European Bio-based Sector¹³⁰. In this consultation 79% of respondents indicate that the limited interest from private financial market participants is related to the lack of understanding of the specificities bio-based industries.

2.2.3. Environmental deficit drivers

The overall environmental performance of the bio-based industry will depend on its performance in the three key unregulated environmental aspects: (1) sourcing of feedstock including biowaste, side streams and residues, (2) indirect land use changes and (3) overall carbon efficiency of bio-based industrial systems. The prospect of future environmental regulation targeting these aspects is questionable – the bio-based industry is so wide and varied in terms of biomass sources, technologies and products that it may not be possible to effectively regulate the entire scope of bio-based activities in the same way as it is possible to regulate the environmental performance of just one particular bio-based value chain of biofuels. In the continuous absence of specific regulation, the environmental deficit problem can be linked to the following driver:

(g) Lack of environmental considerations in the development and implementation of R&I bio-based projects

This driver stems from the lack of a commonly accepted regulatory basis for environmental considerations due to the absence of established assessment methodologies and of broadly accepted sustainability criteria¹³¹. This severely limits the ability to integrate sustainability aspects in decision-making by concerned industries and public authorities.

However, even if such criteria are developed, sustainability considerations may still be missing in the development and implementation of bio-based projects at different TRLs, notably from early innovation to demonstrations until market application.

Due to the absence of active promotion and implementation of sustainability criteria through regulation, voluntary industry commitments, 'soft' policy such as strategies, recommendations and industry standards, or through public pressure, there is a real risk that a number of bio-based projects will be implemented and at a later stage identified as having a poor environmental record. This might result in damage to the reputation of the bio-based industry as a contributor to societal objectives and undermine the public trust in bio-based

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¹²⁹ EIB (2017): Access-to-finance conditions for Investments in Bio-Based Industries and the Blue Economy

EIB (2017): Access-to-finance conditions for Investments in Bio-Based Industries and the Blue Economy

Note that while problem driver 3 (g) also refers to the absence of methodologies/criteria like problem driver 1 (c), these two issues are different. Under problem 1 (c), the relevant driver is about a lack of R&I on environmental impacts of bio-based solutions. Here instead, the driver concerns the absence of a commonly accepted regulatory basis for environmental considerations and decision-making by concerned industries or public authorities; The two are indirectly connected in the sense that addressing driver 1 (c) allows to develop the necessary building blocks to facilitate the solutions of driver 3 (g).

materials, even if the majority of initiatives have a positive contribution. The BBI JU did not have the appropriate governance structure to assess these type of results.

2.3. How will the problem evolve?

The global population and economy are projected to continue growing over the coming decades. This will drive material consumption including demand for bio-based materials and products globally. The demand for bio-based products will increase also in the EU economy.

At the same time, the Commission's aim to reduce the European ecological footprint and to reach the ambitious policy objectives of climate neutrality by 2050, will require the replacement of many of the fossil-based products with bio-based ones. The need for bio-based innovation that will increase economic efficiency of production and address environmental issues will grow.

In the absence of effective measures to address the problems described above, the underlying drivers will continue to affect negatively the development of a circular bio-based industry. R&I will continue to take place as a result of public and private funding, and innovative solutions will reach the market, albeit at a slower pace than is desirable to meet the EU's climate and environmental objectives for the coming decades. The actual societal benefits will fall short of the potential benefits both in terms of economic and environmental performance.

For example, the annual economic benefit expected in 2030 from the global material bio-based innovations in the current innovation pipeline is estimated to 400 million trillion USD¹³². This 'business as usual scenario' represents only a modest increment in the economic value compared to the actual size and potential of the EU bio-based industry.

In terms of environmental performance, many bio-based industrial activities will bring environmental benefits because of their intrinsic environmental performance. However, and as indicated above, there may also be bio-based projects that do not take environmental considerations into account in their design and implementation, thus leading to possible negative impacts on ecosystems or a limited ability to contribute to climate neutrality objectives.

In general, the current situation of not reaping all the potential benefits of bio-based innovation will continue. These forgone societal benefits are the main negative impact of not acting in this area.

3 WHY SHOULD THE EU ACT?

3.1 Subsidiarity: Necessity of EU action

To further develop the bio-based economy, neither single stakeholders nor individual Member States will be able to reach the required critical mass on their own, thus showing the clear necessity of tackling these ambitions on an EU scale. A multi-sectoral approach is needed to combine the strengths of industries, primary producers across regions and EU countries, enabling a sustainable transition from a fossil-based to a sustainable and circular bio-based economy. There is a need to mobilise the actors of the bio-based value chains and

¹³² McKinsey (2020) The Bio Revolution.

to build on the structuring effects already observed in the BBI JU partnership. Actors and stakeholders throughout all segments of the value chain (primary production and waste streams, processing and end applications) are engaged in shaping business models and industrial cooperation which did not exist before, providing evidence of a structuring effect and systemic change in the bio-based industry. To date and through the implementation of the BBI JU, 113 new bio-based value chains were created, many of those involving several sectors and transcending national borders. ¹³³

An innovative value chain is created when its resulting (new) product or service has been tested and validated, and is ready for a specified and accepted market application. To exist, these new value chains need to be economically viable and to fulfil all relevant sustainability criteria. Each of the value chains has business cases or commercialisation plans.

These new bio-based value chains can thus result from innovative cooperation between several often atypical economic actors, which combine feedstock with innovative or traditional technologies and produce new bio-based products or market applications. They have the potential to be replicated across Europe and beyond, and support the development and competitiveness of the European bio-based market and the creation of new bio-based products. ¹³⁴

Such links are clear in the case of the highly forested countries and highly productive agricultural regions, where biomass producers need to be connected to industrial centres in Europe in order to generate new value through the development of integrated sustainable value chains. Another case are those local authorities that require links with industries and support by regions to solve their waste problems in a sustainable way that can also deliver economic added value. It remains very difficult to build and consolidate those links by acting only at the national or local level. Indeed, the need for EU-level intervention in this area was supported by a large majority of respondents to the online public consultation on the proposed CBE initiative.

Moreover, flagship and first-of-its-kind biorefinery plants require costly demonstration. Implementing innovation activities at high Technology Readiness Levels (TRL 6 to 8) requires a strong degree of involvement from all players of the value chain – from primary producers to industry and brand owners. This level of engagement is usually not achievable under standard collaborative research, but only via a partnership as shown by BBI JU. This is why the European Green Deal and the updated Bioeconomy Strategy have indicated the need for a partnership in the bio-based industry.

3.2 Subsidiarity: Added value of EU action

Another rationale for EU-level intervention in this area is that most of the barriers and long-term challenges to further develop the bio-based industry are not adequately addressed at national level but rest firmly upon EU-level regulation. Examples range from sustainable biomass supply to market pull via targets, product standardisation and green public procurement schemes.

A clear EU added value of the proposed CBE initiative lies in its key enabling role for implementing the European Commission's updated Bioeconomy Strategy and Action Plan.

134 ibid

¹³³ BBI JU, Annual Activity Report 2018

A coherent EU-wide approach is also necessary to ensure that the right balance is found between growth (European industrial competitiveness) and sustainability (social and environmental) objectives. ¹³⁵

Tackling these challenges at European level between industry and the EU would allow:

- Carrying out the research and innovation needed, and that no single company, public research institution or Member State can perform alone precisely because only a combined research capacity can deliver the necessary joint efforts for achieving shared market and European Research Area objectives;
- Tackling the absence of an agreed long-term budget plan and strategic technical and
 market objectives to encourage industry and the research community to commit more
 of their own resources. This is needed to reach critical mass, which cannot be
 achieved by acting at the national level alone, given the ambition of the identified
 policy objectives and aspirations;
- Promote an optimal coherence of research and innovation efforts between industry and public actors, thereby avoiding gaps, overlaps and fragmentation of research and innovation coverage, when industry and publicly-funded research do not align their funding and agendas;
- Bringing the green transition to the attention of industry and raising the sustainability bar and corporate responsibility via integrated and continuous programmes covering fundamental research, applied research and EU-level demonstration and flagship activities;
- Addressing the need to strengthen the innovation spirit and cooperation for market development between value chains operating across different countries and sectors. This fosters the exchange and pooling of knowledge and experience, and facilitates the involvement of all market actors, in particular the SMEs.

Stakeholder opinion

87% of respondents to the OPC (including industry, academic and research institutions, public authorities and NGOs) mentioned as "very relevant" the involvement of industry in setting joint long-term agendas to ensure that the proposed European Partnership would meet its objectives. A large part of respondents also indicated that the involvement of academia (47%) and Member States and Associated Countries (44%) is 'very relevant'. The answers are more evenly split with regard to Foundations and NGOs (25%) and other stakeholders (27%).

4 OBJECTIVES: WHAT IS TO BE ACHIEVED?

4.1 General objectives of the initiative

Based on the identified problems, the initiative's main objective would be to contribute to accelerating the development and growth of those segments of the bio-based industry that deliver climate and environmentally efficient and innovative solutions to meet the material needs of the society, while ensuring a sustainable, fair and just economic growth. This acceleration would make the bio-based industry play the role that recent EU policies assigned to it and deliver significant contributions towards climate neutrality, resource

¹³⁵ Philippidis G. et al. (2018) Sailing into Unchartered Waters: Plotting a Course for EU Bio-Based Sectors, *Ecological Economics* 147

efficiency and zero pollution by 2030. To achieve this overarching goal, general and specific objectives are set for the three problem areas described in section 2, namely:

- To accelerate the innovation process and development of bio-based innovative solutions. This does not only imply more intensive basic research in biotechnology and other related scientific and technological disciplines but also accelerating the maturing process to bring innovative solutions to the market through more intensive efforts in experimentation, testing, demonstration and deployment.
- To accelerate market deployment of the existing mature bio-based innovative solutions. This implies supporting a more intensive process that goes from demonstration and first market applications to replication, mainstreaming and scaling up of bio-based industrial activities across Europe, especially in regions that have an autochthonous potential for it (e.g. regions with high production of biomass and biological waste), to achieve the significant positive economic and environmental impact associated with these solutions.
- To ensure a high level of environmental performance of bio-based industrial systems so that their market deployment contributes to the achievement of EU Green Deal objectives. The focus will be on carbon emissions, circularity and ecosystem protection, i.e. the impact areas where the bio-based industry is currently not regulated. This implies the development of scientifically robust metrics and performance benchmarks to inform future policy and business choices, as well as promoting the consideration of sustainability aspects throughout the whole innovation chain (from basic research, to development of innovative solutions, to market deployment) and across the entire bio-based value chains o (from biomass sourcing to industrial processing, production and consumption).

4.2 Specific objectives of the initiative

In order to achieve these general objectives, five specific objectives are defined. These specific objectives respond to each of the problem drivers discussed in Section 2.2:

- (a) to reap the benefits of the advancement in life sciences and in other scientific disciplines for the development and demonstration of sustainable bio-based solutions by increasing the intensity of cross-disciplinary research and innovation activities. This acceleration and cross-fertilisation is expected to take place along the whole innovation chain, from basic research to experimentation, demonstration and to first market applications.
- (b) to increase and integrate the R&I capacity of stakeholders across the European Union that will help to exploit the local bioeconomy potential. The focus will be on the regions that are currently lagging behind the leading Member States and the regions with the greatest bioeconomy gaps. The targeted impact is a more balanced distribution of benefits from bio-based innovation across Member States and regions.
- (c) to increase the R&I capacity for addressing environmental challenges and development of more sustainable bio-based innovations. This implies the need to intensify R&I activities on the sustainability aspects of bio-based industries to ensure that sustainability issues are considered throughout the whole innovation chain and environmental performance are integrated in future innovative solutions. This sustainability aspect includes also the source of biomass and the development of technologies that can efficiently utilise all sorts of biological waste.

- (d) to reinforce the integration of bio-based R&I processes in EU industrial value chains by increasing awareness among industry and other R&I stakeholders of the advances in bio-based solutions and mobilising them to develop strategies for applying bio-based solutions as well as specific projects. Engage industry and other R&I actors to participate in innovation development, in particular in the testing, demonstration and replication phases.
- (e) To reduce the risk for R&I investment in bio-based companies and projects by providing directionality for EU R&I investments in bio-based industries; addressing technological, market and policy barriers, ¹³⁶ and supporting the development of a level playing field for bio-based materials replacing conventional materials.

Stakeholder opinion

Respondents (1783) to the Open Public Consultation across all stakeholder groups (industry, academic and research institutions, public authorities and NGOs etc.) indicated that deployment and piloting activities are very relevant (72%) or relevant (20%) to ensure that the proposed initiative would meet its objectives. No respondents from different stakeholder groups indicated that these activities were 'Not relevant at all'.

(f) to ensure that environmental considerations are taken into account in the development and implementation of R&I bio-based projects, by setting operational sustainability criteria for bio-based industrial systems to support decision making in R&I, market deployment and policy. Sustainability criteria should include robust science-based indicators and benchmarks corresponding to the ambition of the EU Green Deal policies. They should be applicable at sector, value chain, industrial installation and product level and should be based on the life-cycle approach. The application of sustainable criteria should be promoted across the bio-based industry.

The choice of the proper implementation form is fundamental for these objectives to be achieved. Indeed, lessons from previous experience have shown that the mode of implementation and in particular the governance structure and requirements on the private partners are central for the initiative to stay on the desired track.

4.3 Intervention logic of the initiative

The relationship between the general and specific objectives of the potential initiative for a Circular bio-based Europe is shown in the Figure below. The impact pathways are shown in Annex 6, Figures 1 to 3.

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¹³⁶ This refers to policy barriers that can be addressed by the initiative. They include the lack of long term strategic support by public authorities to the development of bio-based industry, e.g. through national and regional bioeconomy strategies.

Problems Problem drivers Lack of R&I Underdeveloped and insufficiently integrated R&I Lack of environmental considerations in the development and implementation of R&I bio-based understanding of the potential of bio-based R&I Ineven playing field for bioprojects disciplines and solutions by based materials the EU to suppor industry and and products Specific objectives of the advancement in life sciences and in other scientific integrate the R&I capacity of stakeholders Reinforce the integration of bio-based R&I processe Ensure environmental considerations are taken into account in the development and implementation of disciplines for the investment in bio-based in EU industrial value R&I bio-based projects development and General objectives

Figure 13: Intervention logic for the initiative on Circular Bio-based Economy

How would success look like?

Accelerate the innovation process and development of bio-based innovative solutions

Should the initiative deliver on its specific objectives, it is expected that it would have the following impacts:

Accelerate market deployment of the existing mature bio-

based innovative solutions

Ensure a high level of environmental

performance of bio-based industrial systems

Scientific impacts

- Accelerated development of bio-based innovations that would deliver environmental and productivity improvements through new bio-based production processes and products based on EU resources;
- ➤ Reinforced scientific and innovation capacity that is necessary for exploitation of the EU potential for bio-based industrial production, including in the regions where currently this capacity is underdeveloped;
- Increased R&I capacity for addressing the key sustainability challenges and trade-offs in the bio-based industry, particularly as regards the carbon neutrality and circular economy transitions.

As a consequence, the EU would maintain its current leadership in bio-based systems and achieve strategic autonomy in an industry that is critical for the long-term sustainability of EU economy.

Economic/technological impacts

- ➤ A number of bio-based innovations demonstrating the economic and environmental potential of specific bio-based solutions would reach the stage of first market application and bring tangible economic and environmental benefits;
- A structured process for collaboration between R&I actors, industry (including SMEs) and other bio-based innovation stakeholders that would facilitate deployment of bio-based innovation;
- Reduced investment risk and improved access to finance for bio-based industrial projects.

In general terms, the initiative would increase the capacity to deploy bio-based innovation that valorises domestic biomass, which would lead to higher growth, competitiveness and resilience of the EU economy.

Environmental/Societal impacts

- > Enhanced circularity and environmental sustainability of the European bio-based industries:
- ➤ Better integration of primary biomass producers in bio-based value chains to contribute to rural development.

As a consequence, the initiative would make the EU economy and society increasingly circular and environmentally sustainable, and would contribute in particular to the EU climate mitigation objective. In terms of social impact, if successful, the proposed initiative will stimulate the involvement of primary biomass producers and waste and side-stream providers in the bio-based industry, which in turn will increase their revenues and revitalise rural and coastal regions as well as municipalities and urban areas.

With efforts maintained over time, all impacts are expected to materialise within the time framework foreseen for the proposed initiative. The choice of the proper implementation form is fundamental for the general and specific objectives to be achieved. Lessons from previous experience, specifically from the BBI JU have shown that the mode of implementation and in particular the governance structure and requirements on the private partners are central for the initiative to deliver on the targets set out in the intervention logic.

4.4 What is needed to achieve these objectives – Key Functionalities needed

Given the focus of the impact assessment on comparing different forms of implementation, the identification of "key functionalities needed" allows making the transition between the definition of the objectives and what would be crucial to achieve them *in terms of implementation*. These functionalities relate to the type and composition of actors that have to be involved, the type of range of activities that should be performed, the degree of directionality needed and the linkages needed with the external environment.

4.4.1 Type and composition of the actors involved

For the initiative to achieve its objectives, there is a need to foster collaboration, contribution, co-design and co-creation involving a wide set of actors and stakeholders across scientific disciplines, industrial sectors, value chains and territories. It is important to ensure openness towards different actors and stakeholders, and guarantee their involvement in defining needs and priorities, in setting innovation and research agendas, as well as in innovation activities. However, each actor and stakeholder group may have different interests (¹³⁷). This requires that the proposed initiative be able to identify joint interests, define objectives and priorities that all stakeholders can support, and ensure an adequate balance of input and benefits for stakeholders involved in the initiative. In particular, it is important that all stakeholders actively support the public interest objectives of the initiative,

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BIOVOICES project (Connecting Biobased Forces for a Sustainable World), Synthesis of market perspectives to develop bio-based value chains, 2018.

and specifically those related to the sustainability of the bio-based industry. One of the underlying issue of the previous BBI initiative was that certain stakeholders were not as involved as desirable at all stages of implementation, even though SME participation was very prominent in the BBI JU.

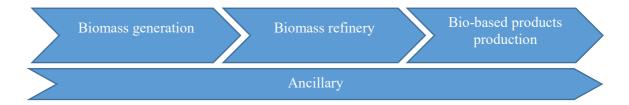
Stakeholder opinion

86% of respondents to the open public consultation (industry, academic and research institutions, public authorities and NGOs) see "a broad group" and 75% "flexibility in composition" as very relevant or relevant for the success of the proposed initiative.

It is therefore foreseen to involve the following stakeholders in the proposed initiative:

Industries: the bio-based industry operates as a broader industrial system that includes biomass producers as upstream actors, the bio-refining segment as the core segment that converts biomass into industrial materials and products, and the downstream segment that processes the bio-based materials into final products (Figure 14). Ancillary actors may include providers of technology and necessary inputs such as energy, as well as services such as transport, consultancy, etc. All segments are very wide, as there are many types of biomass, refining processes, and bio-based materials and products, resulting in thousands of bio-based value chains that are increasingly cross-sectoral. The three segments included in the Figure 14 face different R&I challenges related to their specific function but they all recognise the central role of biomass refining to enable business operations upstream and downstream. All segments are interested in the development of complete bio-based value chains enabled by biorefining technologies.

Figure 14 Basic composition of the bio-based industry



Stakeholder opinion

The open public consultation shows that 97% of 205 respondents (industry, academic and research institutions, public authorities and NGOs etc.) see industry as very relevant or relevant for CBE.

Smaller economic actors, such as farmers and SMEs, have been identified as important players in the bio-based value chains. Their active involvement in the bio-based economy in general contributes to local economic development, job creation, and more dynamism in the regions ¹³⁸. In the BBI JU, SMEs have already increased their participation in projects (40% SME participation ¹³⁹ as compared the Horizon 2020 average and 20% target), but there still is a vast room for further outreach and mobilisation of SMEs especially in the rural, coastal and less advanced regions. Many primary biomass suppliers are SMEs and they have

¹³⁹ Analysis by BBI JU.

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¹³⁸ BBI JU, *The BBI JU SME landscape: Driving impact and innovation*, Brussels, 2019.

already been identified as a special group that needs to play a bigger and more specific role in the bioeconomy and bio-based value chains.

Research organisations¹⁴⁰ have been actively contributing to the whole research spectrum from basic research to pilot plants and commercialisation in the BBI JU, by bringing knowledge capital and research facilities as resources to create new bio-based solutions. The input from scientific partners is needed to generate the most innovative solutions (¹⁴¹). The interest of research organisations in the proposed initiative is to obtain scientific credit and reputation from quality R&I results as well as funding for their research activities.

Stakeholder opinion

The open public consultation shows that 73% of respondents (industry, academic and research institutions, public authorities and NGOs etc.) see research organisations as very relevant or relevant for CBE.

Public bodies from Member States, regions and municipalities can safeguard the public interest and direct the initiative towards societal objectives. They can also promote and create favourable conditions for the development of bio-based industries. This includes the alignment of European, national and local level strategies and providing co-funding from national, regional and local funds. Regional authorities may play a key regulatory role as bio-based activities may require permits issued at the regional level. This important role of public authorities implies that their function is appropriate in the initiative's governance.

Stakeholder opinion

The open public consultation shows that 75% of respondents (industry, academic and research institutions, public authorities and NGOs) see public authorities as very relevant or relevant for CBE.

Civil society organisations such as consumer organisations or non-governmental environmental organisations can actively contribute to the initiative by ensuring the balance of environmental, social and economic objectives in its agenda, and can also raise the visibility and public awareness of the challenges and solutions emerging under the proposed initiative. The role of civil society organisations in balancing interests in a public-private partnership setup seems not to be fully recognised by stakeholders yet.

Stakeholder opinion

The open public consultation shows that 50% of respondents (industry, academic and research institutions, public authorities and NGOs) see civil society organisations as very relevant or relevant for CBE.

4.4.2 Type and range of activities needed

The activities needed for the initiative to succeed and address the R&I deficit described in Section 2 and accelerate the development and maturing of innovation in the bio-based industry, include:

• **public and private R&I activities** that are programmed to ensure the desired directionality to R&I in bio-based innovation;

¹⁴⁰ The open public consultation shows that around 73% of respondents see them as "very relevant" or "relevant" for CBE.

¹⁴¹ European Commission, Interim Evaluation of the Bio-based Industries Joint Undertaking (2014-2016), Brussels, 2017.

- a mobilisation of public and private funding of R&I activities to increase the overall financial support to the sector;
- multidisciplinary projects to reach and mobilise R&I actors from different scientific disciplines;
- intensified R&I activities along the whole innovation chain from low to high TRLs;
- reaching and **mobilising R&I actors in regions** where the intensity of R&I in the biobased systems is inadequate compared to the local potential for bio-based industrial activities in that region.
- R&I activities focussed on issues of public interest. For the proposed initiative, this refers to the **environmental performance of the bio-based industry** both in the terms of understanding the relevant problems and developing solutions to them.

To address the market uptake deficit by accelerating the deployment of innovation in the bio-based industry, the following are needed:

- initiate communication and collaboration between R&I and industrial stakeholders to raise awareness of rapidly evolving knowledge and technology, and facilitate collaboration between industry actors to develop market solutions based on bio-based innovation such as new bio-based products, value chains and business models;
- reach other actors and stakeholders such as national and regional authorities that are able to create more favourable conditions for market uptake, e.g. through bioeconomy strategies and different forms of incentives;
- **de-risk private investment** by using public funds to co-finance close to market projects.

Finally, to address the sustainability deficit and ensure the environmental performance of the bio-based industry, the following are needed:

- set scientifically robust sustainability criteria and performance benchmarks, and apply them in all publicly funded R&I activities in the bio-based industry and to all projects supported by the initiative, and
- promote these criteria beyond the initiative, by agreeing with the private partners that these criteria will become de facto industrial standards to be observed by the industry on voluntary basis.

4.4.3 Priority setting system and level of directionality required

A strategic vision for the proposed Circular bio-based Europe initiative (including its priorities and directionality) that is shared by all shareholders is essential for maximising the positive impact of the initiative. This strategic vision should safeguard public interests, balance the activities towards different general and specific objectives, and reconcile the different priorities of a diverse group of bio-based stakeholders. The focus should be on synergistic solutions that would reconcile potentially conflicting objectives and interests towards an effective contribution to the Green Deal and the Next Generation EU policy objectives.

This shared strategic vision would be defined in the Strategic Innovation and Research Agenda (SIRA) and annual Work Programme documents. These documents would be subject to extensive consultation involving all relevant stakeholders. Decision should be taken within a governance system that ensures balanced representation of the industry and its segments and gives an appropriate role to other stakeholders. In this governance system, the Commission should have the role of the ultimate guardian of the public interest and the

coherence of the initiative with EU policies. This also implies adequate financial contribution of private partners to the initiative.

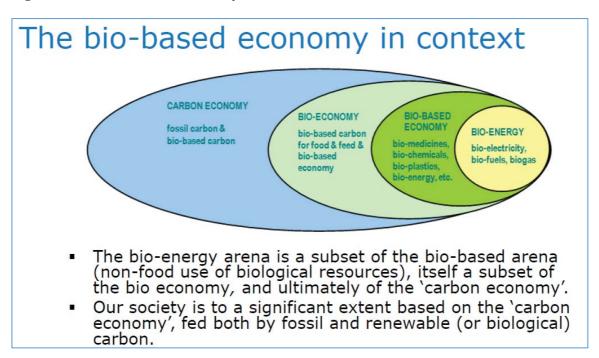
Stakeholder opinion

The open public consultation shows that 66% of 202 respondents (industry, academic and research institutions, public authorities and NGOs etc.) considers securing private investment in bio-based innovation as very relevant or relevant for CBE.

4.4.4 Coherence needed with the external environment

An initiative for a Circular bio-based Europe would need to be firmly anchored to the European Green Deal, the EU Bioeconomy Strategy, the new Circular Economy Action Plan, the new Industrial Strategy, the Farm to Fork Strategy and the Sustainable Development Goals. Figure 15 shows how the bio-based economy is fitting within the larger context of the bioeconomy.

Figure 15: The bio-based economy in context



After: Kwant K.W., Biobased Economy in the Netherlands and the regions – Opportunities & Challenges, Netherlands Enterprise Agency, 2017 (after: van Beeck, N. et al., An innovative perspective: Transition towards a bio-based economy, in: Sustainable Energy Solutions in Agriculture, ed. J. Bundschuh and G. Chen, London, 2014).

Inter alia, the initiative would need to seek synergies in terms of funding projects as well as in terms of programme development with the following programmes and the initiatives mentioned below, while avoiding overlaps. In particular, strong complementarities are expected with Cluster 6 of Horizon Europe as well as with all other initiatives in the same area. It is important to highlight that the proposed CBE initiative's centre of gravity lies with bio-based industry actors and value chains.

• At the EU level¹⁴²: Horizon Europe (mainly Pillar II, Cluster 6), the InvestEU instrument, the European Regional Development Fund (ERDF), the European

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¹⁴² The open public consultation shows that 75% of the respondents see this as very relevant or relevant for CBE.

Agricultural Fund for Rural Development (EAFRD), the LIFE programme, EU's Common Agricultural Policy (CAP), the European Maritime and Fisheries Fund (EMFF), the Agricultural European Innovation Partnership (EIP-Agri), the European Circular Bioeconomy Fund (ECBF), the BIOEAST initiative¹⁴³, and the EU Protein Strategy. Blending approaches promoted by InvestEU¹⁴⁴ could combine e.g. loans for infrastructure with CBE research grants to develop especially large scale biorefineries, where infrastructure needs could be financed with sources other than supporting programmes such as CBE. Joint transdisciplinary projects (¹⁴⁵) with other partnerships ¹⁴⁶, e.g. CCNI (Circular and Climate Neutral Industries; the potential successor of SPIRE), could build on the earlier successful cooperation between BBI JU and SPIRE, which succeeded in turning redundancies into synergies ¹⁴⁷.

- At national and regional levels, CBE would interact with Member States and regions considering the strategies and plans such as bioeconomy strategies and programmes to advance on synergies and partnering for regional developments ¹⁴⁸ for example on synergies with financing instruments and programmes for infrastructure and biorefineries deployment. This will include following up on the recommendations from the BBI JU interim evaluation ¹⁴⁹ to increase participation of the EU-13 Member States, which is partially expected via the above-mentioned synergies with the BIOEAST initiative.
- On the international level, many stakeholders suggested that CBE could be kept open to the international players, especially to technology and research leaders and providers, in order to benefit from collaborations with them, and ensure a European leading role in the international development of the bio-based economy. CBE could follow up on the existing recommendations from the interim evaluation of the BBI JU initiative, to identify win-win strategies for a larger involvement of Third Countries while ensuring the protection of EU industry's interests 150.

Finally, it is worth adding that a favourable policy framework is an important factor for the viability of new bio-based value chains and innovations, especially if markets fail to provide sufficient incentives to pick them up. CBE could contribute to the regulatory aspects ¹⁵¹ and contribute to harmonising standards ¹⁵², developing Life Cycle Assessment methodologies that could support these standards or products, and develop project assessment processes. It can also support expanding the market for bio-based products and solutions by promoting green public procurement. This could contribute to raise awareness, identify regulatory bottlenecks and provide success stories to address regulatory aspects.

¹⁴³ Central-Eastern European Initiative for Knowledge-based Agriculture, Aquaculture and Forestry in the Bioeconomy.

¹⁴⁴ https://ec.europa.eu/commission/priorities/jobs-growth-and-investment/investment-plan-europe-juncker-plan/whats-next-investeu-programme-2021-2027 en

The open public consultation shows that 90% of the respondents see this as very relevant or relevant for CBE.

¹⁴⁶ The open public consultation shows that 73% of the respondents see this as very relevant or relevant for CBE.

¹⁴⁷ like use and capture of CO2 where an agreement between BBI and SPIRE was reached where BBI focused on biogenic sources of CO2 and SPIRE on emissions from other such as non-biogenic processing industries

Dietz, T. et al., Governance of the bioeconomy: A global comparative study of national bioeconomy strategies, Sustainability, 2018.

¹⁴⁹ https://op.europa.eu/en/publication-detail/-/publication/eebcfc39-ae32-11e7-837e-01aa75ed71a1/language-en

¹⁵⁰ https://op.europa.eu/en/publication-detail/-/publication/eebcfc39-ae32-11e7-837e-01aa75ed71a1/language-en

¹⁵¹ The open public consultation shows that around 86% of the respondents see this as very relevant or relevant for CBE.

The open public consultation shows that around 60% of the respondents see this as very relevant or relevant for CBE.

5 WHAT ARE THE AVAILABLE POLICY OPTIONS?

This section describes the specific functionalities that could be provided under the baseline scenario of traditional Horizon Europe calls and under the other possible forms of implementation for the proposed initiative.

5.1 What is the baseline from which options are assessed?

The baseline scenario used in this impact assessment is the basic mode of implementation of the EU R&I programme, i.e. traditional calls without any partnership structure with the industry. This scenario takes into account the existence of the predecessor of this initiative – the BBI JU. The existing BBI JU partnership will continue to have impact through ongoing projects and continuous engagement with the industrial actors at least for the next 4 years, until 2024. This impact is considered as part of the effectiveness of the baseline scenario. Winding up of the BBI JU will have also different costs and benefits that are accounted for in the efficiency assessment of the baseline scenario.

Stakeholder opinion

During the preparation of the Impact Assessment, Member states were also consulted. Overall there is a strong agreement (96%) on the use of a partnership approach for a Circular bio-based Europe and a broad agreement (83%) that the partnership is more effective than traditional calls in achieving the objectives and delivering clear impacts for the EU and its citizens.

Table 1: Key characteristics of the baseline situation – Horizon Europe calls

	Implications of option
Enabling appropriate profile of participation (actors involved)	 The Commission needs to consult extensively with a wide range of stakeholders to translate the strategic R&I agenda for the circular bio-based economy into work programmes. A well-defined process is needed to ensure that the programme committees are properly informed about R&I priorities for the circular bio-based economy.
Supporting implementation of R&I agenda (activities)	 Implementation relies on standard infrastructure underpinning the open calls procedure, drawing on resources of relevant executive agencies and Commission IT systems. Administrative costs for the European Commission are similar to those in Horizon 2020. Calls for proposals are published in the work programmes of Horizon Europe. Transparency and open publication of results ensure their availability to all interested parties.

Ensuring alignment with R&I agenda (directionality)

- Strategic programming and the research agenda are defined by the European Commission via co-creation, with the support of an advisory group and the programme committee.
- Work programmes need to reflect the requirement for R&I across TRLs, with input from representatives of all relevant stakeholders.
- Commission input into specifications and oversight of calls help ensure alignment with overarching policy objectives, but full integration with other programmes requires additional coordination.
- Specification of calls for activities at higher TRLs, particularly demonstration and flagship actions, needs substantial input from industry.

Securing leveraging effects (additionality)

- Pooling and leveraging of resources are not facilitated. Requirements for in-kind contributions can be applied at the project level (reduced funding rates for higher TRLs), but are not high.
- The progress of the R&I effort largely depends on EU funding, with no expectation of a significant triggering of additional industry support.
- Demonstration and flagship projects require significant in-kind support and collaboration from industry, but it is not sure whether critical mass can be reached.
- Given more limited funding than in the past, critical R&I priorities need to be identified from the outset.

Key differences compared to the current situation

Moving from the current BBI JU to Horizon Europe calls (baseline option) would entail the dismantling of the JU with the following consequences:

- The implementation of a common vision and ambitious objectives in the area would not be possible due to the absence of a structured private partner.
- The basis for R&I cooperation under a stable structure would disappear.
- Large scale R&I actions (flagships) could not be implemented, affecting the coverage of TRL
 7-8 and diminishing the impact of the initiative.
- EU support to the area would considerably lower the leveraging of private funding, with a much lower volume of resources available due to significantly lower financial commitment of private partners.
- Discontinuation cost, with a 4-year winding down period for the current JU until 2024 (legal end point of current initiative), will be higher (see rationale at 6.2 Efficiency).

5.2 Description of the policy options

Table 2: Key characteristics of Option 1 – Co-Programmed European Partnership

Enabling appropriate profile of participation (actors involved) There is more flexibility to change the profile of suth new partners joining to support new areas of activity in response to emerging results and changing priorities. This is notwithstanding to the openness principle. Implications of option Option 1 enables participation by all key stakeholders potentially contributing to the specifications and delivery of the strategic R&I agenda. A wide range of stakeholders needs to be consulted to ensure that the R&I agenda, and ultimately the work programmes, are aligned with industry and market needs. There is more flexibility to change the profile of the stakeholder groups consulted over time, with new partners joining to support new areas of activity in response to emerging results and changing priorities. This is notwithstanding to the openness principle. The partnership is based on a memorandum of understanding between the private partner

represented by the industry and the public side represented by the Commission. Strategic programming and the research agenda are defined through co-creation between industry, Commission and relevant stakeholders including programme committee and advisory groups.

Supporting implementation of R&I agenda (activities)

- Implementation relies on standard administrative infrastructure underpinning the open calls
 procedure, drawing on resources of relevant executive agencies and Commission IT systems.
- Administrative costs for the European Commission are slightly higher than under the baseline because of the needed partnering process.
- Calls for proposals are published in the work programmes of Horizon Europe.
- Transparency and open publication of results ensure their availability to interested parties.
- The private partner is responsible for implementing its part of the research agenda.

Ensuring alignment with R&I agenda (directionality)

- Work programmes need to reflect the requirement for R&I activities across TRLs, with input from the various partners to achieve an appropriate balance of activities directed towards different markets.
- The partnership is responsible of ensuring that priorities for calls are specified in line with R&I priorities defined in the Strategic Research and Innovation Agenda.
- R&I activities are likely to focus on the medium-term needs of the industry, but the Commission has full influence on where to put its own focus.
- The programme committee ensures alignment with overarching policy objectives and coordination with related programmes.

Securing leveraging effects (additionality)

- Aspirations for partner contributions are clearly defined from the outset.
- Industry commitments are not legally binding, but based on past experiences they are usually fulfilled.
- Expected in-kind contributions from the private sector are identified in the work programmes.
- The mobilisation of private and public funding is more favourable in a co-programmed form than under the baseline scenario, covering all relevant TRL levels including more capital intensive ones.

Key differences compared to the current situation

Moving from the current BBI JU to Option 1 - Co-programmed European Partnership would entail the dismantling of the JU with the following consequences:

- The implementation of a common vision and ambitious objectives in the area would be less efficient and take longer.
- Reach and mobilise R&I actors from different scientific disciplines would pose a challenge for a co-programmed partnership.
- Without a programme office, reaching national and regional authorities would be less favourable than with a dedicated office, additionally a co-programmed option would create worse conditions for market uptake of new innovative bio-based solutions.
- The basis for R&I cooperation under a stable structure would disappear.
- Discontinuation cost, with a 4-year winding down period for the current JU until 2024 (legal end point of current initiative), will be comparable to the baseline (see rationale at 6.2 Efficiency)

Table 3: Key characteristics of Option 3b – Institutionalised European Partnership based on Article 187 TFEU

Implications of option

Enabling appropriate profile of participation (actors involved)

- The partnership enables participation of all key stakeholders potentially contributing to the specifications and delivery of the strategic R&I agenda through a clearly defined membership structure.
- It provides a forum for co-drafting R&I priorities and the work programmes, ensuring that they are aligned with industry and market needs.
- Participation is less flexible than under other options, but it is nevertheless possible to change the profile of participation over time, with an open Membership policy and new partners joining to support new areas of activity in response to emerging results and changing priorities.

Supporting implementation of R&I agenda (activities)

- A dedicated administrative structure (Joint Undertaking JU) is established to coordinate the specification of R&I activities, manage implementation, and report on the results (with administrative expenditure limited to 4% of the budget and subject to 50:50 allocation between the Commission and private partners).
- The Joint Undertaking provides specific thematic competences for the implementation of the initiative and deploys a broader range of activities, compared to what the executive agencies supervising projects under Option 0 and 1 can provide.
- To reach and mobilise R&I actors from different scientific disciplines, a Joint Undertaking provides a favourable platform for multidisciplinary projects.
- Under the umbrella of a programme office, public and private R&I activities that are programmed to ensure the desired directionality to R&I in bio-based innovation perform better than in a co-programmed form of partnership.

Ensuring alignment with R&I agenda (directionality)

- Both partners, private and the Union, are co-responsible for specifying work programmes
 that are fully in line with the R&I priorities identified by the partners beforehand to fulfil
 European policy needs and the needs of the industry, combining activities across low and
 high TRLs and in different areas.
- The work programmes reflect the medium- to long-term needs of the industry, drawing on the perspectives of different stakeholders.
- Commission participation in the partnership governance (including work programme adoption) helps ensure alignment with overarching policy objectives and enables integration with other programmes.
- R&I activities focus on issues of public interest. In an Institutionalised format this refers to
 the environmental performance of the bio-based industry both in the terms of
 understanding the relevant problems and developing solutions to them.

Securing leveraging effects (additionality)

- Formal commitments and funding requirements are clearly defined from the outset and are legally binding (contribution are defined in the legal act), with the private partners expected to provide 50% to 75% of partnership resources through in-kind and financial contributions.
- Given more limited funding than in the past, critical R&I priorities need to be identified from the outset.
- A Joint Undertaking can assist in de-risking private investment by using public funds to cofinance close to market projects.

Key differences compared to the current situation

Remaining an Institutionalised Partnership under Art 187 TFEU 1 - would entail:

- The CBE partnership would build on the BBI JU structure, allowing for necessary improvements by drawing on lessons learned and past experiences.
- Modifications will be introduced in administrative procedures and practices to ensure that operations are lean and efficient as possible.

- Setting scientifically robust sustainability criteria and performance benchmarks, and apply
 them in all publicly funded R&I activities in the bio-based industry and to all projects
 supported by the initiative, and promote these criteria beyond the initiative, by agreeing
 with the private partners that these criteria will become de facto industrial standards to be
 observed by the industry on voluntary basis.
- The governance structure of the CBE initiative would include two major improvements compared to the current BBI JU.
 - The role of the Deployment Groups is to advice the Governing Board on issues critical to market uptake of bio-based innovation and to promote deployment of sustainable bio-based solutions. Their composition shall ensure appropriate thematic focus and representativeness of the bio-based innovation stakeholders.
 - o In addition to the general Governing Board meetings, the Governing Board shall hold at least once per year a Strategic Meeting with the primary objective to identify challenges and opportunities for sustainable bio-based industry and provide additional strategic orientation for the partnership. In the Strategic Meeting additional chief executive officers or officers with decision-making power of leading European bio-based companies and the Commission, shall be invited. The chairpersons of the States Representative Group, the Scientific Committee and the Deployment Groups may be invited in the role of observers.

5.3 Options discarded at an early stage

Option 2: Co-funded European Partnership and Option 3a: Institutionalised Partnership based on Article 185 TFEU are discarded from the outset.

These two partnership models exclude industries in the partnership agreement, which does not create any basis for involving them in the R&I agenda setting and does not provide adequate incentives for industries to commit to the policy objectives and to programme success. In achieving the key objectives of securing long-lasting competitiveness of the European bio-based industries and ensuring their circularity and sustainability, it is necessary to have involvement and commitment of the industries concerned.

Furthermore, the limited possibility of connecting various sectors would fail to deliver the structuring effect that is highly needed for the development of the EU bio-based industry and of new value chains. This is especially the case with the value chains that could potentially valorise waste biomass by integrating providers of e.g. agricultural and forestry waste, food waste, fisheries waste or urban waste in the production of novel bio-based products.

6 How do the different policy options compare to achieve the expected impacts?

Based on the intervention logic, the initiative aims to deliver scientific, economic/technological and environmental (including societal) impacts through a set of pathways (Section 4.3), which require a number of critical factors in place for the impacts to be

achieved in the best possible way (Section 4.4). In what follows, each option for implementation is assessed in terms of effectiveness, efficiency and coherence compared to the baseline scenario of traditional calls. The analysis is primarily based on the degree to which the different options would cater for the key needed functionalities. All options are compared to the baseline situation of traditional calls, which is thus consistently scored at 0 to serve as reference point.

6.1 Effectiveness

To be in line with the Horizon Europe impact framework, the fulfilment of the specific objectives of the initiative is translated into 'expected impacts' - how success would look like, differentiating between scientific, economic/ technological, and societal (including environmental) impacts. This section considers to which extent the different policy options would allow delivering these expected impacts – comparing what is needed (functionalities) with what each form of implementation can provide in practice. The assessments in this section set the basis for the comprehensive comparative assessment of all retained options against all dimensions in Section 6.4, based on a scoring system.

Scientific impacts

- ➤ Accelerated development of bio-based innovations;
- ➤ Reinforced scientific and innovation capacity for bio-based solutions, including in the regions where this capacity is currently underdeveloped;
- ➤ Increased R&I capacity for addressing the key sustainability challenges.

The baseline option:

A significant scientific impact can be achieved under the baseline scenario. Through traditional Horizon Europe calls, it is possible to set priorities and directionality for R&I activities through strategic programming. Adequate financing can be mobilised for grants targeting low- to medium-TRL projects. However, financing of capital intensive high-TRL projects can be limited because of insufficient mobilisation of private investment under this option. The baseline scenario can also effectively contribute to long-term scientific progress by investing in novel exploratory and interdisciplinary research (score 0).

The scientific and innovation capacity in general will be reinforced under the baseline scenario but there is limited possibility to target those R&I partners and regions where the capacity is currently underdeveloped. Calls for projects are open, which implies that anyone could potentially benefit. However, the interim evaluation of Horizon 2020 and the experience with the predecessor partnership indicate that traditional calls tend to largely attract actors that are already active in public R&I support programmes. Many relevant biobased stakeholders, e.g. biomass producers, bio-waste recyclers, SMEs, etc., especially in the regions where the bio-based industry is less developed, may not have information or capacity to participate in the calls. Lack of capacity and the absence of support structures facilitating outreach (such as from a JU programme office) would be a barrier. Therefore, this option is unlikely to achieve the desired strong impact in terms of diversity of actors and in terms of targeting the underdeveloped regions (score 0).

Finally, the baseline scenario is able to contribute to knowledge development in the area of sustainability through the strategic programming process (score 0).

Option 1 – Co-programmed partnership:

A co-programmed European partnership can deliver more in terms of the scientific impact, mainly due to a higher amount of resources pooled in the programme via contributions of partners and better representation of relevant actors and stakeholders. A co-programmed partnership has also greater capacity than the baseline to support high-TRL projects (demonstrations and flagships) due to the action of private industrial partners. It can effectively set priorities and give directionality to R&I activities, while aligning the public and private R&I agendas (score +).

The co-programmed partnership is flexible in terms of involvement of different partners and can attract and facilitate participation of a wider scope of actors and stakeholders; however it would most likely not specifically target stakeholders and regions with underdeveloped capacity (score +).

The ability to focus the R&I activities on sustainability issues is comparable to the baseline of traditional Horizon Europe calls (score 0).

Option 3b – Institutionalised European Partnership based on Article 187 TFEU:

Similar to the co-programmed partnership, an institutional partnership under Article 187 can deliver more on the scientific impact than the baseline scenario, mainly due to a higher amount of resources pooled in the programme via contributions of partners and better representation of relevant stakeholders. A co-programmed partnership has the greatest capacity to support high-TRL projects due to co-funding of these projects by public and private partners (score +).

It can effectively set priorities and give directionality to R&I activities, while aligning the public and private R&I agendas. Due to the institutionalised form and formal financial commitments by partners, it is less flexible in terms of involvement of different partners but can effectively target specific key stakeholders (primary biomass producers, SMEs) and regions with underdeveloped capacity (score ++).

The ability to focus the R&I activities on sustainability issues is comparable to the baseline scenario (score 0).

Stakeholder opinion:

46% of OPC 1782 respondents (industry, academic and research institutions, public authorities and NGOs)answered that a legal structure would have a very high relevance in terms of achieving certain impacts such as effective implementation of activities; synergies with other EU and national programmes; and collaboration with other European partnerships.

Economic/technological impacts

- ➤ Bio-based innovations reaching first market application and bringing real economic and environmental benefits;
- A structured process for collaboration between R&I actors, industry including SMEs and other bio-based innovation stakeholders focused on the deployment of bio-based innovation;
- ➤ Reduced investment risk and improved access to finance for bio-based industrial projects.

The baseline option:

The baseline scenario has a limited ability to support the market application of bio-based innovation, due to limited resources for large scale, capital-intensive flagship projects, and the absence of mechanisms for collaboration with important deployment stakeholders such as regional authorities or investors. Market uptake is supported mainly by indirect dissemination activities (score 0).

The baseline scenario does not have a structuring effect on the dynamic bio-based industry and no possibility to facilitate business innovation through collaboration along and across bio-based value chains (score 0).

The baseline scenario does not have any tools to address the investment risk for bio-based projects other than generic R&I investment tools and calls planned under the Horizon Europe (score 0).

Option 1 – Co-programmed European Partnership:

A co-programmed partnership has much higher capacity than the baseline scenario to implement capital-intensive demonstration and flagship projects through the actions of private partners. The commitment of partners is however voluntary, and comes without guarantees that the investment actually happens (score +).

The co-programmed partnership can develop a well organised process for collaboration and structuring of the industry. This form of implementation foresees the possibility to establish bodies and processes that will involve relevant partners and facilitate collaboration and business innovation based on bio-based solutions. However, without a more institutionalised form and dedicated structures, this process may not be effective enough to reach the intended objectives (score +).

The co-programmed partnership can also address some investment risks. For instance, by involving the investment community, raising awareness of available bio-based solutions and their techno-economic parameters, or by involving regulatory stakeholders to address some regulatory risks. The co-programmed partnership cannot directly de-risk projects implemented by the private partners (score +).

Option 3b – Institutionalised European Partnership based on Article 187 TFEU:

The institutionalised partnership has much higher capacity than the baseline scenario to implement capital-intensive demonstration and flagship projects through the joint actions of public and private partners. This joint action and co-financing by partners guarantees better than the other options that the investment happens and projects are implemented (score ++).

The institutionalised partnership can develop a well-organised process for collaboration and structuring of the industry. The institutionalised partnership establishes a dedicated body with the capacity to assist the structuring process and to target the relevant actors from industry. It can also involve other deployment stakeholders, e.g. regional authorities, primary biomass producers, and so on in a more formal and structured way, aiming at the creation of favourable conditions for deployment of bio-based innovation. This dedicated body with the necessary expertise and capacity is the key to the effectiveness of these activities (score ++).

The institutionalised partnership can tackle some of the investment risk, e.g. by involving the investment community, raising awareness of the bio-based solutions and their technoeconomic parameters, or by involving regulatory stakeholders to address some regulatory risks. In addition, the co-financing of the demonstration and flagship projects from EU funds

helps to de-risks the private investment in these projects and may attract and convince other investors invest in these projects (score ++).

Stakeholder opinion

With respect to the relevance of coordination, alignment or integration with specific stakeholders' groups in pooling and leveraging resources (such as financial, infrastructure, in-kind expertise etc.)to meet Partnership objectives, the patterns in stakeholders' responses are very similar. In the Open Public Consultation, 76% of respondents from all stakeholder groups (industry, academic and research institutions, public authorities and NGOs) indicated that industry was very relevant. Member States and Associated Countries (54%) were also found to be very relevant. As regards academia, the share of respondents that found their involvement very relevant was somewhat lower (42%) Most of the respondents among different stakeholder groups did not indicate Foundations and NGOs as very relevant (21%).

Environmental/Societal impacts (social, fundamental rights)

- Enhanced circularity and environmental sustainability of the European bio-based industries;
- ➤ Better integration of primary biomass producers in bio-based value chains to contribute to rural development.

The baseline option:

Under the baseline scenario, it is possible to develop sustainability criteria and benchmarks and apply them to all the bio-based projects funded by the EU R&I programme. This scenario does not have any mechanism to enforce or promote the application of sustainability criteria outside of Horizon Europe operations, e.g. by privately funded projects (score 0).

As the baseline scenario has only a limited capacity to integrate primary biomass producers such as farmers in the high-TRL projects and limited structuring effect, it cannot effectively integrate farmers in the bio-based value chains. It is unlikely that this scenario will have significant positive effect on farmers' income and on rural development (score 0).

Option 1 – Co-programmed European Partnership:

Under the co-programmed partnership, the application of sustainability criteria can be guaranteed for the publicly funded R&I actions. Other partners may respect sustainability criteria on a voluntary basis (score 0).

The co-programmed partnership also allows for the involvement of primary biomass producers and can integrate their interest and needs in the activities of the partnership (score +).

Stakeholder opinion

81% of the 207 respondents to the Open Public Consultation (industry, academic and research institutions, public authorities and NGOs) stated that it is either relevant or very relevant to create jobs in the bio-based industry in rural and underdeveloped areas.

Option 3b – Institutionalised European Partnership based on Article 187 TFEU:

Under the institutionalised partnership, the application of sustainability criteria can be guaranteed for the all co-funded R&I actions (the Commission holds a veto power on the

formulation of co-financed calls). The institutionalised form could also foster the acceptance of the sustainability criteria by the industrial partners also beyond the operation of the partnership as an industrial benchmark (score +).

The institutionalised partnership allows for the involvement of primary biomass producers and can integrate their interest and needs in the activities of the partnership. Moreover, the institutionalised partnerships have a designated body that could actively target primary biomass producers so as to integrate them in the partnership activities. (score +)

Impacts on fundamental rights

Impacts on fundamental rights are not expected.

Stakeholder opinion

In the Open Public Consultation, respondents (industry, academic and research institutions, public authorities and NGOs) were asked about the relevance of the Partnership composition, such as the flexibility in the composition of partners over time and the involvement of a broad range of partners (including across disciplines and sectors), to reach Partnership objectives. No statistical differences were found between the views of citizens and other types of respondents.

Ensuring the involvement of a broad range of partners has more 'very relevant' answers (67%) than the flexibility in the composition of partners (48%).

Table 4: Overview of the options' effectiveness compared to the baseline

	Baseline: Horizon Europe calls	Option 1: Co- programmed European Partnership	Option 3b: Institutionalised Article 187 TFEU
Accelerated development of bio-based innovations	0	+	+
Reinforced scientific and innovation capacity for bio- based solutions including in the regions where currently this capacity is underdeveloped	0	+	++
Increased R&I capacity for addressing the key sustainability challenges	0	0	0
Bio-based innovations reaching first market application and bringing real economic and environmental benefits	0	+	++
A structured process for collaboration between R&I actors, industry including SMEs and other bio-based innovation stakeholders focused on deployment of bio-based innovation	0	+	++
Reduced investment risk and improved access to finance for bio-based industrial projects	0	+	++
Enhanced circularity and environmental sustainability of the European bio-based industries	0	0	+
Better integration of primary biomass producers in bio-based value chains to contribute to rural development	0	+	+

Notes: Score ++ : Option presenting a *high* potential compared to baseline; Score +: Option presenting a *good* potential compared to baseline; Score 0: Potential of the baseline.

6.2 Efficiency

In order to compare the policy options consistently in terms of their efficiency, a standard cost model was developed for the external study supporting the impact assessment for the set of candidate Institutionalised Partnerships. The model and the underlying assumptions and analyses are set out in the Common Part of this impact assessment, Section 2.3.2 and in the Methodology Annex 4. A dedicated Annex 3 also provides more information on who is affected and how by this specific initiative in line with the Better Regulation framework. The scores related to the costs set out in this context allow for a "value for money" analysis (cost-effectiveness) in the final scorecard analysis in Section 6.4.

In addition, for this specific initiative under the baseline scenario of traditional calls, there would be winding down and social discontinuation costs for the existing implementation structure of the current Article 187 initiative. There would also be longer term financial cost-savings related to the closing of the structure, related to operations, staff and coordination costs in particular. Overall it is estimated that the overall longer term cost savings from using traditional calls instead of an existing Article 187 initiative would considerably exceed the costs incurred for winding down operations. This overall situation is set as the starting point for the comparison of options. The score of this baseline scenario (traditional Horizon Europe calls) is set to 0 to be used as a reference point.

On this basis, the scores for the costs of the different options range from a value of 0, in case an option does not entail any additional costs compared to the baseline, to a score of (-) when an option introduces limited additional costs when compared to the baseline and a score of (- -) when high additional costs are expected in comparison with the baseline. In case the scores are lower than for the baseline scenario, (+) and (++) are used. For option 1, additional costs for the call and project implementation have been considered. It has been taken into account that for option 3b there are moderate additional costs for the setup of a dedicated implementation structure, as such a structure (BBI JU programme office) already exists.

It is considered that while there is a clear gradation in the overall costs of the policy options, the cost differentials are less marked when one takes into account the expected co-financing rates and the total budget available for each of the policy options, assuming a common Union contribution. From this perspective, there are only one or two percentage points that split the most cost-efficient policy options – the baseline (traditional calls) and the Co-Programmed options – and the least cost-efficient – the Institutionalised Partnership option. Indeed, in terms of cost-efficiency, the Co-Programmed Partnership (Option 1) is 2 percentage points more efficient than the baseline; while an Article 187 Partnership is 2 percentage points less cost-efficient than the baseline. A score of + is therefore assigned for **cost-efficiency** to the Co-Programmed option and a score of (-) for the Institutionalised Partnership policy option¹⁵³.

It should be noted that the potential for the creation of crowding-in effects for industry has been taken into account when assessing the effectiveness of the policy options, above.

Table 5: Matrix on overall costs and cost-efficiency

¹⁵³ The baseline (traditional calls) is scored 0, as explained above.

	Option 0: Traditional calls under the Framework Programme	Option 1: Co- programmed European Partnership	Option 3b – Institutionalised European Partnership based on Article 187 TFEU
Administrative, operational and coordination costs	0	0	
Administrative, operational and coordination costs adjusted per expected cofunding (i.e. costefficiency)	0	+	-

Notes: Score 0 = same costs as for the baseline; score (-) = limited additional costs compared with the baseline; score (-)(-) = substantial additional costs compared with the baseline.

6.3 Coherence

6.3.1 Internal coherence

In this section we assess the extent to which the policy options show the potential of ensuring and maximising coherence with other actions, programmes and initiatives under Horizon Europe, in particular European Partnerships (internal coherence).

Baseline: Horizon Europe Calls

Coherence of the research agenda is likely to be achieved. However, complementarities are limited by the smaller number of actions at higher TRLs, leading to a loss of knowledge transfer from R&I actions to demonstration and deployment activities. This will be reinforced by the lack of continuity in projects teams, as answers to individual calls usually lead to ad-hoc consortia. There will be a limited scope for synergies between projects, as there is a lack of structuring of the community in the absence of a dedicated body. Synergies and complementarities with the rest of Horizon Europe are likely to be achieved. Links with other partnerships (¹⁵⁴) or EIT-KICs (¹⁵⁵) could be made, but they would be ad hoc. The lack of a dedicated team that engages with other partnerships limits the creation of links and might result in duplication or misalignment of work (score 0)

Option 1 – Co-programmed European Partnership:

The Memorandum of Understanding (MoU) envisaged under this option ensures the coherence of the R&I agenda over time. In addition, the flexibility of the governance model would secure the timely involvement of the most relevant actors, ensuring continuity across projects and best internal synergies. As the European Commission retains a strong steering role, coherence with the rest of Horizon Europe is achieved. Both Commission staff and the network's secretariat theoretically have the means to create synergies and complementarities with other partnerships (¹⁵⁴) or KICs (¹⁵⁵), but this depends on the availability and expertise of the staff, and good coordination between them. Its score would therefore be higher than the baseline (score +).

Option 3b – Institutionalised European Partnership based on Article 187 TFEU:

¹⁵⁴ Safe and Sustainable Food System for People, Planet & Climate; Carbon Neutral and Circular Industry; Rescuing Biodiversity; Water4All.

¹⁵⁵ Food; Climate; Raw Materials; Manufacturing.

The institutionalised partnership provides for the creation of a dedicated secretariat (programme office) with specialised staff with a complete understanding of bio-based issues and who would have the means to fully exploit the potential for synergies and complementarities of all actors. It also acts as a single contact point for interested parties. An institutionalised partnership can count on a stronger contribution from industrial partners, secured through a legal agreement, which benefits project partners and ensures a strong structuring effect. The research agenda has to be fully in line with Horizon Europe objectives and therefore coherence with the rest of Horizon Europe is ensured. With the resources to engage with other European partnerships (154) or KICs (155), an institutionalised partnership is able to exploit synergies and complementarities within Horizon Europe. As explained by a majority of interviewees, this is the option with the highest visibility and strongest position to engage with other parties. Its score would therefore be very high compared to the baseline (score ++).

Stakeholder opinion

Some 59% of the 1782 respondents to the Open Public Consultation (industry, academic and research institutions, public authorities and NGOs) consider that setting up a specific legal structure for the proposed initiative Circular Bio-based Europe is either relevant or very relevant.

6.3.2 External Coherence

In this section we assess the extent to which the policy options have the potential of ensuring and maximising coherence with their external environment, including EU-level programmes and initiatives beyond the Framework Programme and/or national and international programmes and initiatives, but also with overarching framework conditions, such as regulation, standardisation, etc. (external coherence).

Baseline: Horizon Europe Calls

Links can theoretically be made with other programmes under the Multiannual Financial Framework 2021-27 (MFF) (beyond Horizon Europe), but on an ad-hoc basis. Under the baseline, there is no dedicated team that could devolve time to engage with other programmes to develop structured, long-lasting synergies. Nonetheless, activities that are unlikely to be carried out through Horizon Europe calls (especially deployment actions) could be envisaged to be funded under other programmes (e.g. InvestEU). Horizon Europe calls are unlikely to contribute to setting up infrastructure, and projects would have to rely on their infrastructure to be provided by other funders.

The absence of Horizon Europe funding for biorefineries impacts on the capacity to conduct research, as other funders are unlikely to match the missing element, leading to a loss of complementarity. No work on regulation can be expected via Horizon Europe calls, and their capacity to contribute to the debate through Coordinating and Support Actions (CSA) is limited. Especially, the results of CSAs in this domain, as well as overall directionality and engagement of the community, might be impeded by the lack of a community structuring effect, scattered actors with highly diverse opinions, and no clear overall identification of needs (score 0).

Option 1 – Co-programmed European Partnership:

The administration of the partnership by an EC executive agency ensures that staff has the means to continuously engage with other programmes beyond Horizon Europe to develop synergies and complementarities. The network's secretariat can also take part in this bridge-making. A wider range of actors involved in the network can create the conditions for stronger synergies with other public bodies at European, national or regional level. Continued alignment with national and regional strategies can be ensured, as under the BBI JU (¹⁴¹). However, in a co-programmed partnership the industry might be less engaged, an issue frequently raised by interviewees (especially companies). It would therefore not benefit from strong complementarities with purely private initiatives, and might attract less attention from brand owners. Overall, its score would be high compared to the baseline (score +).

Option 3b – Institutionalised European Partnership based on Article 187 TFEU:

A strong involvement of the European Commission will be needed to ensure that an institutionalised partnership engages with other Multiannual Financial Framework (MFF) programmes. However, the need to look for complementarities, especially regarding access to finance when demonstration and deployment activities end, creates a strong incentive for the programme office of the partnership to engage with these programmes (e.g. EIB's European Circular Bioeconomy Fund, InvestEU). In addition, it would have the resources to then support project holders in their transition. The proposed initiative could set up a 'onestop' contact point for interested parties to make them aware of the availability of the different funding sources, and of the possibility to combine (more easily) different funding sources.

Involving a wide set of actors within the network who benefit from the structuring effect of an institutionalised partnership, creates the conditions for synergies with other public bodies at European, national, regional and local level. The high level of involvement required of the industry would also encourage them to join forces and develop the links that are necessary to create and strengthen bio-based value chains in an integrated manner. The structuring effect of an institutionalised partnership also provides for the constitution of a common understanding of needs, especially of regulation, infrastructure or human capital. Overall, this options scores very high compared to the baseline (score ++).

Table 6: Overview of the options' potential for ensuring and maximising coherence

	Option 0	Option 1	Option 3b
Internal coherence	0	+	++
External coherence	0	+	++

Score ++: Option presenting a very high potential; Score +: Option presenting a high potential; Score 0: Potential of baseline

6.4 Tabular comparison of options and identification of preferred option

The table below gives a summary of the comparative analysis done above. The table given in Technopolis' Impact Assessment Study Report has been corrected and developed further.

Table 7: Ranking of the policy options

	Criteria	Option 0 – Traditional calls under the Framework Programme	Option 1 – Co- programmed European Partnership	Option 3b- Institutionalised European Partnership based on Article 187 TFEU
	Accelerated development of bio-based innovations	0	+	+
	Reinforced scientific and innovation capacity for bio-based solutions including in the regions where currently this capacity is underdeveloped	0	+	++
	Increased R&I capacity for addressing the key sustainability challenges	0	0	0
	Bio-based innovations reaching first market application and bringing real economic and environmental benefits	0	+	++
	A structured process for collaboration between R&I actors, industry including SMEs and other bio-based innovation stakeholders focused on deployment of bio-based innovation	0	+	++
	Reduced investment risk and improved access to finance for bio-based industrial projects	0	+	++
less	Enhanced circularity and environmental sustainability of the European bio-based industries	0	0	+
Effectiveness	Better integration of primary biomass producers in bio-based value chains to contribute to rural development	0	+	+
erence	Internal coherence	0	+	++
Cohe	External coherence	0	+	++
<u>ح</u>	Overall cost	0	0	
Efficiency	Cost-efficiency	0	+	-

Score ++: High performance; Score +: Medium performance; Score 0: same performance as baseline; Score (-) = limited additional costs compared with the baseline; Score (-)(-) = substantial additional costs compared with the baseline.

The ranking shows that the baseline option performs less well against all dimensions and criteria compared to options 1 and 3b. Even though it reached a higher score against the overall cost criterion, this does balance against its lower performance against all other criteria. The ranking also shows that options 1 scores lower than 3b in various respects. Option 3b is higher overall and more advantageous regarding its expected impacts.

The assessment concludes with a preference for option 3b, the institutionalised partnership. However, considering the challenges faced in implementing the BBI JU, the lessons learned (see section 1.2) have to be taken into account while transiting to a CBE initiative, both on content and on implementation, for example as follows:

- The initiative needs to broaden the scope of its activities and strengthen synergies, while enlarging the range of actively involved stakeholders;
- The private partner of CBE should include representatives of all bio-based economy actors;
- The industrial partners should interact more with other actors in the value chains and help to develop a favourable ecosystem for the bio-based industry as a whole;
- In particular, primary producers such as farmers, foresters, fishermen and producers of biomass from aqueous environments need to be better represented by involving their representatives as partners. In addition, one could reflect about involving representatives of municipalities and waste collectors as partners or in specific fora;
- A more balanced decision-making process would be needed, where diverse stakeholder voices, also from outside the industry, are heard and considered in shaping the research agenda. Better synergies with national and regional developments have to be built, by involving regional authorities in the partnership and its governance;
- The partnership's environmental and socio-economic impact has to be measured constantly and not only ex post;
- The KPIs have to be assessed more accurately beforehand to better reflect what can be achieved by the initiative, and the corporate IT tools need to accommodate for such reporting;
- Biodiversity protection could be mentioned as one of the objectives of the partnership, which could lead to involving more biodiversity specialists in the governance of the partnership, for example in the scientific committee;
- A system has to be put in place to ensure that a situation is avoided in the future in which the private members are unable to fulfil their obligation related to financial contributions. Given the revised Model Finance Regulation, there should be a clear understanding with partners from the very beginning that they have sustainable and reliable long-term sources that will allow them to contribute financially to the administrative costs of the new partnership;
- The complicated way of reporting the private partner's in-kind contributions to operational and additional costs has to be simplified.

Box 4 - Comparison between the preferred option & the current partnership existing in the area taking into account lessons from past evaluations

What continues What is different Art 187 Union Body, with EC as Founding Member Broaden the scope of present activities Strong link with Bio-based Industries and strengthen synergies Structuring of the fragmented European bio-based industry Improved governance system ensuring better representation of stakeholders Building on the momentum established by the high and protection of the public interest participation of the SME sector Increased focus on sustainability and Close collaboration between the scientific community and circularity of bio-based solutions, including utilisation of waste, side-Most of the projects expect to contribute to job creation, as streams and residues as feedstock for around half of them are located in rural and coastal areas bio-based industry Better synergies with other Horizon Europe and national Better involvement of the agricultural primary sector Systemic approach to collaborative research Better involvement of European Overall partner composition involving many segments of regional authorities the bio-based industry and SMEs Definition of new KPIs. Long term financial commitments from the industrial partner.

Regarding the improved governance mentioned above, the Commission will exercise its power as the member of the Governing Board of the partnership and ensure that the new partnership will respond to the recommendations from the evaluation of its predecessor as well as to concerns raised over the balance of public and private interest in partnership operation. The governance will in particular improve in the following aspects:

- Openness, transparency and representativeness: the partnership has to represent (through the private partner) the whole bio-based industry and relevant bioeconomy actors (e.g. farmers and other primary biomass producers).
- Integration and protection of public interest: The public interest will be clearly formulated and anchored in the Strategic Research and Innovation Agenda (SRIA) and operational documents (Annual Work Programmes). This includes that sustainability criteria and benchmarks are met by all projects supported by the partnership.
- Effectiveness in achieving the objectives: All bodies of the partnership will collaborate in programming, implementation and monitoring of activities to maximise the impact. New formations of stakeholders important for deployment of bio-based innovation (e.g. regional authorities and investors) deployment groups will be formed to assist the partnership in acceleration of market application of bio-based innovation.

7 THE PREFERRED OPTION - HOW WILL ACTUAL IMPACTS BE MONITORED AND EVALUATED?

7.1 The preferred option

In Table 8, below, the alignment of the preferred option of Institutionalised European Partnership under Article 187 TFEU with the selection criteria for European Partnerships defined in Annex III of the Horizon Europe Regulation is depicted. Seeing that the design process of the candidate Institutionalised Partnerships is not yet concluded and several of the related topics are still under discussion, the criteria of additionality/directionality and long-term commitment are covered in terms of *expectations* rather than ex-ante demonstration.

Table 8: Alignment with the selection criteria for European Partnerships

Criterion	Alignment of the preferred option
Higher level of effectiveness	The Institutionalised Partnership is more effective than the Horizon Europe calls in achieving the related objectives of the programme through involvement and commitment of industry partners, as well as engaging other actors (Member States, regions, academia and civil society organisations) through a governance model that needs to be more participative than the one that is currently operated in the BBI JU.
Coherence and synergies	Coherence and synergies of the Institutionalised Partnership within the EU research and innovation landscape will be ensured through the formal agreements between the proposed initiative and other initiatives, as well as through the co-creative process of the agenda setting and dedicated efforts in the course of implementation by the support team.
Transparency and openness	The preferred option offers an adequate level of transparency and openness in the selection of priorities and objectives and the involvement of partners and stakeholders from across the entire value chain, from different sectors, backgrounds and disciplines, including international actors (when relevant and not interfering with European competitiveness). Formalised procedures will offer clear modalities for promoting SME participation, as well as for disseminating and exploiting results.
Additionality and directionality	The preferred option offers high additionality, namely high potential for structuring the bio-based industries and ensures directionality by formalising commitments of partners toward achieving specific targets, eventually feeding high-level policy objectives.
Long-term commitment	In the case of Institutionalised European Partnerships, established in accordance with Article 187 TFEU, the financial and/or in-kind contributions from partners other than the Union will at least be

Criterion	Alignment of the preferred option
	equal to 50 % and may reach up to 75 % of the aggregated European Partnership budgetary commitments. It is expected that most of the commitment will be realised via in-kind and, to a lesser extent, financial contributions within projects, rather than at the programme level.

7.2 Objectives and corresponding monitoring indicators

7.2.1 Operational objectives

To deliver on the general and specific mid- and long-term objectives, the proposed CBE partnership aims to achieve several operational objectives in the short term. These also include activities going beyond R&I and that can be implemented under Horizon Europe. This reflects the definition of European Partnerships in the Horizon Europe regulation as initiatives where the Union and its partners "commit to jointly support the development and implementation of a programme of research and innovation activities, including those related to market, regulatory or policy uptake."

For each of the specific objectives, the following operational objectives could be identified:

(a) to reap the benefits of the advancement in life sciences and in other scientific disciplines for the development and demonstration of sustainable bio-based solutions

- Support interdisciplinary research projects advancing the development, experimentation, demonstration and deployment of bio-based industrial solutions;
- Mobilise corporate and national R&I actors to fund research and innovation action in bio-based innovation;
- Coordinate and align EU, national and corporate R&I strategies to give R&I in bio-based solutions appropriate priority.

(b) to increase and integrate the R&I capacity of stakeholders across the Union to develop more sustainable bio-based innovations

- Support the regional R&I actors in the development of their R&I programs, smart specialisation strategies, rural development programmes and other relevant strategic plans to prioritise the bio-based sector;
- Engage regional R&I actors to participate in EU funded collaborative projects to facilitate transfer of skills and competences;
- Support research action to better understand the environmental performance and risks of the bio-based industry and bio-based industrial systems;
- Support R&I actions that integrate sustainability aspects in the innovation development along the whole innovation chain;
- Develop technology solutions to the problems that currently prevent low quality heterogeneous biological waste from use as a feedstock for bio-based industry.

(c) to reinforce the integration of bio-based R&I processes in EU industrial value chains

- Establish a mechanism that will facilitate collaboration between R&I and industrial actors:
- Support national and regional authorities to develop their bioeconomy strategies and policies to create favourable environment for deployment of bio-based innovation;
- Support demonstration and flagship projects involving industrial actors.

(d) To reduce the risk for R&I investment in bio-based companies and projects

- Support R&I actions to improve techno-economic performance of bio-based systems;
- Support R&I actions that address the scientific and technological issues related to biomass feedstock and that are source of concerns for stability of supply;
- Recommend measures to national and regional policy makers that can reduce the risk to investment and improve access to finance for bio-based projects;
- Facilitate collaboration between R&I and industrial actors to create new value chains to develop markets and demand for bio-based products;
- Step up co-financing, together with industry and/or with private investors, of the first market application projects (flagships).

(e) to ensure environmental considerations are taken into account in the development and implementation of R&I bio-based projects

- Develop sustainability criteria for all relevant levels of decision-making in the bio-based sector through a collaborative R&I action;
- Apply the sustainable criteria to all EU funded R&I projects in the bio-based industry;
- Negotiate with the bio-based industry a voluntary commitment that the EU sustainability criteria will be accepted as the industry standard and observed by industry in their activities outside of publicly funded R&I projects;
- Promote the sustainability criteria among national and regional authorities so that they are applied in their policy actions including bioeconomy strategies and financial incentives through the CAP and regional development funds.

7.2.2 Monitoring indicators

The table below suggests a number of possible key monitoring indicators for tracking the progress of the initiative towards its specific objectives in addition to the ones identified for the Horizon Europe key impact pathways.

Table 9: Monitoring indicators in addition to the Horizon Europe key impact pathway indicators

	Short-term (typically as of year 1+)	Medium-term (typically as of year 3+)	Long-term (typically as of year 5+)
Scientific impact	N of scientific publications from CBE projects N of participants from the regions with limited bio-based R&I capacity N of projects addressing the sustainability knowledge gap	N of patents from CBE projects N of CBE projects with new technologies demonstrated	N of technologies and products patented or demonstrated in CBE that reached the market and have been commercialised Scientific performance of the EU increases in international statistics on bio-based and circular economy
Technological / economic impact	N of new circular bio-based building blocks identified N of new circular bio-based value-chains created N of new biorefineries set up N of new circular bio-based products created	N of jobs created as a result of the new value chains, technologies and (commercialised) products Value added created as a result of the new value chains, technologies and	Economic performance indicators (turnover, export, etc.) of the EU increases in international statistics on biobased and circular economy or products Performance of the EU on

	Short-term	Medium-term	Long-term
	(typically as of year 1+)	(typically as of year 3+)	(typically as of year 5+)
	N of new feedstock suppliers engaged in projects or new value chains N of new cross-sectoral collaborations	(commercialised) products N / % of regions with new building blocks, value chains, biorefineries and products	sustainable biomass production and sustainable use of bio- waste improved. Investments in the EU of in the circular bio-based industry increased
Societal impact	N of feedstock suppliers reached by information campaigns on opportunities of the bio-based and circular economy N of new feedstock suppliers in CBE projects N of SMEs engaging in CBE projects N of activities on streamlining regulations, standards and certifications	N of new feedstock suppliers engaged in new value chains N of regulations, standards and certifications schemes improved by CBE results, tested and/or launched	Global performance of the EU in creation of high-quality jobs in the circular bio-based economy increased Increased income of primary producers active in the circular bio-based sector
Environ- mental impact	New ways of bio-waste valorisation (or diversion from discard) introduced New ways to avoid CO ₂ emissions avoidance or new carbon sink functions More efficient biomass use processes introduced Sustainable primary production practices introduced as parts of new value chains	Tons of biomass waste valorised of diverted from discard Tons of CO ₂ emissions avoided or sunk Change (%) in efficiency of biomass use per ton of biobased product Square km of land on which sustainable agricultural or forestry practice is envisaged to be introduced as part of new value chains	Diffusion of sustainable practices on biomass and waste valorisation beyond CBE projects National and regional climate neutrality improved Circular economy targets approached Biodiversity enhancement observed as a result of sustainable biomass supply to bio-based value chains Ecosystem services improved or emerged as a result of sustainable biomass supply to bio-based value chains

7.2.3 Evaluation framework

The evaluation of the Partnership will be done in full accordance with the provisions laid out in Horizon Europe Regulation Article 47 and Annex III, with external interim and ex-post evaluations feeding into the overall Horizon Europe evaluations. As set in the criteria for European Partnerships, the evaluations will include an assessment of the most effective policy intervention mode for any future action; and the positioning of any possible renewal of the Partnership in the overall European Partnerships landscape and its policy priorities. In the absence of renewal, appropriate measures will be developed to ensure phasing-out of Framework Programme funding according to conditions and timeline agreed with the legally committed partners ex-ante.



Brussels, 23.2.2021 SWD(2021) 37 final

PART 17/19

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT REPORT Accompanying the document

Proposal for a COUNCIL REGULATION establishing Joint Undertakings under Horizon Europe

European Partnership for a Circular Bio-based Europe

{COM(2021) 87 final} - {SEC(2021) 100 final} - {SWD(2021) 38 final}

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Annex 1 Procedural information

1. LEAD DG, DECIDE PLANNING REFERENCES

Lead DG: Directorate General Research and Innovation (RTD)

Decide number: PLAN/2019/5305

2. ORGANISATION AND TIMING

Institutionalised partnerships are foreseen in Articles 185 and 187 of the Treaty on the Functioning of the European Union (TFEU). The preliminary agreement on Horizon Europe contained a list of possible areas for institutionalised partnerships based on Article 185 and 187. For each of these areas the Commission considered 12 potential institutionalised partnerships. Their set up involves new EU legislation and the establishment of dedicated implementing structures and therefore an impact assessment for each of these initiatives.

Following political validation in June 2019, the impact assessment process started with the publication of inception impact assessments for each initiative in August 2019.

An inter-service steering group (ISSG) on research and innovation partnerships under Horizon Europe was set up in May 2019 and held 4 meetings before submission of the Staff Working Document to the Regulatory Scrutiny Board (7 May 2019, 19 June 2019, 5 December 2019, 20 January 2020). The ISSG consisted of representatives of the Secretariat-General, Directorate-General for Budget, Directorate-General for Research and Innovation Directorate-General for Communications Networks, Content and Technology, Directorate-General for Mobility and Transport, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, Directorate-General for Energy, Directorate-General for Environment, Directorate-General for Climate Action, and the Legal Service.

An online public stakeholder consultation was launched between September and November 2019, gathering 1635 replies for all 12 initiatives.

3. CONSULTATION OF THE RSB

Two upstream meetings with the Regulatory Scrutiny Board of were held on 10 July 2019 and 30 September 2019.

In accordance with the feedback received from the Regulatory Scrutiny Board on 12.06.2020 the Staff Working Document has been revised as presented in Figure 1. These revisions were endorsed by the Inter Service Steering Group on 27.07.2020.

4. EVIDENCE, SOURCES AND QUALITY

To ensure a high level of coherence and comparability of analysis for all candidate initiatives, an external study was procured to feed into the impact assessments of the 12 candidate

institutionalised partnerships ¹ (Technopolis Group, 2020). It consisted of an horizontal analysis and individual thematic analyses for each of the initiatives under review.

For all initiatives, the evidence used includes desk research partly covering the main impacts and lessons learned from previous partnerships. A range of quantitative and qualitative data sources complement the evidence base, including evaluations; foresight studies; statistical analyses of Framework Programmes application and participation data and Community Innovation Survey data; analyses of science, technology and innovation indicators; reviews of academic literature; sectoral competitiveness studies and expert hearings. The analyses included a portfolio analysis, a stakeholder and social network analysis in order to profile the actors involved as well as their co-operation patterns, and an assessment of the partnerships' outputs (bibliometrics and patent analysis). A cost modelling exercise was performed in order to feed into the efficiency assessments of the partnership options. Public consultations (open and targeted) supported the comparative assessment of the policy options. For each initiative up to 50 relevant stakeholders were interviewed by the external contractor (policymakers, business including SMEs and business associations, research institutes and universities, and civil organisations, among others). In addition the analysis was informed by the results of the Open Public Consultation (Sep – Nov 2019), the consultation of the Member States through the Strategic Programme Committee and the online feedback received on the Inception Impact Assessments of the set of candidate Institutionalised European Partnerships.

A more detailed description of the methodology and evidence base used, completed by thematic specific methodologies, is provided in Annexes 4 and 6.

Figure 1 Modifications to the draft Staff Working Document based on comments received from the Regulatory Scrutiny Board

Responses to the positive opinion with reservations of the Regulatory Scrutiny Board

(B) Summary of findings

Despite improvements, the intervention logic is still not specific to the circular biobased economy and does not focus on the choice of the type of partnership.

Section 5.2 Description of the policy options has been further improved to clarify the best form of partnership for this initiative, and links with the intervention logic are clarified.

Conclusions from evaluating the predecessor partnership are more present in the report, but they do not directly feed into the problem definition, the intervention logic, and the choice of options.

Box 3 'Support for the field in the previous Framework Programmes – key strengths & weaknesses identified' under section 1.2 on EU relative positioning in the field explains how the continuous evaluation of the predecessor partnership BBI JU was carried out since its set-up in 2014. As a result, the new CBE initiative builds on the success of its predecessor while having evolved by learning from its shortfalls. These learnings

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¹ Technopolis Group, 2020, forthcoming.

are now better reflected in the problem definition, the intervention logic and choice of options.

The report does not always present the different and sometimes critical stakeholders' opinions.

The stakeholders' opinions are highlighted throughout the report. The diverging views of the Member States are now also presented under section 5.1 What is the baseline from which options are assessed.

(C) What to improve

The central point of the assessment, i.e. the choice of the best form of a research partnership for the circular bio-based economy, is still largely absent from the intervention logic. This makes assessing different types of partnerships difficult, as the link between options, problems and objectives is not properly established.

The main shortfall in the intervention logic was the missing link between the objectives and options (i.e. forms of partnership). The description of options included in the first version of the Impact Assessment followed closely the descriptive characteristics of options set for all R&I partnerships in the common part of the IA. The relevance of these characteristics for achieving the CBE objectives was therefore, not obvious.

To address this point, an additional description specifically related to objectives and functionalities was added to the tables in section 5.2. Thus the link between objectives and options was reinforced. This description is also a basis for scoring options later in the text.

The problem description should better integrate the results of the evaluation of the current partnership. These include a number of organisational issues that are directly relevant for the choice of the best form of research partnership.

In the intervention logic the organisational issues identified in the evaluation of the current partnership are related to the functionalities necessary for achievement of objectives. New elements of description were added to the tables in section 5.2 on how different types of partnership are able to deal with these organisational issues.

The report should better explain the functioning and expected performance of the governance systems foreseen under

There are elements of governance that are intrinsically linked to policy options (forms of partnership) and other elements of

each option. For instance, it should explain how these systems would help secure sufficient private sector financial contributions. better It should also describe what the different partners would contribute to the partnership, other than finance. It should also describe how the governance systems would address the potential risk of industry capture.

governance that are choices within each policy option. The former are now described in section 5.2. The latter are described for the preferred policy option in section 6.4. The risk of industry capture will be mitigated by explicit formulation of public interest objectives and their integration into strategic/programming documents and operational rules.

The Commission is committed to use its power as a member of the Governing Board to ensure (a) transparency and representativeness of the partnership; (b) definition of public interests partnership and their integration into the SIRA and programming documents (Annual Work Programmes); and (c) improvement of effectiveness, among others by involving innovation stakeholders through 'deployment stakeholders groups'.

The report should further clarify the scoring system and in particular the relative importance of the different criteria. It should better justify and explain the assessment of options against the different criteria.

The scoring is better justified by new elements of description of policy options that are related to functionalities and the ability to achieve objectives.

The report should more comprehensively present different stakeholder views. In particular, it should include more critical voices throughout the report. The Board notes that the estimated costs and benefits of the preferred option in this initiative, as summarised in the attached quantification tables.

The current version of the Impact Assessment report deals with two main criticisms by nonindustrial stakeholders (see, for example, the critical report by the Corporate Europe Observatory). The criticism related potential environmental impacts (land use change, impact on biodiversity and carbon emissions, etc.) is now addressed by the new general objective to ensure a high level of environmental performance of bio-based industry with related specific and operational objectives. The concern that the partnership may serve the interest of the private partner and less the public interests is addressed through the requirement on the governance of the future partnership (section 6.4).

Stakeholders' opinions are highlighted throughout the report. The diverging views of

the Member States are now also presented under section 5.1 on What is the baseline from which options are assessed.

(D) Conclusion DG RTD must revise the report in accordance with the Board's findings before launching the interservice consultation. If there are any changes in the choice or design of the preferred option in the final version of the report, the DG may need to further adjust the attached quantification tables to reflect this.

There report was revised to take account of the Boards comments. There were no changes made with regard to the choice or the design of the preferred option.

Annex 2 Stakeholder Consultation

1. OVERVIEW FOR ALL CANDIDATE INSTITUTIONALISED EUROPEAN PARTNERSHIPS

1.1. Introduction

In line with the Better Regulation Guidelines,² the stakeholders were widely consulted as part of the impact assessment process of the 12 candidates for institutionalised partnerships, including national authorities, the EU research community, industry, EU institutions and bodies, and others. These inputs were collected through different channels:

- A feedback phase on the inception impact assessments of the candidate initiatives in August 2019, gathering 350 replies for all 12 initiatives on the "Have your say" web portal during a period of 3 weeks;
- A structured consultation of Member States performed by the EC services over 2019 through the Shadow Strategic Configuration of the Programme Committee of Horizon Europe (in line with the Article 4a of the Specific Programme of Horizon Europe). This resulted in 44 possible candidates for European Partnerships identified as part of the first draft Orientations Document towards the Strategic Plan for Horizon Europe (2021-2024), taking into account the areas for possible institutionalised partnerships defined in the Regulation.
- An online public stakeholder consultation administered by the EC, based on a structured questionnaire, open between September and November 2019, gathering 1635 replies for all 12 initiatives;
- A targeted consultation run by the external study contractors with a total of 608 interviews performed as part of the thematic studies by the different study teams between August 2019 and January 2020.

1.2. Horizontal results of the Open Public Consultation

The consultation was open to everyone via the EU Survey online system.³ The survey contained two main parts to collect views on general issues related to European partnerships (in Part 1) and specific responses related to one or more of the 12 candidate initiatives (as selected by a participant). The survey was open from 11 September till 12 November 2019. The consultation was available in English, German and French and advertised widely through the European Commission's online channels as well as via various stakeholder organisations.

1.2.1. Profile of respondents

In total, 1635 respondents filled in the questionnaire of the open public consultation. Among them, 272 respondents (16.64%) were identified to have responded to the consultation as part of a campaign (coordinated responses). Based on the Better Regulation Guidelines, the groups of respondents where at least 10 respondents provided coordinated answers were labelled as 'campaigns', segregated and analysed separately and from other responses. In total 11

³ https://ec.europa.eu/eusurvey/runner/ConsultationPartnershipsHorizonEurope

² https://ec.europa.eu/info/files/better-regulation-guidelines-stakeholder-consultation_en

campaigns were identified, the largest of them includes 57 respondents⁴. In addition, 162 respondents in the consultation also display similarities in responses but in groups smaller than 10 respondents. Hence, these respondents were not labelled as campaigns and therefore were not excluded from the general analysis.

Table 1: Country of origin of respondents (N=1635)

Country	Number of respondents	Percentage of respondents
Germany	254	15.54%
Italy	221	13.52%
France	175	10.70%
Spain	173	10.58%
Belgium	140	8.56%
The Netherlands	86	5.26%
Austria; United Kingdom	61	3.73%
Finland	49	3.00%
Sweden	48	2.94%
Poland	45	2.75%
Portugal	32	1.96%
Switzerland	28	1.71%
Czechia	24	1.47%
Greece	23	1.41%
Norway; Romania	22	1.35%
Denmark	20	1.22%
Turkey	19	1.16%
Hungary	14	0.86%
Ireland	12	0.73%
United States	11	0.67%
Estonia; Slovakia; Slovenia	10	0.61%
Bulgaria; Latvia	9	0.55%
Bosnia and Herzegovina	7	0.43%
Lithuania	4	0.24%
Canada; Croatia; Israel	3	0.18%
China; Ghana; Iceland; Japan; Luxembourg; Morocco	2	0.12%
Bhutan; Botswana; Cyprus; Iran; Malta; Mexico; Moldova; Mongolia; Palestine; Russia; Serbia; South Africa; Tunisia; Ukraine; Uruguay	1	0.06%

As shown in Figure 2, the three biggest **categories of respondents** are representatives of companies and business organisations (522 respondents or 31.9%), academic and research institutions (486 respondents or 29.7%) and EU citizens (283 respondents or 17.3%). Among the group of respondents that are part of campaigns, most respondents are provided by the same groups of stakeholders, namely company and business organisations (121 respondents or 44.5%), academic and research institutions (54 respondents or 19.8%) and EU citizens (42 respondents or 15.4%).

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⁴⁴ The candidate Institutionalised Partnership Clean Hydrogen has the highest number of campaigns, namely 5. A few initiatives, such as Innovative SMEs, Smart Networks and Systems, were not targeted by campaigns. Some campaign respondents decided to provide opinions about several partnerships.

283 10% 20% 50% 60% 70% 80% 100% Company/business organisation Academic/research institution ■ EU citizen ■ Public authority Other Business association ■ Non-governmental organisation (NGO) ■ Non-EU citizen ■ Consumer organisation

■ Trade union

Figure 2 Type of respondents (N=1635) - For all candidate initiatives

Environmental organisation

Among all consultation respondents, 1303 (79.69%) have been **involved in the on-going research and innovation framework programme** Horizon 2020 or the preceding Framework Programme 7, while 332 respondents (20.31%) were not. In the group of campaign respondents, the share of those who were involved in these programmes is higher (245 respondents out of 272 or 90.07%) than in the group of non-campaign respondents (1058 out of 1363 or 77.62%). When respondents that participated in the Horizon 2020 or in the preceding Framework Programme 7 were asked to indicate in which capacity they were involved in these programmes, the majority stated they were a beneficiary (1033 respondents) or applicant (852 respondents). The main stakeholder categories, e.g. companies/business organisation, academic/research institutions, etc., show a similar distribution across the capacities in which they 'have been involved in Horizon 2020 or in the Framework Programme 7' as the overall population of consultation respondents.

Among those who have been involved in Horizon 2020 or the preceding Framework Programme 7, 1035 respondents (79.43%) are/were involved in a partnership. The share of respondents from campaigns that are/were involved in a partnership is higher than for noncampaign respondents, 89.80% versus 77.03% respectively. The list of partnerships under Horizon 2020 or its predecessor Framework Programme 7 together with the numbers, percentages of participants is presented in Table 4Error! Reference source not found., the table also show the key stakeholder categories for each partnership. Most consultation respondents participated in the following partnerships: Fuel Cells and Hydrogen 2 (FCH2) Joint Undertaking, Clean Sky 2 Joint Undertaking, European Metrology Programme for Innovation and Research (EMPIR) and in Bio-Based Industries Joint Undertaking. The comparison between the non-campaign and campaign groups of respondents shows that the overall distribution is quite similar. However, there are some differences. For the campaign group almost a half of respondents is/was involved in the Fuel Cells and Hydrogen 2 (FCH2) Joint Undertaking, a higher share of campaign respondents is/was participating in Clean Sky 2 Joint Undertaking and in Single European Sky Air Traffic Management Research (SESAR) Joint Undertaking.

When respondents were asked in which **role**(s) **they participate**(d) in a **partnership**(s), over 40% indicated that they act(ed) as partner/member/beneficiary in a partnership. The second largest group of respondents stated that they applied for funding under a partnership. The roles selected by non-campaign and campaign respondents are similar.

Table 4: Partnerships in which consultation respondents participated (N=1035)

Name of the partnership	Number and % of respondents from both groups (n=1035)	Number and % of respondents from a non-campaign group (n=815)	Academic/researc h institutions	Business associations	Company/busines s organisations	Company/busines s organisations	EU citizens	NGOs	Public authority
Fuel Cells and Hydrogen 2 (FCH2) Joint Undertaking	354 (33.33%)	247 (30.31%)	97	9	37	43	41	8	5
Clean Sky 2 Joint Undertaking	195 (18.84%)	145 (17.79%)	57	2	10	27	37	1	7
European Metrology Programme for Innovation and Research (EMPIR)	150 (14.49%)	124 (15.21%)	64	0	13	9	14	2	19
Bio-Based Industries Joint Undertaking	142 (13.72%)	122 (14.97%)	39	8	20	27	14	1	6
Shift2Rail Joint Undertaking	124 (11.98%)	101 (12.40%)	31	7	5	31	14	3	7
Electronic Components and Systems for European Leadership (ECSEL) Joint Undertaking	111 (10.72%)	88 (10.80%)	42	2	7	20	12	0	5
Single European Sky Air Traffic Management Research (SESAR) Joint Undertaking	66 (6.38%)	46 (5.64%)	10	3	3	20	3	2	3
5G (5G PPP)	53 (5.12%)	47 (5.77%)	20	1	6	14	5	0	1
Eurostrars-2 (supporting research-performing small and medium-sized enterprises)	44 (4.25%)	40 (4.91%)	17	0	6	1	7	0	6
Innovative Medicines Initiative 2 (IMI2) Joint Undertaking	37 (3.57%)	35 (4.29%)	18	2	3	3	2	4	3
Partnership for Research and Innovation in the Mediterranean Area (PRIMA)	28 (2.71%)	26 (3.19%)	15	0	3	1	2	0	2
European and Developing Countries Clinical Trials Partnership	25 (2.42%)	24 (2.94%)	12	0	1	2	3	3	2
Ambient Assisted Living (AAL 2)	22 (2.13%)	21 (2.58%)	11	2	1	1	3	0	3
European High- Performance Computing Joint Undertaking (EuroHPC)	22 (2.13%)	18 (2.21%)	6	0	2	3	5	0	2

For the remaining of the consultation respondents could provide their views on each/several of the candidate initiatives. The majority of respondents (31.4%) provided their views on the Clean Hydrogen candidate partnership. More than 45% of respondents from the campaigns selected this partnership. Around 15% provided their views for European Metrology, Clean Aviation and Circular Bio-based Europe. The share of respondents in the campaign group that chose to provide views on the Clean Aviation candidate partnership is of 20%. The smallest number of respondents provided opinions on the candidate initiative 'EU-Africa research partnership on health security to tackle infectious diseases – Global Health'.

Table 5: Candidate Institutionalised Partnerships for which consultation respondents provide responses (N=1613)

Name of the candidate Institutionalised European partnership	Number and % of respondents from both groups (n=1613)	Number and % of respondents from a non-campaign group (n=1341)		
Clean Hydrogen	506 (31.37%)	382 (28.49%)		
European Metrology	265 (16.43%)	225 (16.78%)		
Clean Aviation	246 (15.25%)	191 (14.24%)		
Circular bio-based Europe	242 (15%)	215 (16.03%)		
Transforming Europe's rail system	184 (11.41%)	151 (11.26%)		
Key Digital Technologies	182 (11.28%)	162 (12.08%)		
Innovative SMEs	111 (6.88%)	110 (8.20%)		
Innovative Health Initiative	110 (6.82%)	108 (8.05%)		
Smart Networks and Services	109 (6.76%)	107 (7.98%)		
Safe and Automated Road Transport	108 (6.70%)	102 (7.61%)		
Integrated Air Traffic Management	93 (5.77%)	66 (4.92%)		
EU-Africa research partnership on health security to tackle infectious diseases – Global Health	49 (3.04%)	47 (3.50%)		

1.2.2. Characteristics of future candidate European Partnerships

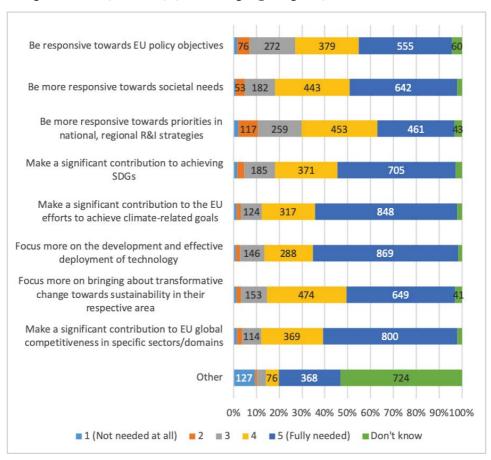
Respondents were asked to assess what areas, objectives, aspects need to be in the **focus of the future European Partnerships** under Horizon Europe and to what extent. According to Figure 6, a great number of respondents consider that a significant contribution by the future European Partnerships is 'fully needed' to achieve climate-related goals, to the development and effective deployment of technology and to EU global competitiveness in specific sectors/domains. Overall, respondents' views reflect that many aspects require attention of the Partnerships. The least attention should be paid to responding towards priorities of national, regional R&D strategies, including smart specialisation strategies, according to respondents.

Overall, only minor differences can be found between the main stakeholder categories. Academic/research institutions value the responsiveness towards EU policy objectives and focus on development and effective deployment of technology a little less than other respondents. Business associations, however, find that the future European Partnerships under Horizon Europe should focus a little bit more on the development and effective deployment of

technology than other respondents. Furthermore, business associations, large companies as well as SMEs value the role of the future European Partnerships for significant contributions to EU global competitiveness in specific sectors domains a little higher than other respondents. Finally, both NGOs and Public authorities put a little more emphasis on the role of the future European Partnerships for significant contributions to achieving the UN SDGs. The views of citizens (249, or 18.3%) do not reflect significant differences with other types of respondents. However, respondents that are/were directly involved in a partnership under Horizon 2020 or its predecessor Framework Programme 7 assign a higher importance of the future European Partnerships to be more responsive towards EU policy objectives and to make a significant contribution to achieving the UN's Sustainable Development Goals.

A qualitative analysis of the "other" answers highlights the importance of collaboration and integration of relevant stakeholders to tackle main societal challenges and to contribute to policy goals against which fragmentation of funding and research efforts across Europe should be avoided. Additionally, several respondents suggested that faster development and testing of technologies, acceleration of industrial innovation projects, science transfer and market uptake are needed. Next to that, many respondents provided answers related to the hydrogen and the energy transition, which corresponds to the high number of respondents that provided answers to the candidate initiative on this topic.

Figure 6: To what extent do you think that the future European Partnerships under Horizon Europe need to (N=1363) (non-campaign replies) For all candidate initiatives



1.2.3. Main advantages and disadvantages of Institutionalised European Partnerships

An open question asked to outline the main advantages and disadvantages of participation in an Institutionalised European Partnership (as a partner) under Horizon Europe (1551 respondents). The advantages mentioned focus on the development of technology, overall collaboration between industry and research institutions, and the long-term commitment. Disadvantages mentioned are mainly administrative burdens. An overview is provided below.

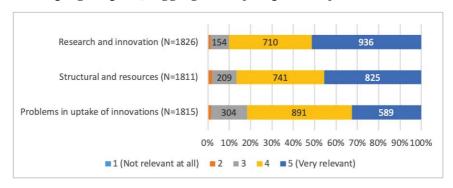
Advantages mentioned: Long term commitment, stability, and visibility in financial, legal, and strategic terms; Participation of wide range of relevant stakeholders in an ecosystem (large/small business, academics, researchers, experts, etc.); Complementarity with other (policy) initiatives at all levels EU, national, regional; Efficient and effective coordination and management; High leverage of (public) funds; Some innovative field require high levels of international coordination/standardisation (at EU/global level); Ability to scale up technology (in terms of TRL) through collaboration; Networking between members; Direct communication with EU and national authorities

Disadvantages mentioned: Slow processes; System complexity; Continuous openness to new players should be better supported as new participants often bring in new ideas/technologies that are important for innovation; Lower funding percentage compared to regular Horizon Europe projects; Cash contributions; Administrative burdens; Potential for IPR constraints.

1.2.4. Relevance of EU level to address problems in Partnerships' areas

Respondents were asked to rate the relevance of research and innovation efforts at EU level efforts to address specific problems in the area of partnerships. Research and innovation related problems were rated as most relevant across all candidate initiatives, followed by structural and resources problems and problems in the uptake of innovations. Overall, all three areas were deemed (very) relevant across the partnerships, as more than 80% of respondents found these challenges (very) relevant. Only minor differences were found between stakeholder categories. Research and innovation problems were found slightly more relevant by academic/research institutions, yet slight less relevant by large companies and SMEs. Structural and resource problems were indicated as slightly more relevant by NGOs, but slightly less by academic/research institutions. While both NGOs and public authorities find slightly more relevant to address problems in uptake of innovation than other respondents. The views of citizens are not differing significantly. Respondents that are/were directly involved in a current/preceding partnership find, however, the need to address problems related to the uptake of innovations slightly more relevant than other respondents.

Figure 9: To what extent do you think this is relevant for research and innovation efforts at EU level to address the following problems in relation to the candidate partnership in question? (non-campaign replies) Aggregation of responses of all candidate initiatives



1.2.5. Horizon Europe mode of intervention to address problems

Respondents were asked to indicate how these challenges could be addressed through Horizon Europe intervention. Just over 50% of all respondents indicated that institutionalised partnerships were the best fitting intervention, with relatively strong differences between stakeholder categories. The use of Institutionalised Partnership was indicated more by business associations and large companies, but less by academic/research institutions and SMEs. While academic/research institutions valued traditional calls more often, this was not the case for business associations, large companies and public authorities. Public authorities indicated a co-programmed intervention more often than other respondents. Citizens indicated slightly less often that institutionalised partnerships were the best fitting intervention. Respondents that are/were directly involved in a current/preceding partnership, selected the institutionalised partnership intervention in far higher numbers (nearly 70%).

Figure 10: In your view, how should the specific challenges described above be addressed through Horizon Europe intervention? (non-campaign replies) For all candidate initiatives



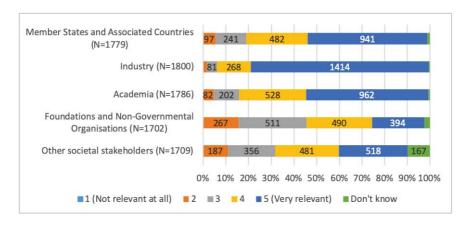
When asked to reflect on their answers, respondents that pointed to the need for using institutionalised partnership mentioned the long-term commitment of collaboration, a common and ambitious R&I strategy as well as the overall collaboration between industry and research institutions. Others shared positive experiences with other modes of interventions:

- Traditional calls, because of their flexibility and integration of a wide range of actors, as long as the evaluation panels do not deviate from the policy focus. This was mentioned by 94 participants, including companies (25), academics (26) and EU citizens (25).
- Co-funded partnership, as a mechanism to ensure that all participants take the effort seriously, while allowing business partnerships to develop. This approach was deemed suitable based on previous experiences with ERANETs. This was raised by 84 participants, 36 of them academic respondents, 18 companies and 16 EU citizens.
- Co-programmed partnerships, to tackle the need to promote and engage more intensively with the private sector. This was mentioned by 97 participants, most of them companies (34), followed by academics (22), business associations (15) and EU citizens (11).
 - 1.2.6. Relevance of a set of elements and activities to ensure that the proposed European Partnership would meet its objectives

Setting joint long-term agendas

Respondents were asked how relevant it is for the proposed European Partnerships to meet their objectives to have a strong involvement of specific stakeholder groups in setting joint long-term agenda. All respondents see stakeholders from industry as the most relevant, followed by academia and governments. The involvement of foundations and NGOs as well as other societal stakeholders were, however, still found to be (very) relevant by more than 50% of the respondents. Most respondents indicated the stakeholder group they belong to themselves or that represent them as relevant to involve.

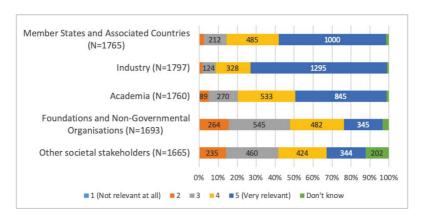
Figure 11: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives - Setting joint long-term agenda with strong involvement of: (non-campaign replies) For all candidate initiatives



<u>Pooling and leveraging resources through coordination, alignment and integration with stakeholders</u>

Respondents were asked how relevant it is for the proposed European Partnership to meet its objectives to pool and leverage resources (financial, infrastructure, in-kind expertise, etc.) through coordination, alignment and integration with specific groups of stakeholders. Respondents see stakeholders from industry as the most relevant, followed by academia and governments (Member States and Associated Countries). The involvement of foundations and NGOs as well as other societal stakeholders are also still found to be (very) relevant for more than 50% of the respondents. Similarly as described for the question on setting joint long-term agendas, most stakeholder categories valued their own involvement higher than other respondents – although also here differences between stakeholder categories were minor.

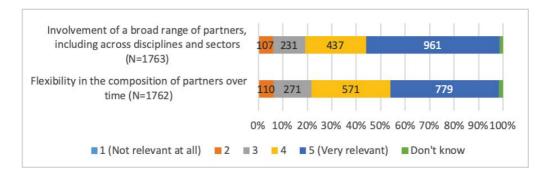
Figure 12: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives – Pooling and leveraging resources (financial, infrastructure, in-kind expertise, etc.) through coordination, alignment and integration with: (non-campaign replies) For all candidate initiatives



Composition of the partnerships

Regarding the composition of the partnership most respondents indicated that for the proposed European Partnership to meet its objectives the composition of partners needs to be flexible over time and that a broad range of partners, including across disciplines and sectors, should be involved (see Figure 13). When comparing stakeholder groups only minor differences were found. Academic/research institutions and public authorities found the involvement of a broad range of partners and flexibility in the composition of partners over time slightly more relevant than other respondents, while large companies found both less relevant. SMEs mainly found the flexibility in the composition of partners over time less relevant than other respondents, while no significant differences were found regarding the involvement of a broad range of partners. Citizens provided a similar response to non-citizens. Respondents that are/were directly involved in a current/preceding partnership, when compared to respondents not involved in a current/preceding partnership, indicated a slightly lower relevance of the involvement of a broad range of partners and flexibility in the composition of partners over time.

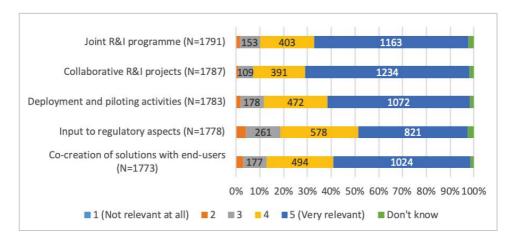
Figure 13: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives – Partnership composition (non-campaign replies) Aggregation of responses of all candidate initiatives



Implementation of activities

Most respondents indicated that implementing activities like a joint R&I programme, collaborative R&I projects, deployment and piloting activities, providing input to regulatory aspects and the co-creation of solutions with end-users are all (very) relevant for the partnerships to be able to meet its objectives. Minor differences were found between the main stakeholder categories, the differences found were in line with their profile. As such, academic/research institutions found joint R&I programme & collaborative R&I projects slightly more relevant and deployment and piloting activities, input to regulatory aspects and co-creation with end-users slightly less relevant than other respondents. For SMEs an opposite pattern is shown. Large companies, however, also found collaborative R&I projects slightly more relevant than other respondents, as well as input to regulatory aspects. The views of citizens are similar to non-citizens. Respondents that are/were directly involved in a current/preceding partnership, when compared to respondents not involved in a current/preceding partnership, show a slightly higher relevance across all activities.

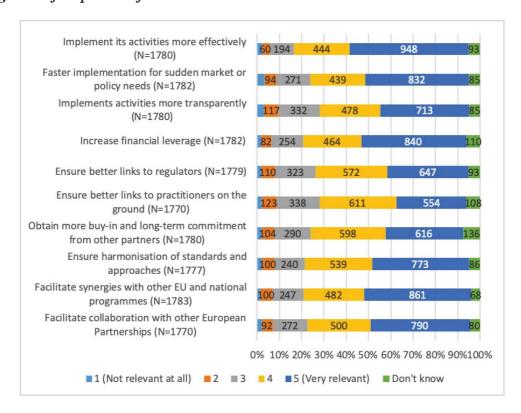
Figure 14: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives – Implementing the following activities (non-campaign replies) For all candidate initiatives



1.2.7. Relevance of setting up a legal structure (funding body) for the candidate European Partnerships to achieve improvements

Respondents were asked to reflect on the relevance of setting up a legal structure (funding body) for achieving a set of improvements, as shown in the Figure below. In general, 70%-80% of respondents find a legal structure (very) relevant for these activities. It was found most relevant for implementing activities in a more effective way and least relevant for ensuring a better link to practitioners on the ground, however differences are small.

Figure 15: In your view, how relevant is to set up a specific legal structure (funding body) for the candidate European Partnership to achieve the following? (non-campaign replies) Aggregation of responses of all candidate initiatives

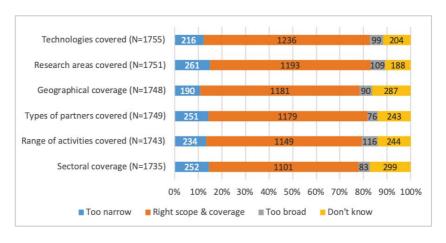


When comparing stakeholder categories there are only minor differences. Academic/research institutions indicated a slightly lower relevance for transparency, better links to regulators as well as obtaining the buy-in and long-term commitment of other partners. SMEs also indicated a lower relevance regarding obtaining the buy-in and long-term commitment of other partners. Large companies showed a slightly higher relevance for implementing activities effectively, ensure better links to regulators, obtaining the buy-in and long-term commitment of other partners, synergies with other EU/MS programmes and collaboration with other EU partnerships. NGOs find it slightly more relevant to implement activities faster for sudden market or policy needs. Public authorities, however, find it slightly less relevant to facilitate collaboration with other European Partnerships than other respondents. The views of citizens show a slightly lower relevance for a legal structure in relation to implementing activities in an effective way. Respondents that are/were directly involved in a current/preceding partnership indicated a higher relevance across all elements presented.

1.2.8. Scope and coverage of the candidate European Partnerships based on their inception impact assessments

Consulted on the scope and coverage for the partnerships, based on their inception impact assessments, the large majority feels like the scope and coverage initially proposed in the inception impact assessments is correct. However, about 11% to 15% of the respondents indicated the scope and coverage to be too narrow. About 11%-17% of respondents answered "Don't know". Overall, differences between the main stakeholder categories were found to be minor. Academic/research institutions indicated slightly more often that the research area was "too narrow" then other respondents. SMEs on the other hand indicated slightly more often that the research area and the geographical coverage were "too broad". NGOs and public authorities, however, found the geographical coverage slightly more often "too narrow". Large companies found the range of activities slightly more often "too broad" and the sectoral focus slightly more often "too narrow" when compared to other respondents. The views of citizens are the same as for other respondents. Respondents that are/were directly involved in a current/preceding partnership more often indicated that the candidate institutionalised European Partnership have the "right scope & coverage".

Figure 16: What is your view on the scope and coverage proposed for this candidate institutionalised European Partnership, based on its inception impact assessment? (non-campaign replies) Aggregation of responses of all candidate initiatives



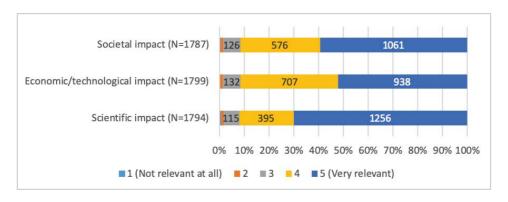
1.2.9. Scope for rationalisation and alignment of candidate European Partnerships with other initiatives

When asked whether it would be possible to rationalise a specific candidate European Institutionalised Partnership and its activities, and/or to better link with other comparable initiatives, nearly two thirds of respondents answered "Yes" (1000, or 62%), while over one third answered "No" (609, or 39%). Nearly no differences were found between stakeholder categories, only large companies and SMEs indicated slightly more often "Yes" in comparison to other respondents. The views of citizens are the same as for other respondents. Respondents that are/were directly involved in a current/preceding partnership, indicated "No" more often, the balance is about 50/50 between "Yes" and "No" for this group.

1.2.10. Relevance of European Partnerships to deliver targeted scientific, economic/technological and societal impacts

Finally, respondents were asked to rate the relevance of partnership specific impacts in three main areas: Societal; Economic/technological; and Scientific impacts. All three areas were deemed (very) relevant across the candidate partnerships. Scientific impact was indicated as the most relevant impact, more than 90% of respondents indicated that this as (very) relevant. Only minor difference between stakeholder groups were found. Academic/research institutions found scientific impacts slightly more relevant, while large companies found economic and technological impacts slightly more relevant than other respondents. NGOs found societal impact slightly more relevant, while SMEs found this slightly less important. Citizens did not a significantly different view when compared to other respondents. Respondents that are/were directly involved in a current/preceding partnership find all impacts slightly more relevant than other respondents.

Figure 17: In your view, how relevant is it for the candidate European Institutionalised Partnership to deliver on the following impacts? (non-campaign replies) Aggregation of responses of all candidate initiatives



1.3. Stakeholder consultation results for this specific initiative

1.3.1. Feedback to the inception impact assessment on candidate initiatives for Institutionalised Partnerships

Following the publication of the inception impact assessment, a feedback phase of 3 weeks allowed any citizen to provide feedback on the proposed initiatives on the "Have your say" web portal. In total 340 feedbacks were collected for all initiatives.

For the initiative "Circular Bio-Based Europe" 19 individual feedbacks were collected, mainly from businesses (2 responses), business associations (6 responses), academic institutions (5 responses, including 2 anonymous), public authorities (3 responses) and NGOs (3 responses).⁵ Among the elements mentioned were:

- Eight stakeholders (all businesses, two business associations, three academic institutions, one NGO and two public authorities) welcomed the integration of circular economy objective and highlighting the high relevance of the circular economy topic in the context of biobased industries
- Eight stakeholders (all businesses, some business associations, over half academic institutions, one public authority) commented on the model of the new initiative and welcomed the Institutional Partnership model. Comments included that this model represents the deepest level of integration and engagement; that it is the best way forward as it will contribute to longevity and sustainability, through integration, engagement. Some mentioned positive experience and the proven efficiency of the current Bio-based Industries Joint Undertaking structure. Some stakeholders commented on the commitment issue, and noted that only IP provides the legal means to ensure the private partner meets a defined minimum level of commitments.
- One public authority stakeholder while supporting the IP model, commented on importance of assuring an appropriate governance model that is aligned with the public interest, industry needs and the needs of other key stakeholders such as primary producers and end users. They suggest that the role of the MS in the governance is strengthened including via synergies with national programmes, more open process of programme topic generation, information sharing with the MS as in other parts of Horizon, transparency on the real (in-kind and in-cash) contributions actually provided by industry.
- One stakeholder from NGO sector criticized the models of public-private partnerships (ETPs, JTIs, JUs) with industry having an increasing say in determining strategic research agendas and promoting own needs at the expense of EC funds.
- Several stakeholders suggested to ensure that thematic coverage included additional topics as listed below:
 - Three stakeholders commented on importance of inclusion of bioenergy sector in the sectorial coverage of the new initiative, commenting that it can also contribute to the circular economy and its synergies with other bio-based sectors.
 - There stakeholders from business, business associations and regional government, stressed the relevance of *wastewater* in the circular bio-based economy as an important source of nutrients and chemicals
 - One association extensively argued about importance of promoting R&I on plantbased proteins under the new initiative.

⁵ Feedback on inception impact assessment to be found on https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2019-4972449/feedback_en?p_id=5722347

- One business association suggested to include a focus on *renewable gases* from agricultural waste in the topical scope of the initiatives.
- Two stakeholders (from academia and NGO), highlighted the importance to consider environmental impact of creating new demand for biomass (e.g. food security, impact on ecosystems, resource conflicts outside EU), and ensure maintenance or improvement of biodiversity.
 - 1.3.2. Structured consultation of the Member States on European partnerships

A structured consultation of Member States through the Shadow Strategic Configuration of the Programme Committee Horizon Europe in May/ June 2019 provided early input into the preparatory work for the candidate initiatives (in line with the Article 4a of the Specific Programme of Horizon Europe). This resulted in 44 possible candidates for European Partnerships identified as part of the first draft Orientations Document towards the Strategic Plan for Horizon Europe (2021-2024), taking into account the areas for possible institutionalised partnerships defined in the Regulation.

The feedback provided by 30 countries (all Member States, Iceland and Norway) has been analysed and summarised in a report, with critical issues being discussed at the Shadow Strategic Programme Committee meetings.

We can summarise the findings of the report in 6 main takeaways:

Overall positive feedback on the proposed portfolio, but thematic coverage could be improved

The results indicate a high level of satisfaction with the overall portfolio, the level of rationalisation achieved, and policy relevance. While delegations are in general satisfied with the thematic coverage, the feedback suggests the coverage could be improved in cluster 2 "Culture, creativity and inclusive society" and cluster 3 "Civil Security for Society".

Large number (25) of additional priorities proposed for partnerships by delegations

Despite high satisfaction with the portfolio and candidates put forward by the Commission, countries put forward a high number of additional priorities to be considered as European Partnerships. A closer examination suggests that these additional proposals are motivated by very different reasons. Whilst some proposals are indeed trying to address gaps in the portfolio and reach a critical mass, then, others are driven by the wish to maintain existing networks, currently not reflected in the Commission proposal (e.g. those based on JPIs, ERA-NETs). In addition, some proposals reflect worries over some topics not being sufficiently covered in the existing proposals, but could be possibly well covered within the scope of existing partnerships, or by traditional calls under the Framework Programme.

Critical view on the high number and openness of Joint Undertakings

Country feedback suggests dissatisfaction with the high number of proposed Article 187 TFEU partnerships. Notably smaller as well as EU-13 countries raise concerns with regards to the potential insufficient transparency and openness of the partnership model. In the feedback, countries either directly support or ask to carefully analyse whether the objectives of this proposal could be reached with the co-programmed model.

For those partnerships that will be set up on the basis of Article 187, the country feedback stresses the need to ensure a clear shift towards openness in the governance, membership policy and allocation of funding of these partnerships. Notably, it is emphasised that the JU rules should not have any limitations or entry barriers to the participation of SMEs and other partners, including from academia.

Although the feedback suggests a general criticism, there are few concrete and broadly supported proposals, including to reduce the number of institutionalised partnerships mergers or by alternative implementation modes.

Lack of cross-modal perspective and systematic approach to mobility

The current proposal foresees 5 partnerships in the area of transport (for rail, air traffic management, aviation, connected and automated driving, zero-emission road transport), and 2 that in closely related technologies for radically reducing carbon emissions (hydrogen, batteries). Several delegations would wish to see a systemic approach to developing mobility and addressing related challenges (optimisation of overall traffic, sustainable mobility solutions for urbanisation), and do not support a mode-dependent view only. This suggests the need to discuss how to ensure greater cooperation between transport modes and cross-modal approaches in establishing partnerships in the area of mobility.

Partnership composition: the role of Member States in industry partnerships

The composition and types of partners is an important element for the success of a partnership, e.g. to ensure the right expertise and take-up of results. Ensuring broad involvement without overly complicating the governance of the partnership remains an important an important challenge in the design of future partnerships.

In the feedback, several Member States express their interest to join as a partner in partnerships that have traditionally been industry-led. However, individual comments suggest there are different views on what their involvement means in practice, with some countries expressing readiness to commit funding, while others support limiting their involvement to alignment of policies and exploiting synergies. This suggests the need to discuss further what the involvement of Member States means in practice (notably in terms of contributions, in the governance), and what would be possible scenarios/options in Horizon Europe. There is special interest in testing and deployment activities, in synergies with Cohesion Funds and CEF priorities and investments.

Although it is too early to determine the interest of industry/ businesses in the topics proposed for partnerships where the main partners are public authorities, their involvement in in public centric partnerships will also be an important question in the design and preparation of future proposals.

Some proposals are more mature than others

The analysis of feedback per partnership candidates suggests that some proposals are more mature, while others would need more time to determine the scope, objectives, partner composition and contribution and appropriate mode of implementation. This relates to in particular to partnerships with no predecessors and those where the main partners are public. It suggests that the proposals would need to be developed at different paces in order to achieve good quality, and thus, not all partnership proposals may be ready for implementation at the start of Horizon Europe.

For the initiative "Circular Bio-Based Europe" the following overall feedback was received from Member States. Delegations identified a number of aspects that could be reinforced in the proposal for the "Circular Bio-based Europe" partnership that would increase its relevance for national priorities. They suggest e.g. to broaden the scope towards forestry, waste and marine bio-resources; to give more emphasis to local production of biomass and to create opportunities for the development of local small-scale technological solutions for rural regions and urban areas. The proposed use of Article 187 is supported by 26%, but also questioned by 26% of the responses, with 48% requiring more information. Overall the results of the Member State consultation confirm strongly the high relevance of the proposed European partnership for a Circular bio-based Europe. While 43% of the countries are undecided at this stage, 15 have expressed an interest to participate (BE, DE, ES, FI, FR, CR, HU, IE, IT, MT, NL, RO, SE, SK, SI), and only one country has at this stage expressed that there is no national interest to participate (IS). Overall there is a strong agreement (96%) on the use of a partnership

approach for a Circular bio-based Europe and a broad agreement (83%) that the partnership is more effective than traditional calls in achieving the objectives and delivering clear impacts for the EU and its citizens. The majority of countries indicate good agreement with the proposed objectives at short, medium and long term and the expected scientific, economic and societal impacts at European level.

1.3.3. Targeted consultation of stakeholders

In addition to the consultation exercises coordinated by EC services, the external study thematic teams performed targeted consultations with businesses, research organisations and other partners on different aspects of potential European Partnerships.

Approach to the targeted consultation

The objectives of the interviews in the context of this impact assessment was to collect view of people on the following topics:

- Overall and specific objectives that the potential Circular bio based partnership/initiative could address
- Target groups, membership and openness
- Role and activities of the initiative
- Leverage effect in the potential partnership
- Coordination, structuring and mobilisation needs
- Key Performance Indicators (KPI)
- Costs and benefits of the potential initiative
- Need for a Circular bio-based Europe
- Research needs
- Contribution to EU policies
- Governance / organisation
- Collaborations with other initiatives
- Benefits of EU action

The selection of interviewees was discussed with the steering committee members. The key point was to approach the actors who are well informed about the ongoing partnership work either by being involved in projects, governance board or cooperation activities. A few companies not involved in the current partnership activities have also been approached. Description of the categories of actors interviewed is made in the next section.

The potential interviewees were contacted by email invitations that included the explanation of the context of the assignment, letter of support from the EC and the interview guide with a list of topics and relevant questions to be discussed (provided in the annex report). The interview guide (referred as the questionnaire) contained 50 questions divided by sections mentioned above.

The interviewees were given a freedom to use the interview as a guidance for the interview discussions and not forced to address all questions and topics presented here. In many cases the interview was organised by topical sections, in a few cases interviewees structurally followed question by question in providing their answers. Some interviewees preferred to provide written answers to the questionnaire. Finally, the interviewees were guaranteed their anonymity.

Overview of respondents to the targeted consultation

In total, 63 interviews have been conducted. However, that number does not correspond to the actual number of individuals interviewed since group interviews were also conducted with actors belonging from the same stakeholder category.

Moreover, situations were found where actors were belonging to several stakeholder categories, i.e. actors managing a BBI JU Flagship project could also be present in the BBI JU Team and Governing Board category. To avoid duplicates, such situations were resolved by allocating the individuals to their "main" category. That means that from one single interview, multiple visions and experiences could be collected⁶.

In total, 14 stakeholders categories were established as follow:

- The European Commission
- Member States with a bioeconomy strategy
- Member States without a bioeconomy strategy
- Regions
- BBI JU Team and Governing Board
- BBI JU Flagship
- BBI JU Other projects
- Companies BBI JU related
- Companies not BBI JU related
- Other Initiatives
- Business and industry associations
- NGOs and consumer associations
- Research and RTOs
- Experts

Key results/messages from the targeted consultation

The main findings of the interviews have been described by sections. Some sections received less input than others since they were more technical and required specific knowledge on the subject, which some actors did not have to provide relevant answers. Some sections received more input, such as the "objectives" section, which proved successful in generating enthusiasm and opinions from the interviewees and did not require technical knowledge.

Objectives

In general, interviewees were agreeing with the objectives of the future initiative, however, many of them stipulated that in the future initiative, the objectives should be more focused, and the scope should be enlarged to be more open to more sectors (e.g. waste management, food, soil etc.) and cover value chains that have not been covered before, such as for example plant based proteins. More emphasis should also be put on the circularity and on the environmental sustainability aspect of the objectives, as well as on the socio-economic aspect including the creation of jobs and growth, especially in rural areas and remote and economically vulnerable regions. Some interviewees suggested to link the objectives with the SDGs and to take a more regional perspective in that regard.

Creating a market for the bio-based economy and bringing products to commercialization were objectives often suggested by many stakeholders coming from different categories. In that path, a higher focus on improving the competitiveness of the EU industry was mentioned.

⁶ For further details on distribution statistics, see also the supporting study by Technopolis (2020).

According to the majority of the interviewees such objectives should be set and defined upfront, with a degree of flexibility, by the European Commission and the industry in a collaborative manner. A few interviewees suggested to leave that role for the European Commission only or for the industry only. However, many stakeholders suggested to involve more actors in the process such as primary producers, farmers, universities, member states, public and local authorities, regions, small cooperatives and SMEs. The importance of the role (consultative or full decision-making power) of each actor mentioned depended on the type of stakeholder category interviewed. Nonetheless, a point of agreement was found on having a balance between all actors in order to not have smaller actors eclipsed by the bigger ones. Such a balance was also mentioned when addressing the TRL levels that should be emphasized: some respondents said that the initiative should not exclude any TRL levels and have a balance of focus, while others said to focus mostly on higher TRL projects as they can bring impact much faster than the lower TRL projects. Yet, others suggested to focus mostly on lower TRL levels in order to not impede innovation. Another suggestion was made on involving the public and the consumers and informing them better about the bio-based economy and bio-based products. This consideration was generally linked to creating a market for bio-based products and related objectives.

Arguments regarding the different options varied greatly among the different stakeholder categories and can be exposed as such:

- A CPP is considered lighter, more flexible and as giving more influence to the EC. However, as it is less dependent on industry contributions and not requiring legally binding commitment, it also might generate less engagement with stakeholders and make it more difficult to stimulate industry who consider that the EC has too much say. Moreover, some consider that CPP will not allow long-term projections and will not have balanced representation of various TRLs in the overall project portfolio of the initiative.
- A CFP is depicted as problematic since it does not envisage involvement of the private sector
 in the initiative. Nonetheless, member states would have more weight which is considered as
 benefiting for some but creates the drawback of focusing too much on academic topics of
 research, therefore not sufficiently promoting innovations close to market and reflect industry
 needs.
- An IPP has been described as administratively more regulated and therefore less flexible in governance and other rules, difficult to steer and less inclusive/largely industry driven in the decision-making on the content of the work programme. However, it is considered very efficient in structuring very diverse sectors around bio-based value chains and bio-economy, as well as being the best option to cross the valley of death, boost the bio-economy and bring products to the market. The IPP is said to generate a higher engagement and commitment of industry (however many mentioned that the rules about commitments should focus on project level contributions and rather than on the programme level in order to secure industries interest and commitment), allows collaboration with other sectors and serves as a bridge between private actors and the EC. This option has a long-term approach and gives the predictability needed.

Some participants also explained that changing the structure of the potential initiative would create negative impacts and would lose the impetus. A statement often expressed is to have an improved version of the BBI JU, isolated suggestions for a "hybrid model" that would combine the flexibility of CPP and a strong back office/secretariat team from the IPP model.

Regarding the definition of the target groups, the panel agreed on having flexibility on the coverage of the target groups while keeping a degree of stability to ensure the sufficient involvement of actors. However, the interviewees suggested to include more stakeholders of the bio-economy in the future

initiative; therefore expressing a need to redefine the target group coverage. Groups that have been the most mentioned were SMEs, regional and local authorities, biomass producers and primary producers, members states, universities, academia, NGOs, citizens and consumers.

The majority of the interviewees expressed an interest to have open calls instead of closed calls to ensure innovation and competitiveness. However, suggestions have been made to have more focused calls and have calls only for small-size actors such as SMEs, who should also have a special status. Only a few suggested foreseeing a priority in the calls for the members, which implies to have a differentiation between members and non-members. Some stakeholders also expressed the need to have earmarked funding for Eastern and Central Europe countries.

Regarding the engagement on research priorities, different views were voiced. A lot of the interviewees suggested to involve more actors such as SMEs, NGOs, universities and regional and local actors in the advisory board. Some suggested having academia and industry leading the research priorities, others found it to be the role of the industry with the involvement of member states in order to align on national strategies. Others expressed an interest in including brand owners in the initiative, to get a close-to-market perspective and focus.

Regarding the different options for the future initiative, it has been expressed that CPP would be better suited for member states who would have a bigger influence, on the other hand CPP is depicted as not attractive for non-traditional bio-economy sectors who would not engage. However, IPP has been described as having more capacity to involve and represent more actors.

Roles and activities

An argument that has been expressed by many interviewees was to have a common understanding of the initiative, to have a clear methodology and definitions set beforehand. However, a clear interest has been expressed toward keeping a certain flexibility in the definition of the role and activities of the initiative, while stability was also considered a necessity.

The proposed role and activities were globally approved by the majority of the interviewees, nonetheless, updating the objectives and expanding the scope of the activities was a clear requested. It was suggested to have activities addressing new technologies in the annual work programme, to promote technology transfer and dissemination, establish network and awareness raising activities, create more and more ambitious CSA and be more involved in smaller entrepreneurial actions. Moreover, more administrative activities were suggested such as establishing a control mechanism and a follow-up board.

Regarding the different options for the future initiative, CPP has been described to have the potential to allow evolving objectives and activities, while the IPP has been considered as too rigid in this respect. However, the was found to IPP generate more visibility and has a dedicated service for activities.

Leverage effect

The subject of the leverage effect has sparked a lot of different opinions and views. Among them an agreement has been found on the difficulties to generate in-cash contributions either from the big industries or from the smaller industries. For the big industries, it has been considered impossible and delusional to get them to contribute to a "common pot" without them knowing in advance what they will get in return for their contribution. This has been described as "paying for the competition". The same perspective was applied to the smaller actors, with the situation being even more complex as they often do not have the financial means. In-cash contributions have therefore been described as difficult. However, some expressed that in-cash was required from industries since the in-kind contribution is a way of circumventing co-financing. Others expressed that both contributions should be requested. Nonetheless, the commitment of industry was considered a necessity.

It has also been mentioned that the EC should be defining the requirements of contributions, and do it in advance. Moreover, some interviewees voiced that the commitment from companies depends on the commitment of the EC: the stronger the commitment of the EC, the stronger the commitment from companies. Another way considered to increase the leverage effect is to focus on high TRL projects, or on mid to later stages projects.

The IPP has been considered better placed to increase the leverage effect as it involves stable partners and has the potential to build momentum.

Coordination, structuring and mobilisation

It has been agreed among the panel that the coordination between and across sectors is important and required for the bio-based industry. It makes sense to mobilize and coordinate actors such as smaller stakeholders, SMEs, primary producers, regions, local authorities, member states, academia, end users, brand owners etc.

It has been mentioned that the IPP might be the best option to achieve the coordination, structuring and mobilisation objectives as this option is able to inform, mobilize primary sectors, create robustness of value chains and thus, generate cooperation across sectors. However, others stipulated that the coordination with academia should be done by Horizon Europe and not by the initiative. It has also been mentioned that the structuring effect requires cooperation with the policy level to be fostered. Added to that, since structures already exist within the current partnership, a continuation should be envisaged.

KPIs

Regarding the KPIs, a lot of suggestions have been made by the interviewees to include more and broader topics. First of all, it has been suggested to define the KPIs in advance and establish a more thorough definition, as the KPIs are sometimes too abstract and not easily translatable. In addition, a clearer method to assess the KPIs was requested. Then, a qualitative approach instead of a quantitative approach was described as more suited for the KPIs.

Regarding the subjects in particular, among the suggestions made, one could find to better link the KPIs with the SDGs, to have KPIs related to climate, to sustainability, to regional participation, to jobs, growth etc. It was also mentioned to link the KPIs with the number of flagships, with the products arriving on the market, with the commercialised technologies, with new value chains etc.

Costs and benefits

Regarding the costs and benefits, the CPP option has been described as cheaper and lighter than the IPP option. However, in the CPP the costs of development are deferred, so it might be that the costs of CPP and IPP will be the same when considering all costs. Moreover, it appears that CPP is too subjective on contributions, which is not the case in the IPP. Indeed, as the commitment of industry is considered as required and crucial, it should be ensured through legally binding commitment. In addition, an IPP appears to give the predictability needed, pairing with the opinion of a lot of interviewees stipulating that long-term funding is required for the initiative. In that regard, an issue pointed out was the lack of continuity, which led some interviewees to stipulate that follow up of investments is more important than financial contribution itself. Thus, a proper monitoring system has been suggested.

On the other hand, it has been advised to reduce bureaucracy, simplify reporting, achieve more with the same amount of contributions and creating a lighter structure of organization.

Need for Circular bio-based Europe

Regarding the timeframe of the EU partnership on Circular bio-based Europe, an agreement has been found among the panel for a long-term period, going from 7 to 10 years to sometimes as long as possible. Others suggested that it should match the financial framework, or to stop the initiative when it is not contributing to EU policy anymore.

A clear need towards the future initiative has been expressed by the majority of the interviewees. Without an initiative, investments in bio-based industry might happen outside the EU, therefore not ensuring EU's competitiveness. Moreover, the development of the industry might be much slower and the cooperation between different actors and sectors might not happen.

According to the panel, an initiative is needed to provide support, to encourage the intersectoral and value chain cooperation, to deliver EC's objectives, to promote social and sustainable ideas and support eco-innovation. In addition, the partnership is considered as having a facilitating role in the bio-based industry.

Research needs

Concerning the research needs and the process for setting priority research topics, different views have been expressed. The first view mentioned that the EC should be the main actor to set the agenda, a second view suggested to have the EC deciding in collaboration with industry. However, the role of the industry in this collaboration varied from a full collaboration to only being heard by the EC. A third view suggested to have the private sector to lead the research agenda and controlled by the university. Others said that there should be a balance between the actors, which led the interviewees to suggest involving more stakeholder in the process of setting up the research priorities such as primary producers, the EU13 countries, to engage more the SRG and the scientific committee.

In addition, the topics of the research priorities have been subject to some improvements to be closer to market, to focus on higher value products and commercialisation and on higher TRL projects. Nonetheless, is has been mentioned that the research agenda should come from the need to achieve environmental targets of the EC and address the societal challenges as well.

Contribution to EU policies

The future initiative might be contributing to the EU policy objectives by promoting and raising awareness about the bio-based industry, promoting existing standards or labels but also by de-risking investment and filling the funding gap in the industry. In that regard, the future initiative needs to accompany the industry and producers in promoting bio-based products. It might also accelerate the market uptake of solutions to contribute to the EU policy objectives by collaborating with and involving smaller stakeholders such as SMEs and consumers.

It has been recognised that policy had to change and that it is benefiting to have projects followed up by policies measures. It has been considered crucial to monitor how the future initiative will be contributing to EU policies objectives.

Regarding the options of the future initiative, an IPP is considered suited to promote and raise awareness, however it is less flexible and it has been mentioned that the EC has minor access to information. CPP has been considered easier by few interviewees.

Governance/organisation

Regarding the governance of the future initiative, it was suggested to involve many new actors. Member states, as a potential actor, have been sparking the most diverging opinions; some interviewees said member states should be involved others were opposing their involvement since if they do not speak with one voice it would create confusion, others suggested to communicate with them instead of involving them closely. In addition, universities, academia and research institutes were mentioned as actors to be included, as well as public services who should get a better representation.

Interviewees urged to give SMEs a better representation and participation which might be best guaranteed by the IPP. It has been also advised to look at the possibilities for regions to participate.

Openness and flexibility, according to the panel, should be secured for new key actors, member states, partners and target groups. For example, a flexibility for smaller actors in terms of time should be accorded. However, in some instances the inclusion of international actors in the initiative was not deemed appropriate..

Collaboration with other initiatives

Collaboration with other initiatives has been described as important but sometimes difficult. Collaboration might scale out synergies and might be optimising efforts through synergies, which is considered as important. Collaboration with national and regional levels has been suggested, however collaboration with international level sparked less enthusiasm as it is harder even if considered valuable since it can bring technologies from the outside to the EU.

Collaboration with NGOs, smaller developers, brands, agri business and citizens has been mentioned as having a role to play. Establishing links with other public and private partnerships were suggested to cover potential overlaps, and collaboration with initiative like CAP, SPIRE and others have also been described to be beneficial.

Benefits of EU action

According to the panel, an EU initiative is needed for the bio-based industry since the industry is considered too young to develop by itself. In addition, the EU initiative has a structuring effect and is thus needed to drive and coordinate multiple stakeholders. The following arguments on the necessity to have an EU initiative were put forward; bridging the valley of death, de-risking, advances on R&D, bringing incentives to operate in the EU, ensuring EU's competitiveness etc.

In that regard, some have expressed the need for an IPP, while others said that CPP might be too light to ensure the objectives and overcome the potential barriers.

1.3.4. Open Public Consultation

APPROACH TO THE OPEN PUBLIC CONSULTATION

The consultation was open to everyone via the EU Survey online system⁷. The survey contained two main parts and an introductory identification section. The two main parts collected responses on general issues related to European partnerships (in Part 1) and specific responses related to 1 or more of the 12 candidate initiatives (as selected by a participant).

The survey contained open and closed questions. Closed questions were either multiple choice questions or matrix questions that offered a single choice per line, on a Likert-scale. Open questions were asked to clarify individual choices.

The survey was open from 11 September till 12 November 2019. The consultation was available in English, German and French. It was advertised widely through the European Commission's online channels as well as via various stakeholder organisations.

The analysis of the responses was conducted by applying descriptive statistic methods to the answers of the closed questions and text analysis techniques to analyse the answers of the open questions. The

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⁷ https://ec.europa.eu/eusurvey/runner/ConsultationPartnershipsHorizonEurope

keyword diagrams in this report have been created by applying the following methodology: First, the open answer questions were translated into English. This was followed by cleaning of answers that did not contain relevant information, such as "NA", "None", "no comment", "not applicable", "nothing specific", "cannot think of any", etc. In a third step, common misspellings were corrected, such as "excellence" instead of "excellence", or "partnership" instead of "partnership". Then, then raw open answers were tokenised (i.e. split into words), tagged into parts of speech (i.e. categorised as a noun, adjective, preposition, etc.) and lemmatised (i.e. extraction of the root of each word) with a pre-trained annotation model in the English language. At this point, the second phase of manual data cleaning and correction of the automatic categorisation of words into parts of speech was performed. Finally, the frequency of appearance and co-occurrences of words and phrases were computed across the dataset and the different sub-sets (e.g. partnerships, stakeholder groups). Data visualisations were created based on that output.

The keyword graphs in the following sections have been built based on the relationships between words in the open responses of the survey participants. It features words that appear in the same answer either one after the other or with a maximum distance of two words between them. Each keyword is represented as a node and each co-occurrence of a pair of words is represented as a link. The size of the nodes and the thickness of the links vary according to the number of times that keywords are mentioned and their co-occurrence, respectively. In order to facilitate the visualisation of the network, the keyword graphs have been filtered to show the 50 most common co-occurrences. Although the keywords do not aim to substitute a qualitative analysis, they assist the identification of the most important topics covered in the answers and their most important connections with other topics, for later inspection in the set of raw qualitative answers.

1.3.5. Relevance of a set of elements and activities to ensure that the proposed European Partnership would meet its objectives

Setting joint long-term agendas

Respondents were asked how relevant the involvement of actors is in setting joint long-term agenda to ensure that the proposed European Partnership would meet its objectives (see Figure 23). The highest amount of respondents indicated that the involvement of Industry is 'very relevant'. A large part of respondents also indicated that the involvement of Academia and Member States and Associated Countries is 'very relevant'. The answers are more evenly split with regard to Foundations and NGOs and Other stakeholders.

Academic/research institution, as well as EU citizen and public authorities indicated that the involvement of Industry and Academia are 'very relevant' followed by Member States and Associated Countries and Foundations and NGOs as the second choice. Business association indicated that the involvement of Industry and Member States, Associated Countries and Academia is the most relevant, however Foundations and NGOs in turn is the least important. SMEs and businesses (250+) indicated similar preferences in the OPC, where the involvement of Industry and Member States and Associated Countries is the most relevant, the least relevant is involvement of Foundations and NGOs. NGOs think that the engagement of Industry and Foundations and NGOs will contribute the most.

Figure 23: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives? - Responses for the Circular Bio-based Europe Initiative - Setting joint long-term agenda with strong involvement of

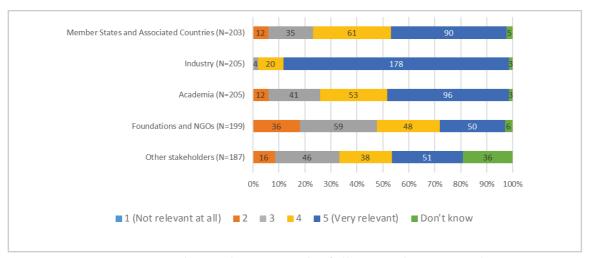
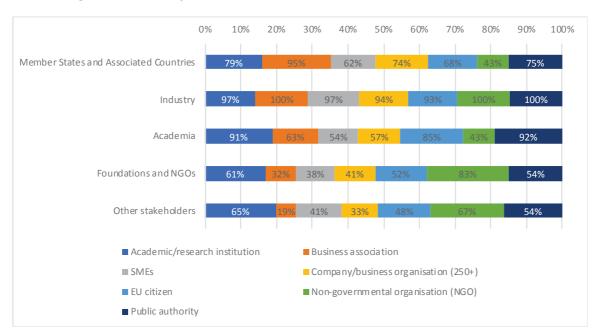


Figure 24: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives? - Responses for the Circular Bio-based Europe Initiative - Setting joint long-term agenda by stakeholder type with strong involvement of



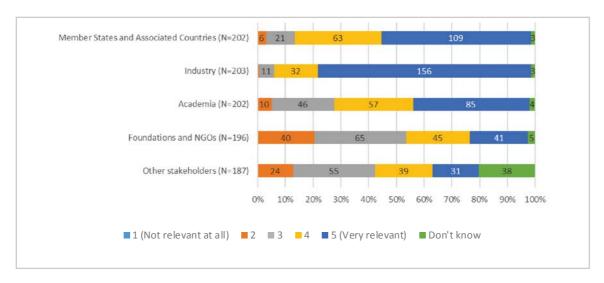
Pooling and leveraging resources through coordination, alignment and integration with stakeholders

With respect to the relevance of coordination, alignment or integration with specific stakeholders' groups in pooling and leveraging resources, such as financial, infrastructure, in-kind expertise etc., to meet Partnership objectives, the patterns are very similar. More than two third of respondents in all stakeholder groups indicated that industry was very relevant. Member States and Associated Countries were very relevant for business associations, Academic/research institution, EU citizen and Public authority.

With regard to Academia the least of respondents felt that they were very relevant. However, Academic/research institution, EU citizen and Public authority consider this element as relevant. Most of the respondents among different stakeholder groups did not indicate Foundations and NGOs as very relevant. No respondents from different stakeholder groups indicated that any of the categories was

'Not relevant at all'. No statistical differences were found between the views of citizens and other respondents.

Figure 25: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives - Responses for the Circular Bio-based Europe Initiative - Pooling and leveraging resources (financial, infrastructure, in-kind expertise, etc.) through coordination, alignment and integration with:

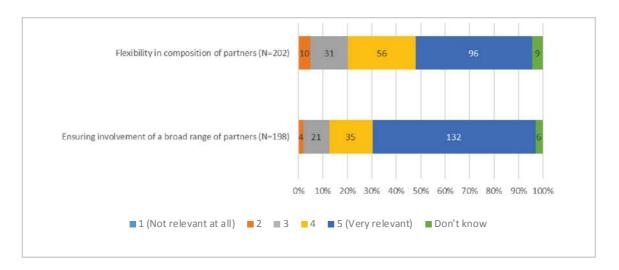


Relevance of the partnership composition

Respondents were asked about the relevance of the Partnership composition, such as the flexibility in the composition of partners over time and the involvement of a broad range of partners (including across disciplines and sectors), to reach Partnership objectives. As is visible in Figure 26, ensuring involvement of a broad range of partners has more 'very relevant' answers (132, 66.67%) than the flexibility in the composition of partners (96, 47.52%). Overall 80% of respondents have given flexibility either a score of 4 or 5 (very relevant), while 84% have given the broad range of partners a score of 4 or 5 (very relevant).

No statistical differences were found between the views of citizens and other respondents.

Figure 26: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives - Responses for the Circular Bio-based Europe Initiative - Partnership composition

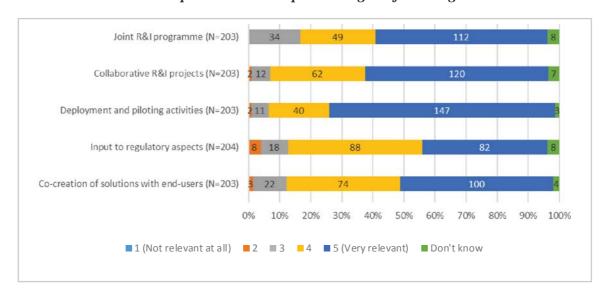


Relevance of activities

Respondents were asked to provide opinions on the relevance of implementing a set of activities for meeting the objectives of the candidate Circular Bio-based Europe Partnership. Among activities were listed – a joint R&D programme, collaborative R&D projects, deployment and piloting activities, input to regulatory aspects and co-creation of solutions with end-users. Out of 203 respondents, 147 (72.41%) indicated that deployment and piloting activities are very relevant to ensure that the Partnership would meet its objectives. Collaborative R&I projects have also been considered as very relevant by a large number of respondents (120 respondents or 59.11%). In particular, a large majority of academics, business associations and EU citizens, and all respondents from public authorities, indicated collaborative R&I projects as relevant. In contrast, input to regulatory aspects is considered less relevant by respondents. However, still a large share of academics, business associations, businesses (250+), public authorities and other types of respondents indicated this element as relevant.

Respondents that are/were involved in a current/preceding partnership found joint R&I programmes more relevant than other respondents. Overall, this element was considered as relevant by more than half of business associations, business organisations and NGOs, and by more than two thirds of academics, EU citizens and public authorities.

Figure 27: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives - Responses for the Circular Bio-based Europe Initiative - Implementing the following activities



1.3.6. Relevance of setting up a legal structure (funding body) for the candidate European Partnerships to achieve improvements

Respondents were also asked to assess the relevance of a specific legal structure (funding body) for the candidate European Partnership to implement several activities. According to Figure 28 most respondents indicated that a specific legal structure was 'very relevant' to implement its activities more effectively. The majority of stakeholders from business associations, SMEs, businesses (250+), public authorities and EU citizens indicated a high relevance of a legal structure for a more effective implementation of activities.

Respondents that are/were involved in a current/preceding partnership found the effective implementation of activities, increased financial leverage and the collaboration with other partnerships more relevant than other respondents.

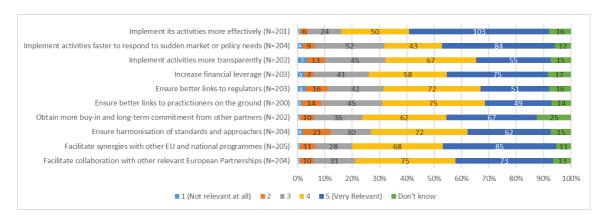
Overall, the majority of respondents in all stakeholder groups indicated the set-up of a legal structure as relevant or highly relevant to: implement activities more effectively and more transparently; increase financial leverage; ensure better links to practitioners on the ground; obtain more buy-in and long-term commitments from other partners; ensure harmonization of standards; and facilitate synergies with other EU and national programmes.

A legal structure was considered relevant or highly relevant for a faster implementation of activities to respond to sudden market or policy needs by the majority of respondents in all stakeholder groups, with the exception of business associations where more than half considered it relevant to a smaller degree.

Contrarily to all other stakeholder groups, a moderate majority of EU citizens considered a legal structure either close to not relevant or relevant to a smaller degree to ensure better links to regulators. Similarly, the majority of NGOs indicated a specific legal structure to be close to not relevant or relevant only to a small degree to facilitate collaboration with other relevant European Partnerships.

The number of respondents that have indicated that they view a measure as 'not relevant at all' is very small across all the measures and all stakeholder groups.

Figure 28: In your view, how relevant is to set up a specific legal structure (funding body) for the candidate European Partnership to achieve the following? - Responses for the Circular Bio-based Europe Initiative

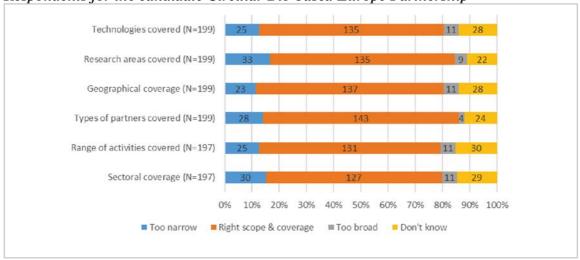


1.3.7. Scope and coverage of the candidate European Partnerships based on their inception impact assessments

Respondents were asked to assess the scope and coverage of the Circular Bio-based Europe Partnership, based on its inception impact assessment. The clear majority of the respondents across all stakeholder groups have indicated that the partnership has the right scope and coverage across all areas, although geographical coverage and types of partners covered have the highest number of right scope and coverage answers. On average, a very small share of respondents have indicated that they felt the scope and coverage were too broad, while a slightly higher but still small share of respondents have indicated that the scope was too narrow. In particular, a higher share of NGOs compared to other stakeholders groups, have indicated this with regards to technologies covered. Similarly, a higher share of academics compared to other stakeholder groups, have indicated geographical coverage, research areas, range of activities and sectoral coverage to be too narrow, although the majority still considered these as correctly covered.

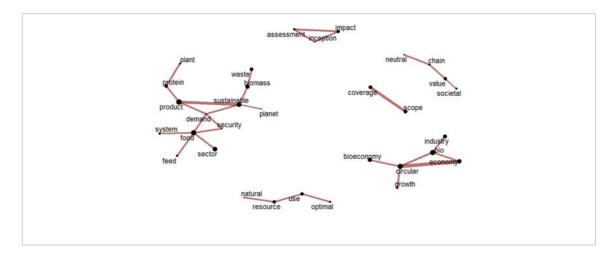
No statistical differences were found between the views of citizens and other respondents.

Figure 29: What is your view on the scope and coverage proposed for this candidate institutionalised European Partnership, based on its inception impact assessment? Respondents for the candidate Circular Bio-based Europe Partnership



Aside from this multiple-choice question, the respondents were also asked to provide any comment that they may have on the proposed scope and coverage for this candidate Institutionalised Partnership. The keyword analysis used for open questions resulted in the graph shown below. This analysis showed the respondents used this question to talk about sustainable biomass, plant protein, food security as well as the circular (bio)economy and an inception impact assessment.

Figure 30: Assessment of open answers with regard to the proposed scope and coverage for this candidate Institutionalised Partnership, 30 most common co-occurring keywords (N=69)



Two business respondents endorse the vision as it has been formulated by the BIC including food security & demand for sustainable products; sustainable planet; jobs and growth in the circular bioeconomy; and circular bioeconomic society. An EU citizen suggested additionally including the development of biomimetic materials for large-scale applications in the energy and construction sector. A representative of academia pointed out that the point of view of the citizens has to be considered. Another representative of academia emphasized that it is necessary to finance innovative technologies. A representative of a regional authority underlined that regional or bigger geographical coverage is needed in terms of volumes and market. A representative of a large company drew the attention to the significant potential coming from the Industrial Symbiosis.

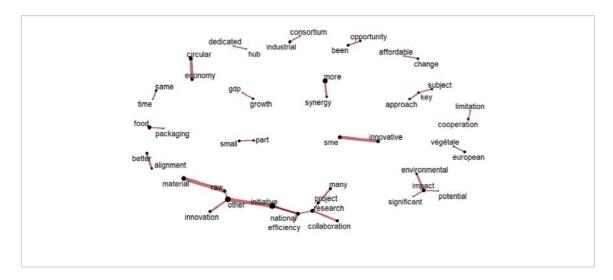
1.3.8. Scope for rationalisation and alignment of candidate European Partnerships with other initiatives

The respondents were also asked if it they thought it would be possible to rationalise the candidate European Institutionalised Partnership and its activities, and/or to better link it with other comparable initiatives. 100 respondents (57.47%) have indicated that they think this is the case.

No statistical differences were found between the views of citizens and other respondents.

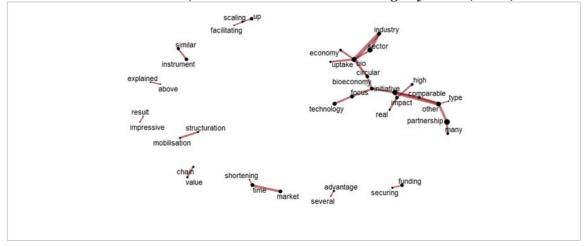
The respondents who answered affirmatively were asked to indicate which other comparable initiatives this proposed partnership could be linked with. The keyword analysis used for open questions resulted in the graph shown in Figure 31. This analysis showed the respondents used this question to talk about several initiatives with which it should actively cooperate and foster links, including Innovative SMEs (suggested by a large company); the HEU missions on "Soil health and food" and on " Healthy Oceans, Seas, Coastal and Inland Waters' (suggested by an academic); and European Platforms such as SUSCHEM on plastic circular economy and the materials platform EUMAT (suggested by an academic). Making these links would ensure the initiative reaches its potential of significant environmental impact.

Figure 31: Assessment of open answers with regard to the proposed scope and coverage for this candidate Institutionalised Partnership, 30 most common co-occurring keywords (N=53)



For the respondents who answered negatively on the previous question, the results of the analysis resulted in the chart shown in Figure 32 showing the co-occurrences of keywords. The results show that respondents are interested in the uptake of bioeconomy and circular initiatives by the industry and having real impact comparable to other types of partnerships. Respondents acknowledged that the candidate partnership is the only initiative at EU level that specifically addresses the challenges of the biotechnology sector. A medium company underlined that the Institutionalized Partnership is necessary to enable shorter development and scale-up technologies; to bring new bio-based products to the market; and further strengthen EU's position in the global bio-economy market. A medium company acknowledged that while the bioeconomy will take place in regions, it requires a very broad stakeholder network to identify the relevant technologies and bring them to higher TRLs.

Figure 32: Assessment of open answers on the question why other comparable initiatives are not suitable to be linked, 30 most common co-occurring keywords (N=15)



1.3.9. Relevance of European Partnerships to deliver targeted scientific, economic/technological and societal impacts

Respondents were asked to assess the relevance of the candidate European Institutionalised Partnership to deliver on listed impacts. According to Figure 33, among societal impacts, a greater number of respondents suggest that the Partnership would be 'very relevant' for reducing greenhouse emissions, for maximisation of valorisation of organic waste, and agriculture and forestry residues, and for replacement of oil-based chemicals and materials with bio-based and biodegradable ones. In

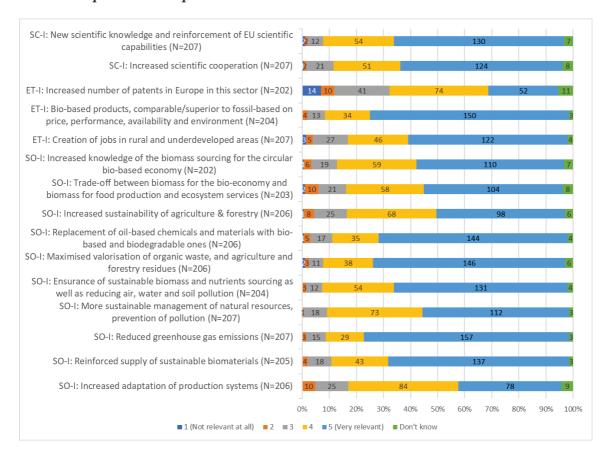
comparison, the least number of respondents considered that the partnership would be 'very relevant' for increasing adoption of production systems. Among economic/technological impact categories, a greater number of respondents (150 out of 204, or 73.53%) indicated that the Partnership would be 'very relevant' for delivery of bio-based products that are comparable and/or superior to fossil-based products. The pattern of responses on impacts in the area of science are very similar – over 60% of respondents believe that the Partnership would be 'very relevant' for generating new scientific knowledge and for increasing scientific cooperation.

The majority of respondents across all stakeholder groups considered European Partnerships to be either very relevant or relevant to deliver the targeted scientific, social and economic impacts. Citizens found the societal impact related to sustainable management of natural resources and the economic/technological impact related to the creation of jobs in rural and underdeveloped areas more relevant.

A greater share of businesses (250+), SMEs, public authorities and NGOs, compared to other stakeholder groups - although still not the majority - considered European Partnerships to be either not relevant or relevant to a smaller degree to deliver targeted social impacts.

An even higher share of the abovementioned stakeholder groups - although not the majority - considered European Partnerships to be either not relevant or relevant to a smaller degree to deliver targeted economic impacts.

Figure 33: In your view, how relevant is it for the candidate European Institutionalised Partnership to deliver on the following impacts? Responses for the candidate Circular Biobased Europe Partnership



1.3.10. Summary of campaigns results for this specific initiative

One campaign has been identified among respondents that decided to provide views on the candidate Partnership on Circular Biobased Europe. This campaign consists of 20 respondents (campaign #5).

Table 6: Overview of responses of the first campaign (campaign #5) (N=20)

Question category	Summary of responses
Research and innovation problems	The answer category "lack of understanding of the circular and bio-based economy" was assessed 'very relevant' by all respondents. The other categories received a score of 4, on average.
Structural and resource problems	With exception of two respondents, all respondents gave a high score (5 'very relevant') for a category "limited collaboration and pooling of resources between public actors and private actors etc.". The other category received a lower score (between 3 and 4).
Problems in uptake of digital innovations	Most respondents considered that the following categories are 'very relevant': "lack of competitiveness with the traditional products/materials", "lack of private investment", "lack of public investment". Other answer categories received a lower score, on average.
Preferred Horizon Europe intervention	Institutionalised Partnership option was selected by most respondents. Only one respondent indicated that the challenges can be better addressed via "co-funded

Question category	Summary of responses
	partnership".
	When respondents were asked to explain their choice, almost all of them used the following quote: "Challenges mentioned above require joint investments, setting up new value chains and creating synergies. An iPPP addresses the multi-actor nature of the bio-based industries and enables long-term collaboration of different sectors (industry, academia, society, member states, regions) to solve these challenges and to create a favourable climate for investment in the bio-based sector in Europe".
Relevance of actors for setting join long-term agenda	Almost all respondents consider that involvement of industry is 'very relevant'. The involvement of "Member States and Associated Countries" is considered 'relevant' (score 4) by most respondents. Other categories received a slightly lower score, on average.
Relevance of actors for pooling and leveraging resources	Almost all respondents consider that involvement of industry is 'very relevant'. The involvement of "Member States and Associated Countries" is considered 'relevant' (score 4) by most respondents. Other categories received a slightly lower score, on average.
Partnership composition	Most respondents suggest that "involvement of a broad range of partners, etc." is 'very relevant'. The second answer category received a lower score, on average.
Implementation of activities	Across all respondents consider that "deployment and piloting activities" are 'very relevant'. Other answer categories were given a score of 4 'relevant', on average.
Relevance of the legal structure	With exception of one respondent, all respondents consider that the legal structure would be 'very relevant' for implementing Partnership activities more effectively. Other answer categories received an average score of 4 'relevant'. The lowest score (namely, 3) was given to the category "implement activities faster to respond to sudden market or policy needs".
Scope and coverage of the candidate Partnership	Across all answer categories, most respondents consider that the elements are of right scope and coverage.
	Respondents were offered an opportunity to provide comments on the proposed scope and coverage of the Institutionalised Partnership. Most of them included the following quote:
	"Scope (cf. 2050 vision signed by BIC & 14 associations):
	1. Food security and demand for sustainable products (integrated, efficient production of food, feed, bio-based products, services, energy with minimal environmental impact)
	2. A sustainable planet (carbon-neutral value chains, optimal use of natural resources, protect environment, add societal value)
	3. Jobs & growth in the circular bioeconomy (mobilise local feedstock)
	4. Circular bioeconomic society (participating citizens)."
Rationalisation of the candidate Partnership and linking to other initiatives	90% of respondents (18 out of 20) consider that it would not be possible to rationalise the candidate Partnership and its activities, and/or to better link it with other comparable initiatives.
	Respondents were asked to explain their answer, most of them inserted a following quote: "There is no similar instrument to address the challenges for the bio-based sector in the EU like an iPPP: it covers a funding gap, enables scaling up and shorter time to market through focus on higher TRL (5-8), provides grants (vis a vis loans and which don't have the same effect), bio-based industry sector is still very fragmented

Question category	Summary of responses
	between actors and across geographies, essential to continue on-going structuration."
Societal impact	Almost all respondents consider that the Partnership would be 'very relevant' to deliver on most categories of results. The exceptions include: "increased adaptation of production systems", "more sustainable management of natural resources, prevention of pollution", "increased sustainability of agriculture & forestry" and "increased knowledge of the biomass sourcing for the circular bio-based economy". In those categories, the average score is 4 'relevant'.
Economic/technological impact	For the categories "creation of jobs in rural and underdeveloped areas" and "increased number of patents in Europe in this sector", majority of respondents indicated that impacts are 'very relevant'. The remaining answer category received a score of 4, on average.
Scientific impact	Across all listed categories, majority of respondents indicated that impacts are 'very relevant'.

Annex 3 Who Is Affected And How?

1. PRACTICAL IMPLICATIONS OF THE INITIATIVE

- The proposed institutionalised partnership enables participation of all key stakeholders potentially contributing to the specifications and delivery of the strategic R&I agenda through a clearly defined membership structure. The stakeholders concerned are specified in the table below.
- It provides a forum for co-drafting R&I priorities and the work programmes, ensuring that they are aligned with industry and market needs.
- Participation is less flexible than under other options, but it is nevertheless possible to change the profile of participation over time, with new partners joining to support new areas of activity in response to emerging results and changing priorities.

SUMMARY OF COSTS AND BENEFITS

Description	Estimation (quantitative or qualitative)	Comments						
Direct benefits								
A more competitive primary sector producing biomass		Higher and secure income for primary producers (also in less-favoured regions); secured supply for bio-based industries; economic growth for SMEs.						
Cost savings for municipalities and regions regarding waste disposal		Part of the biowaste sold to the bio-based industry as raw material						
A more competitive bio- based industry sector		Secured biomass supply for bio-based industries; economic growth for SMEs.						
Access to more sustainable products by brand-owners and consumers		Continuously increasing demand satisfied						
<u> </u>	Indirect benefits	<u> </u>						
Reduction of CO ₂ emissions due the switch from fossilto bio-based		A larger proportion of chemicals and materials including plastics produced from biomass and biowaste.						

Biodiversity conservation or enhancement	As a result of lower toxicity bio-based products developed and as a result of sustainable management of natural resources, especially biodiversity-friendly biomass generation.
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(1) Estimates are relative to the baseline for the preferred option as a whole (i.e. the impact of individual actions/obligations of the <u>preferred</u> option are aggregated together); (2) Please indicate which stakeholder group is the main recipient of the benefit in the comment section;(3) For reductions in regulatory costs, please describe details as to how the saving arises (e.g. reductions in compliance costs, administrative costs, regulatory charges, enforcement costs, etc.; see section 6 of the attached guidance).

II. Overview of direct and indirect costs – Preferred option								
		Citizens/	Citizens/Consumers		Businesses (8)		Administrations (9)	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent	
Management/ Administrative costs	Direct costs				€ 1 m per year over 10 years (¹⁰)		€ 1 m per year over 10 years (¹⁰)	
	Indirect costs							
Personnel costs	Direct costs				€ 1.25 m per year over 10 years (for 25 FTE) (11) € 0.4 m per year over 11 years for 4 FTE (12)		€ 1.25 m per year over 10 years (for 25 FTE) (11)	
	Indirect costs						€ 0.5 m per year over 11 years for 5 FTE at operational and coordi- nating Com- mission	

⁸ Sum of below: 10+12.5+4.4 = EUR 26.9 m.

⁹ Sum of below: 10+12.5+5.5 = EUR 28 m.

¹⁰ Other expenses and finance costs of the BBI JU programme office were EUR 2.1 m in 2018 (Accounts 2018, p.8), to be paid 50:50 by the EC and the private partner.

¹¹ BBI JU programme office staff cost with 20 staff was EUR 2 m in 2018 (Accounts 2018, p. 8). Extrapolation to 25 staff in CBE. To be paid 50:50 by the EC and the private partner.

¹² The private partner's secretariat. Estimation.

				units
Coordination costs (or transaction costs)				
Budget expenditure/investment costs		€ 1,000 to 3,000 m over the whole pe- riod (¹³)	€ 1,000 m over the whole peri- od (14)	

(1) Estimates to be provided with respect to the baseline; (2) costs are provided for each identifiable action/obligation of the <u>preferred</u> option otherwise for all retained options when no preferred option is specified; (3) If relevant and available, please present information on costs according to the standard typology of costs (compliance costs, regulatory charges, hassle costs, administrative costs, enforcement costs, indirect costs; see section 6 of the attached guidance).

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¹³ 100-300% private contribution (also pending MFF decision and breakdown of the budget). No contribution commitment from private partner yet.

¹⁴ Pending MFF decision and breakdown of the budget.

Annex 4 Analytical Methods

The methodology for each impact assessment is based on the Commission Better Regulation Guidelines¹⁵ to evaluate and compare options with regards to their **efficiency**, **effectiveness** and **coherence**. This is complemented by integrating the **conditions and selection criteria** for European Partnerships, as well as requirements for setting up Institutionalised Partnerships.¹⁶

1. OVERVIEW OF THE METHODOLOGIES EMPLOYED

In terms of **methods and evidence used**, the set of impact assessments for all candidate Institutionalised European Partnerships draw on an external study covering all initiatives in parallel to ensure a high level of coherence and comparability of analysis. ¹⁷ (.

All impact assessments mobilised a mix of qualitative and quantitative data collection and analysis methods. These methods range from desk research and interviews to the analysis of the responses to the Open Consultation, stakeholder analysis and composition/portfolio analysis, bibliometrics/patent analysis and social network analysis, and a cost-effectiveness analysis.

The first step in the impact assessment studies consisted in the definition of the context and the problems that the candidate partnerships are expected to solve in the medium term or long run. The main data source in this respect was desk research. This includes grey and academic literature to identify the main challenges in the scientific and technologic fields and in the economic sectors relevant for the candidate partnerships, as well as the review of official documentations on the policy context for each initiative.

In the assessment of the problems to address, the lessons to be learned from past and ongoing partnerships were taken into account, especially from relevant midterm or ex-post evaluations.

The description of the context of the candidate institutionalised European Partnerships required a good understanding of the corresponding research and innovation systems and their outputs already measured. Data on past and ongoing Horizon 2020 projects, including the ones implemented through Partnerships, served as basis for descriptive statistic of the numbers of projects and their respective levels of funding, the type of organisations participating (e.g. universities, RTOs, large enterprises, SMEs, public administrations, NGOs, etc.) and how the funding was distributed across them. Special attention was given to analysing the participating countries (and groups of countries, such as EU, Associated Countries, EU13 or EU15) and industrial sectors, where relevant. The sectoral analysis required enriching the eCORDA data received from the European Commission services with sector information extracted from ORBIS, using the NACE codification up to level 2. These

¹⁵ European Commission (2017), Better Regulation Guidelines (SWD (2017) 350)

¹⁶ A pivotal element of the present analysis is the so-called two-step 'necessity test' for European Partnerships, used to establish: step 1) the need for a partnership approach in the first place, followed by step 2) a justification for the form of Institutionalised Partnership. The necessity test is described in Annex 6. This impact assessment focuses on the second step of the test.

¹⁷ Technopolis Group (2020), Impact Assessment Study for Institutionalised European Partnerships under Horizon Europe

data enabled the identification of the main and, where possible, emerging actors in the relevant systems, i.e. the organisations, countries and sectors that would need to be involved (further) in a new initiative.

A Social Network Analysis was performed by the contractors using the same data. It consisted in mapping the collaboration between the participants in the projects funded under the ongoing R&I partnerships. This analysis revealed which actors – broken down per type of stakeholders or per industrial sector – collaborate the most often together, and those that are therefore the most central to the relevant research and innovation systems.

The data provided finally served a bibliometric analysis run by the contractor aimed at measuring the outputs (patents and scientific publications) of the currently EU-funded research and innovation projects. A complementary analysis of the Scopus data enabled to determine the position and excellence of the European Union on the international scene, and identify who its main competitors are, and whether the European research and innovation is leading, following or lagging behind.

A cost modelling exercise was performed in order to feed into the efficiency assessments of the partnership options.

The conclusions drawn from the data analysis were confronted to the views of experts and stakeholders collected via three means:

- The comments to the inception impact assessments of the individual candidate institutionalised European Partnerships;
- The open public consultation organised by the European Commission from September to November 2019;
- The interviews (up to 50) conducted by each impact assessment study team conducted between August 2019 and January 2020 (policymakers, business including SMEs and business associations, research institutes and universities, and civil organisations, among others).

The views of stakeholders (and experts) were particularly important for determining the basic functionalities (see further below) that the future partnerships need to demonstrate to achieve their objectives as well as their most anticipated scientific, economic and technological, and societal impacts. The interviews allowed more flexibility to ask the respondents to reflect about the different types of European Partnerships. Furthermore, as a method for targeted consultation, it was used to get insights from the actors that both the Study Teams and the European Commission were deemed the most relevant. For the comparative assessment of impacts, the external contractors confronted the outcomes of the different stakeholder consultation exercises to each other with a view of increasing the validity of their conclusions, in line with the principles of triangulation.

Annex 2 includes also the main outcomes of the stakeholder consultation exercises.

2. METHOD FOR ASSESSING THE EFFECTIVENESS, EFFICIENCY AND COHERENCE OF EACH OPTION - THE USE OF FUNCTIONALITIES

Given the focus of the impact assessment on comparing different forms of implementation, the Better Regulation framework has been adapted to introduce "functionalities". These are used to reflect what is needed in terms of implementation for each candidate initiative to be able to deliver on its objectives. The functionalities are the distinguishing factors between the different options and are directly linked to the European Partnerships' selection criteria of openness and transparency, additionality and directionality (see Annex 6). Based on the objectives identified and the targeted impact, functionalities describe what this requires in terms of implementation. Each form of implementation is then assessed to establish to which degree it would allow for these functionalities to be covered, e.g. the type and composition of actors that can be involved ('openness'), the range of activities that can be performed (including additionality and level of integration), the level of directionality and integration of stakeholders' R&I strategies¹⁸; the possibilities offered for coherence and synergies with other components of Horizon Europe, including other Partnerships (internal coherence), and the coherence with other EU, national or regional policy environments, including with the relevant regulatory and standardisation framework (external coherence). This approach guides the identification of discarded options and allows a structured comparison of the options against the selection criteria for European Partnerships.

Figure 3 Overview of key functionalities of each form of implementation of European Partnerships

Baseline: Horizon Europe calls	Option 1: Co- programmed	Option 2: Co- funded	Option 3.1: Institutionalised Article 185	Option 3.2: Institutionalised Article 187					
Type and compositi	Type and composition of actors (including openness and roles)								
Partners: N.A., no common set of actors that engage in planning and implementation Priority setting: open to all, part of Horizon Europe	Partners: Suitable for all types: private and/or public partners, foundations Priority setting: Driven by partners, open stakeholder consultation, MS in	Partners: core of national funding bodies or governmental research organisations Priority setting: Driven by partners, open stakeholder	Partners: National funding bodies or governmental research organisation Priority setting: Driven by partners, open stakeholder consultation	Partners: Suitable for all types: private and/or public partners, foundations Priority setting: Driven by partners, open stakeholder					
Strategic planning Participation in R&I activities: fully open in line with standard Horizon Europe rules	comitology Participation in R&I activities: fully open in line with standard Horizon Europe rules	consultation Participation in R&I activities: limited, according to national rules of partner countries	Participation in R&I activities: fully open in line with standard Horizon Europe rules, but possible derogations	consultation Participation in R&I activities: fully open in line with standard Horizon Europe rules, but possible derogations					
Type and range of a	ctivities (including add	itionality and level of	integration)						
Activities: Horizon Europe standards that allow broad range of individual	Activities: Horizon Europe standard actions that allow broad range of individual actions,	Activities: Broad, according to rules/programmes of participating States, State-aid	Activities: Horizon Europe standards that allow broad range of individual actions, support to regulatory	Activities: Horizon Europe standards that allow broad range of individual actions, support to					

¹⁸ The criterion on the ex-ante demonstration of partners' long term commitment depends on a series of factors that are unknown at this stage, and thus fall outside the scope of the analysis.

Baseline: Horizon Europe calls	Option 1: Co- programmed	Option 2: Co- funded	Option 3.1: Institutionalised Article 185	Option 3.2: Institutionalised Article 187
actions Additionality: no additional activities and investments outside the funded projects Limitations: No systemic approach beyond individual actions	support to market, regulatory or policy/ societal uptake Additionality: Activities/investment s of partners, National funding Limitations: Limited systemic approach beyond individual actions.	rules, support to regulatory or policy/ societal uptake Additionality: National funding Limitations: Scale and scope depend on the participating programmes, often smaller in scale	or policy/societal uptake, possibility to systemic approach Additionality: National funding	regulatory or policy/societal uptake, possibility to systemic approach (portfolios of projects, scaling up of results, synergies with other funds. Additionality: Activities/investments of partners/ national funding
Directionality				
Priority setting: Strategic Plan and annual work programmes, covering max. 4 years. Limitations: Fully taking into account existing or to be developed SRIA/ roadmap	Priority setting: Strategic R&I agenda/ roadmap agreed between partners and COM, covering usually 7 years, including allocation of Union contribution Input to FP annual work programme drafted by partners, finalised by COM (comitology) Objectives and commitments are set in the contractual arrangement.	Priority setting: Strategic R&I agenda/ roadmap agreed between partners and COM, covering usually 7 years, including allocation of Union contribution Annual work programme drafted by partners, approved by COM Objectives and commitments are set in the Grant Agreement.	Priority setting: Strategic R&I agenda/ roadmap agreed between partners and COM, covering usually 7 years, including allocation of Union contribution Annual work programme drafted by partners, approved by COM Objectives and commitments are set in the legal base.	Priority setting: Strategic R&I agenda/ roadmap agreed between partners and COM, covering usually 7 years, including allocation of Union contribution Annual work programme drafted by partners, approved by COM (veto-right in governance) Objectives and commitments are set in the legal base.
Coherence: internal industrial strategies	(Horizon Europe) and	external (other Union	programmes, national	programmes,
Internal: Between different parts of the Annual Work programme can be ensured by COM External: Limited for other Union programmes, no synergies with national/regional programmes and activities	Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Limited synergies with other Union programmes and industrial strategies If MS participate, with national/regional programmes and activities	Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Synergies with national/regional programmes and activities	Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Synergies with national/regional programmes and activities	Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Synergies with other Union programmes and industrial strategies If MS participate, with national/ regional programmes and activities

On the basis of the evidence collected, the thematic impact assessments evaluate the effectiveness of the various policy options along three dimensions corresponding to the

different categories of likely impacts: scientific, economic and technological, and societal (including environmental). Each impact assessment considers to which extent the different policy options fulfil the desirable 'functionalities' and are therefore likely to produce the targeted impacts. In addition, where specific impacts (e.g. on fundamental rights) are relevant for a candidate Partnership, these are assessed in the corresponding report and according to the Better Regulation Guidelines and Toolbox. This analysis results in a scoring of the policy options with a three-point scale. Scores vary from + to +++, where + refers to low potential for reaching the likely impacts, ++ to a good potential, and +++ to a high potential. The effectiveness assessment of the different options does not use a compound score but concludes on as many scores as there are expected impacts. This is done to increase transparency and accuracy in the assessment of options. Qualitative and quantitative evidence is provided to motivate each score.

A similar approach is followed to evaluate the coherence of options with the overarching objectives of the EU's R&I policy, and distinguishes between internal and external coherence. Specifically, internal coherence corresponds to the consistency between a given implementation mode and the other actions under Horizon Europe. External coherence refers instead to the alignment with other initiatives at EU, national and international level beyond Horizon Europe that are relevant to a thematic area. Each option (implementation mode) is assessed following a three-point qualitative scale.

To compare the expected costs and benefits of each option (efficiency), the thematic impact assessments broadly follow a cost-effectiveness approach to establish to which extent the intended objectives can be achieved for a given cost. A preliminary step in this process is to obtain a measure of the expected costs of the policy options, to be used in the thematic assessments. As the options correspond to different implementation modes, relevant cost categories generally include the costs of setting-up and running an initiative. For instance, setup costs includes items such as the preparation of a European Partnership proposal and the preparation of an implementation structure. The running costs include the annual work programme preparation costs. Where a Partnership already exists, discontinuation costs and cost-savings are also taken into account²⁰. The table below provides an overview of the cost categories used in the impact assessment and a qualitative scoring of their intensity when compared to the baseline option (traditional calls). Providing a monetised value for these average static costs would have been misleading, because of the different features and needs of each candidate initiative.²¹ The table shows the overall administrative, operational and coordination costs of the various options. These costs are then put into context in the impact assessments to reflect the expected co-financing rates and the total budget available for each of the policy options, assuming a common Union contribution (cost-efficiency):

The costs related to the baseline scenario (traditional calls under Horizon Europe) are pre-dominantly the costs of implementing the respective Union contribution via calls and project, managed by the executive agencies (around 4%, efficiency of 96% for the

¹⁹ For further details, see Better Regulation Toolbox # 57.

²⁰ Discontinuation costs will bear winding down and social discontinuation costs and vary depending on e.g. the number of full-time-equivalent (FTEs) staff concerned, the type of contract (staff category and duration) and applicable rules on termination (e.g. contracts under Belgian law or other). If buildings are being rented, the cost of rental termination also apply. As rental contracts are normally tied to the expected duration of the current initiatives, these termination costs are likely to be very limited. In parallel, there would also be financial costsavings related to the closing of the structure, related to operations, staff and coordination costs in particular. This is developed further in the individual efficiency assessments.

²¹ A complete presentation of the methodology developed to assess costs as well as the sources used is described in the external study supporting this impact assessment (Technopolis Group, 2020).

- overall investment).
- For a Co-Programmed partnership the costs of preparation and implementation increase only marginally compared to the baseline (<1%), ²² but lead to an additional R&I investment of at least the same amount than the Union contribution ²³ (efficiency of 98% for the overall investment).
- For a Co-Funded partnership the additional R&I investment by Member States accounts for 2,3 times the Union contribution²⁴. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the national programmes, can be estimated at 6% of the Union contribution (efficiency of 98% related to the overall investment).²⁵
- For an Article 185 initiative the additional R&I investment by Member States is equal to the Union contribution²⁶. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the dedicated implementation structure, can be estimated at 7% of the Union contribution (efficiency of 96% related to the overall investment).
- For an Article 187 initiative the additional R&I investment by partners is equal to the Union contribution²⁷. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the dedicated implementation structure, can be estimated at 9% of the Union contribution (efficiency of 94% related to the overall investment).

Figure 4 - Intensity of additional costs compared with Horizon Europe Calls (for Partners, stakeholders, public and EU)

Cost items	Baseline: traditional calls	Option 1: Coprogrammed	Option 2 Co-funded	Option 3a - Art. 185	Option 3b -Art. 187
Preparation and set-up costs					
Preparation of a partnership proposal (partners and EC)	0		↑ ↑		
Set-up of a dedicated implementation structure		0		Existing: ↑ New: ↑↑	Existing: ↑↑ New: ↑↑↑
Preparation of the SRIA / roadmap	0		$\uparrow \uparrow$		
Ex-ante Impact Assessment for partnership		0		↑ ↑	↑
Preparation of EC proposal and negotiation		0		$\uparrow \uparrow$	↑
Running costs (Annual cycle of implementa	ntion)				
Annual Work Programme preparation	0		1		

²² Specifically, some additional set-up costs linked for example to the creation of a strategic research and innovation agenda (SRIA) and additional running costs linked with the partners role in the creation of the annual work programmes and the Commission's additional supervisory responsibilities. A CPP will have lower overall costs than each of the other types of European Partnership, as it will function with a smaller governance and implementation structure than will be required for a Co-Funded Partnership or an Institutionalised Partnership and – related to this – its calls will be operated through the existing HEU agencies and RDI infrastructure and systems.

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²³ Minimum contributions from partners equal to the Union contribution.

²⁴ Based on the default funding rate for programme co-fund actions of 30%, partners contribute with 70% of the total investment.

²⁵ These costs reflect set-up costs and additional running costs for partners, and the Commission, of the distributed, multi-agency implementation model.

²⁶ Based on the minimum requirement in the legal basis that partners contribute at least 50% of the budget.

²⁷ Based on the minimum requirement in the legal basis that partners contribute at least 50% of the budget.

Cost items	Baseline: traditional calls	Option 1: Co- programmed	Option 2 Co-funded	Option 3a - Art. 185	Option 3b -Art. 187
Call and project implementation	0	0 In case of MS contributions: ↑	↑	1	1
Cost to applicants	Comparable, unless there are strong arguments of major difference oversubscription			fferences in	
Partners costs not covered by the above	0	\uparrow	0	\uparrow	↑
Additional EC costs (e.g. supervision)	0	\uparrow	↑	\uparrow	$\uparrow \uparrow$
Winding down costs					
EC		0			$\uparrow\uparrow\uparrow$
Partners	0	\uparrow	0	↑	↑

Notes: 0: no additional costs, as compared with the baseline; \uparrow : minor additional costs, as compared with the baseline; $\uparrow \uparrow$: medium additional costs, as compared with the baseline; $\uparrow \uparrow \uparrow$: higher costs, as compared with the baseline.

The cost categories estimated for the common model are then used to develop a scorecard analysis and further refine the assessment of options for each of the 12 candidate Institutionalised Partnerships. Specifically, the scores related to the set-up and implementation costs are used in the thematic impact assessments to consider the scale of the expected benefits and thereby allow a simple "value for money" analysis (**cost-effectiveness**). In carrying out the scoring of options, the results of fieldwork, desk research and stakeholder consultation undertaken and taken into account.

3. METHOD FOR IDENTIFYING THE PREFERRED OPTION – THE SCORECARD ANALYSIS

For the **identification of the preferred option**, the scorecard analysis builds a hierarchy of the options by individual criterion and overall in order to identify a single preferred policy option or in case of an inconclusive comparison of options, a number of 'retained' options or hybrid. This exercise supports the systematic appraisal of alternative options across multiple types of monetary, non-monetary and qualitative dimensions. It also allows for easy visualisation of the pros and cons of each option. Each option is attributed a value of 1 to 3, scoring the adjudged performance against each criterion with the three broad appraisal dimensions of effectiveness, efficiency and coherence.²⁸ The scorecard analysis was used to highlight those options that stand out as not being dominated by any of the other options in the group: such options are then retained as the preferential ones in the remainder of the analysis. It also allowed for easy visualisation of the pros and cons of alternative options.

Specifically, the scores related to the set-up and implementation costs are used in the thematic impact assessments to consider the scale of the expected benefits and thereby allow a simple "value for money" analysis (cost-effectiveness). In carrying out the scoring of options, the results of fieldwork, desk research and stakeholder consultation undertaken and taken into account.

These costs essentially refer to the administrative, operational and coordination costs of the various options. The figure shows how the scoring of costs range from a value of 0, in case an option does not entail any additional costs compared to the baseline (traditional calls), to a score of (-) for options introducing limited additional costs relative to the baseline and a score

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²⁸ In the thematic impact assessments, scores are justified in a detailed manner to avoid arbitrariness and spurious accuracy. A qualitative or even quantitative explanation is provided of why certain scores were given to specific impacts, and why one option scores better or worse than others.

of (--) when substantial additional costs are expected in comparison with the baseline. Should the costs of a policy option be lower than those of the baseline, (+) and (++) are used.

It is considered that while there is a clear gradation in the overall costs of the policy options, the cost differentials are less marked when one takes into account the expected co-financing rates and the total budget available for each of the policy options, assuming a common Union contribution. From this perspective, there are only one or two percentage points that split the most cost-efficient policy options – the baseline (traditional calls) and the Co-Programmed policy options – and the least cost-efficient – the Institutionalised Partnership option. A score of + is therefore assigned for cost-efficiency to the Co-Programmed and Co-Funded options, a score of 0 to the Article 185 option and a score of (-) for the Article 187 Institutionalised Partnership policy option.

Figure 5 Scoring of costs

	Baseline: Horizon Europe calls	Option 1: Co- programmed	Option 2: Co- funded	Option 3a: Institutionalised 185	Option 3b: Institutionalised 187
Administrative, operational and coordination costs	0	(0)	(-)	()	()
Administrative, operational and coordination costs adjusted per expected co-funding (i.e. cost- efficiency)	0	(+)	(+)	(0)	(-)

Notes: Score 0 = same costs as for the baseline; score (-) = limited additional costs compared with the baseline; score (-)(-) = substantial additional costs compared with the baseline.

Annex 5 Subsidiarity Grid

1. Can the Union act? What is the legal basis and competence of the Unions' intended action?

1.1 Which article(s) of the Treaty are used to support the legislative proposal or policy initiative?

This proposal is based on (1) Article 185 TFEU which stipulates that in implementing the multiannual framework programme, the Union may make provision, in agreement with the Member States concerned, for participation in research and development programmes undertaken by several Member States, including participation in the structures created for the execution of those programmes; and (2) Article 187 TFEU according to which the Union may set up joint undertakings or any other structure necessary for the efficient execution of Union research, technological development and demonstration programmes (both Articles are under Title XIX of the TFEU - Research and Technological Development and Space).

The proposal aims to implement Article 8 of the Commission proposal for Horizon Europe the future EU research and innovation (R&I) programme for 2021-2027, according to which, "European Partnerships shall be established for addressing European or global challenges only in cases where they will more effectively achieve objectives of Horizon Europe than the Union alone and when compared to other forms of support of the Framework programme". The Horizon Europe proposal has received the political agreement of the Council and the European Parliament.

1.2 Is the Union competence represented by this Treaty article exclusive, shared or supporting in nature?

Research is a shared competence between the EU and its Member States according to the TFEU. Article 4 (3) specifies that in the areas of research, technological development and space, the European Union can carry out specific activities, including defining and implementing programmes, without prejudice to the Member States' freedom to act in the same areas.

Subsidiarity does not apply for policy areas where the Union has **exclusive** competence as defined in Article 3 TFEU²⁹. It is the specific legal basis which determines whether the proposal falls under the subsidiarity control mechanism. Article 4 TFEU³⁰ sets out the areas where competence is shared between the Union and the Member States. Article 6 TFEU³¹ sets out the areas for which the Unions has competence only to support the actions of the Member States.

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https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12008E004&from=EN https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12008E006:EN:HTML

2. Subsidiarity Principle: Why should the EU act?

2.1 Does the proposal fulfil the procedural requirements of Protocol No. 2³²:

- Has there been a wide consultation before proposing the act?
- Is there a detailed statement with qualitative and, where possible, quantitative indicators allowing an appraisal of whether the action can best be achieved at Union level?

This proposal and the accompanying impact assessment were supported by a wide consultation of stakeholders, both during the preparation of the Horizon Europe proposal and - later on, all the candidates for European Partnerships. Member States were consulted via the Shadow Strategic configuration of the Horizon Europe Programme Committee. On candidates for institutionalised Partnerships based on Article 185/187 of the TFEU, an Open Public Consultation (OPC) was held between 11 September and 6 November 2019. Over 1 600 replies were received. In addition, targeted consultation activities were undertaken to prepare the present impact assessment. In particular, for each of the candidate partnerships, an external consultant interviewed a representative sample of stakeholders. The need for EU action as well as its added value were covered in those interviews.

The explanatory memorandum and the impact assessment (horizontal part, Section 3) contain a dedicated section on the principle of subsidiarity, as explained in question 2.2 below.

2.2 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the conformity with the principle of subsidiarity?

The impact assessment accompanying the proposal features a horizontal part on relevant common elements to all the candidate partnerships, including the conformity of the proposed initiative with the principle of subsidiarity (Section 3). Moreover, the individual assessments of each candidate partnership include additional details on subsidiarity, touching in particular on the specificities of a candidate partnership that could not be adequately reflected in the horizontal part of the impact assessment. This will also be reflected in the explanatory memorandum.

2.3 Based on the answers to the questions below, can the objectives of the proposed action be achieved sufficiently by the Member States acting alone (necessity for EU action)?

National action alone cannot achieve the scale, speed and scope of support to R&I needed for the EU to meet its long-term Treaty objectives, to deliver on the EU's strategic policy priorities (including the climate and energy goals set out in the Paris Agreement, and the European Green Deal), and to contribute to tackling global challenges and meeting the

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 $^{^{32}\} https://eur-lex.europa.eu/legal-content/\underline{EN/TXT/HTML/?uri=CELEX:12016E/PRO/02\&from=EN/2016E/PRO/02&from=EN/2016E/FRO/02&from=EN/2016E/FRO/02&from=EN/2016E/FRO/02&from=EN/2016E/FRO/02&from=EN/2016E/FRO/02&from=EN/2016E/FRO/02&from=EN/2016E/FRO/02&from=EN/2016E/FRO/02&from=EN/2016E/FRO/02&from=EN/2016E/FRO/02&from=EN/2016E/FRO/02&From=EN/2016E/FRO/02&From=EN/2016E/FRO/02&From=EN/2016E/FRO/02&From=EN/2016E/FRO/02&From=EN/2016E/FRO/02&From=EN/2016E/FRO/02&From=EN/2016E/FRO/02&From=EN/2016E/FRO/02&From=EN/2016E/FRO/02&From=EN/2016E/FRO/02&From=EN/2016E/FRO/02&From=$

Sustainable Development Goals (SDGs).

(a) Are there significant/appreciable transnational/cross-border aspects to the problems being tackled? Have these been quantified?

The thematic areas covered by the candidate partnerships feature a series of challenges in terms of cross-border/transnational aspects, need to pool resources, need for a critical mass to meet intended policy objectives, need to coordinate different types of actors (e.g. academia, industry, national and regional authorities) across different sectors of the economy and society, which cannot be tackled to the same degree by Member States alone. This is particularly true for the research and innovation (R&I) dimension of the proposed initiative: the importance of a multi-centre and interdisciplinary approach, cross-country data collection and research, and the need to develop and share new knowledge in a timely and coordinated manner to avoid duplication of efforts are key to achieve high quality results and impact. The Interim Evaluation of Horizon 2020 and the impact assessment of Horizon Europe provide extensive qualitative and quantitative evidence on the above points. In addition, Sections 1 and 2 of the individual impact assessments on the candidate partnerships include more detail on the necessity to act at EU-level in specific thematic areas. Finally, it is worth noting that not all Member States have the same capacity or R&I intensity to act on these challenges. As the desired policy objectives can be fully achieved only if the intended benefits are widespread across the Member States, this requires action at the EU-level.

(b) Would national action or the absence of the EU level action conflict with core objectives of the Treaty³³ or significantly damage the interests of other Member States?

As per Article 4(3) TFEU, national action does not conflict with core objectives of the Treaty in the area of R&I. The absence of EU level action in this area would however prevent the achievement of core objectives of the Treaty. Indeed, national action alone cannot achieve the scale, speed and scope of support to R&I needed for the EU to meet its long-term Treaty objectives on e.g. competitiveness, to deliver on the EU's strategic policy priorities, and to contribute to tackling global challenges and meet the Sustainable Development Goals (SDGs).

(c) To what extent do Member States have the ability or possibility to enact appropriate measures?

As foreseen by Article 4(3) TFEU, this proposal does not hamper Member States' ability to enact appropriate measures in the field of R&I. However, the scale and complexity of the policy objectives pursued by the present initiative cannot be fully addressed by acting at national level alone.

(d) How does the problem and its causes (e.g. negative externalities, spill-over effects)

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³³ https://europa.eu/european-union/about-eu/eu-in-brief en

vary across the national, regional and local levels of the EU?

As described in the horizontal part of the impact assessment accompanying the present proposal, several problems (e.g. on competitiveness, global challenges, demographic change) and their underlying causes affect the EU as a whole rather than individual Member States. Where important differences between Member States are present, these are described in Sections 1 and 2 of the individual impact assessments.

(e) Is the problem widespread across the EU or limited to a few Member States?

The problem of coordinating R&I efforts in the thematic areas covered by the candidate partnerships affects all Member States, albeit to different degrees. However, from a general EU perspective, available evidence shows that the EU as a whole needs to step up efforts and investments in thematic areas that are crucial to tackle present and future policy challenges on several fronts, e.g. ageing population, global technological trends, and climate change to name a few. The way these problems affect the EU and its Member States is described in the horizontal part of the impact assessment and in Sections 1 and 2 of the individual impact assessments.

(f) Are Member States overstretched in achieving the objectives of the planned measure?

As indicated in the horizontal part of the impact assessment and in Sections 1 and 2 of the individual assessments, the sheer scale, speed and scope of the needed support to R&I would overstretch national resources, without guaranteeing the achievement of the intended objectives. Acting at EU-level would achieve greater impact in a more effective and efficient manner.

(g) How do the views/preferred courses of action of national, regional and local authorities differ across the EU?

No specific differences between the views of national, regional and local authorities emerged from the stakeholder consultation.

2.4 Based on the answer to the questions below, can the objectives of the proposed action be better achieved at Union level by reason of scale or effects of that action (EU added value)?

EU funded R&I activities, including those covered by the present proposal, produce demonstrable benefits compared to the corresponding national and regional initiatives, due to the scale, speed and scope achievable by acting at the EU level. In addition, the proposed initiatives should be seen as complementary and reinforcing national and sub-national initiatives in the same area.

(a) Are there clear benefits from EU level action?

Quantitative and qualitative evidence of the benefits of EU level action are available in the interim evaluation of Horizon 2020 and in the impact assessment of Horizon Europe, among others. An analysis of the emerging challenges in each thematic areas, of the EU's competitive positioning, as well as feedback gathered from different types of stakeholders for the present impact assessment indicate that EU level action remains appropriate also for the present proposal. In addition, the benefits of acting at EU-level have been illustrated by the success and the impact achieved by the predecessors to the proposed initiative.

(b) Are there economies of scale? Can the objectives be met more efficiently at EU level (larger benefits per unit cost)? Will the functioning of the internal market be improved?

EU funded R&I activities, including those covered by the present proposal, produce demonstrable benefits compared to the corresponding national and regional initiatives, due to the scale, speed and scope achievable by acting at the EU level. This is the case both in terms of effectiveness in achieving intended policy objectives, but also in terms of efficiency. Positive impact is also visible in terms of competitiveness: recent data on EU funded R&I activities indicate that EU-funded teams grow 11.8% faster and are around 40% more likely to be granted patents or produce patents applications than non-EU funded teams. Efficiency gains are also visible in terms of dissemination of results to users beyond national borders, including SMEs and citizens. EU funded R&I is more effective in leveraging private investment. Finally, there are clear additionality benefits (i.e. EU R&I funding does not displace or replace national funding), as the EU focuses on projects that are unlikely to be funded at national or regional level. Overall, this is beneficial to the functioning of the internal market in several respects, including human capital reinforcement through mobility and training, the removal of barriers to cross-border activity for economic players including SMEs, easier access to finance and to relevant knowledge and research, and increased competition in the area of R&I.

(c) What are the benefits in replacing different national policies and rules with a more homogenous policy approach?

A homogeneous policy approach in the various thematic areas covered by the present proposal would reduce fragmentation and increase efficiency and effectiveness in meeting the intended policy objectives. Indeed fragmentation, persisting barriers in the internal market and differences in the resources available to Member States are some of the key problems that stand in the way of fully achieving the intended policy objectives and reaching the required critical mass to obtain tangible results. Specific detail on how these issues differ in each thematic area are illustrated in Sections 1 and 2 of the individual impact assessments, so as to reflect the specificities of each case.

(d) Do the benefits of EU-level action outweigh the loss of competence of the Member States and the local and regional authorities (beyond the costs and benefits of acting at

national, regional and local levels)?

The proposed initiative does not lead to a loss of competence of the Member States. In fact, the proposed initiative should be seen as complementary and reinforcing national and subnational initiatives in the same area. Previous quantitative and qualitative assessments of Horizon Europe and Horizon 2020 have shown that the proposed EU-level action do not displace national ones and tend to concentrate on initiatives that would not have been funded by the Member States themselves, or would not have reached the same scale and ambition without EU-level intervention, due to their complexity and trans-national nature.

(e) Will there be improved legal clarity for those having to implement the legislation?

Yes. The proposed initiatives will be implemented in line with the Horizon Europe single set of rules for participation; this will ensure increased clarity and legal certainty for end beneficiaries, other stakeholders and programme administrators. It will also reduce the administrative burden for beneficiaries, and for the Commission services. In addition, the accessibility and attractiveness of the broader Horizon Europe programme, in particular for applicants with limited resources, would be sustained.

3. Proportionality: How the EU should act

3.1 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the proportionality of the proposal and a statement allowing appraisal of the compliance of the proposal with the principle of proportionality?

The principle of proportionality underpins the entire analysis of the candidate partnerships. Specifically, the analysis included in the accompanying impact assessment is structured along the following logic: 1. Justification of the use of a partnership approach in a given area (including considerations on additionality, directionality, link with strategic priorities) instead of other forms of intervention available under Horizon Europe; 2. If the partnership approach is deemed appropriate, proportionality considerations guide the assessment of which type of partnership intervention (collaborative calls, co-programmed, co-funded or institutionalised partnership) is most effective in achieving the objectives. This will also be reflected in the explanatory memorandum.

3.2 Based on the answers to the questions below and information available from any impact assessment, the explanatory memorandum or other sources, is the proposed action an appropriate way to achieve the intended objectives?

The proposed initiative only focuses on areas where there is a demonstrable advantage in acting at the EU-level due to the scale, speed and scope of the efforts needed for the EU to meet its long-term Treaty objectives and deliver on its strategic policy priorities and commitments. In addition, the present proposal leaves full freedom to the Member States to

pursue their own actions in the policy areas concerned. This will also be reflected in the explanatory memorandum.

(a) Is the initiative limited to those aspects that Member States cannot achieve satisfactorily on their own, and where the Union can do better?

The proposed initiative only focuses on areas where there is a demonstrable advantage in acting at the EU-level due to the scale, speed and scope of the efforts needed for the EU to meet its long-term Treaty objectives and deliver on its strategic policy priorities and commitments.

(b) Is the form of Union action (choice of instrument) justified, as simple as possible, and coherent with the satisfactory achievement of, and ensuring compliance with the objectives pursued (e.g. choice between regulation, (framework) directive, recommendation, or alternative regulatory methods such as co-legislation, etc.)?

For each of the candidate partnerships, the analysis carried out in the accompanying impact assessment has explored several options for implementation. A comparative assessment of the merits of each option also included an analysis of the simplicity of the intervention, its proportionality and effectiveness in achieving the intended objectives. This is reflected in the fact that a tailored approach has been suggested for each candidate partnership, ranging from looser forms of cooperation to more institutionalised ones, depending on the intended policy objectives, specific challenges, and desired outcome identified in each case.

(c) Does the Union action leave as much scope for national decision as possible while achieving satisfactorily the objectives set? (e.g. is it possible to limit the European action to minimum standards or use a less stringent policy instrument or approach?)

The proposed approach leaves full freedom to the Member States to pursue their own actions in the policy areas covered by the present proposal.

(d) Does the initiative create financial or administrative cost for the Union, national governments, regional or local authorities, economic operators or citizens? Are these costs commensurate with the objective to be achieved?

The proposed initiatives do create financial and administrative costs for the Union, national governments and, depending on the chosen mode of implementation, for regional and local authorities. In addition, economic operators and other stakeholders potentially involved in the candidate partnerships will also incur some costs linked to implementation. The financial cost of the proposed initiative is covered under the Horizon Europe programme. Its exact amount is still subject to political decision. As regards the candidate partnerships and the different modes of implementation (co-programmed, co-funded, institutionalised), the relevant costs and benefits are assessed in the individual impact assessments covering each candidate partnership. The additional administrative costs of implementation via partnerships are

limited, when compared to the administrative costs of implementation through traditional calls. As indicated by comparable experience with previous initiatives and in feedback provided by a variety of stakeholders, these costs are expected to be fully justified by the benefits expected from the proposed initiative. Where available, additional details on costs are provided in Annex 3 of the impact assessment.

(e) While respecting the Union law, have special circumstances applying in individual Member States been taken into account?

Where relevant, differences between Member States in capacity and stage of advancement of R&I in specific thematic areas have been taken into account in the individual impact assessments.

Annex 6 Additional background information

1. BACKGROUND INFORMATION FOR ALL INITIATIVES

1.1. Selection criteria of European Partnerships

Partnerships based on Article 185 and 187 TFEU shall be implemented only where other parts of the Horizon Europe programme, including other forms of European Partnerships would not achieve the objectives or would not generate the necessary expected impacts, and if justified by a long-term perspective and high degree of integration. At the core of this impact assessment is therefore the need to demonstrate that the impacts generated through a Partnership approach go beyond what could be achieved with traditional calls under the Framework Programme – the Baseline Option. Secondly, it needs to assess if using the Institutionalised form of a Partnership is justified for addressing the priority.

The necessity test for a European Partnership (as set out in the Horizon Europe regulation) has two levels:

- 1. The justification for implementing a priority with a European Partnership to address Horizon Europe and EU priorities. This is linked to demonstrating that a European Partnership can produce added value beyond what can be achieved through other Framework Programme modalities, notably traditional calls in the work programmes (Option 0 Baseline).
- 2. The justification for the use of the form of Institutionalised Partnership: Once it has been demonstrated that a partnerships approach is justified, co-programmed and/or co-funded forms are considered for addressing the priorities as they are administratively lighter, more agile and easier to set-up (Options 1 and/or 2). As Institutionalised Partnerships require setting up a legal framework and the creation of a dedicated implementation structure, they have to justify higher set-up efforts by demonstrating that it will deliver the expected impacts in a more effective and efficient way, and that a long-term perspective and high degree of integration is required (Option 3).

The outcomes of the 'necessity test' is presented together with the preferred option.

Figure 6 Horizon Europe selection criteria for the European Partnerships

Common selection criteria & principles	Specifications
1. More effective	Delivering on global challenges and research and innovation objectives
(Union added value) clear impacts for the EU and	Securing EU competitiveness
its citizens	Securing sustainability
	Contributing to the strengthening of the European Research and Innovation Area
	Where relevant, contributing to international commitments

Common selection	Specifications
criteria & principles	Specifications
2. Coherence and synergies	Within the EU research and innovation landscape
sylici gies	Coordination and complementarity with Union, local, regional, national and, where relevant, international initiatives or other partnerships and missions
3. Transparency and openness	Identification of priorities and objectives in terms of expected results and impacts
	Involvement of partners and stakeholders from across the entire value chain, from different sectors, backgrounds and disciplines, including international ones when relevant and not interfering with European competitiveness
	Clear modalities for promoting participation of smes and for disseminating and exploiting results, notably by smes, including through intermediary organisations
4. Additionality	Common strategic vision of the purpose of the European Partnership
and directionality	Approaches to ensure flexibility of implementation and to adjust to changing policy, societal and/or market needs, or scientific advances, to increase policy coherence between regional, national and EU level
	Demonstration of expected qualitative and significant quantitative leverage effects, including a method for the measurement of key performance indicators
	Exit-strategy and measures for phasing-out from the Programme
5. Long-term	A minimum share of public and/or private investments
commitment of all the involved parties	In the case of institutionalised European Partnerships, established in accordance with article 185 or 187 TFEU, the financial and/or in-kind, contributions from partners other than the Union, will at least be equal to 50% and may reach up to 75% of the aggregated European Partnership budgetary commitments

1.2. Overview of potential functions for a common back office among Joint Undertakings

Functions	Current situation	Option of joint back- office	Comments
Organising calls for grant and proposal evaluations	Each JU organises this independently.	A central organisation of evaluation, logistics, contracting evaluators, managing the data of the evaluation results Central database of potential evaluators with domain expertise in thematic areas of partnerships	The evaluations would still need to be supervised by the Scientific staff of the individual Joint Undertakings (consensus meetings of expert evaluators etc)
Human Resources related matters	Each JU has own HR policy and resources Quite some resources spent on recruitment in some JUs	More generic resources and expertise for HR matters More consistency in HR	Ensuring consistency with EC HR policies is already in place

Financial management	Some HR facilities are procured from external contractors Some JUs have a Service Level Agreement with COM for HR Each JU conducts own financial contract management; differences between JUs Each JU is audited separately. Auditing at project level more frequent than in other Horizon 2020 parts and outsourced by JUs thus differences ECA: too many audits on JUs	policy Shared HR investment for specialised expertise (IP and legal) Financial management by one core team of financial staff Would reduce the number of interfaces for audits and simplifies the auditing of the all JUs Harmonisation of project auditing	Simplifies the harmonisation of financial management across JUs in line with Horizon Europe
Communication (internal and external)	Each JU has a separate communication strategies, teams and resources	A common back-office can support activities such as event organisation, dissemination of results, setting up website communication Can help create a more visible Partnership brand	A considerable share of communication activity is partnership specific (addressing particular target groups, synthesising project results) however there are generic communication activities that can be shared Needs to avoid duplication of efforts
Data management on calls, project portfolios, information on project results	Most JUs but not all use e- Corda for project data Overall IT integration of JUs still difficult	Harmonised data management Reduction of IT systems and support that is procured	This will need to happen regardless of the common back office but will likely be more smooth if managed centrally

2. BACKGROUND INFORMATION FOR THIS SPECIFIC INITIATIVE

2.1. Bio-economy and the bio-based industry: definitions and background information

The bioeconomy is defined as, "all sectors and systems that rely on biological resources (animals, plants, micro-organisms and derived biomass, including organic waste), their functions and principles. It includes and interlinks: land and marine ecosystems and the services they provide; all primary production sectors that use and produce biological resources (agriculture, forestry, fisheries and aquaculture); and all economic and industrial sectors that use biological resources and processes to produce food, feed, bio-based products, energy and services. Its sectors and industries³⁴ have strong innovation potential due to their use of a wide range of sciences, enabling and industrial technologies, along with local and tacit knowledge³⁵." While biotechnology is at the heart of bio-based processes, health biotechnology and biological medicines are not included in the European Union's (EU) bioeconomy definition. According to the Joint Research Centre³⁶, in 2015 the bioeconomy in the EU-28 generated ~EUR 2.3 trillion of turnover, which was a 5% increase from 2014. Applying the newest methodology, the JRC estimates³⁷ that in 2015 for the EU-28 the bioeconomy reached €1,460.6 billion value added, which is 11% of the GDP. Bio-based industries accounted for over EUR 600 billion of this total. However, it should be noted that in their review of quantitative approaches for measuring the contribution of the bioeconomy to the total economy, authors stress the lack of harmonized approaches for cross-country comparison, with the exception of the European Commission Joint Research Centre (JRC) dashboards for the EU Member States. The quantification reported in these dashboards follows a methodology elaborated by the JRC in collaboration with the nova-Institute. As example of measurements of bioeconomy size, JRC estimates that 20% of the Finnish chemical industry contributed to the bioeconomy in 2015, whereas the bio-based proportion of the same industry was estimated at 36% by the Natural Resources Institute Finland (Luke) for the same year. This implied a variation in the value added of the bio-based chemical industry ranging from €348,000 (JRC) to €734,000 (Luke). Because of methodological heterogeneities, the JRC reports the size of Finland's bioeconomy to be €13 billion, or 7% of the GDP in 2015, based on the value added approach, whereas the official statistics of Luke indicate considerably higher values of €21.3 billion or 12% of the GDP. Such a large difference highlights the need for a more objective, unified approach to quantify the size of the bioeconomy. The JRC estimate that the bioeconomy added EUR 621 billion of value in the EU, representing 4.2% of the EU's Gross Domestic Product (GDP) and provided employment to over 18 million persons in the EU, mainly in agriculture and the manufacture of food and beverages. Bio-based industries employ ~4 million people in the EU³⁸. In 2015, the highest value-added annual growth occurred in the manufacture of bio-based chemicals (excluding biofuels) (+26%), bio-electricity production (+15%) and rubber and bio-based plastics manufacture (+13%), generating altogether an additional EUR 3.5 billion of value

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Bio-based industries include: forest-based industries, bio-based chemicals and plastics, paper & paper products, biofuels & bioenergy, bio-based textile sector and pharma.

³⁵ European Commission. A sustainable bioeconomy for Europe: strengthening the connection between economy, society and the environment-Updated bioeconomy strategy. European Commission (2018).

³⁶ European Commission. Brief on jobs and growth of the bioeconomy 2009-2015. European Commission's Knowledge Centre for Bioeconomy, Joint Research Centre.

³⁷ European Commission. How big is the bioeconomy (2020), Joint Research Centre

³⁸ Cefic. Landscape of the European Chemical Industry 2018

added compared to 2014³⁹. Further, it is estimated that one million new jobs could be created in the bio-based industries by 2030. It is anticipated that the biotechnology sector will play a key role in realising this potential⁴⁰.

The transition to a bio-based economy is powered by several drivers. These include⁴¹;

• the need to develop an environmentally, economically and socially sustainable global economy • an over-dependency of many countries on fossil fuel imports and therefore their need to diversify energy sources • the anticipation that fossil fuels such as oil, gas and coal will reach peak production soon • tackling climate change by taking measures to reduce GHG emissions • and the need to stimulate regional and rural development.

For instance, by replacing fossil-based products with bio-based products (which tend to have a smaller carbon footprint⁴²) the chemical industry can make a critical contribution to the EU's climate goals, whilst simultaneously generating new job opportunities in the regions⁴³. There is potential in major industrial sectors such as chemicals and plastics to replace fossil-based carbon with renewable and recycled carbon as raw materials. Sources of renewable and recycled carbon from all types of biomass • recycled carbon from recycling of already existing plastics and other organic chemistry products (mechanical and chemical recycling) • recycled carbon from direct CO2 utilisation of fossil point sources (while they still exist) as well as from permanently biogenous point sources and direct air capture.

Globally, governments and private companies are already providing support and investing in the transformation of the chemical industry⁴⁵. Further, most of the large chemical and pharmaceutical producers have sustainability high on their agendas. Many of them are setting targets to improve the sustainability of their products in the mid to long term to 2050⁴⁶. To achieve these targets businesses are improving sustainability in their entire value chains by considering: sustainable feedstock for their products, use of renewable energy in the manufacturing process, and reducing the environmental impact of the product end-of-life and disposal.

In the EU, the European Environmental Agency (EEA) has been advising that bio-based and biodegradable alternatives to fossil equivalents should be used where the risk of dispersion into the ecosystem is high, e.g. lubricants, materials that are subject to wear and tear, and disposable products.

³⁹ European Commission. A sustainable bioeconomy for Europe: strengthening the connection between economy, society and the environment-Updated bioeconomy strategy. European Commission

⁴⁰ European Commission. A sustainable bioeconomy for Europe: strengthening the connection between economy, society and the environment-Updated bioeconomy strategy. European Commission

⁴¹ IEA n. d. Bio-based chemicals – Value-added products from biorefineries (2018)

⁴² Note: not all bio-based products have a smaller carbon footprint when compared to their fossil equivalents

⁴³ Bio-based Industries Consortium. Strategic Innovation & Research Agenda (SIRA) – Bio-based industries for development and growth in Europe (2017).

⁴⁴ Carus M, Raschka A. nova-Paper #10: Renewable Carbon is Key to a Sustainable and Future-Oriented Chemical Industry - Bio-based Economy (2019).

⁴⁵ LBNet. UK Top Bio-based Chemicals Opportunities (2017)

⁴⁶ LBNet. UK Top Bio-based Chemicals Opportunities (2017)

The raw materials used by the chemicals industry are ~50% organic (fossil and bio-based) and ~50% inorganic (minerals, metals)⁴⁷. The chemicals, plastics and pharmaceuticals sectors include several fully bio-based (e.g. natural dyes and pigments, enzymes, fatty acids) and partly bio-based products. Based on Eurostat data, in 2015, out of 534 products in the NACE Division 20 (Manufacture of chemicals and chemical products), 110 products were fully or partly biobased. Around 40% of these 110 products were 100% bio-based (e.g. tanning extracts of vegetable origin, sorbitol, tall oil), 24% of these products had a bio-based share of at least 10% (e.g. ethylene glycol, carboxylic acid, adipic acid) and the remaining 36% of products had lower bio-based shares (e.g. acetic acid, methanol, epoxy resins). Most of the products (424 in total) in the NACE Division 20 are therefore non bio-based⁴⁸. Hence, there is potential to increase the share of bio-based in partly bio-based products, and to research and develop methods for manufacturing bio-based versions of fossil-based products.

Environmental benefits

Chemicals or materials produced from biomass can help to reduce CO2 emissions, by replacing fossil-based resources and feedstocks. Any fossil-based ingredient can be replaced by renewable biomass resources or biomass residues. The carbon in fossil resources was captured millions of years ago and is released at the fossil-based products' end of life. This release of carbon dioxide (CO2) contributes to an increase of greenhouse gas concentration in the atmosphere. Greenhouse gases are one of the major drivers of climate change. To stay below the 1.5-2°C target of global warming, 70% of all coal reserves and at least one third of oil and natural gas reserves need to stay in the ground or their CO2 emissions have to be kept from entering the atmosphere. In comparison, CO2 released by renewable resources was recently captured and will be captured again when biomass is regrown to produce new products. This way, the carbon is kept in a shorter cycle (under sustainable cultivation practices). When biomass is used instead of fossil resources, fossil carbon can remain in the ground. This way, renewable biomass resources contribute to limiting climate change and global warming. As bio-based products are produced from plants that have sequestered atmospheric carbon dioxide during their growth, they can help reduce carbon dioxide emissions associated with fossil-based plastic and contribute to climate change mitigation. For example, bio-based polyethylene resin produced by the Brazilian bioplastic company Braskem sequesters 2.15 tonnes of CO2eq. for every tonne of resin produced i.e. it acts as a carbon sink. In comparison, the production of traditional oil-based polyethylene emits 1.83 tonnes of CO2eq ⁴⁹. However, it should be noted that most bio-based plastics have the same product characteristics as their traditional oil-based equivalent. For example, biobased PET is identical to fossil-based PET. Simply because a bio-based plastic is made from natural resources doesn't mean it is biodegradable. Bio-based plastics can be just as durable as oilbased plastic. Bio-based plastic with improved barrier properties for gases (e.g. carbon dioxide and oxygen) can lead to a longer shelf-life of packaged products. Synvina's recylable PEF⁵⁰ offers a significant advantage to the packaging industry in comparison to alternative

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⁴⁷ Piotrowski S, Carus M, Carres D. European Bioeconomy in Figures 2008-2015: Update, April 2018

⁴⁸ Piotrowski S, Carus M, Carres D. European Bioeconomy in Figures 2008-2015: Update, April 2018

⁴⁹ NNFCC, 2018. Market Perspective: Bio-based & Biodegradable Plastic in the UK (2019)

Synvina, n.d. PEF – Game-changing plastic. Available at: https://www.synvina.com/products/pef/ Date last accessed: 29/03/2019. PEF is referred as the next generation polyester with high potential to replace polyethylene terephthalate (PET), a durable fossil-based polymer. PEF offers numerous benefits compared to PET, such as, superior barrier performance as well as mechanical and thermal properties; high glass transition temperature and lower melting point; recyclable and hence reduced carbon footprint. It cost competitive at industrial scale.

bio-based plastics or barrier materials. Moreover, it also offers a higher mechanical strength, thus thinner PEF packaging can be produced and fewer resources are required. PEF is suitable as the main component or as a barrier layer in cups and trays, flexible packaging as well as bottles for carbonated and non-carbonated soft drinks, water, dairy products, still and sports drinks, alcoholic beverages as well as personal and home care products. An important challenge for the growth of bio-based plastics is the communication of sustainability drivers and credentials to raise awareness, social acceptance and uptake of bio-based plastic products. Therefore, the entire value chain must ensure accurate knowledge transfer to the brandowners to make correct and poignant labelling for the end-consumer to understand any positive environmental impact of their choice to purchase a bio-based plastic product.

Low toxicity of bio-based products is an important benefit for both environment and consumer use, e.g. in specific sectors of bio-based industry such as packaging for food contact, or cosmetics. Petro-chemical alternatives never satisfy the natural-based attribute and could potentially be more toxic in comparison. Manufacturers also use popular ingredients from the health and food sectors in cosmetic products. Different biobased materials (strictly from biomass and not inorganic materials) have different functionalities. For example, substances extracted from plants and other types of biomass can be used to increase shelf life and protect against UV degradation. Many natural substances have bioactive effects such as preserving, healing, anti-inflammatory or emollient effects. Lox toxicity is an important environmental benefit of bio-based agrochemicals, which can contribute to biodiversity preservation, especially if combined with sustainable management of biomass cultivation (e.g. mixed rotation systems, agro-forestry, use of perennial crops, use of certification schemes etc). Bio-based crop protection products start degrading soon after application resulting in little or no toxic residue 5152. However, the drawback is that they need to be applied more frequently in order to be effective. Examples of crop protection products include vegetable or fish oils as well as plant essential oils.

As a result of the potential toxicity, often even at very low levels, the application of crop protection products is strictly regulated in Europe⁵³. Policy control measures in the EU are driven by the objectives of protecting human health and the environment (consumers, operator safety, protection of water quality and biodiversity).

European resource independence

A strong European bioeconomy would replace fossil-based products with renewable alternatives, and reduce the EU's dependency on fossil resources like oil, coal and natural gas. Biomass resources can be grown locally in the EU, in contrast to fossil resources, of which the majority is imported. In the long run, the organic chemistry will strive to become circular and apply reusable raw materials to become largely independent from limited fossil resources.

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Saxena, H., O., Tripathi, Y., C., Kakkar, A., Mohammad, N., 2014. Botanicals as biopesticides: Active chemical constituents and biocidal action. DOI: 10.13140/2.1.2182.4802. Available at: https://www.researchgate.net/profile/YOGESH_TRIPATHI/publication/271073676_Botanicals_as_biopesticides_Active_chemical_constituents_and_biocidal_action/links/54f142690cf2f9e34efdc2f6/Botanicals-as-biopesticides-Active-chemical-constituents-and- biocidal-action.pdf Date last accessed: 29/03/2019 [11] Warwick Crop Centre, 2018. What are biopesticides? The AMBER project

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⁵³ Eurostat, 2018. Agri-environmental indicator - consumption of pesticides

This could in the future also be achieved with recycling and CO2 utilisation, but currently biomass is the most readily available option.

The sustainability challenge

Studies have shown considerable potential for the cultivation of biomass for energy and material use on a global level, even under consideration of sustainability criteria such as biodiversity preservation, climate protection or food security. In a sustainable bioeconomy, cultivation and processing of biomass has to be based on sustainable agriculture and forestry, where environmental aspects as well as social and labour standards are given serious consideration. Besides agriculture and forestry, residual biomass can be an important resource for a sustainable bioeconomy. Strong instruments to support the development of a sustainable bioeconomy are certification schemes and labels for renewable raw materials and bio-based products.

The European chemical industry needs to step up the efforts on the path to actively increase its sustainability. One of the goals is to make products that are less harmful to the environment and less toxic to the consumers, and environment, but perform just as well as conventional products or even better. Sourcing an increasing part of its feedstock from biomass is an important way for the chemical industry to become more sustainable. Substituting fossil resources with biomass generally leads to reduced GHG emissions and is an important tool to reach our climate targets. The current share of renewable raw material use in the EU organic chemical industry was estimated by Cefic at around 10% in 2015, but the Bio-based Industries Consortium (BBI JU SIRA2017) set the ambition to reach a bio-based feedstock share of 25% by the year 2030. Many technical solutions to replace fossil resources by biomass have already been developed and currently efforts are undertaken to scale up the production of new, more sustainable products made from biomass.

The contribution to UN Sustainable Development Goals

The bioeconomy is at the centre of sustainable development and products made from renewable biomass resources can contribute to achieving the UN Sustainable Development Goals. The production of bio-based chemical products supports in particular the achievement of the following SDGs: SDG 8 - Decent work and economic growth: The bio-based chemical industry can provide new jobs and additional income, in particular in rural communities, and create opportunities to export value-added bio-based products. SDG 9 - Industry, innovation and infrastructure: The bio-based chemical industry is evolving quickly. Many bio-based technologies are entirely new ideas, which require and support innovation and infrastructure development. SDG 11 - Sustainable cities and communities: Bio-based chemistry links surrounding rural areas to urban centres, e.g. by setting up innovative processing plants ("biorefineries") that transform agricultural residues and parts of municipal solid waste into chemical building blocks. SDG 12 - Responsible consumption and production: The bio-based chemical industry contributes to optimised use of biomass and wastes, decouples production and consumption from fossil energy sources and raises consumer awareness. SDG 13 -Climate action: The use of renewable biomass resources in the chemical industry reduces the use of fossil-based resources and their related greenhouse gas emissions. SDG 15 - Life on land: Through promoting sustainable management of forests and natural resources, bio-based chemistry can support the combat against desertifi

Circularity issues

The bioeconomy can contribute to a circular economy, which helps us to move away from a linear economy of "take, make and dispose". The bioeconomy and circular economy go hand in hand. Reducing waste and making optimal use of natural resources are important goals of both the circular economy and the bioeconomy. The circular economy strives to reduce resource consumption. Roughly 90% of the raw materials used in manufacturing become waste before the product leaves the factory. And most products get thrown away within the first six months of their life. But even in a fully circular economy, some input of new raw materials remains necessary. Biomass can provide a sustainable input, because it is renewable and regrows naturally. Chemicals and materials from biomass are part of the natural cycle. They can provide a sustainable input of new materials for a circular economy. The bioeconomy can furthermore make use of many (organic) waste streams and hereby support the circular economy.

Within agriculture, more than half the globally harvested dry mass consists of agricultural residues and inedible biomass, such as cereal and legume straw; shoots of tuber, oil and sugar; vegetable crop stalks, leaves and shoots; and fruit and nut tree prunings. A major barrier to increasing the use of agricultural and forestry residues are the costs associated with adapting harvest logistics, which are often higher than costs of primary fossil materials. Also, residues are an important factor for soil quality and need to remain on the field to a certain extent in order to avoid the depletion of nutrients. Local biorefining systems that smartly match residue supply and material demand need to be developed, as the wide dispersal of residues does not fit the economies of scale of the existing industrial oilbased production system.

- Municipal solid waste contains food waste, which is a potential feedstock for the bio-based chemistry – signifying a high amount of fermentable materials which are mixed up with non-fermentable materials, which are thus difficult to access.

According to recent insights from the S2Biome project, the amount of available lignocellulosic biomass in the EU by 2030 is estimated to be at least around one billion tonnes. However, the biomass types that are currently used by the chemical industry are mainly sugar (from sugar beets and starchcrops) and vegetable oils such as rapeseed, soya and palm oil. Switching to other types of feedstock proves difficult both from a technical and an economic perspective.

– Marine streams: The oceans offer large opportunities for the cascading use in the bioeconomy. These include for example the use of fisheries discards (~40% of caught fish), algal biorefineries, seaweed farming, multi-use of marine space in off-shore platforms, zero-waste and circular aquaculture, new products from jellyfish, new pharmaceuticals from marine ecosystems. Stakeholders mentioned algae in particular as a promising feedstock choice for the future. The BBI-JU also supports a number of algae-based projects for the bioeconomy, e.g. the ABACUS project, the VALUEMAG project or the MAGNIFICENT project. The results of several previous projects, however, also give reason for some caution of expectations. The utilisation of algae is not easy and so far quite costly.

Focused research and development could be directed towards cascading use and utilizing of currently unused waste streams. There are several EU projects ongoing that focus on the

utilization of such waste streams: Some examples are the Lifecab project⁵⁴, the Embraced project⁵⁵ and the Agrimax project⁵⁶

Empowering primary producers and global best practice

- Enable producers to make informed decisions on the use of their residues
- Ensure that producers are receiving a fair price for collecting waste that can be used as a 3rd generation feedstock.
- Actively involve producers as stakeholders
- Relevant international example: US Biomass Crop Assistance Program, which provides funds to farmers and forester landowners that grow and harvest "non-conventional" biomass. Examples are perennial crops or agricultural and forestry residues, which are intended to be used for energy and bio-based products in biomass conversion facilities. A similar system could be established in the EU, e.g. via the Common Agricultural Policy.

Bringing solutions to the market

Many products on the market are already made from chemicals or materials based on renewable biomass resources, beyond traditional bio-based resources, such as wood or paper. The chemical industry already offers a broad variety of products made from renewable resources. Some examples include: compostable plastic bags, personal care products, natural detergents, plant-based drinking bottles, planting pots for garden use or automotive parts, e.g. insulation materials, or composites with natural fibres used in dashboards. Even though these products are made from biomass, they can look, feel and perform as conventional, fossilbased products or even better. For example, in the building sector, an increasing number of architects and construction companies return to applying construction materials produced from renewable resources, and it is more than just wood for the walls. Insulation, flooring and paints can be made from bio-based materials as well, where they provide a healthier and more comfortable indoor climate. Renewable raw materials are also widely used in cleaning products or packaging sectors. Biotechnology provides bio-based ingredients such as enzymes for detergents. Enzymes can help in reducing the environmental impact of washing and cleaning products by using less energy and water, while providing the same or better cleaning results under milder conditions.

Competitiveness of the EU bio-based industry

In 2015, 10% of the total volume of organic chemicals raw materials/feedstock used for EU chemicals production was bio-based. 2030 aspirational target is to increase bio-based

LIFECAB Project [Internet]. [cited 2019 Jan 7]. Available from:http://ec.europa.eu/environment/life/project/Projects/index.cfm?fuseaction=search.dspPage&n_proj_id =6190

⁵⁵ Embraced - Project - Establishing a multi-purpose biorefinery for the recycling of the organic content of Absorbent Hygiene Products Waste in circular economy. [Internet]. [cited 2019 Jan 21]. Available from: https://www.embraced.eu/project

⁵⁶ AGRIMAX – Agri and food waste valorisation co-ops based on flexible multi-feedstocks biorefinery processing technologies for new high added value applications [Internet]. [cited 2019 Jan 7]. Available from: http://agrimax-project.eu/

feedstock use to 25%. Besides the product group specific analysis of barriers (see market segment analysis below), some wider issues exist that concern the chemical industry in the bioeconomy. These are referred to as general barriers, and can be classified according to increasing the bio-based share in the chemical industry into six main categories. For each of these categories, several actions can be attributed.

Barriers 1, 4, 5 and 6 are in direct scope of the present Impact Assessment. The barriers 2 and 3 remain of importance, however can be considered beyond the scope.

Barrier 1. Access to feedstock (including low availability of sustainable biomass, and non-level playing field with competing uses of biomass such as for bioenergy). Actions attributed: Increasing yields of production of biomass, establishing and identifying new sources of feedstock, increasing efficiency of biomass supply chains, developing sustainable biorefineries, and establishing a balance between various types of uses of sustainable biomass.

Barrier 2. Competition with established fossil industry (including bio-based alternatives not cost-competitive, and lower performance of bio-based alternatives). Actions attributed: Implementing market pull instruments (e.g. labelling, procurement, certification), reducing fossil feedstock support, increasing performance characteristics of bio-based products by R&D investments, promoting industry- or voluntary incentives.

Barrier 3. Regulatory barriers (including lack of policy harmonization, limited long-term reliability). Actions attributed: Harmonisation of standards, policies and regulations, providing stability and reducing risk by long-term regulatory policy, guidance, support and clarification for policy for bio-based products.

Barrier 4. Societal barriers (including lack of information, awareness and expertise, or unrealistically high expectations). Actions attributed: promoting labels, standards, improving education and training, design and implement visible, inclusive, transparent and coherent communication effort for the bioeconomy and bio-based sectors, improve participatory approaches and network building, improve social acceptance and promote trust to manage unrealistically high expectations.

Barrier 5. Markets, Finance & Investment (including low availability of funding for early stage and scale-up, low funding for start-ups and SMEs). Actions attributed: developing green investment funding schemes and programmes, reuce high transaction costs for start-ups and scale-up operations, support easier market entry of SMEs e.g. via innovative tax schemes and support measures, strengthen communication channels for financing opportunities.

Barrier 6. Research & Development (including ongoing need for funding, limited guidance and direction of R&D, and limited understand of ecological boundaries and innovation adoption and diffusion). Actions attributed: deploying additional, targeted financial instruments, improving access to finance for R&D opportunities, maximising impact of EU R&D programmes, enhancing knowledge on biodiversity, ecostystems and bioeconomy.

Key market segment study analysis (plastics/polymers, agrochemicals, surfactants, bio-based fibres, solvents, adhesives, cosmetics)

Plastics/polymers

The trend towards bio-based plastics is driven by changing consumer demands with increased awareness of environmental impacts of the plastics industry.

- To make plastic products more resource efficient and to reduce GHG emissions, the emphasis is on increasing the use of renewable feedstock using lower energy processing, while reducing the dependency on fossil resources.
- Several innovative small and large companies are responding to consumer demands towards a more sustainable plastics economy. These companies have made substantial investments in R&D for bio-based plastics designed with the circular economy in mind, e.g. PLA, PEF and bio-PTT.
- Bio-based production of plastics/polymers in Europe is >1,200 kt/yr, while fossil-based production is ~70,000 kt/yr.
- Therefore, out of the analysed product groups, the addressable market of fossil-based plastics/polymers production in Europe is the largest (large addressable market is considered as >10,000 kt).
- Diverse bioplastics are being developed that can be drop-ins, compostable and non-biodegradable, but few are truly biodegradable.
- Some bio-based plastics listed meet the desired sustainability characteristic for low GHG emissions, which is a key driver for thermoplastics. Low human toxicity is an important driver for some thermoplastics used in healthcare and food packaging, e.g. bio-PVC.
- Recyclability is the sustainability characteristic that most conventional plastics and their biobased alternative plastics already possess. However, some bio-based plastics, such as PLA and PHAs cannot be recycled with current well-established recycling infrastructure and there is evidence that recyclability is a desired sustainability characteristic of these bio-based plastics. Therefore, further R&D in product development and recycling techniques is required to ensure that recyclability does not compromise performance.
- Bio-based drop-ins may not be compostable/biodegradable but would be recyclable otherwise, biopolymers might conflict with recycling goals. Non-biodegradable biopolymers could also contribute to carbon sequestration.
- Biodegradability is considered an important end-of-life pathway, especially when recycling is no longer technically possible. Additives are available that could increase the rate of biodegradation in treated plastic products, though claims need to be appropriately verified.
- Producers of bio-based plastic should provide adequate labelling to inform customers of types of biobased plastics to raise awareness about bio-based plastic alternatives and end-of-life processing.
- Although TRLs for some the bio-based plastics listed are already at 9, there are some that require further R&D (including investment) and industrial trials to improve technical properties and reduce production costs to successfully grow at commercial scale.

• Some of the leading manufacturers are Genomatica, Versalis, Cargill, Synbra Technology, Novamont, BASF SE, Natureworks, Corbion, Braskem, Secos Group, Biome Technologies, FKuR Kunststoff, Innovia Films, and Toray Industries.

Agrochemicals

There is a growing market for fertiliser coatings that are bio-based and biodegradable, as well as for biostimulants (including chitosan, seaweed extracts) and biological seed treatment (including botanicals).

- Biodegradability, low human toxicity and low ecotoxicity are the desired sustainability characteristics in agrochemicals. However, the bio-based chemical has to at least have the same level of performance as the fossil-based agrochemical.
- Bio-based chemical building blocks such as bio-based lactic acid, methanol and fatty alcohols present an opportunity for converting conventional fossil-based agrochemicals into partly bio-based equivalents. The performance of the latter should be, at least, at par with the fossil-based agrochemicals.
- Bio-based crop protection products start degrading soon after application resulting in little or no toxic residue. However, the drawback is that they need to be applied more frequently in order to be effective. Formulation of bio-based crop protection products can be improved to address this issue.
- New bio-based crop protection products can help address the issue of pesticide resistance in pest populations.
- European agrochemical industry is strictly regulated. Use of new ingredients in products is subject to long and often expensive approval procedures. There is a low risk category within the legislation 1107/2009 that places plant protection products on the market. This could be readily adapted for speedier approval of biobased pesticides and is already ratified by the European Parliament. However, it is yet to be actioned by the European Commission.
- Key actors of European agrochemical industry include: Syngenta, Bayer Crop Science, Corteva (Dow Agrosciences, DuPont and Pioneer merger), BASF, Sipcam-Oxon

Surfactants

Bio-based surfactants are produced as high value products, typically for high-end customer products, such as personal care and home care products.

- Methyl ester sulfonate (MES) offers the biggest opportunity to shift from fossil to bio-based surfactants. It could be a bio-based alternative for linear alkyl benzene sulfonate (LAS) and has high potential to be used in cosmetic products.
- The demand for bio-based surfactants strongly depends on household spending.
- There is drive/requirement for clear labelling, so consumers can increasingly opt to buy product using biobased alternatives.

- The key drivers for bio-based surfactants are their biodegradability, lower human toxicity and lower ecotoxicity, especially in environments where these sustainability characteristics are required.
- Production of bio-based surfactants in Europe is
- \sim 1,100 kt/yr, while fossil-based production is \sim 2,400 kt/yr.
- The addressable market of fossil-based surfactants production in Europe is medium-sized (1,000-10,000 kt/yr) in comparison to the other eight product groups.
- Besides being made from renewable feedstock, the main advantages of bio-based surfactant are possible antimicrobial properties; better performance compared
- to fossil equivalents which allows to use smaller quantities of surfactants; better foaming properties; higher selectivity for application at lower temperatures, higher pH and salinity; ability to achieve regulatory compliances with regard to (environmental) safety and use of lowcost feedstocks (i.e. fats and oils, sugars).
- Due to the advanced product properties the use of biobased surfactants is possible in a wide range of product applications (cleaning, personal care, food processing, agrochemicals and textiles). However, these products remain niche due to their limited cost competitiveness compared to conventional products.
- Bio-based surfactants are usually used in end product formulations where the modification of one component has an impact on the overall composition and performance, which causes additional development costs. This cost barrier could be overcome by targeted support and funded research towards new product formulations. The clear advantage for companies is flexibility in composition, as long as a certain performance can be ensured.
- Due to the limited number of large-scale producers a secured steady supply of bio-based surfactants is uncertain which creates risk for suppliers like personal and home care producers.
- Key companies producing bio-based surfactants include Evonik, Ecover, Henkel, Saraya, Soliance, Wheatoleo and Nouryon.

Bio-based fibres

Bio-based man-made fibres production in Europe is >600 kt/yr, while fossil-based production is ~4,800 kt/yr.

- The addressable market of fossil-based man-made fibre production in Europe is medium-sized (1,000-10,000kt) in comparison to the other analysed product groups.
- Consumer demand and initiatives by producers have driven the increase in the use of biobased and recycled feedstock, as well as sustainability across the man-made fibres supply chain.
- Recyclability is the sustainability characteristic that all conventional and several bio-based alternatives have. However, recycling is not easy in case of blends such as fabric made of polyester and cotton with a small percentage of elastane. Another example is PLA which

cannot be recycled with PET in established recycling infrastructure. Therefore, there is scope for further R&D in recycling techniques for different fibres.

- There is a drive to make conventional plastics such as PET and nylon biodegradable by adding 'additives'. While these additives are available on the market, the claims of biodegradation rarely pass rigorous testing and review. However, it does show that biodegradability is considered important for synthetic polymers when they approach end-of-life and cannot be recycled anymore.
- The production of some biosynthetic fibres could potentially result in low GHG emissions and some have low toxicity effect.
- Some bio-based fibres, such as bio-PTT, can be produced at lower cost compared to their fossil-based equivalents, and have properties that surpass fossil-based equivalents in fibre applications.
- There are several bio-based man-made fibres that are still at research and demonstration scale. Further R&D and industrial trials are needed to bring these fibres to commercial scale. Example of an ongoing projects in Europe is FIBFAB (H2020 project) on PLA fibre.
- Some of the companies that are actively involved in

bio-based man-made fibres market include: DuPont (Sorona®), Sofila (use Arkema's Rilsan®), Aquafil, RadiciGroup (Radilon® DT 40EP25W), BASF, Solvay, Distrupol, Sateri (viscose), Lenzing (TENCELTM), AlgiKnit.

Solvents

Bio-based solvents production in Europe is <0.5 kt/yr, while fossil-based production is $\sim5,000$ kt/yr. The addressable market of fossil-based solvents production in Europe is medium-sized (1,000-10,000kt) in comparison to the other eight product groups.

- The uptake of bio-based solvents is driven by the EU policy on VOC emissions and by REACH. Those biobased alternatives which meet the criteria of low toxicity and low VOC, compared to the fossil-based counterpart, are likely to be considered as valid alternative provided that they meet the functionally requirements of the solvent in specific applications.
- Conventional and bio-based solvents identified are biodegradable (some more than others), and there is concerted effort from the industry to recover and recycle solvents where possible. This is driven by legislation that aims to reduce the adverse impact of solvents (VOCs) on human beings and the environment. It should be noted that solvents can be recovered and recycled in some sectors and applications but not in others.
- Industries are taking as many steps as possible to remain competitive, by reducing waste and recycling spent solvents. It is very important for producers, especially the ones who are using solvents for extraction, to be able to recycle and reuse the solvent. Extraction is a common processing step in chemical, food, pharmaceutical and mining industry.
- For products that are likely to end up in the environment, complete biodegradability is a relevant sustainability driver. This is the case of solvents that are typically used in formulation of cleaning products (household cleaners, personal care) or agrochemicals. However, the

biggest industrial end-group in which solvents are used are paints and coatings, in which solvents evaporate after the paint has been applied, thus dissipating into the air. In such cases, biodegradability is not a relevant sustainability driver.

- Many 'dedicated' bio-based solvents included in this analysis claim to have low toxicity effects compared to fossil equivalents.
- The production of some identified bio-based solvents has been reported to release less GHG emissions compared to fossil equivalents.
- Bio-based solvents need to meet the functional requirement of the fossil equivalents that they intend to replace in different applications. There is significant scope for R&D and demonstration scale projects to develop a wide range of bio-based solvents and formulations that can be used in different applications.
- Some of the companies actively involved in the biobased solvents market include: Cellulac, BioAmber, Green Biologics, DuPont-Tate & Lyle, Pennakem Europa SAS, Circa, Roquette, Cargill, Solvay-Rhodia

Adhesives

Production cost is an important driver in the adhesives segment.

- The key sustainability driver is to reduce human toxicity by lowering Volatile Organic Compounds (especially for the wood building industry which is one of the most significant markets for adhesives).
- Environmental and health concerns related to formaldehyde create a major opportunity for the development and growth of bio-based chemicals which could replace formaldehyde. Biobased 5-HMF and lignin derivatives are among the most promising candidates.
- A range of bio-based raw materials such as diacids, diols and natural polyols building blocks are available as a drop-in or dedicated replacement of fossil-based building blocks for adhesives and sealants.
- Keeping suitable mechanical properties while reducing the emission of VOCs is the key development and innovation trend in the adhesives segment.
- Bio-based alternatives must deliver the desired mechanical performance characteristics and water resistance requirements in adhesives. Meeting these requirements may initially rely on the development of mixed bio and fossil-based adhesives.
- Legislation may lead to accelerating the transition from synthetic adhesive to bio-based adhesives by regulating the presence of VOCs and the presence of recyclable materials, especially in the building industries.
- Some companies active in the development of new biobased adhesives are: VTT (Finalnd), Arkema (France), Weiss Chemie + Technik (Germany) and Covestro (Germany)

Cosmetics

The share of bio-based chemicals in cosmetics produced in the EU is about 40%, which is the highest among all product groups that are considered in RoadToBio.

- European consumers' emerging environmental awareness and a growing trend for natural products is driving the uptake of bio-based chemicals in cosmetics. Costs are less important constraints in the cosmetics segment.
- Biodegradability and low human toxicity are the main desired sustainability characteristics in the cosmetics product group. Bio-based products such as botanical extracts and vegetable oils have these key characteristics. However, bio-based solvents such as acetone are toxic and non-biodegradable, thereby presenting an opportunity for development and commercialisation of novel bio-based solvents that are safe to use and dispose.
- Functional ingredients and chemical building blocks used in cosmetics such as preservatives, solvents and surfactants are still mainly derived from fossil feedstock and therefore not sustainable. Low GHG emissions is a desired sustainability characteristic for building blocks such as solvents and surfactants that are used in cosmetics. The bio-based chemicals identified in the sample could lead to low GHG emissions compared to the fossil equivalents.
- By volume of use, botanical extracts and vegetable oils outweigh building blocks like lactic acid and succinic acid. In order to attain higher bio-based share in the cosmetics product group, these two subgroups will play a vital role and therefore should be the subject of further research and product development.
- Bio-based preservatives underperform in comparison to the fossil derived ones. This area of cosmetics presents an opportunity for the development and further growth of bio-based chemicals. European cosmetics industry is strictly regulated. Ingredients such as preservatives, UV-filters, nanomaterials or colorants are subject to long and often expensive approval procedures. Other ingredients must be safe for cosmetic use by meeting the requirements of EU legislations (cf. REACH and Cosmetic Regulation)
- Opportunities also exist in using alternate feedstocks like algae, and technology for the extraction and preservation of bioactive ingredients.

2.2. Glossary

1G feedstock First generation feedstock: the source of carbon is sugar, lipid or starch directly extracted from a plant. The crop is actually or potentially considered to be in competition with food.

- **2G** feedstock Second generation feedstock: the carbon is derived from cellulose, hemicellulose, lignin or pectin. For example this may include agricultural, foresty wastes or residues, or purpose-grown non-food feedstocks (e.g. Short Rotation Coppice, Energy Grasses).
- 3G feedstock Third generation feedstock: the carbon is derived from aquatic autotrophic organism (e.g. algae). Light, carbon dioxide and nutrients are used to produce the feedstock "extending" the carbon resouce available for biochemicals production. This means, however, that a heterotrophic organism (using sugar or cellulose to produce biochemicals) would not be considered as 3G.

Bio-based drop-in chemicals: bio-based versions of existing petrochemicals which have established markets. They are chemically identical to existing fossil-based chemicals.

Bio-based smart drop-in chemicals: a special sub-group of drop-in chemicals. They are also chemically identical to existing chemicals based on fossil hydrocarbons, but their bio-based pathways provide advantages compared to the conventional pathways.

Drop-in chemicals are considered to be 'smart drop-ins' if at least two of the following criteria apply:

- The Biomass Utilization Efficiency from feedstock to product is significantly higher compared to other drop-ins.
- Their production requires significantly less energy compared to other production alternatives.
- Time-to-product is shorter due to shorter and less complex production pathways compared to the fossil-based counterpart or other drop-ins.
- Less toxic or harsh chemicals are used or occur as by-products during their production process compared to the fossil-based counterpart or other drop-ins.

Dedicated bio-based chemicals: chemicals which are produced via a dedicated pathway and do not have an identical fossil-based counterpart. As such, they can be used to produce products that cannot be obtained through traditional chemical reactions and products that may offer unique and superior properties that are unattainable with fossil-based.



Brussels, 23.2.2021 SWD(2021) 37 final

PART 18/19

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT REPORT Accompanying the document

Proposal for a COUNCIL REGULATION establishing the Joint Undertakings under Horizon Europe

European Partnership for Clean Hydrogen

{COM(2021) 87 final} - {SEC(2021) 100 final} - {SWD(2021) 38 final}

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Glossary

Term or acronym	Meaning or definition
BEV	Battery Electric Vehicle
CCS / CCU	Carbon Capture and Storage/Carbon Capture and Utilisation
CEF	Connecting Europe Facility
CHP	Combined Heat and Power
EP	European Partnerships under Horizon Europe
FCEV	Fuel Cell Electric Vehicle
FCH JU (and FCH 2 JU)	Fuel Cells and Hydrogen Joint Undertaking, the current EU partnership on hydrogen research and innovation under Horizon 2020
GHG	Greenhouse Gas
HRS	Hydrogen Refuelling Station
InnovFin EDP	Energy Demo projects funded by the European Investment Bank's InnovFin programme
IPCEI	Important Projects of Common European Interest
KBA	Knowledge and research Based Actor
LNG	Liquid Natural Gas
NECP	National Energy and Climate Plan
PEM	Polymer electrolyte membrane (refers to electrolysi type of electrolyser)
PV	Photovoltaic Solar
SME	Small and Medium Enterprises
SMR	Steam Methane Reformer
SRIA	Strategic Research and Innovation Agenda
SoA	State of the Art
SOFC	Solid Oxide Fuel Cell
TRL	Technology readiness level

PART 1 - COMMON FOR ALL CANDIDATE INSTITUTIONALISED EUROPEAN PARTNERSHIPS

1. BACKGROUND AND CONTEXT TO EUROPEAN PARTNERSHIPS IN HORIZON EUROPE AND FOCUS OF THE IMPACT ASSESSMENT—WHAT IS DECIDED

1.1. Focus and objectives of the impact assessment

This impact assessment accompanies the Commission proposal for Institutionalised European Partnerships to be funded under Horizon Europe, the 2021-2027 Framework Programme for EU Research and Innovation (R&I). It sets out to help decide in a coordinated manner the right form of implementation for specific candidate initiatives based on a common approach and methodology to individual assessments². It also provides an horizontal perspective on the portfolio of candidate European Partnerships to identify further efficiency and coherence gains for more impact.

European Partnerships are initiatives where the Union, together with private and/or public partners (such as industry, public bodies or foundations) commit to support jointly the development and implementation of an integrated programme of R&I activities. The rationale for establishing such initiatives is to achieve the objectives of Horizon Europe more effectively than what can be attained by other activities of the programme.³

Based on the Horizon Europe Regulation, European Partnerships may be set up using **three different forms**: "Co-funded", "Co-programmed" and "Institutionalised". The setting-up of **Institutionalised Partnerships** involves new EU legislation and the establishment of dedicated implementing structures based on Article 185 or 187 of the Treaty on the Functioning of the EU (TFEU). This requires an impact assessment to be performed.

The Horizon Europe Regulation defines **eight priority areas**, scoping the domains in which Institutionalised Partnerships could be proposed⁴. Across these priority areas, **13 initiatives** have been identified **as suitable candidate initiatives** for Institutionalised Partnerships because of their objectives and scope. This impact assessment aims to identify whether 12 of these initiatives⁵ need to be implemented through this form of implementation and would not deliver equally well with traditional calls of Horizon Europe or other lighter forms of European Partnerships under Horizon Europe. This means assessing whether each of these initiatives meets the necessity test set in the **selection criteria** for European Partnerships in the Horizon Europe Regulation, Annex III.

This assessment is done **without any budgetary consideration**, as the overall budget of the Multiannual Financial Framework of the EU – and hence of Horizon Europe – for the next financing period is not known at this stage.⁶

¹ Horizon Europe Regulation (common understanding), https://data.consilium.europa.eu/doc/document/ST-7942-2019-INIT/en/pdf
² Passed on the Europe of Constant of Constant of the Europe of Constant of

² Based on the European Commission Better Regulation framework (SWD (2017) 350) and supported by an external study coordinated by Technopolis Group (to be published in 2020).

³ For further details on these points, see below Section 1.2.2.

⁴ Set out in the Annex Va of the Horizon Europe Regulation (common understanding). https://data.consilium.europa.eu/doc/document/ST-7942-2019-INIT/en/pdf

⁵ Only 12 are subject to this impact assessment, as one initiative on High Performance Computing has already been subject to an impact assessment in 2017 (SEC(2018) 47).

⁶ EU budget commitments to the European Partnership candidates can only be discussed and decided following the political agreement on the overall Multiannual Financial Framework and Horizon Europe budgetary

1.2. The political and legal context

1.2.1. Shift in EU priorities and Horizon Europe framework

European priorities have evolved in the last decades, and reflect the social, economic, and environmental challenges for the EU in the face of global developments. In her Political Guidelines for the new European Commission 2019 – 2024⁷, the new Commission President put forward six overarching priorities, which reach well beyond 2024 in scope⁸. Together with the Sustainable Development Goals (SDGs), these priorities will shape future EU policy responses to the challenges Europe faces, and thus also give direction to EU research and innovation.

As part of the Multi-annual Financial Framework (MFF) 2021-27 the new EU Framework Programme for Research and Innovation Horizon Europe will play a pivotal role for Europe to lead the social, economic, and environmental transitions needed to achieve these European policy priorities. It will be more impact driven with a strong focus on delivering European added value, but also be more effective and efficient in its implementation. Horizon Europe finds its rationale in the daunting challenges that the EU is facing, which call for "a radical new approach to developing and deploying new technologies and innovative solutions for citizens and the planet on a scale and at a speed never achieved before, and to adapting our policy and economic framework to turn global threats into new opportunities for our society and economy, citizens and businesses." While Horizon Europe continues the efforts of strengthening the scientific and technological bases of the Union and foster competitiveness, a more strategic and impact-based approach to EU R&I investment is taken. Consequently, the objectives of Horizon Europe highlight the need to deliver on the Union strategic priorities and contribute to the realisation of EU objectives and policies, contribute to tackling global challenges, including the Sustainable Development Goals by following the principles of the Agenda 2030 and the Paris Agreement. 10

In this context, at least 35 % of the expenditure from actions under the Horizon Europe Programme will have to contribute to climate action. Furthermore, a Strategic Plan is co-designed with stakeholders to identify key strategic orientations for R&I support for 2021-2024 in line with the EU priorities. In the Orientations towards the first Strategic Plan for Horizon Europe, the need to strategically prioritise and "direct a substantial part of the funds towards the areas where we believe they will matter the most" is emphasised. The Orientations specify, that actions under Pillar II of Horizon Europe "Global Challenges and European Industrial Competitiveness" will target only selected themes of especially high impact that significantly contribute to delivering on the political priorities of the Union. Most of the candidate European Partnerships fall under this Pillar.

envelopes. The level of EU contribution for individual partnerships should be determined once there are agreed objectives, and clear commitments from partners. Importantly, there is a ceiling to the partnership budgets in Pillar II of Horizon Europe (the legal proposal specifies that the majority of the budget in pillar II shall be allocated to actions outside of European Partnerships).

⁷ https://ec.europa.eu/info/strategy/priorities-2019-2024 en

⁸ 1.A European Green Deal; An economy that works for people; A Europe fit for the Digital Age; Promoting our European way of life; A Stronger Europe in the World; and 6.A New push for European Democracy

⁹ EC (2018) A Modern Budget for a Union that Protects, Empowers and Defends. The Multiannual Financial Framework for 2021-2027. Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, COM(2018) 321 final

¹⁰ Article 3, Common understanding regarding the proposal for Horizon Europe Framework Programme.

1.2.2. Key evolutions in the approach to partnerships in Horizon Europe

Since their start in 1984 the successive set of Framework Programmes uses a variety of instruments and approaches to support R&I activities, address global challenges and industrial competitiveness. Collaborative, competition-based and excellence-driven R&I projects funded through Work Programmes are the most traditional and long-standing approach for implementation. Since 2002, available tools also include **partnerships**, whereby the Union together with private and/or public partners commit to jointly support the development and implementation of a R&I programme. These were introduced as part of creating the European Research Area (ERA) to align national strategies and overcome fragmentation of research effort towards an increased scientific, managerial and financial integration of European research and innovation. Interoperable and integrated national research systems would allow for better flows of knowledge, technology and people. Since then, the core activities of the partnerships consist of building critical mass mainly through collaborative projects, jointly developing visions, and setting strategic agendas.

As analysed in the **interim evaluation of Horizon 2020**¹¹, a considerable repertoire of partnership initiatives have been introduced over time, with 8 forms of implementation ¹² and close to 120 partnership initiatives running under Horizon 2020 - without clear exit strategies and concerns about their degree of coherence, openness and transparency. Even if it is recognised that these initiatives allow setting long-term agendas, structuring R&I cooperation between otherwise dispersed actors, and leveraging additional investments, the evaluation points to the complexity generated by the proliferation of instruments and initiatives, and their insufficient contribution to policies at EU and national level.

Box 1 Key lessons from the interim evaluation of Horizon 2020 and R&I partnerships

- The **Horizon 2020 Interim Evaluation** concludes that the overall partnership landscape has become overly complex and fragmented. It identifies the need for rationalisation, improve their openness and transparency, and link them with future EU R&I missions and strategic priorities.
- The **Article 185 evaluation** finds that these public-public partnerships have scientific quality, global visibility and networking/structuring effects, but should in the future focus more on the achievement of policy impacts. From a systemic point of view, it found that the EU public-to-public cooperation (P2P) landscape has become crowded, with insufficient coherence.
- The **Article 187 evaluation** points out that Public-Private Partnership (PPP) activities need to be brought more in line with EU, national and regional policies, and calls for a revision of the Key Performance Indicators. As regards the **contractual PPPs (cPPPs)** their reviews identified challenges of coherence among cPPPs and the need to develop collaborations and synergies with other relevant initiatives and programmes at EU, national and regional level.

Over 80% of respondents to the Open Public Consultation (OPC) indicated that a significant contribution by future European Partnerships is 'fully needed' to achieve climate-related goals, to develop and effectively deploy technology, and for EU global competitiveness in specific sectors/domains. Views converged across all categories of respondents, including citizens, industry and academia.

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¹¹ Interim evaluation of Horizon 2020, Commission Staff Working Document, SWD(2017)221 and 222 Interim evaluation of the Joint Undertakings operating under Horizon 2020 (Commission Staff Working Document, SWD(2017) 339); Evaluation of the Participation of the EU in research and development programmes undertaken by several Member States based on Article 185 of the TFEU, Commission Staff Working Document, SWD (2017)340)

¹² E.g. initiatives based on Article 187 (Joint Technology Initiatives), Article 185 TFEU, Contractual Public-Private Partnerships (cPPPs), Knowledge & Innovation Communities of the European Institute of Innovation & Technology (EIT-KICs), ERA-NETs, European Joint Programmes, Joint Programming Initiatives.

The impact assessment of Horizon Europe identifies therefore the need to rationalise the EU R&I funding landscape, in particular with respect to partnerships, as well as to reorient partnerships towards more impact and delivery on EU priorities. To address these concerns and to realise the higher ambition for European investments, Horizon Europe puts forward a major simplification and reform for the Commission's policy on R&I partnerships¹³. Reflecting its pronounced systemic nature aimed at contributing to EU-wide 'transformations' towards the sustainability objectives, Horizon Europe indeed intends to make a more effective use of these partnerships with a more strategic, coherent and impact-driven approach. Key related changes that apply to all forms of European Partnerships encapsulated in Horizon Regulation are summarised in the Box below.

Box 2 Key features of the revised policy approach to R&I partnerships under Horizon Europe based on its impact assessment

- ✓ **Simpler architecture & toolbox** by streamlining 8 partnership instruments into 3 implementation forms (Co-Funded, Co-Programmed, Institutionalised), under the umbrella 'European Partnerships'
- ✓ More systematic and transparent approach to selecting, implementing, monitoring, evaluating and phasing out all forms of partnerships (criteria for European Partnerships):
 - The selection of Partnerships is embedded in the strategic planning of Horizon Europe, thereby ensuring coherence with the EU priorities. The selection criteria require that partnerships are established with stronger ex-ante commitment and higher ambition.
 - The implementation criteria stipulate that initiatives adopt a systemic approach in achieving impacts, including broad engagement of stakeholders in agenda-setting and synergies with other relevant initiatives to promote the take-up of R&I results.
 - A harmonised monitoring & evaluation system will be implemented, and ensures that progress is analysed in the wider context of achieving Horizon Europe objectives and EU priorities.
 - All partnerships need to develop an exit strategy from Framework Programme funding. This new approach is underpinned by principles of openness, coherence and EU added value.

✓ Reinforced impact orientation:

- Partnerships are established only if there is evidence they support achieving EU policy objectives
 more effectively than other Horizon Europe actions, by demonstrating a clear vision and targets
 (directionality) and corresponding long-term commitments from partners (additionality).
- European Partnerships are expected to provide mechanisms based on a concrete roadmap to join
 up R&I efforts between a broad range of actors towards the development and uptake of innovative
 solutions in line with EU priorities, serving the economy and society, as well as scientific progress.
- They are expected to develop close synergies with national and regional initiatives, acting as dynamic change agents, strengthening linkages within their respective ecosystems and along the value chains, as well as pooling resources and efforts towards the common EU objectives.

Under Horizon Europe, a 'European Partnership' 14 is defined as "an initiative where the Union, prepared with early involvement of Member States and/or Associated Countries, together with private and/or public partners (such as industry, universities, research organisations, bodies with a public service mission at local, regional, national or international level or civil society organisations including foundations and NGOs), commit to jointly support the development and implementation of a programme of research and innovation activities, including those related to market, regulatory or policy uptake."

The Regulation further specifies that European Partnerships shall adhere to the "principles of Union added value, transparency, openness, impact within and for Europe, strong leverage effect on sufficient scale, long-term commitments of all the involved parties, flexibility in implementation, coherence, coordination and complementarity with Union, local, regional, national and, where relevant, international initiatives or other partnerships and missions."

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¹³ Impact assessment of Horizon Europe, Commission Staff Working Document, SWD(2018)307.

¹⁴ Article 8 and Annex III of the Horizon Europe Regulation (common understanding))

1.3. Why should the EU act

1.3.1. Legal basis

Proposals for Institutionalised European Partnerships are based on:

- 1) Article 185 TFEU which allows the Union to make provision, in agreement with the Member States concerned, for participation in research and development programmes undertaken by several Member States, including participation in the structures created for the execution of those programmes; or
- 2) Article 187 TFEU according to which the Union may set up joint undertakings or any other structure necessary for the efficient execution of Union research, technological development and demonstration programmes.¹⁵

1.3.2. Subsidiarity

The EU should act only in areas where there is demonstrable advantage that the action at EU level is more effective than action taken at national, regional or local level. Research is a shared competence between the EU and its Member States according to the TFEU. Article 4 (3) specifies that in the areas of research, technological development and space, the EU can carry out specific activities, including defining and implementing programmes, without prejudice to the Member States' freedom to act in the same areas. The candidate initiatives focus on areas where there is a demonstrable value added in acting at the EU level due to the scale, speed and scope of the efforts needed for the EU to meet its long-term Treaty objectives and deliver on its strategic policy priorities and commitments. In addition, the proposed initiatives should be seen as complementary and reinforcing national and subnational activities in the same area. Overall European Partnerships find their **rationale in addressing a set of systemic failures**¹⁶:

- Their primary function is to create a platform for a strengthened **collaboration** and knowledge exchange between various actors in the European R&I system and an enhanced **coordination** of strategic research agendas and/or R&I funding programmes. They aim to address **transformational failures** to better align agendas and policies of public and private funders, pool available resources, create critical mass, avoid unnecessary duplication of efforts, and leverage sufficiently large investments where needed but hardly achievable by single countries.
- The concentration of efforts and pooling of knowledge on common priorities to solve multi-faceted societal and economic challenges is at the core of these initiatives. Specifically, enhanced cross-disciplinary and cross-sectoral collaboration and an improved integration of value chains and ecosystems are among the key objectives of these instruments. In the light of Horizon Europe, the aim is to drive system transitions and transformations towards EU priorities.
- Especially in fast-growing technologies and sectors such as ICT, there is a need to **react to emerging opportunities** and address systemic failures such as shortage in skills or critical mass or cross-sectoral cooperation along the value chains that would hamper attainment of future European leadership and/or strategic autonomy.
- They also aim to address **market failures** predominantly to enhancing industry investments thanks to the sharing of risks.

¹⁵ Both Articles are under Title XIX of the TFEU - Research and Technological Development and Space.

¹⁶ The Interim Evaluation of Horizon 2020 and the impact assessment of Horizon Europe provide qualitative and quantitative evidence on these points. Sections 1 and 2 of each impact assessment on candidate European Partnerships include more detail on the necessity to act at EU level in specific thematic areas.

2. THE CANDIDATE EUROPEAN PARTNERSHIPS – WHAT NEEDS TO BE DECIDED

2.1. Portfolio of candidates for Institutionalised European Partnerships

The new approach for more objective-driven and impactful European Partnerships is reflected in the way candidate Partnerships have been identified. It involved a co-design exercise aiming to better align these initiatives with societal needs and policy priorities, while broadening the range of actors involved. Taking into account the 8 areas for Institutionalised European Partnerships set out in the Horizon Europe Regulation 17, a co-design exercise as part of the Strategic Planning process of Horizon Europe lead to the identification of 49 candidates for Co-funded, Co-programmed or Institutionalised European Partnerships 18. Out of these, 13 were identified as suitable candidate Institutionalised Partnerships because of their objectives and scope 19. Whilst the Co-Funded and Co-Programmed Partnerships are linked to the comitology procedure (including the adoption of the Strategic Plan and the Horizon Europe Work Programmes), Institutionalised Partnerships require the adoption of legislation and are subject to an impact assessment. The Figure below gives an overview of all candidate European Partnerships according to their primary relevance to Commission priorities for 2019-2024.

Figure 1 - Overview of the candidates for Co-Funded, Co-Programmed and Institutionalised European Partnerships according to Horizon Europe structure

Cluster 1: Health	Cluster 4: Digital, Industry & Space	Cluster. 5: Climate, Energy & Mobility	Cluster 6: Food, Bioeconomy, Agriculture,	
Innovative	Key digital technologies	Clean Hydrogen	Circular Bio-based Europe	
Health Initiative	Smart networks & services	Safe & automated road transport	Safe & sustainable food	
EU-Africa Global Health	High-Performance Computing	Transforming EU's rail system	system	
Large-scale	European Metrology	Clean Aviation	Climate-neutral, sustainable & productive blue bio-	
innovation & transformation of	AI-Data-Robotics	Integrated Air Traffic Management	economy	
health systems	Photonics	European industrial battery value	Animal Health	
Personalised	Made in Europe	chain	Water4All	
Medicine	Clean steel – low-carbon steelmaking	Zero-emission waterborne transport	Accelerating farming	
ERA for Health	Carbon neutral & circular	Zero-emission road transport	systems transitions	
Rare diseases	industry	Built environment & construction	Environmental observations for sustainable agriculture	
One-Health Anti Microbial	Global competitive space systems	Clean energy transition	Rescuing biodiversity	
Resistance Chemicals risk	Geological Service for Europe	Sustainable, smart & inclusive cities & communities	EIT Food	
assessment	EIT Digital	EIT Climate	Cluster 2: Culture, Creativit	
EIT Health	EIT Manufacturing	EIT InnoEnergy	& Inclusive Society	
EIT Raw Materials		EIT Urban Mobility	EIT Cultural and Creative Industries	
Horizon Europe Pillar III - Cross-Pillars Cross-Pillars				
Innovative SMEs European Open Science Cloud				

Source: Technpolis group (2020)

¹⁷ Horizon Europe Regulation (common understanding), Annex Va.

¹⁸ Shadow configuration of Strategic Programme Committee for Horizon Europe. The list of candidate European Partnerships is described in "Orientations towards the Strategic Plan of Horizon Europe" - Annex 7 Only 12 are subject to this impact assessment, as one initiative on High Performance Computing has already been subject to an impact assessment in 2017 (SEC(2018) 47)

There are only three partnerships for which implementation as an Institutionalised Partnership under Article 185 is an option, i.e. European Metrology, the EU-Africa Global Health partnership, and Innovative SMEs. Ten partnerships are candidates for Institutionalised Partnerships under Article 187. Overall the initiatives can be categorised into 'horizontal' partnerships and 'vertical' partnerships.

The 'horizontal' partnerships have a central position in the overall portfolio, as they are expected to develop methodologies and technologies for application in the other priority areas, ultimately supporting European strategic autonomy in these areas as well as technological sovereignty. These 'horizontal' partnerships are typically proposed as Institutionalised or Co-programmed Partnerships, in addition to a number of EIT KICs, they cover mainly the digital field in addition to space, creative industries and manufacturing, but also the initiative related to Innovative SMEs. 'Vertical' partnerships are focused on the needs and development of specific application areas, and are primarily expected to support enhanced environmental sustainability thereby addressing Green Deal related objectives. They also deliver on policies for more people centred economy, through improved wellbeing of EU citizen and the economy, like health related candidate European Partnerships.

2.2. Assessing the necessity of a European Partnership and possible options for implementation

Horizon Europe Regulation Article 8 stipulates that Institutionalised European Partnerships based on Article 185 and 187 TFEU shall be implemented only where other parts of the Horizon Europe programme, including other forms of European Partnerships would not achieve the objectives or would not generate the necessary expected impacts, and if justified by a long-term perspective and high degree of integration. At the core of this impact assessment is therefore the need to demonstrate that the impacts generated through a Partnership approach go beyond what could be achieved with traditional calls under the Framework Programme – the Baseline Option. Secondly, it needs to assess if using the Institutionalised form of a Partnership is justified for addressing the priority.

For all candidate Institutionalised European Partnerships the options considered in this impact assessment are the same, i.e.:

- Option 0 Baseline option Traditional calls under the Framework Programme
- Option 1 Co-programmed European Partnership
- Option 2 Co-funded European Partnership
- Option 3 Institutionalised Partnership
 - o Sub-option 3a Institutionalised Partnerships based on Art 185 TFEU
 - o Sub-option 3b Institutionalised Partnerships based on Art 187 TFEU

2.2.1. *Option 0 - Baseline option – Traditional calls*

Under this option, strategic programming for R&I in the priority area will be done through the mainstream channels of Horizon Europe. The related priorities will be implemented through **traditional calls** of Horizon Europe covering a range of actions, mainly R&I and/or innovation actions but also coordination and support actions, prizes or procurement. Most actions involve consortia of public and/or private actors in ad hoc combinations, while some actions are single actor (mono-beneficiary). There will be no dedicated implementation structure and no support other than what is foreseen in the related Horizon Europe Work Programme. This means that discontinuation costs/benefits of predecessor initiatives should be factored in for capturing the baseline situation when relevant.

Under this option, strategic planning mechanisms in the Framework Programme will allow for a high level of flexibility in the ability of traditional calls to respond to particular needs over time, building upon additional input in co-creation from stakeholders and programme committees involving Member States. The Union contribution to addressing the priority covers the full duration of the initiative, during the lifetime of Horizon Europe. Without a formal EU partnership mechanism, it is less likely that the stakeholders will develop a joint Strategic Research Agenda and commit to its implementation or agree on mutual commitments and contributions outside their participation in funded projects.

2.2.2. European Partnerships

Under this set of options, three different forms of implementation are assessed: Co-funded, Co-Programmed, Institutionalised European Partnerships. These have **commonalities that cannot serve as a distinguishing factor in the impact assessment process**. They are all based on agreed objectives and expected impacts and underpinned by Strategic Research and Innovation Agendas / roadmaps that are shared and committed to by all partners in the partnership. They all have to follow the same set of criteria along their lifecycle, as defined in the Horizon Europe Regulation (Annex III), including ex ante commitment from partners to mobilise and contribute resources and investments. The Union contribution is defined for the full duration of the initiative for all European Partnerships. The Horizon Europe legal act introduces few additional requirements for Institutionalised Partnerships, e.g. the need for long-term perspective, strong integration of R&I agendas, and financial contributions.

Figure 2 - Key differences in preparation and implementation of European Partnerships

Type	Legal form	Implementation	
Co-Programmed	Contractual arrangement / MoU	Division of labour , whereby Union contribution is implemented through Framework rogramme and partners' contributions under their responsibility.	
Co-Funded	Grant Agreement	Union provides co-funding for an integrated programme with distributed implementation by entities managing and/or funding national research and innovation programmes	
Institutionalised based on Article 185/187 TFEU	Basic act (Council regulation, Decision by European Parliament and Council)	Integrated programme with centralised implementation	

The main differences between the different forms of European Partnerships are in their preparation and in the way they function, as well as in the overall impact they can trigger. The Co-Programmed form is assessed as the simplest, and the Institutionalised the most complex to prepare and implement. The functionalities of the different form of Partnerships – compared to the baseline option – are presented in Figure 3. They relate to the types of actors Partnerships can involve and their degree of openness, the types of activities they can perform and their degree of flexibility, the degree of commitment of partners and the priority setting system, and their ability to work with their external environment (coherence), etc. These key distinguishing factors will be at the basis of the comparison of each option to determine their overall capacity to deliver what is needed at a minimised cost.

Figure 3 Overview of the functionalities provided by each form of European Partnerships, compared to the traditional calls of Horizon Europe (baseline)

Baseline: Horizon	Option 1: Co-	Option 2: Co-Funded		Option 3b:	
Europe calls	Programmed		nalised Art 185	Institutionalised Art 187	
Type and composition of actors (including openness and roles)					
Partners: N.A., no common set of actors that engage in planning and	Partners: Suitable for all types: private and/or public partners, foundations	Partners: core of national funding bodies or govern-mental research organisations	Partners: National funding bodies or governmental research organisation	Partners: Suitable for all types: private and/or public partners, foundations	
implementation <u>Priority setting:</u> open to all, part of Horizon Europe Strategic	Priority setting: Driven by partners, open stakeholder consultation, MS in comitology	Priority setting: Driven by partners, open stakeholder consultation	Priority setting: Driven by partners, open stakeholder consultation	Priority setting: Driven by partners, open stakeholder consultation	
planning Participation in R&I activities: fully open in line with Horizon Europe rules	Participation in R&I activities: fully open in line with Horizon Europe rules	Participation in R&I activities: limited, according to national rules of partner countries	Participation in R&I activities: fully open in line with Horizon Europe rules, but possible derogations	Participation in R&I activities: fully open in line with Horizon Europe rules, but possible derogations	
Type and range of acti	vities (including additiona	lity and level of integrat	ion)	<u> </u>	
Activities: Horizon Europe standards that allow broad range of individual actions Additionality: no additional activities and investments outside the funded projects Limitations: No systemic approach beyond individual actions	Activities: Horizon Europe standard actions that allow broad range of individual actions, support to market, regulatory or policy/ societal uptake Additionality: Activities/investments of partners, National funding Limitations: Limited systemic approach	Activities: Broad, according to rules/programmes of participating States, State-aid rules, support to regulatory or policy/societal uptake Additionality: National funding Limitations: Scale & scope depend on participating programmes, often	Activities: Horizon Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to systemic approach Additionality: National funding	Activities: Horizon Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to systemic approach (portfolios of projects, scaling up of results, synergies with other funds. Additionality: Activities/investments of partners/ national funding	
Priority-setting process	beyond individual actions s and directionality	smaller in scale		partiters/ national funding	
Priority setting: Strategic Plan and annual work programmes, covering max. 4 years. Limitations: Fully taking into account existing or to be developed SRIA/ roadmap	Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Input to FP annual work programme drafted by partners, finalised by EC (comitology) Objectives & commitments set in contractual arrangement	Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Annual work programme drafted by partners, approved by EC Objectives & commitments set in Grant Agreement	Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Annual work programme drafted by partners, approved by EC Objectives & commitments set in legal act	Priority setting: Strategic R&I agenda/ roadmap agreed between partners & EC, covering usually 7 years, incl. allocation of Union contribution Annual work programme drafted by partners, approved by EC (vetoright in governance) Objectives & commitments set in legal act	
,	Coherence: internal (Horizon Europe) & external (other Union programmes, national programmes, industrial strategies)Internal: CoherenceInternal: CoherenceInternal: CoherenceInternal: Coherence				
Internal: Coherence between different parts of the FP Annual Work programme can be ensured by EC External: Limited for other Union programmes, no synergies with national/regional programmes & activities	Internal: Coherence among partnerships & with parts of the FP Annual Work programme can be ensured by partners & EC External: Limited synergies with other Union programmes & industrial strategies. If MS participate, with national/ regional	among partnerships & with parts of the FP	Internal: Coherence among partnerships & with parts of the FP Annual Work programme can be ensured by partners & EC External: Synergies with national/ regional programmes & activities	Internal: Coherence among partnerships & with parts of the FP Annual Work programme can be ensured by partners & EC External: Synergies with other Union programmes and industrial strategies If MS participate, with national/ regional programmes & activities	
programmes &	MS participate, with	1 0		national/ region	

2.2.2.1. Option 1 - Co-programmed European Partnership

This form of European Partnership is **based upon a Memorandum of Understanding or a Contractual Arrangement** signed by the Commission and the private and/or public partners. Private partners are represented by industry associations, which also support the daily management of the partnership. This type of partnership would allow for a large degree of flexibility for the activities, partners and priorities to continuously evolve. The commitments of partners are political efforts described in the contractual arrangement and the contributions from partners are provided in kind more than financially. The priorities for the calls, proposed by the Partnership's members for integration in the Horizon Europe's Work Programmes, are subject to further input from Member States (comitology) and Commission services. The Union contribution is implemented within the executive agency managing Horizon Europe calls for research and innovation projects proposals. The full array of Horizon Europe instruments can be used, ranging from research and innovation (RIA) types of actions to coordination and support actions (CSA) and including grants, prizes, and procurement.

2.2.2.2. Option 2 – Co-funded European Partnership

The Co-funded European Partnership is **based on a Grant Agreement** between the Commission and a consortium of partners, resulting from a specific call in the Horizon Europe Work Programme. This form of implementation only allows to address public partners at its core. Typically these provide co-funding to a common programme of activities established and/or implemented by entities managing and/or funding national R&I programmes. The recipients of the EU co-funding implement the initiative under their responsibility, with national funding/resources pooled to implement the programme with co-funding from the Union. The expectation is that these entities would cover most if not all EU Member States. Calls and evaluations would be organised centrally, beneficiaries in selected projects would be funded at national level, following national funding rules.

2.2.2.3. Option 3 – Institutionalised European Partnership

This type of Partnership is the most complex and high-effort arrangement, and requires meeting additional requirements. Institutionalised European Partnership are based on a Council Regulation (Article 187 TFEU or a Decision by the European Parliament and Council (Article 185 TFEU) and are implemented by dedicated structures created for that purpose. These regulatory needs limit the flexibility for a change in the core objectives, partners, and/or commitments as these would require amending legislation. The basic rationale for this type of partnership is the need for a strong integration of R&I agendas in the private and/or public sectors in the EU in order to address a strategic challenge. It is therefore necessary to demonstrate that other forms of implementation would not achieve the objectives or would not generate the necessary expected impacts, and that a long-term perspective and high degree of integration is needed. For both Article 187 and 185 initiatives, contributions from partners can be in the form of financial and in-kind contributions. Eligibility for participation and funding follows by default the rules of Horizon Europe, unless a derogation is introduced in the basic act.

Option 3a - Institutionalised Partnerships based on Article 185 TFEU

Article 185 of the TFEU allows the Union to participate in programmes jointly undertaken by Member States and limits therefore the scope to **public partners** which are Member States and Associated Third Countries. This type of Institutionalised Partnership aims

therefore at reaching the greatest possible impact through the integration of national and EU funding, aligning national strategies in order to optimise the use of public resources and overcome fragmentation of the public research effort. It brings together R&I governance bodies of most if not all EU Member States (legal requirement: at least 40% of Member States) as well as Associated Third Countries that designate a legal entity (Dedicated Implementation Structure) of their choice for the implementation. By default, participation of non-associated Third Countries is not foreseen. Such participation is possible only if it is foreseen in the basic act and subject to conclusion of an international agreement.

Option 3b - Institutionalised Partnerships based on Article 187 TFEU

Article 187 of the TFEU allows the Union to set up joint undertakings or any other structure necessary for the efficient execution of EU research, technological development and demonstration programmes. This type of Institutionalised Partnership brings together a stable set of **public and private partners** with a strong commitment to taking a more integrated approach and requires the set-up of a dedicated legal entity (Union body, Joint Undertaking (JU)) that carries full responsibility for the management of the Partnership and implementation of the calls. Different configurations are possible:

- Partnerships focused on creating strategic industrial partnerships where, most often, the partner organisations are represented by one or more industry associations, or in some cases individual private partners;
- Partnerships coordinating national ministries, public funding agencies, and governmental research organisations in the Member States and Associated Countries;
- Or a combination of the two: the so-called tripartite model.

Participation of non-associated Third Countries is only possible if foreseen in the basic act and subject to conclusion of an international agreement.

2.3. Overview of the methodology adopted for the impact assessment

The methodology for each impact assessment is based on the Commission Better Regulation Guidelines²⁰ to evaluate and compare options with regards to their **efficiency**, **effectiveness** and coherence. This also integrates **key selection criteria for European Partnerships**.

Box 2 Summary of European Partnerships selection criteria²¹

- *Effectiveness* in achieving the related objectives and impacts of the Programme;
- Coherence and synergies of the European Partnership within the EU R&I landscape;
- *Transparency* & *openness* as regards the identification of priorities and objectives and the involvement of partners & stakeholders from the entire value chain, backgrounds & disciplines;
- Ex-ante demonstration of *additionality* and *directionality*;
- Ex-ante demonstration of the partners' *long term commitment*.

2.3.1. Overview of the methodologies employed

In terms of **methods and evidence used**, the impact assessments draw on an external study covering all candidate Institutionalised European Partnerships in parallel to ensure a high level of coherence and comparability of analysis, in addition to an horizontal analysis.²² For

²¹ For a comprehensive overview of the selection criteria for European Partnerships, see Annex 6.

²⁰ European Commission (2017), Better Regulation Guidelines (SWD (2017) 350)

²² Technopolis Group (2020), Impact Assessment Study for Institutionalised European Partnerships under Horizon Europe, Final Report, Study for the European Commission, DG Research & Innovation

all initiatives, the understanding of the overall context of the candidate institutionalised European Partnerships relied on desk research, including among others the lessons learned from previous partnerships. This was complemented by the analysis of a range of quantitative and qualitative evidence, including evaluations of past and ongoing initiatives; foresight studies; statistical analyses of Framework Programmes application and participation data, and Community Innovation Survey data; analyses of science, technology and innovation indicators; reviews of academic literature; sectoral competitiveness studies and expert hearings. The analyses included a portfolio analysis, a stakeholder and social network analysis in order to profile the actors involved as well as their co-operation patterns, and an assessment of the partnerships' outputs (bibliometrics and patent analysis). A cost modelling exercise was performed in order to feed into the efficiency assessments of the partnership options, as described below. Public consultations (both open and targeted) supported the comparative assessment of the policy options. For each initiative, up to 50 relevant stakeholders were interviewed by the external contractor (policymakers, business including SMEs and business associations, research institutes and universities, and civil organisations, among others). In addition, the analysis was informed by the results of the Open Public Consultation run between September and November 2019, the consultation of Member States through the Strategic Programme Committee and the online feedback received on the Inception Impact Assessments of the set of initiatives.

A more detailed description of the methodology and evidence base that were mobilised, completed by thematic specific methodologies, is provided in Annexes 4 and 6.

2.3.2. *Method for identifying the preferred option*

The first step of the assessments consisted in scoping the problems that the initiatives are expected to solve given the overall economic, technological, scientific and social context, including the lessons to be learned from past and ongoing partnerships on what worked well and less well. This supported the identification of the objectives of the initiative in the medium and long term with the underlying intervention logic – showing how to get there.

Given the focus of the impact assessment on comparing different forms of implementation, the Better Regulation framework has then been adapted to introduce "key functionalities **needed**" - making the transition between the definition of the objectives and what would be crucial to achieve them in terms of implementation. The identification of "key functionalities needed" for each initiative as an additional step in the impact assessment is based on the distinguishing factors between the different options (see Section 2.2.1). In practical terms, each option is assessed on the basis of the degree to which it would allow for the key needed functionalities to be covered, as regards e.g. the type and composition of actors that can be involved ('openness'), the range of activities that can be performed (including additionality and level of integration), the level of directionality and integration of R&I strategies; the possibilities offered for coherence and synergies with other components of Horizon Europe, including other Partnerships (internal coherence), and the coherence with the wider policy environments, including with the relevant regulatory and standardisation framework (external coherence). This approach guides the identification of discarded options while allowing at the same time a structured comparison of the options not only as regards their effectiveness, efficiency and coherence, but also against a set of other key selection criteria for European Partnerships (openness, transparency, directionality)²³.

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²³ The criterion on the ex-ante demonstration of partners' long term commitment depends on a series of factors that are unknown at this stage, and thus fall outside the scope of the analysis.

In line with the Better Regulation Framework, the assessment of the effectiveness, efficiency and coherence of each option is made compared to the baseline. Therefore, for each of these aspects the performance of using traditional calls under Horizon Europe is first estimated and scored 0 to serve as a reference point. This includes the discontinuation costs/benefits of existing implementation structures when relevant. The policy options are then scored compared to the baseline with a + and - system with a two-point scale, to show a slightly or highly additional/lower performance compared to the baseline. A scoring of 0 of a policy option means that it would deliver as much as the baseline option.

On the basis of the evidence collected, the intervention logic of each initiative and the key functionalities needed, the impact assessments first evaluate the **effectiveness** of the various policy options to deliver on their objectives. To be in line with the Horizon Europe impact framework, the fulfilment of the specific objectives of the initiative is translated into 'expected impacts' - how success would look like -, differentiating between scientific, economic/ technological, and societal (including environmental) impacts. Each impact assessment considers to which extent the different policy options provides the 'key functionalities needed' to achieve the intended objectives. The effectiveness assessment does not use a compound score but shows how the options would deliver on the different types of expected impacts. This is done to increase transparency and accuracy in the assessment of options²⁴.

A similar approach is followed to evaluate the coherence of options with the overarching objectives of the EU's R&I policy, and distinguishes between **internal** and **external coherence**. Specifically, internal coherence covers the consistency of the activities that could be implemented with the rest of Horizon Europe, including European Partnerships (any type). External coherence refers to the potential for synergies and/or complementarities (including risks of overlaps/gaps) of the initiative with its external environment, including with other programmes under the MFF 2021-27, but also the framework conditions at European, national or regional level (incl. regulatory aspects, standardisation).

To compare the expected costs and benefits of each option (efficiency), the thematic impact assessments broadly follow a cost-effectiveness approach²⁵ to establish to which extent the intended objectives can be achieved for a given cost. A preliminary step in this process is to obtain a measure of the expected costs of the policy options, to be used in the thematic assessments. As the options correspond to different implementation modes, relevant cost categories generally include the costs of setting-up and running an initiative. For instance, set-up costs includes items such as the preparation of a European Partnership proposal and the preparation of an implementation structure. The running costs include the annual work programme preparation costs. Where a Partnership already exists, discontinuation costs and cost-savings are also taken into account²⁶. The table below provides an overview of the cost categories used in the impact assessment and a qualitative scoring of their intensity when compared to the baseline option (traditional calls). Providing a monetised value for these

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²⁴ In the thematic impact assessments, scores are justified in a detailed manner to avoid arbitrariness and spurious accuracy. A qualitative or even quantitative explanation is provided of why certain scores were given to specific impacts, and why one option scores better or worse than others.

²⁵ For further details, see Better Regulation Toolbox # 57.

²⁶ Discontinuation costs will bear winding down and social discontinuation costs and vary depending on e.g. the number of full-time-equivalent (FTEs) staff concerned, the type of contract (staff category and duration) and applicable rules on termination (e.g. contracts under Belgian law or other). If buildings are being rented, the cost of rental termination also apply. As rental contracts are normally tied to the expected duration of the current initiatives, these termination costs are likely to be very limited. In parallel, there would also be financial cost-savings related to the closing of the structure, related to operations, staff and coordination costs in particular. This is developed further in the individual efficiency assessments.

average static costs would have been misleading, because of the different features and needs of each candidate initiative.²⁷ The table shows the overall administrative, operational and coordination costs of the various options. These costs are then put into context in the impact assessments to reflect the expected co-financing rates and the total budget available for each of the policy options, assuming a common Union contribution (cost-efficiency):

- The costs related to the baseline scenario (traditional calls under Horizon Europe) are pre-dominantly the costs of implementing the respective Union contribution via calls and project, managed by the executive agencies (around 4%, efficiency of 96% for the overall investment).
- For a Co-Programmed partnership the costs of preparation and implementation increase only marginally compared to the baseline (<1%), but lead to an additional R&I investment of at least the same amount than the Union contribution²⁸ (efficiency of 98% for the overall investment).
- For a Co-Funded partnership the additional R&I investment by Member States accounts for 2,3 times the Union contribution²⁹. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the national programmes, can be estimated at 6% of the Union contribution (efficiency of 98% related to the overall investment).
- For an Article 185 initiative the additional R&I investment by Member States is equal to the Union contribution³⁰. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the dedicated implementation structure, can be estimated at 7% of the Union contribution (efficiency of 96% related to the overall investment).
- For an Article 187 initiative the additional R&I investment by partners is equal to the Union contribution³¹. The additional costs compared to the baseline of preparing and implementing the partnership, including the management of the Union contribution implemented by the dedicated implementation structure, can be estimated at 9% of the Union contribution (efficiency of 94% related to the overall investment).

Figure 4 - Intensity of additional costs compared with Horizon Europe Calls (for Partners, stakeholders, public and EU)

Cost items	Baseline: traditional calls	Option 1: Coprogrammed	Option 2 Co-funded	Option 3a - Art. 185	Option 3b -Art. 187
Preparation and set-up costs					
Preparation of a partnership proposal (partners and EC)	0		$\uparrow \uparrow$		
Set-up of a dedicated implementation structure		0		Existing: ↑ New: ↑↑	Existing: ↑↑ New: ↑↑↑
Preparation of the SRIA / roadmap	0		$\uparrow \uparrow$		
Ex-ante Impact Assessment for partnership		0		↑ ↑	1
Preparation of EC proposal and negotiation		0		↑ ↑	1

²⁷ A complete presentation of the methodology developed to assess costs as well as the sources used is described in the external study supporting this impact assessment (Technopolis Group, 2020).

²⁹ Based on the default funding rate for programme co-fund actions of 30%, partners contribute with 70% of the total investment.

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²⁸ Minimum contributions from partners equal to the Union contribution

³⁰ Based on the minimum requirement in the legal basis that partners contribute at least 50% of the budget.

³¹ Based on the minimum requirement in the legal basis that partners contribute at least 50% of the budget.

Cost items	Baseline: traditional calls	Option 1: Coprogrammed	Option 2 Co-funded	Option 3a - Art. 185	Option 3b -Art. 187
Running costs (Annual cycle of implementation)					
Annual Work Programme preparation	0				
Call and project implementation	0	0 In case of MS contributions: ↑	\uparrow	1	↑
Cost to applicants	Comparable, unless there are strong arguments of major differences in oversubscription				
Partners costs not covered by the above	0	↑	0	↑	↑
Additional EC costs (e.g. supervision)	0	↑	↑	↑	$\uparrow \uparrow$
Winding down costs					
EC	0		$\uparrow \uparrow \uparrow$		
Partners	0	↑	0	↑	↑

Notes: 0: no additional costs, as compared with the baseline; \uparrow : minor additional costs, as compared with the baseline; $\uparrow \uparrow$: medium additional costs, as compared with the baseline; $\uparrow \uparrow \uparrow$: higher costs, as compared with the baseline.

The cost categories estimated for the common model are then used to develop a scorecard analysis and further refine the assessment of options for each of the 12 candidate Institutionalised Partnerships. Specifically, the scores related to the set-up and implementation costs are used in the thematic impact assessments to consider the scale of the expected benefits and thereby allow a simple "value for money" analysis (cost-effectiveness)³². In carrying out the scoring of options, the results of fieldwork, desk research and stakeholder consultation undertaken and taken into account.

For the **identification of the preferred option**, the scorecard analysis builds a hierarchy of the options by individual criterion and overall in order to identify a single preferred policy option or in case of an inconclusive comparison of options, a number of 'retained' options or hybrid. This exercise supports the systematic appraisal of alternative options across multiple types of monetary, non-monetary and qualitative dimensions. It also allows for easy visualisation of the pros and cons of each option. Each option is attributed a score of the adjudged performance against each criterion with the three broad appraisal dimensions of effectiveness, efficiency and coherence.

As a last step, the alignment of the preferred option with key criteria for the selection of European Partnerships is described, reflecting the outcomes of the 'necessity test'. The monitoring and evaluation arrangements are concluding the assessment, with an identification of the key indicators to track progress towards the objectives over time.

2.4. Horizontal perspective on candidate Institutionalised European Partnerships

2.4.1. Overall impact orientation, coherence and efficiency needs

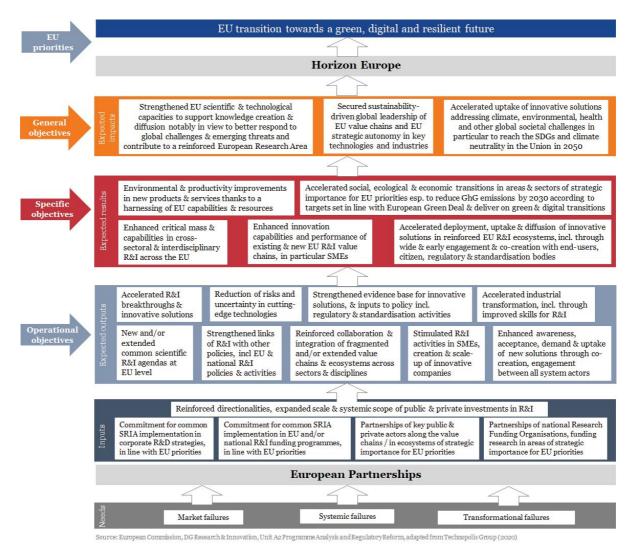
The consolidated **intervention logic** for the set of candidate Institutionalised European Partnerships in the Figure below builds upon the objectives as reported in the individual impact assessments.

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³² More details on the methodology can be found in Annex 4.

³³Certain aspects of the selection criteria will be further addressed/ developed at later stages, notably in the context of preparing basic acts (e.g. Openness and Transparency; Coherence and Synergies), in the Strategic Research and Innovation Agendas (e.g. Directionality and Additionality), and by collecting formal commitments (Ex-ante demonstration of partners' long-term commitment).

Figure 5 – Overall intervention logic of the European Partnerships under Horizon Europe



When analysed as a package the 12 candidate Institutionalised European Partnerships are expected to support the achievement of the European policy priorities targeted by Horizon Europe by pursuing the following joint general objectives:

- a) Strengthening and integrating EU scientific and technological capacities to support knowledge creation and diffusion notably in view to better respond to global challenges and emerging threats and contribute to a reinforced European Research Area;
- b) Securing sustainability-driven global leadership of EU value chains and EU strategic autonomy in key technologies and industries; and
- c) Accelerate the uptake of innovative solutions addressing climate, environmental, health and other global societal challenges contributing to Union strategic priorities, in particular to reach the Sustainable Development Goals and climate neutrality in the Union in 2050.

In terms of specific objectives, they jointly aim to:

- a) Enhance the critical mass and scientific capabilities in cross-sectoral and interdisciplinary research and innovation across the Union;
- b) Accelerate the social, ecological and economic transitions in areas and sectors of strategic importance for Union priorities, in particular to reduce greenhouse gas

- emissions by 2030 according to the targets set in line with the European Green Deal, and deliver on the green and digital transition;
- c) Enhance the innovation capabilities and performance of existing and new European research and innovation value chains, in particular SMEs;
- d) Accelerate the deployment, uptake and diffusion of innovative solutions in reinforced European R&I ecosystems, including through wide and early engagement and co-creation with end-users, citizen and regulatory and standardisation bodies;
- e) Deliver environmental and productivity improvements in new products and services thanks to a harnessing of EU capabilities and resources.

In terms of their operations, taking an horizontal perspective on all initiatives allows for the identification of further possible collective efficiency and coherence gains for more impact:

- Coherence for impact: The extent and speed by which the expected results and impacts will be reached, will depend on the scale of the R&I efforts triggered, the profile of the partners involved, the strength of their commitments, and the scope of the R&I activities funded. To be fully effective it comes out clearly that future partnerships need to operate over their whole life cycle in full coherence with their environment, including potential end users, regulators and standardisation bodies. This relates also to the alignment with relevant EU, national or regional policies and synergies with R&I programmes. This needs to be factored in as of the design stage to ensure a wide take-up and/or deployment of the solutions developed, including their interoperability.
- Collaboration for impact: Effectiveness could also be improved collectively through enhanced cross-disciplinary and cross-sectoral collaboration and an improved integration of value chains and ecosystems. An adequate governance structure appears in particular necessary to ensure cross-fertilisation between all European Partnerships. This applies not only to initiatives where similar R&I topics are covered and/or the same stakeholders involved or targeted, but also to the interconnections needed between the 'thematic' and the 'vertical' Partnerships, as these are expected to develop methodologies and technologies for application in EU priority areas. Already at very early stages of preparing new initiatives, Strategic Research and Innovation Agendas and roadmaps need to be aligned, particularly for partnerships that develop enabling technologies that are needed in other Partnerships. The goal should be to achieve greater impacts jointly in light of common challenges.
- Efficiency for impact: Potential efficiency gains could also be achieved by joining up the operational functions of Joint Undertakings that do not have a strong context dependency and providing them through a common back-office³⁴. A number of operational activities of the Joint Undertakings are of a technical or administrative nature (e.g. financial management of contracts), or procured from external service providers (e.g. IT, communication activities, recruitment services, auditing) by each Joint Undertaking separately. If better streamlined this could create a win-win situation for all partners leading to better harmonization, economies of scales, and less complexity in supervision and support by the Commission services.

³⁴ See Annex 6 for an overview of key functions/roles that could be provided by a common back office.

2.4.2. Analysis of coherence of the overall portfolio of candidate initiatives at the thematic level

Looking at the coherence of the set of initiatives at the thematic level, the "digital centric" initiatives have a strong focus on supporting the digital competitiveness of the EU ecosystem. Their activities are expected to improve alignment and coordination with Member States and industry for the development of world-competitive EU strategic digital technology value chains and associated expertise. Addressing the Key Digital Technologies, the 5G and 6G connectivity needs as part of a Smart Networks and Services initiative and the underlying supercomputing capacities through a European High Performance Computing initiative present potential for synergies that can be addressed through cooperative actions (e.g. joint calls, coordinated support activities, etc.). They may as well profit from and contribute to Partnerships envisaged for Photonics, AI, data, robotics, Global competitive space system and Made in Europe, together with the EIT Digital. Synergies between these initiatives and several programmes (Digital Europe and Connecting Europe as well as cohesion programmes) are needed in areas where EU industry has to develop leadership and competitiveness in the global digital economy. They are expected to impact critical value chains including on sectors where digital is a strong enabler of transformation (health, industrial manufacturing, mobility/transport, etc.).

The transport sector face systemic changes linked to decarbonisation and digitalisation. Large scale R&I actions are needed to prepare the transition of these complex sectors to provide clean, safer, digital and economically viable services for citizens and businesses. Past decades have shown that developing and implementing change is difficult in transport due to its systemic nature, many stakeholders involved, long planning cycles and large investments needed. A systemic change of the air traffic network through an Integrated Air Traffic Management initiative should ensure safety and sustainability of aviation, while a Clean Aviation initiative should focus on the competitiveness of tomorrow's clean aircrafts made in Europe. The initiative for Transforming Europe's rail system would comprehensively address the rail sector to make it a cornerstone in tomorrow's clean and efficient door-to-door transport services, affordable for every citizen as well as the most climate-friendly mode of transport for freight. Connected and Automated Mobility is the future of road transport, but Europe is threatened to fall behind other global regions with strong players and large harmonised markets. The initiative Safe and Automated Road Transport would bring stakeholders together, creating joint momentum in digitalising road transport and developing new user-based services. Stronger links and joint actions will be established between initiatives to enable common progress wherever possible. The Clean Hydrogen initiative would be fundamental to that regard. Synergies would also be sought with partnerships driving the digital technological developments.

To deliver a deep decarbonisation of highly emitting industrial sectors such as the steel, transport and chemical industries would require the production, distribution and storage of **hydrogen** at scale. The candidate hydrogen initiative would have a central positioning in terms of providing solutions to the challenges for sustainable mobility and energy, but also is expected to operate in synergies with other industry related initiatives. The initiative would interact in particular with initiatives on the zero emission road and water transport, transforming Europe's railway system, clean aviation, batteries, circular industry, clean steel and built environment partnerships. There are many opportunities for collaboration for the delivery and end-use of hydrogen. However, the Clean Hydrogen initiative would be the only partnership focused on addressing hydrogen production technologies.

Metrology, the science of measurement, is an enabler across all domains of R&I. It supports the monitoring of the Emissions Trading System, smart grids and pollution, but also

contributes to meeting demands for measurement techniques from emerging digital technologies and applications. More generally, emerging technologies across a wide range of fields from biotechnologies, new materials, health diagnostics or low carbon technologies are giving rise to demands requiring a world-leading EU metrology system.

The initiative for a **Circular Bio-based Europe** is intended to solve a shortage of industry investments in the development of bio-based products whose markets do not have yet certain long-term prospects. The **Innovative Health Initiative** and **EU-Africa Global Health** address the lack of investments in the development of solutions to specific health challenges. The initiative on **Innovative SMEs** supports innovation-driven SMEs in participating in international, collaborative R&I projects with other innovative firms and research-intensive partners. As a horizontal initiative it is expected to help innovative SMEs to grow and to be successfully embedded in global value chains by developing methodologies and technologies for potential application in the other partnership areas or further development by the instruments of the European Innovation Council.

The description of the interconnections between all initiatives for each Horizon Europe cluster is provided in the policy context of each impact assessment and further assessed in the coherence assessment for each option.

PART 2 - THE CANDIDATE EUROPEAN PARTNERSHIP ON CLEAN HYDROGEN

1. INTRODUCTION: THE POLITICAL AND LEGAL CONTEXT

Hydrogen is the most abundant element in the universe, making up more than 90 percent of all of the atoms. However, nature does not provide hydrogen in its elemental form. Hydrogen can be derived from water and other chemical compounds. Electricity or heat is needed to liberate hydrogen from the chemical compound. Among its many uses, researchers have been studying hydrogen with great interest because of its potential as a sustainable energy source. While hydrogen is a clean fuel, with no emissions at all, it is still more expensive than other energy sources, and its production is not pollution free as most of the hydrogen currently produced comes from natural gas, a process that generates carbon dioxide (CO₂). Researchers have therefore been looking for alternative and more environmentally friendly ways of producing 'clean hydrogen' that would ideally eliminate CO₂ emissions from the process. Hydrogen, as an energy carrier, is progressively viewed as a means to increase the share of renewables in European energy markets, to store and transport large amounts of electricity and to provide energy for sectors otherwise difficult to decarbonise. Hydrogen enables sector integration between the electricity system and industry and between buildings and transport. The focus on hydrogen applications has evolved gradually and in the future will increasingly centre on clean hydrogen. Due to the flexibility and versatility of hydrogen and a multitude of hydrogen end-use applications, deployment of clean hydrogen at scale would support the targeted transition to carbon neutrality by 2050 in the EU. This document focuses on assessing the most effective, efficient and coherent way of implementing an initiative which would focus on joint European research and innovation activities on Clean Hydrogen under Horizon Europe.

1.1. Emerging challenges in the field

Achieving a climate-neutral EU economy by 2050 calls for the EU to ensure a deep decarbonisation of highly emitting industrial sectors such as steel, transport and chemical industries (refineries and fertilizers plants). That would require production, distribution and storage of hydrogen at scale. Hydrogen applications have progressed significantly over the past decade. Several important technologies have been developed from low technology readiness levels to market-readiness, with the scope of hydrogen applications continuously broadening. ^{37,38,39,40,41}

³⁵ World Energy Council (2018), Hydrogen an enabler of the Grand Transition: Future Energy Leader position paper – available at https://www.worldenergy.org/assets/downloads/1Hydrogen-an-enabler-of-the-Grand-Transition_FEL_WEC_2018_Final.pdf

³⁶ Financial Times (2019), Hydrogen could help decarbonise the global economy – available at https://www.ft.com/content/959d08e2-a899-11e9-984c-fac8325aaa04
³⁷ Fuel Cell and Hydrogen 2 Joint Undertaking (2019), Hydrogen Roadmap Europe, available at

https://www.fch.europa.eu/news/hydrogen-roadmap-europe-sustainable-pathway-european-energy-transition

International Energy Agency (2019), The Future of Hydrogen – available at https://www.iea.org/hydrogen2019/

³⁹ Vattenfall (2019), Hydrogen, an important step towards independence from fossil fuels – available at https://group.vattenfall.com/press-and-media/news--press-releases/newsroom/2019/hydrogen-an-important-step-towards-independence-from-fossil-fuels

⁴⁰ Hydrogen Europe (2017), Decarbonise Industry, available at https://hydrogeneurope.eu/decarbonise-industry

⁴¹ Power Engineering International (2019), Hydrogen: The hope for 'hard-to-decarbonise' sectors – available at https://www.powerengineeringint.com/2019/09/26/hydrogen-the-hope-for-hard-to-decarbonise-sectors/

Nevertheless, the sector is still in a pre-deployment stage and massive cost reductions across the entire supply chain are necessary to enable mass commercialisation to meet decarbonisation needs at energy system level. In order to achieve these cost reductions, the sector must tackle problems such as market failure for first movers and fragmentation among players and lack of critical mass. By virtue of hydrogen's versatility, the 'sector' is spread over various applications in energy, transport and industry, but also over actors and countries.

Developing the hydrogen economy requires investments in hydrogen generation and end-use equipment in sectors that are difficult to decarbonize by other means, such as heavy duty transport. It will also require investments in hydrogen storage, transportation, and distribution infrastructure – whose absence is currently stalling the rollout of market-ready hydrogen applications. Large scale integrated hydrogen generation systems will be developed (e.g. clean hydrogen from photovoltaics and wind).

At the same time, continuous research and development will be required to ensure that hydrogen technologies are technically improved, highly efficient, and as competitive as possible. The scope of hydrogen applications is increasing from its present focus on transport, fuel cells and electrolysers, and is expanding to include the energy sector (power, heating and gas), industry and new transport applications (maritime, aviation, rail, heavy transport). With the constant emergence of new applications, the supply chain becomes more complex and continuous improvements (new materials , efficiency, reliability, lifetime october of the supply chain becomes more complex and continuous improvements.

The lack of a regulatory framework supporting and governing the use of hydrogen applications adds to these challenges.⁵³ For many years, hydrogen applications were not

⁴² World Energy Council (2019), New Hydrogen Economy – Hope or Hype?: Innovation Insights Brief – available at https://www.worldenergy.org/assets/downloads/WEInnovation-Insights-Brief-New-Hydrogen-Economy-Hype-or-Hope.pdf

⁴³ The International Council on Clean Transporation (2017), Developing hydrogen fueling infrastructure for fuel cell vehicles: A status update – available at https://theicct.org/sites/default/files/publications/Hydrogen-infrastructure-status-update ICCT-briefing 04102017 vF.pdf

International Energy Agency (2019), The Future of Hydrogen – available at https://www.iea.org/hydrogen2019/

⁴⁵ ScienceDaily (2019), Researchers design a roadmap for hydrogen supply network – available at https://www.sciencedaily.com/releases/2019/09/190912124835.htm

⁴⁶ Phys.org (2019), Scientists find way to help fuel cells work better, stay clean in the cold – available at https://phys.org/news/2019-01-scientists-fuel-cells-cold.html

⁴⁷ The scope expansion has been addressed in the frame of the structured consultation of Member States fiche for Clean Hydrogen, June 2019

⁴⁸ The Appendix: Analytical report on the Strategic Value Chain (SVC) on Hydrogen technologies and systems in the frame of the Strategic Forum on IPCEI (called the "IPCEI Appendix"), points out the special technoeconomic challenges of reducing the cost, increasing the efficiency and reducing the use of Critical Raw Materials (from FCH JU lists) (p 29)

⁴⁹ The "IPCEI Appendix" addresses, as example, the development and qualification of new materials to continue improving high pressure hydrogen storage (p 10)

⁵⁰ Example of buses lifetime addressed in the "Competitiveness Analysis" (p 67)

⁵¹ The "IPCEI Appendix" points out the cost of producing hydrogen should be reduced (p 13), FCEV should cost similar to electrical vehicles (p14), technologies cost reduction is also a question of competitiveness with other regions especially Asian competitors (p28). The "Competitiveness Analysis" illustrates cost decrease expectations by 2030, for many different applications, depending on mass production (p 48)

⁵² See Annex 6 for general information on the hydrogen sector.

⁵³ European Commission and Hydrogen Europe (2019), Hydrogen for Climate Action: How to kick start the EU Hydrogen Industry to achieve the EU climate goals? –available at

technologically advanced enough to motivate the EU to develop and adopt hydrogen legislation. However, policy guidelines at local, national and EU-levels are increasingly necessary to enable hydrogen's market entry on a large scale. ^{54,55,56}

Finally the international dimension of hydrogen deployment and upscaling of production at global level has to be addressed. For example, the import of cheap clean hydrogen from wind and solar energy, produced outside of Europe, might become more important in the mid-term. These deployments urge the setting up of international standards, the development of the required infrastructure and developing a methodology on defining emissions from each unit of hydrogen produced.

1.2. EU relative positioning in the field

Europe is currently in an excellent position to achieve a significant level of penetration of hydrogen and fuel cell technologies over the next decade, at a level that can: (a) prove that hydrogen can fulfil a key role towards fighting climate change and improving public health; (b) act as a central pillar in decarbonisation and elimination of other harmful emissions of everyday activities; and (c) positively impacting the economy thanks to a broad and competitive supply chain that keeps Europe in a leading position and creates a new wave of highly skilled jobs.

The latter was recognized by the **Strategic Forum for Important Projects of Common European Interest (IPCEI**⁵⁷) which identified six key strategic value chains⁵⁸ of specific importance for EU's industries and competitiveness among which an "**Hydrogen technologies and systems**" value-chain. It is worth mentioning that European industry is active in all areas of the hydrogen economy along the whole value chain⁵⁹. To name a few:

• In Clean hydrogen production firstly, through electrolysis technologies. 60 The EU is a scientific and industrial leader in today's global electrolysis industry, with competitors in China, Japan and the US less active. 51 Second, through other technologies (incl. Steam

 $\underline{\text{https://static1.squarespace.com/static/5d3f0387728026000121b2a2/t/5d9f23c486e0ee312c6380a7/1570710475}}\\ \underline{\text{026/Framework H2+for+Climate+Action final.pdf}}$

⁵⁴ European Commission and Joint Research Centre (2019), Hydrogen use in EU decarbonisation scenarios, available at https://ec.europa.eu/jrc/sites/jrcsh/files/final insights into hydrogen use public version.pdf

⁵⁵ Fuel Cells and Hydrogen Joint Undertaking 10th Stakeholder Forum (2017), Fuel Cell and Hydrogen Technology: Europe's Journey to a Greener World, available at https://op.europa.eu/en/publication-detail/-/publication/15d2c3b7-c502-11e7-9b01-01aa75ed71a1

[/]publication/15d2c3b7-c502-11e7-9b01-01aa75ed71a1

56 Hydrogen Europe (2018), EU Legislative framework for implementation of Hydrogen in different applications – available at https://www.waterstofnet.eu/ asset/ public/powertogas/Conference/10-Nicolas-Brahy Hydrogen-Europe-HyLaw- Regulation-Overview.pdf

https://www.clustercollaboration.eu/news/call-applications-strategic-forum-important-projects-commoneuropean

https://ec.europa.eu/commission/sites/beta-political/files/euco-sibiu-eu_industry_fit_for_the_future.pdf, where in total, three of the value chains are directly relevant to hydrogen: the "Hydrogen technologies and systems", "Low CO2 emissions industry" and "Clean, connected and autonomous vehicles"

systems", "Low CO2 emissions industry" and "Clean, connected and autonomous vehicles"

The main trends are coming from the study on Value Chain and Manufacturing Competitiveness Analysis for Hydrogen and Fuel Cells Technologies, Evidence Report, E4tech (UK) Ltd for FCH 2 JU in partnership with Ecorys and Strategic Analysis Inc, 2018. These are completed by the Hydrogen, enabling a zero emission Europe, technology roadmaps full pack, Sept 2018, Hydrogen Europe.

ScienceDirect (2019), Electrolysers: an Overview – available at https://www.sciencedirect.com/topics/engineering/electrolysers

⁶¹ Euractiv (2019), EU-wide innovation support is key to electrolysis in Europe – available at https://www.euractiv.com/section/energy-environment/opinion/eu-wide-innovation-support-is-key-to-electrolysis-in-europe/

- Methane Reforming with Carbon Capture Storage/Use⁶²) which could be useful in a transition phase, although not all of them are necessarily relevant for the proposed Clean Hydrogen initiative, but rather for other funding instruments.
- In Hydrogen distribution and storage: 63 EU industry and particularly EU SMEs are at the forefront of hydrogen handling and logistics with many leading companies focusing on multiple applications and technologies, including hydrogen refuelling stations (HRS), liquefaction facilities, and ammonia and methanol conversion plants.
- In Hydrogen end use in transport where hydrogen and fuel cells can play an important role fostering a low-carbon road transport system. In particular, hydrogen is envisioned to play a vital decarbonisation role in long-distance transport (e.g. for long-haul heavy goods vehicles and coaches), in buses and truck fleets, in aviation, in rail transport, and in the maritime sector. Although Directive 2014/94/EU "on the deployment of alternative fuels infrastructure" does not set out any obligation for Member States to indicate an appropriate number of publicly accessible hydrogen supply points in their national policy frameworks (NPFs), hydrogen is included in 14 NPFs and some Member States, for example Germany, have defined ambitious targets for hydrogen infrastructure.
- In Hydrogen end use there are solutions for hydrogen to decarbonise the natural gas grid through the blending & upgrade of natural gas to a pure hydrogen grid and then supplying heating and power for buildings. In the European decarbonisation context, these solutions may be appropriate in certain market segments or in specific conditions, e.g. islands; power generation (providing seasonal storage on renewable electricity); hydrogen replacing natural gas for process heat in industry.
- In Hydrogen end uses in industry: Clean hydrogen can be supplied as industrial feedstock. Potential end-use sectors for hydrogen in industry include steel and iron manufacturers. Main current end-users such as refineries, ammonia plants and other chemical manufacturers could be supplied with clean hydrogen. Organisations involved with the multiple demonstration projects ongoing in Europe will soon have unrivalled expertise in the integration of clean hydrogen as a feedstock for industry. 68,69,70

ScienceDirect (2019), Hydrogen Production: An overview – available at https://www.sciencedirect.com/topics/chemistry/hydrogen-production

⁶³ Joint Research Centre (2016), 4th International Workshop on Hydrogen Infrastructure and Transportation Report, https://publications.jrc.ec.europa.eu/repository/bitstream/JRC103586/4%20int%20workshop%20on%2 https://publications.jrc.ec.eu/repository/bitstream/JRC103586/4%20int%20workshop%20on%2 <a href="https://publications.jrc.ec.eu/repository/bitstream/JRC103586/4%20int%20workshop%20on%2 <a href="https://publications.jrc.ec.eu/repository/bitstream/JRC103586/4%20int%20workshop%20on%2 <a href="https://publications.jrc.ec.eu/repository/bitstream/JRC103586/4%20int%20workshop%2 <a href="https

⁶⁴ Hydrogen Europe (2017), Hydrogen safety – available at https://hydrogeneurope.eu/hydrogen-safety

⁶⁵ A Clean Planet for all - A European long-term strategic vision for a prosperous, modern, competitive and climate neutral economy, p111

climate neutral economy, p111

66 Fuel Cell and Hydrogen 2 Joint Undertaking (2019), Hydrogen Roadmap Europe, available at https://www.fch.europa.eu/news/hydrogen-roadmap-europe-sustainable-pathway-european-energy-transition

https://www.fch.europa.eu/news/hydrogen-roadmap-europe-sustainable-pathway-european-energy-transition 67 The Commission Delegated Regulation (EU) 2019/1745 of 13 August 2019 "supplementing and amending Directive 2014/94/EU amends the technical specifications for hydrogen refuelling points for motor vehicles set out in the Annex II of the Directive. The amended standards will apply from 12 November 2021.

⁶⁸e.g. the H2FUTURE project is injecting green hydrogen into steel production, thereby eliminating greenhouse gas emissions that would normally ensue. Demonstrating that even energy-dependent sectors can rely on this technology will make for increasingly green industrial production (FCH JU success stories)

⁶⁹ Refhyne, launched in 2018, is on course to build the largest hydrogen electrolysis plant of its kind in the world, with a capacity of 10MW, at the Rhineland refinery in Germany (FCH JU success stories)

⁷⁰ In 2016, SSAB, LKAB and Vattenfall formed a joint venture project with the aim of replacing coking coal in ore-based steel making with H2. In 2018, a pilot plant was planned and designed in Lulea and the Norbotten iron ore fields to provide a testing facility for green H2(produced by electrolysis) to be used as a reducing agent in steel-making. Project partners state that using this production method could make steel (the Technology Roadmap, Hydrogen Europe)

At global level, Europe is confronted with fierce competition from countries which are also promoting the use of hydrogen as a clean and alternative energy vector and have developed hydrogen strategies and policies. This is the case for the United States, Japan, Korea and China which are all developing large R&I programmes addressing similar segments of the Hydrogen value-chain mentioned above. However, one can notice from Figure 6 below that Europe has a relatively privileged position being ahead of global competition or among the global leaders in a few segments of the hydrogen value-chain.

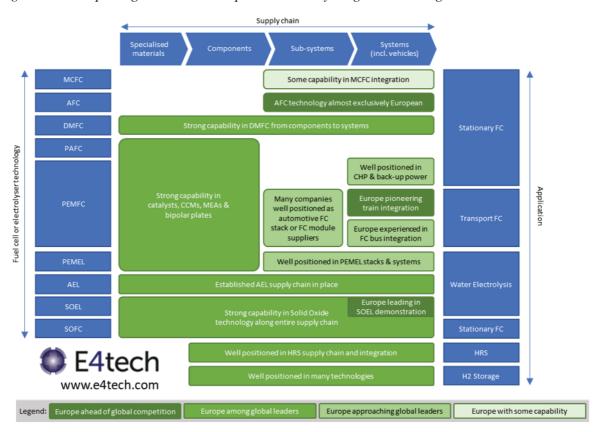


Figure 6 – European global leadership in various hydrogen technologies⁷¹

In terms of R&I performance and in particular - publishing⁷², Europe is showing strong leadership in publishing peer reviewed papers concerning electrolysis technologies (884 papers vs 1,568 papers from the rest of the world) as well as non-electrolysis production methods (1,549 papers vs 4,266). As regards fuel cell technologies, Europe (with 4,971 papers) is competing with the United States for the second position against Asia (10,493 papers). Asia's strong publications record in this field is often using their national language and publishing in national journals.

Overall, Europe is exceptionally active in PEM fuel cells with namely 2,780 papers and 448 patents filed covering this topic. Concerning patenting, Asia is the frontrunner compared to the rest of the world. Among the various sectors, Europe is clearly advancing well in Solid Oxide and PEM Electrolysis technologies, with more than 500 patents filed.

⁷² Source: TIM FCH-adapted datasets available at https://www.fch.europa.eu/page/tools-innovation-monitoring-tim.

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⁷¹ The main trends are coming from the study on Value Chain and Manufacturing Competitiveness Analysis for Hydrogen and Fuel Cells Technologies, Evidence Report, E4tech (UK) Ltd for FCH 2 JU in partnership with Ecorys and Strategic Analysis Inc, oct 2018. These are completed by the Hydrogen, enabling a zero emission Europe, technology roadmaps full pack, Sept 2018, Hydrogen Europe

Box 3 Support for the field in the previous Framework Programmes – key strengths & weaknesses identified

What was/is being done with EU research and innovation funding until now

Dedicated R&I activities related to hydrogen applications have been supported since 2008. This covers traditional (collaborative) projects but also support provided through the Fuel Cell and Hydrogen Joint Undertakings (FCH JU and FCH 2 JU) under FP7 and Horizon 2020, which cover all stages/fields of the hydrogen value chain described above.

The first FCH JU was set up in 2008 as a public-private partnership between the EU, industry and the research community with a budget of EUR 470 million. The objective was to promote coordination and collaboration across Europe's fragmented FCH sector, to pool resources and to develop a long term, integrated, pan-European research and innovation agenda.

The programme entered its second phase, with FCH 2 JU, in Horizon 2020.

FCH 2 JU is a public-private partnership with 3 members: the industry grouping Hydrogen Europe, the research grouping Hydrogen Europe Research and the European Commission. The focus is on accelerating the commercialisation of fuel cells and hydrogen technologies to ensure a world leading, competitive European FCH industry while increasing jobs. The objectives of FCH 2 JU, organised around the energy and transport, pillars are the following:

- Clean transport: Reduce fuel cell system costs for transport applications
- Green hydrogen production: Increase efficiency and reduce costs of hydrogen production, mainly from water electrolysis and renewables
 - Heat & electricity production: Increase fuel cell efficiency and lifetime
- Hydrogen storage for grid balancing: Demonstrate on a large-scale hydrogen's capacity to harness power from renewables and support its integration into the energy system
 - Minimal use of critical raw materials: Reduce platinum loading

What has or is being achieved so far

The main achievements of the FCH JU and FCH 2 JU are that they contributed⁷³ to structure and mobilise an otherwise fragmented landscape of different sectors and industries by convincing competing or different, unrelated stakeholders to work together towards clear objectives⁷⁴, and that they developed successful mechanisms for fostering continued technological innovation.

For example, FCH 2 JU enabled key European fuel cell stack manufacturers such as Nedstack, Proton-motor, Powercell, Symbio and Elringklinger to nurture and to kick start competitive industrial-scale production of automotive fuel cell stacks in the EU, allowing Europe to compete with other regions of the world. FCH 2 JU was also instrumental in scaling up electrolysis technology, through recent projects such as REFHYNE⁷⁵ and

75 https://refhyne.eu/

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⁷³ Commission Staff Working Document - Interim Evaluation of the Joint Undertakings operating under Horizon 2020, {SWD (2017) 339 final}

⁷⁴ The objectives of the FCH JU, as laid down it its founding regulation.

DJEWELS⁷⁶. However, further improvements are still needed in terms of costs, efficiency, reliability, while reaching the Giga-Watt scale. The FCH JU is also supporting initiatives at regional level, such as the HEAVENN project⁷⁷, which can help create local/regional value chains and demonstrate the role of hydrogen to integrate renewables in the energy system and decarbonise sectors that lag behind like transport and industry.

What are the key areas for improvement & unmet challenges?

However, a number of systemic challenges already identified in the interim evaluation of FCH 2 JU⁷⁸ risk derailing the progress already achieved and will have to be better addressed in a new Clean Hydrogen Initiative. These challenges include:

- i) Pre-Normative Research (PNR) and even though not directly addressed in the proposed initiative, Regulation, Codes and Standards barriers, most notably the lack of technical regulations and/or accepted standards which prevent large scale, international deployment of standardised products;
- ii) Funding concentration, and the need to ensure that the current geographical distribution of projects supported by the present JU is not reinforced by any lack of information/openness/transparency to entities from countries where participation is low, in particular EU13;
- iii) The involvement of Member States and in particular the role of the State Representative Group which is not as effective as it should be;
- iv) Knowledge management, open data and knowledge transfer, human resource developments and trainings are all necessary components to ensure that deployment takes place consistently in different sectors of the economy and finally,
- v) The need for more attention to safety of FCH technologies necessary to building the confidence needed for widespread take-up. The relatively few projects introducing hydrogen in new settings (in buses, homes or in refuelling stations alongside conventional fuels) has not allowed products to be rolled-out commercially.

1.3. EU policy context beyond 2021

Hydrogen has been a field of interest for the EU since a few decades. However, the political context has evolved very significantly in the last five years with all Member States of the EU having signed and ratified the Conference of the Parties (COP21) Paris agreement and the European Union committing to contribute to delivering the Sustainable Development Goals (SDGs).

In 2018, the European Commission published "A Clean Planet for all", the strategic long-term vision of the Commission for a prosperous, modern, competitive and climate-neutral economy by 2050. The communication sets out a clear vision of how to achieve climate neutrality by 2050, recognising that "the role of hydrogen is likely to become more

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⁷⁶ https://www.fch.europa.eu/news/fch-ju-funds-pioneering-green-hydrogen-project

⁷⁷ https://www.fch.europa.eu/page/energy#HEAVENN

⁷⁸ Commission Staff Working Document - Interim Evaluation of the Joint Undertakings operating under Horizon 2020, {SWD (2017) 339 final}

prominent in a fully decarbonised energy system," and including hydrogen and fuel cells in its list of "transformational carbon-neutral solutions that EU research should focus on." ⁷⁹

At the end 2019, the Commission presented its new priorities for the coming years, including the European Green Deal, a new growth strategy that aims to transform the EU into a fair and prosperous society, with a modern, resource-efficient and competitive economy, where there are no net emissions of greenhouse gases in 2050 and where economic growth is decoupled from resource use. It states that EU industry needs 'climate and resource frontrunners' to develop the first commercial applications of breakthrough technologies in key industrial sectors by 2030. Priority areas include clean hydrogen, fuel cells and other alternative fuels, energy storage, and carbon capture, storage and utilisation. In this context, Hydrogen is also prominent in the Strategies and Communications for Hydrogen⁸⁰ for Energy System Integration⁸¹ as well as the launch of the European Clean Hydrogen Alliance. The European Clean Hydrogen Alliance⁸² aims to bring all stakeholders together and identify technology needs, investment opportunities, regulatory barriers and enablers to build a clean hydrogen ecosystem in the EU. On 28 May the Communication on "Europe's moment: Repair and Prepare for the Next Generation", was adopted which highlights in particular the important role of hydrogen in the EU economic recovery plan. The second pillar of this proposal is particularly relevant and includes clean hydrogen among the clean technologies and value chains which need to be supported and strengthened.

Actions are starting to enforce climate policies that would trigger intensive/deep decarbonisation in heavy industry and heavy transport sectors in which clean hydrogen applications represent some of the only feasible carbon-reduction solutions.⁸³

In Horizon Europe, Hydrogen is part of the research and innovation activities funded under the Pillar II, Cluster: Climate, Energy and Mobility which aims at contributing to the attainment of at least three of the six main ambitions for Europe: 'A European Green Deal', 'A people-centred economy' and 'A Digital Europe'. It is supportive of several of the Sustainable Development Goals, particularly SDG7 (Affordable and clean energy), Climate Actions (SDG13) and Sustainable Cities and Communities (SDG11). The long term targeted impact of this cluster corresponds directly to the main objectives of fostering climate action, while at the same time improving the sustainability, security and competitiveness of the energy and transport industry, as well as the quality of the services that these sectors bring to citizens and society at large. The hydrogen economy addresses many different technological solutions and applications concerning different actors and linkages to various sectors. Adequate collaboration and connection with the relevant sectors are therefore required along the whole value chain.

⁷⁹ European Commission (2018), A Clean Planet for all: A European strategic long-term vision for a prosperous, modern, competitive and climate neutral economy, Communication from the Commission to the European Parliament, the European Council, the Council, The European Economic and Social Committee, The Committee of the Regions and the European Investment Bank COM(2018)773, available at https://eurlex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52018DC0773

⁸⁰ COM(2020) 301 final: A hydrogen strategy for a climate-neutral Europe

⁸¹ COM(2020) 229 final: Powering a climate-neutral economy: An EU Strategy for Energy System Integration

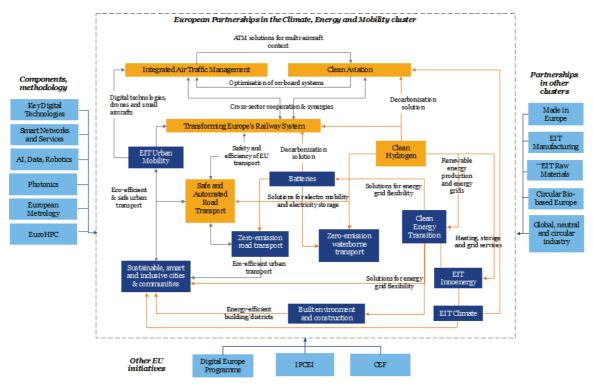
⁸² https://ec.europa.eu/growth/industry/policy/european-clean-hydrogen-alliance_en

⁸³ European Commission Press Release (2019), Energy Union: Commission calls on Member States to step up ambition in plans to implement Paris agreement – available at https://ec.europa.eu/commission/presscorner/api/files/document/print/en/ip 19 2993/IP 19 2993 EN.pdf

In addition to an initiative for Clean Hydrogen, other initiatives are put forward as possible partnerships under Horizon Europe. Potential initiatives in the Climate, Energy and Mobility cluster are shown in Figure 7. This shows not only the horizontal positioning of the potential Clean Hydrogen initiative, in terms of providing solutions to the challenges for sustainable mobility and energy, but also opportunities for synergies with a wide set of initiatives in other clusters (especially the digital and industry cluster). In addition, an initiative related to Clean Hydrogen would need to also link with the maritime sector, the power (especially the renewable energy sector), and the gas sector (especially gas grid operators). Strong collaboration would be needed between these initiatives to ensure proper integration of technologies into applications aiming to decarbonize the concerned sectors. It is important to note that some of these initiatives would probably not succeed or have the expected impact without an ambitious Clean Hydrogen Initiative able to supply hydrogen at scale.

Synergies with other EU programmes and networks which address hydrogen would also be needed, in particular: the European Energy Research Alliance (EERA) and its "Joint Programme on Fuel Cells and Hydrogen"⁸⁴; the High Level Expert Group on Energy-Intensive Industries which developed the Industrial Transformation Master Plan for climate-neutral industry by 2050⁸⁵ highlighting the key role of hydrogen; funds and financing mechanisms that would support innovation and industrialisation and would help to bridge the "valley of death", in particular the Connecting European Facility (CEF)⁸⁶, the ETS Innovation Fund, and the European Investment Bank, with loans provided by InnovFin EDP.

Figure 7: Potential interconnections between partnership initiatives in the Climate, Energy and Mobility cluster of Horizon Europe



⁸⁴ https://www.eera-set.eu/eera-joint-programmes-jps/list-of-jps/fuel-cells-and-hydrogen/

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⁸⁵ Masterplan for a Competitive Transformation of EU Energy-intensive Industries Enabling a Climate-neutral, Circular Economy by 2050, Report from the High-Level Group on Energy-Intensive Industries

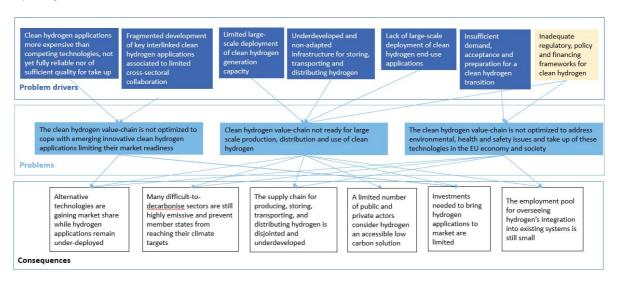
⁸⁶ EC (2018), Proposal for a Regulation of the European Parliament and of the Council establishing the Connecting Europe Facility, COM(2018) 438 final

2. PROBLEM DEFINITION

2.1. What is/are the problems?

Given the scale of the challenges ahead for a sustainable energy transition, the current scientific, technological and economic positioning of Europe in the field, and the overarching EU policy context, a set of problems have been identified where EU research and innovation in the field of Clean Hydrogen would have a specific role to play (see Figure 8).

Figure 8: Problem tree behind an initiative for European research and innovation on Clean Hydrogen



The part in yellow is not within the scope of the proposed Clean Hydrogen initiative. Important to mention is that the initiative seeks to address in particular research aspects related to production, distribution, infrastructure and storage of hydrogen.

2.1.1. The clean hydrogen value-chain not optimized to cope with emerging clean hydrogen applications limiting their market readiness.

Hydrogen applications have been developed in the FCH 2 JU to different levels of technological readiness. Those at higher Technology Readiness Levels (TRL) – including stationary fuel cells, light FCEVs, fuel cell buses and small scale electrolysers – are basically ready for market deployment; however, they remain comparatively more expensive than competitor technologies. St. Substantial R&I effort is still needed to improve their efficiency, cost, durability and manufacturability.

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⁸⁷ Financial Times (2019), Hydrogen could help decarbonise the global economy – available at https://www.ft.com/content/959d08e2-a899-11e9-984c-fac8325aaa04

World Energy Council (2018), Hydrogen an enabler of the Grand Transition: Future Energy Leader position paper – available at https://www.worldenergy.org/assets/downloads/1Hydrogen-an-enabler-of-the-Grand-Transition FEL WEC 2018 Final.pdf

To develop an efficient clean hydrogen ecosystem, hydrogen will need to be produced in the power sector mainly from renewable energy sources, distributed via the gas-transmission sector or via the transport sector, and used in the transport, industry, and building sectors. 91,92 However, it is difficult to motivate actors across these traditionally independent sectors to work together on collaborative R&I projects and develop strong collaborative frameworks. 93,94

Scientific advancement for key hydrogen technologies is still required, and current energyuse systems in heavy industry and heavy transport will need to be technically adapted before they can use hydrogen as a fuel.⁹⁵

In order for clean hydrogen to become competitive with conventional fuels for transport and fossil-based feedstock (with the inclusion of the cost of carbon), some technology routes need further improvements in particular in sectors that are difficult to decarbonise by other means, such as heavy duty transport (trucks, coaches, trains and ships) – especially in the areas of investment cost reduction and efficiency increases 96.

The Clean hydrogen value-chain not ready for large scale production, 2.1.2. distribution and use of hydrogen

Currently, few complete value chains for hydrogen, from production to end-use, are operational across the EU. 97,98 Several hydrogen applications still need to be technologically improved and tested before they can be successfully implemented into larger scale systems. 99,100 This will be the core focus of the proposed partnership. While recent demonstration projects have affirmed the success and potential value of individual hydrogen technologies, knowledge transfer between project teams and across industries remains limited. ^{101,102} As stated by the IEA, ¹⁰³ "for novel applications (especially those at low TRLs)

⁸⁹ Power Engineering International (2019), Hydrogen: The hope for 'hard-to-decarbonise' sectors – available at https://www.powerengineeringint.com/2019/09/26/hydrogen-the-hope-for-hard-to-decarbonise-sectors/

Strategic Research and Innovation Agenda, Hydrogen Europe, December 2019 (p 10)

⁹¹ International Journal of Hydrogen Energy (2019), Flexible sector coupling with hydrogen: A climatesupply for transport road https://www.sciencedirect.com/science/article/abs/pii/S0360319919312121

⁹² Clean Energy Wire (2018), Sector coupling – Shaping an integrated renewable energy system – available at https://www.cleanenergywire.org/factsheets/sector-coupling-shaping-integrated-renewable-power-system

Gas Infrastructure Europe (2018), Sector coupling and policy recommendations - available at https://ec.europa.eu/info/sites/info/files/gie - position paper - sector coupling p2g.pdf

94 Eurelectric for the 32nd European Regulatory Gas Forum (2019), Sector coupling: The electricity industry

perspective – available at https://ec.europa.eu/info/sites/info/files/eurelectric - sector coupling.pdf

95 Joint Research Centre of the European Commission (2018), "Green hydrogen opportunities in selected industrial processes" – available at https://ec.europa.eu/jrc/en/science-update/green-hydrogen

⁹⁶ Strategic Research and Innovation Agenda, Hydrogen Europe, December 2019 (p 19), also confirmed by

interviews ⁹⁷ E4tech (2017), Study on Supply Chain for Hydrogen and Fuel Cells Technologies Manier (2019). Renewable and Sustainable E 98 Lei Li, Hervé Manier, Marie-Ange Manier (2019), Renewable and Sustainable Energy Reviews, Hydrogen network design: An optimization-oriented review, https://www.sciencedirect.com/science/article/abs/pii/S1364032118308633

CE Delft (2018), Feasibility study into blue hydrogen: Technical, economic & sustainability analysis available at https://www.cedelft.eu/en/publications/download/2585
Academic Press (2018), Hydrogen Supply Chains: Design, Deployment and Operation, Chapter 7 Hydrogen

Applications: Overview of the Key Economic Issues and Perspectives https://www.sciencedirect.com/science/article/pii/B9780128111970000075

Fuel Cells and Hydrogen Joint Undertaking (2018), FCH JU – Success Stories: a partnership dedicated to clean energy and transport in Europe -- available at https://www.fch.europa.eu/sites/default/files/FCHJUsuccessstories-brochure-WEB-fin.pdf

and complex demonstrations, there might still be a case for public R&D support. Demonstration projects must be linked to overall energy policies and strategies, to avoid one-off projects that do not contribute to sustainable scale-up".

Regarding the distribution of hydrogen, there are still many different R&I issues to address which is leading to a slow development of infrastructure and holding back widespread adoption. Infrastructural construction requires planning and coordination that brings together national and local governments, industry and investors. Transport, storage and distribution are at risk of becoming a bottleneck for the accelerated rollout of hydrogen technologies at scale. This central pillar between production and consumption will require new (pipelines, refuelling stations) and old (existing gas infrastructure, salt caverns) solutions to work together in a decarbonised energy system.

In addition to its relatively high costs, its "difficult-to-prove" quality, reliability and efficiency, several other factors have inhibited hydrogen's integration into existing large-scale systems and markets. Important players in industry and in the public sector have not yet developed strong, coordinated policies or set strategic visions regarding the future role of hydrogen. Feven though there is today a consensus around the fact that clean hydrogen is the best and sometimes only alternative to decarbonise hard to abate sectors, larger-scale markets for hydrogen production and use have not yet been created. Competing technologies are gaining a share in markets where hydrogen could play a role, but where higher costs are preventing its uptake. Por example, renewable power plant operators increasingly rely on batteries to store excess electricity, rather than on electrolysers and hydrogen storage options. As hydrogen applications do not currently play larger roles in the power, industry and transport sectors, the hydrogen supply chain remains disjointed and underdeveloped. 113,114,115

¹⁰² E4tech (2019), Study on Value Chain and Manufacturing Competitiveness Analysis for Hydrogen and Fuel Cell Technologies – available at https://www.fch.europa.eu/sites/default/files/Findings%20Report%20v4.pdf

¹⁰³ IEA, the Future of hydrogen, 2019, page 181

¹⁰⁴ IEA, the Future of hydrogen, 2019, page 14

¹⁰⁵ Strategic Research and Innovation Agenda, Hydrogen Europe, December 2019 (p 10)

¹⁰⁶ McKinsey & Company (2018), Decarbonization of industrial sectors: The next frontier – available at https://www.mckinsey.com/business-functions/sustainability/our-insights/how-industry-can-move-toward-a-low-carbon-future

¹⁰⁷ Norton Rose Fulbright (2019), The potential of hydrogen to accelerate the energy transition – available at https://www.nortonrosefulbright.com/en/knowledge/publications/e9f3153d/the-potential-of-hydrogen

Fuel Cell and Hydrogen 2 Joint Undertaking (2019), Hydrogen Roadmap Europe, available at https://www.fch.europa.eu/news/hydrogen-roadmap-europe-sustainable-pathway-european-energy-transition

Smart Energy International (2019), 2019 energy storage trends – available at https://www.smart-energy.com/industry-sectors/storage/2019-energy-storage-trends/

¹¹⁰ McKinsey & Company (2017), Battery storage: The next disruptive technology in the power sector – available

https://www.mckinsey.com/~/media/McKinsey/Business%20Functions/Sustainability/Our%20Insights/Battery %20storage%20The%20next%20disruptive%20technology%20in%20the%20power%20sector/Battery-storage-The-next-disruptive-technology-in-the-power-sector.ashx

¹¹¹ Deloitte (2019), New market. New entrants. New challenges. Battery Electric Vehicles – available at https://www2.deloitte.com/content/dam/Deloitte/uk/Documents/manufacturing/deloitte-uk-battery-electric-vehicles.pdf

vehicles.pdf

112 P. Denholm, J. Nunemaker, P. Gagnon, W. Cole for the National Renewable Energy Laboratory of the US Department of Energy (2019), The Potential for Battery Energy Storage to Provide Peaking Capacity in the United States – available at https://www.nrel.gov/docs/fy19osti/74184.pdf

¹¹³E4tech (2017), Study on Supply Chain for Hydrogen and Fuel Cells Technologies

Element Energy Ltd on behalf of the UK Department for Business, Energy & Industrial Strategy (2018), Hydrogen supply chain evidence base – available at

Market-enabling regulatory frameworks to govern the production and use of key clean hydrogen applications are currently not adequate. However, as clean hydrogen has gained traction as a potential decarbonisation solution, policy makers at the European level and in some Member States have started to consider designing and implementing coordinated strategic guidelines and regulations for hydrogen. 120

> 2.1.3. The clean hydrogen value-chain not address optimized environmental, health and safety issues and take up of these technologies in the EU economy and society

The 382 respondents to the Open Public Consultation on the Clean Hydrogen initiative, expressing their views on the needs of the future European Partnerships under Horizon Europe, indicated that this initiative would make a significant contribution to the EU efforts to achieve climate-related goals.

Difficult-to-decarbonise sectors including maritime transport, aviation, heavy-duty trucking, rail, and energy-intensive industry remain high emitters. Without the decarbonisation of these key sectors, it will be almost impossible for EU Member States to meet their climate targets. 121 It is widely recognised that clean hydrogen can significantly contribute to this effort. 122,123

Nevertheless, recent research initiatives focused on the public perception of hydrogen show that public awareness of hydrogen technologies is still relatively limited. 124,125 There are also

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment data/file/760479/H2 supply chain evidence - publication version.pdf

HyTrEc2 in collaboration with the Aberdeen City Council and Pale Blue Dot (2018), Hydrogen Supply Chain Mapping Report – available at https://northsearegion.eu/media/9504/hydrogen-supply-chain-mappingreport-30.pdf
116 Lloyd's Register (2017), Hydrogen – Safety Considerations and Future Regulations – available at

https://www.fch.europa.eu/sites/default/files/3.%20Joseph%20Morelos%20-%20H2Safety.pdf

International Energy Agency (2019),The Future of Hydrogen https://www.iea.org/hydrogen2019/

Fuel Cell and Hydrogen 2 Joint Undertaking (2019), Hydrogen Roadmap Europe, available at https://www.fch.europa.eu/news/hydrogen-roadmap-europe-sustainable-pathway-european-energy-transition

Hydrogen Europe Vision on the Role of Hydrogen and Gas Infrastructure on the Road Toward a Climate Neutral Economy - A Contribution to the Transition of the Gas Market, April 2019, https://fsr.eui.eu/wp-

content/uploads/2019 Hydrogen-Europe-Vision-on-the-role-of-Hydrogen-and-Gas-Infrastructure.pdf

120 Hydrogen Europe (2018), EU Legislative framework for implementation of Hydrogen in different applications identifies EU framework that could be adapted to support adequately hydrogen like the RED, the AFID. the emission standards. the https://www.waterstofnet.eu/ asset/ public/powertogas/Conference/10-Nicolas-Brahy Hydrogen-Europe-HyLaw- Regulation-Overview.pdf

Power Engineering International (2019), Hydrogen: The hope for 'hard-to-decarbonise' sectors -

https://www.powerengineeringint.com/2019/09/26/hydrogen-the-hope-for-hard-to-decarbonise-sectors/
European Commission and Hydrogen Europe (2019), Hydrogen for Climate Action: How to kick start the Hydrogen Industry to achieve the EU climate goals? -available https://static1.squarespace.com/static/5d3f0387728026000121b2a2/t/5d9f23c486e0ee312c6380a7/1570710475 026/Framework H2+for+Climate+Action final.pdf

Hydrogen Europe (2017), Decarbonise Industry, https://hydrogeneurope.eu/decarbonise-industry

¹²⁴ Wuppertal Institute for Climate, Environment and Energy (2010), Public attitudes towards and demand for hydrogen and fuel cell vehicles: A review of the evidence and methodological implications - available at https://epub.wupperinst.org/frontdoor/deliver/index/docId/3370/file/3370 Yetano Roche.pdf

lingering concerns among the public regarding hydrogen safety. ^{126,127} At the same time, very few public initiatives have focused on educating the public with respect to hydrogen. ^{128,129}

Additionally, the EU and Member States have the potential to stimulate investments in clean hydrogen by adopting adequate measures that would drive widespread emission reductions in difficult-to-decarbonise sectors. Such measures could create market conditions for hydrogen applications in sectors where it is currently difficult for hydrogen to gain access. 132

2.2. What are the problem drivers?

2.2.1. Clean hydrogen applications more expensive than competing technologies, and not yet fully reliable nor of sufficient quality for take up

Since research on many technologies is still relatively novel, mechanisms for producing and using hydrogen are still expensive and relatively unrefined. Technologies for hydrogen production, distribution and end-use should still be technically and systematically improved.¹³³

Scientific advancement will be required to secure cost reductions and efficiency improvements in the production and use of applications at higher TRLs. Cost reduction and efficiency gains will ensure that hydrogen technologies can compete and gain market share in end-use sectors that cheaper low-carbon technologies currently dominate. ^{134,135}

¹²⁵ Revista Internacional de Sociología (2017), The Public Acceptance of Hydrogen Fuel Cell Applications in Europe – available at https://dspace.library.uu.nl/handle/1874/370207

¹²⁶ HySafe (2019), Safety of Hydrogen as an Energy Carrier – available at http://www.hysafe.org/IA_strategy

MATGAS 2000 AIE (2015), Hydrogen: applications and safety considerations – available at https://www.h2euro.org/wp-content/uploads/2017/09/Hydrogen-applications-and-safety-considrations.pdf

¹²⁸ International Congress on Education, Innovation and Learning Technologies (2015), The Challenge to teach hydrogen energy in engineering – available at https://www.researchgate.net/publication/282704070 The Challenge to Teach Hydrogen Energy in Engine ering A Proposal of a Computer Simulation Tool

¹²⁹ Fuel Cell and Hydrogen Joint Undertaking (2017), Project NET – Novel Education and Training Tools Based on Digital Applications Related to Hydrogen and Fuel Cell Technology – available at https://www.fch.europa.eu/project/novel-education-and-training-tools-based-digital-applications-related-hydrogen-and-fuel-cell
https://www.fch.europa.eu/project/novel-education-and-training-tools-based-digital-applications-related-hydrogen-and-fuel-cell
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ambition in plans to implement Paris agreement — available at https://ec.europa.eu/commission/presscorner/api/files/document/print/en/ip_19_2993/IP_19_2993_EN.pdf

European Commission and Joint Research Centre (2019), Hydrogen use in EU decarbonisation scenarios, available at https://ec.europa.eu/jrc/sites/jrcsh/files/final_insights_into_hydrogen_use_public_version.pdf

¹³² Fuel Cells and Hydrogen Joint Undertaking 10th Stakeholder Forum (2017), Fuel Cell and Hydrogen Technology: Europe's Journey to a Greener World, available at https://op.europa.eu/en/publication-detail/-publication/15d2c3b7-c502-11e7-9b01-01aa75ed71a1

[/]publication/15d2c3b7-c502-11e7-9b01-01aa75ed71a1

133 World Energy Council (2019), Innovation Insights Brief: New Hydrogen Economy, Hope or Hype? – available at https://www.worldenergy.org/assets/downloads/WEInnovation-Insights-Brief-New-Hydrogen-Economy-Hype-or-Hope.pdf

International Energy Agency (2019), The Future of Hydrogen – available at https://www.iea.org/hydrogen2019/

Fuel Cell and Hydrogen 2 Joint Undertaking (2019), Hydrogen Roadmap Europe, available at https://www.fch.europa.eu/news/hydrogen-roadmap-europe-sustainable-pathway-european-energy-transition

Consistent scientific development at lower TRLs will also be necessary to ensure that Europe's hydrogen technologies achieve the highest possible technical quality so they can compete with their international equivalents as hydrogen markets develop worldwide. 136,137

> Fragmented development of key interlinked clean hydrogen applications 2.2.2. associated to limited cross-sectoral collaboration

The FCH JU and FCH 2 JU primarily supported the development of key hydrogen applications to higher TRLs¹³⁸ though only a few pilot projects so far have included multisector actors from multiple links in the hydrogen value chain. 139

Research on different hydrogen applications is starting to become integrated, but overall the development of key applications remains fragmented, with restricted co-creation of new products and services and a limited capitalisation from high TRL ready to lower TRL ready applications along all value chains. Lack of coordination leads to inefficiencies that can increase the costs of hydrogen technologies. Fragmented technological development adds complexity to hydrogen's entry into mass markets. 140

2.2.3. *Limited large-scale deployment of clean hydrogen generation capacity*

Many industrial and research stakeholders interviewed for the impact assessment consider that the FCH 2 JU has not supported enough large-scale demonstration projects on clean hydrogen production, especially in large-scale coupling with renewable power plants to generate necessary investments in mass manufacturing capacity for production equipment.¹⁴¹ Large-scale demonstration projects are vital in proving the feasibility of and potential for using large-scale electrolysers. 142 They instil in investors the confidence necessary to back wider market deployment of these technologies. This issue will be partly addressed in the Horizon 2020 Green Deal Call, under preparation.

> 2.2.4. Underdeveloped infrastructure and non-adapted for storing, transporting and distributing hydrogen

Transportation, distribution, and refuelling infrastructure will be necessary to enable the uptake of hydrogen in the power, transport, and industry sectors. 143 Cross-border infrastructural networks spanning significant distances between Member States will need to

Hydrogen (2017), Global Trends and Outlook for Hydrogen - available at https://ieahydrogen.org/pdfs/Global-Outlook-and-Trends-for-Hydrogen Dec2017 WEB.aspx

¹³⁷ IRENA (2018), Hydrogen from Renewable Power: Technology Outlook for the Energy Transition – available https://www.irena.org/-/media/Files/IRENA/Agency/Publication/2018/Sep/IRENA Hydrogen from renewable power 2018.pdf

Consensus from the majority of interviewees.

Fuel Cells and Hydrogen Joint Undertaking (2018), Success Stories: A partnership dedicated to clean energy and transport in Europe - available at https://www.fch.europa.eu/sites/default/files/FCHJUsuccessstories-brochure-WEB-fin.pdf

140 E4tech (2019), Study on Value Chain and Manufacturing Competitiveness Analysis for Hydrogen and Fuel

Cell Technologies – available at https://www.fch.europa.eu/sites/default/files/Findings%20Report%20v4.pdf ¹⁴¹ Consensus following interviews with stakeholders in industry and in research organisations.

¹⁴² Fuel Cells and Hydrogen Joint Undertaking (2018), Success Stories: A partnership dedicated to clean energy and transport in Europe - available at https://www.fch.europa.eu/sites/default/files/FCHJU- successstories-brochure-WEB-fin.pdf

143 Jorg Gigler and Marcel Weeda on behalf of TKI Nieuw Gas (2018), Outlines of a Hydrogen Roadmap –

https://www.topsectorenergie.nl/sites/default/files/uploads/TKI%20Gas/publicaties/20180514%20Roadmap%2 0Hydrogen%20TKI%20Nieuw%20Gas%20May%202018.pdf

be constructed to connect optimal clean hydrogen production regions to optimal hydrogen consumption regions. 144,145 Development of the required infrastructure will require R&I activities, for example to address the challenges of injection of hydrogen into the gas grid, demonstration of large volume refuelling stations (> 1 tonne of hydrogen per day) and to address issues related to transportation of liquid hydrogen by trucks.

Infrastructure development goes beyond the scope of the proposed partnership and will be supported by other funding programmes such as the Connecting Europe Facility (CEF). However, this requires intense coordination between industrial players and policy makers in different Member States. Infrastructure development has stalled partly in response to a perceived lack of demand for hydrogen. However, hydrogen applications cannot enter mass markets or deploy at large scale until this infrastructure is in place.

The construction of an integrated infrastructural network will also bring together important players from different segments of the hydrogen value chain and will form the backbone of a more cohesive, complete hydrogen ecosystem. 146

2.2.5. *Lack of large-scale deployment of clean hydrogen end-use applications*

There have not been enough large-scale demonstration projects on key technologies to generate the necessary investments in mass manufacturing capacity for end-use products and equipment. 147 Large-scale demonstration projects are vital in proving the feasibility of and potential for using large-scale fuel cell applications (Combined Heat and Power (CHP) systems, vehicles...), burners or turbines. 148

2.2.6. Insufficient demand, acceptance and preparation for clean hydrogen solutions

Public awareness and public knowledge on hydrogen are still limited. Existing and previous partnerships on clean hydrogen have prioritised technological development, with less research devoted to engaging and educating the public. Very few initiatives have sought to educate the public on the role hydrogen might play in large-scale decarbonisation. 149150

Local and regional community organisations and authorities – which can play instrumental roles advocating for clean hydrogen integration into their regional economies - often lack the up-to-date information needed to design policy proposals and to allocate funding

38

¹⁴⁴ Joint Research Centre (2016), 4th International Workshop on Hydrogen Infrastructure and Transportation Report, https://publications.jrc.ec.europa.eu/repository/bitstream/JRC103586/4%20int%20workshop%20on%2

⁰h2%20infra%20final%20pdfonline.pdf
¹⁴⁵ Compendium of Hydrogen Energy (2016), Building a hydrogen infrastructure in the EU – available at https://www.sciencedirect.com/science/article/pii/B9781782423645000129?via%3Dihub

146 International Energy Agency (2019), The Future of Hydrogen — https://www.iea.org/hydrogen2019/

¹⁴⁷ Consensus following interviews with stakeholders in industry and in research organisations.

¹⁴⁸ Fuel Cells and Hydrogen Joint Undertaking (2018), Success Stories: A partnership dedicated to clean energy and transport in Europe - available at https://www.fch.europa.eu/sites/default/files/FCHJUsuccessstories-brochure-WEB-fin.pdf

Revista Internacional de Sociología (2017), The Public Acceptance of Hydrogen Fuel Cell Applications in Europe – available at https://dspace.library.uu.nl/handle/1874/370207

Hyacinth (2017), Public Awareness and Social Acceptance – available at http://hyacinthproject.eu/publicawareness-and-social-acceptance/

efficiently. 151 There is also evidence to suggest that the public remains concerned regarding the safety of hydrogen technologies. 152,153,154

Additionally, further educational efforts will be required to train the engineers, executives, and policy-makers necessary to support the integration of hydrogen into existing systems and markets and to develop the capacity required to enable a cross-sectoral hydrogen transition. ¹⁵⁵

Beyond education and communication, one of the roles of the proposed initiative will be on co-creating solutions, starting from the users' needs (user which can be citizen but also public authorities), along with testing and experimentation. Research on social sciences and humanities will be key to understand and analyse how to get citizens' engagement on these relatively disruptive hydrogen solutions.

2.2.7. Inadequate regulatory, policy and financing frameworks for clean hydrogen

This issue is out of the direct scope of the proposed initiative but it is important that these aspects should be considered early enough to be able to engage with standardisation and regulatory bodies, anticipating what would be needed for increased demand, acceptance, and ultimately uptake of hydrogen solutions. In this context, Pre-Normative Research (PNR) will be an important aspect of the proposed initiative.

Policy makers would need to develop a regulatory framework to govern the production and use of clean hydrogen applications. EU regulation concerning renewable energy, alternative fuel infrastructure, gas infrastructure, market design, CO₂ emission standards and clean vehicles would need to be adapted in order for clean hydrogen to be recognised for its climate contribution. ¹⁵⁶ A clear definition of clean hydrogen should be the first step to ensure the proper integration into all regulatory frameworks. The lack of coordinated regulatory frameworks complicates hydrogen's entry into mass markets. Needless to say, harmonised regulatory frameworks would encourage investors and enable more hydrogen applications to be deployed at larger scales.

2.3. How will the problem(s) evolve?

Without any action, it is anticipated that:

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¹⁵¹ Fuel Cells and Hydrogen Joint Undertaking 10th Stakeholder Forum (2017), Fuel Cell and Hydrogen Technology: Europe's Journey to a Greener World, available at https://op.europa.eu/en/publication-detail/-publication/15d2c3b7-c502-11e7-9b01-01aa75ed71a1

Hydrogen Europe (2017), Hydrogen safety – available at https://hydrogeneurope.eu/hydrogen-safety
MATGAS 2000 AIE (2015), Hydrogen: applications and safety considerations – available at https://www.h2euro.org/wp-content/uploads/2017/09/Hydrogen-applications-and-safety-considrations.pdf
Hydrogen Europe (2017), Hydrogen safety – available at https://hydrogeneurope.eu/hydrogen-safety

¹⁵⁵ Fuel Cells and Hydrogen Joint Undertaking (2011), Project Hyprofessionals – Development of Educational Programmes and Training Initiatives Related to Hydrogen Technologies and Fuel Cells in Europe – available at https://www.fch.europa.eu/project/development-educational-programmes-and-training-initiatives-related-bydrogen-technologies-an

hydrogen-technologies-an

136 Hydrogen Europe (2018), EU Legislative framework for implementation of Hydrogen in different applications – available at https://www.waterstofnet.eu/ asset/ public/powertogas/Conference/10-Nicolas-Brahy Hydrogen-Europe-HyLaw- Regulation-Overview.pdf

- Hydrogen applications will not be able to be deployed at scale, nor will they be able to achieve cost reductions;
- Improving the environmental performance of energy intensive industries will be more complex, lengthy, expensive and will hinder reaching the 2050 targets; and
- Several European industrial sectors will be at greater risk of losing competitiveness in the global market.

The core problems in the field of clean hydrogen will persist and worsen over time, if action is not taken to address them. 157

The costs of clean hydrogen solutions will not decrease on their own. Without action hydrogen technologies will not be in a position to compete with competitor low-carbon technologies like BEVs and battery storage, since those will likely achieve further cost reductions and efficiency gains as they have already achieved economies of scale. ¹⁵⁸. As a consequence, Europe's competitive positioning in the hydrogen industry will deteriorate. ¹⁵⁹

It will become increasingly difficult for hydrogen solutions to enter mass markets and deploy at large scales, if policy makers and industrial players begin to regard hydrogen as a less viable solution. Unless efforts are made to promote technological advancements across sectors and develop cohesive, complete value chains for hydrogen production, distribution, and use, heavy industry and heavy transport sectors will not be able to integrate clean hydrogen solutions into their operations. ¹⁶⁰ Sector coupling will then likely be regarded as infeasible. Difficult-to-decarbonise sectors will remain highly emissive and Member States will not be able to achieve their climate targets. ¹⁶¹

Mass manufacturing capacities will not be developed, and the hydrogen value chains will not effectively industrialise, preventing efficiency gains and potential cost reductions. ¹⁶²

If the public is not sufficiently educated regarding hydrogen solutions, these are unlikely to garner the support they need for wider-scale deployment. Additionally, it will be more difficult to overcome concerns regarding hydrogen safety if proper educational mechanisms are not put into place. Finally, the workforce required to enable a cross-sector, cross-border hydrogen transition will be underequipped if further educational efforts are not made to build capacity. ¹⁶³

International Energy Agency (2019), The Future of Hydrogen – available at https://www.iea.org/hydrogen2019/

Fuel Cell and Hydrogen 2 Joint Undertaking (2019), Hydrogen Roadmap Europe, available at https://www.fch.europa.eu/news/hydrogen-roadmap-europe-sustainable-pathway-european-energy-transition
European Commission and Hydrogen Europe (2019), Hydrogen for Climate Action: How to kick start the

European Commission and Joint Research Centre (2019), Hydrogen use in EU decarbonisation scenarios, available at https://ec.europa.eu/jrc/sites/jrcsh/files/final insights into hydrogen use public version.pdf ¹⁶² E4tech (2019), Study on Value Chain and Manufacturing Competitiveness Analysis for Hydrogen and Fuel

Cell Technologies – available at https://www.fch.europa.eu/sites/default/files/Findings%20Report%20v4.pdf
Hydrogen and Fuel Cells Program of the US Department of Energy (2019), Education – available at https://www.hydrogen.energy.gov/education.html

3. WHY SHOULD THE EU ACT?

3.1. Subsidiarity: Necessity of EU action

In the context of the specific complex and interlinked value chains of clean hydrogen where costs, risks and an important number of players for new developments depend on effective cooperation, **inter-sectoral collaboration at the European level** is essential to succeed in demonstration and deployment at scale. The exchange and pooling of knowledge between the stakeholders is critical to avoid duplication, extract lessons and especially successes in order to improve fundamental and applied research. Standards and norms should be addressed at international level, where the EU should ensure having only one voice.

The European hydrogen industry and research stakeholders, when acting alone or through small size consortia, do not have all the required knowledge from fundamental scientific to market oriented, are not integrating all concerned sectors and are not able to manage all the risks. In addition, they do not have sufficient size for the type of risk-sharing projects involved for expensive demonstration of innovative solutions. The nature and the size of the challenges also go beyond the capacity of individual Member States.

Due to the increasing number of applications, derived from existing emerging uses and targeted in the proposed initiative, collaboration and coordination between industrial and research base actors active in the hydrogen economy is essential. It is a prerequisite to retain the competitive position of the concerned industrial sectors.

3.2. Subsidiarity: Added value of EU action

There are several national R&I schemes, such as in Germany, France, Denmark and Italy which are, committing significant budgets on hydrogen - in total approximately EUR 1 billion funding over a seven-year period. However, these are insufficiently coordinated within the Member States, between Member States and with the EU, thus leading to a possible duplication of activities and lack of efficiency.

With a clear climate policy and clear objectives for 2030 and for 2050, there is a strong need for directionality of European investments as well as additionality. EU action would complement the national schemes (reflected in NECPs) to provide a clearer policy approach, especially as innovations are urgently needed to realise the climate action plan and its

Overall the results of the Member States consultation on the Inception Impact Assessment confirm the relevance of the proposed initiative on Clean Hydrogen, with 82% considering it very or somewhat relevant for their research organisations, including universities, 79% for their national policies and priorities, and 72% respondents found the proposed partnership as relevant for their industry. In terms of overcoming fragmentation within Europe, the challenges of delivering improved coordination between Member States' clean hydrogen research and innovation support remain significant, therefore increasing the importance of an EU action.

objectives.

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¹⁶⁴ Figures from the IEA's Energy Technology RD&D Budget Database, 2011-2018

¹⁶⁵ Competitiveness of the EU Aerospace Industry with focus on Aeronautics Industry, Ecorys, 2009

^{1.} European Partnerships under Horizon Europe: results of the structured consultation of Member States

4. **OBJECTIVES: WHAT IS TO BE ACHIEVED?**

4.1. General objectives of the initiative

Based on the identified problems, the overall objective of the proposed Clean Hydrogen initiative is to produce noticeable, quantifiable contributions towards the achievement of climate targets in 2030 and pave the way for climate neutrality by 2050. Reaching this long term vision means capacity to supply hydrogen at scale and simultaneously boosting demand. Therefore, the scope of hydrogen applications has to increase from its present focus in FCH 2 JU on transport applications (passenger cars and buses), fuel cells and electrolysers, by addressing R&I issues related to production, distribution and storage of clean hydrogen to supply hard to decarbonise sectors such as heavy industries (steel, cement, chemical, ...) and heavy duty transport applications (trucks, buses, rail, ships, ...). With the emergence of these new applications, the supply chain has become more complex and continuous improvements ¹⁶⁶ (new materials ¹⁶⁷, efficiency, reliability, lifetime ¹⁶⁸, cost ¹⁶⁹) are needed for all applications.

The following general objectives have been identified:

- Strengthen and integrate EU scientific capacity to support the creation, exploitation and sharing of knowledge to accelerate the development and improvement of advanced clean hydrogen applications ready for market, across energy, transport, building and industrial end-uses.
- Enable large scale deployment capacity for key parts of the clean hydrogen value chain and strengthen the competitiveness of the EU clean hydrogen value chain (notably SMEs) making the most of all future opportunities, accelerating the market entry of innovative competitive clean solutions to support the decarbonisation of the EU economy. 171
- Ensure a safe and frictionless deployment of clean hydrogen technologies for the greening of hydrogen generation and use through innovative solutions.

These objectives address the clean hydrogen economy from a broad perspective and are aligned with the objectives of the Horizon Europe framework. If pursued, they will contribute to the pursuit of several Sustainable Development Goals including: SDG7 (Affordable and clean energy); SDG11 (Sustainable Cities and communities); and SDG13 (Climate action) and to a lesser extend SDG8 (Decent work and economic growth) and SDG9 (Industry, innovation and infrastructure). 172

¹⁶⁶ The Appendix: Analytical report on the Strategic Value Chain (SVC) on Hydrogen technologies and systems in the frame of the Strategic Forum on IPCEI (called the "IPCEI Appendix"), points out the special techno-economic challenges of reducing the cost, increasing the efficiency and reducing the use of Critical Raw Materials (from FCH JU lists) (p 29)

The "IPCEI Appendix" addresses, as example, the development and qualification of new materials to continue improving high pressure hydrogen storage (p 10)

¹⁶⁸ Example of buses lifetime addressed in the "Competitiveness Analysis" (p 67)

¹⁶⁹ The "IPCEI Appendix" points out the cost of producing hydrogen should be reduced (p 13), FCEV should cost similar to electrical vehicles (p14), technologies cost reduction is also a question of competitiveness with other regions especially Asian competitors (p28). The "Competitiveness Analysis" illustrates cost decrease expectations by 2030, for many different applications, depending on mass production (p 48)

See Annex 6 for general information on the hydrogen sector.

¹⁷¹ Please see Chapter 1 f or an in-depth discussion on EU competitive positioning across member states and different hydrogen applications.

¹⁷² European Commission International Cooperation and Development (2019), The Sustainable Development Goals – available at https://ec.europa.eu/europeaid/policies/sustainable-development-goals en

4.2. Specific objectives of the initiative

In order to achieve the general objectives, seven specific objectives are defined. These specific objectives respond to each of the problem drivers discussed in Section 2.2. The list of specific objectives is the following:

- Improve through research and innovation the cost-effectiveness, reliability and quality of clean hydrogen applications developed in the EU. The objective is to deliver hydrogen based solutions at a price equivalent to the alternatives by 2030;
- Reinforce the EU scientific and industrial ecosystem for innovative clean hydrogen applications;
- Demonstrate and scale-up clean hydrogen applications to stimulate large-scale generation capacity. The objective is to produce clean hydrogen at a cost of ~EUR 1.5-3/kg by 2030, allowing penetration into mass markets ¹⁷³;
- Accelerate through demonstration the co-deployment of EU storage, transport and distribution infrastructures for innovative clean hydrogen solutions. The objective is to reduce the distribution costs to less than EUR 1/kg of hydrogen at scale by 2030 174.
- Prove the economic and industrial capacity of clean hydrogen to provide long-term climate neutral innovative solutions across the power and gas, maritime, aviation, rail, heavy duty transportation, building and industrial sectors;
- Increase public and private awareness, acceptance, demand and uptake of clean hydrogen solutions.

Note that issues relating to the policy, regulatory and financial framework have to be addressed in parallel and/or factored in so that the initiative is enabled to achieve its objectives and effectively contribute to the climate policies and targets from a broader perspective.

Intervention logic of the initiative

Many of the respondents to the Open Public Consultation took the opportunity to underline key messages regarding the initiative:

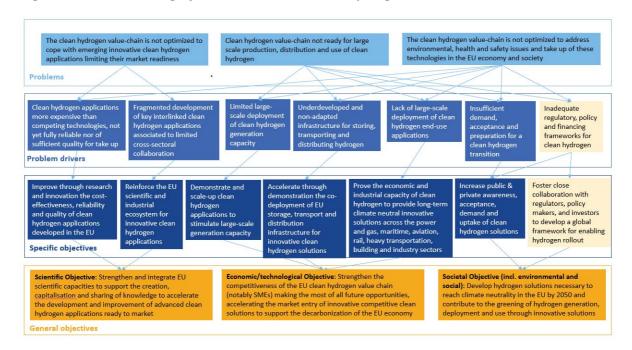
- The global positioning of Europe: outlining the role of global competition (including the role of technology), the importance of autonomy for Europe and the ability of Europe to act as a key player at the global level.
- The need for a balance between policy objectives and private sector interests.
- The importance of the transition between research and innovation (implementing research results in the market).
- The importance of multidisciplinary and specifically cross-sectoral/cross-partnership collaboration.

The relationship between the general and specific objectives of the potential initiative on Clean Hydrogen is shown in Figure 9.

¹⁷³ Production costs of clean hydrogen are linked to Electrolyser costs. Those have already been reduced by 60% in the last ten years, and are expected to halve in 2030 compared to today with economies of scale. In areas with low-cost renewable electricity, electrolysers are expected to be able to compete with fossil-fuel hydrogen in 2030.

^{1&}lt;sup>74</sup> Distribution costs can vary dramatically between transport means (e.g. pipeline (15 cents/kg) versus trucks versus liquid carriers, etc....) and context of usage. The figure of "less than 1 euro" is for the specific case of transport by truck for mobility application.

Figure 9: Intervention Logic for the initiative on Clean Hydrogen



How would success look like?

Should the initiative deliver on its specific objectives, it is expected that it would translate in practice into the following impacts:

Scientific impacts

➤ Hydrogen applications are more competitive, efficient and reliable. A key milestone would be the achievement of the time-bound targets of producing clean hydrogen at a cost of ~EUR 1.5-3/kg and to reduce the distribution costs to less than EUR 1/kg of hydrogen at scale by 2030. The EU maintains its leading position for cutting edge research and innovation in hydrogen applications

If the initiative can push for continued technical improvement of hydrogen applications and encourage distinct industries to collaborate on research projects, new potential science- and technology-based applications for hydrogen are likely to emerge. Additionally, the EU will be able to maintain the role it currently plays as a global hub for hydrogen research and innovation for the primary benefit of EU leading research institutions and innovative SMEs.

Economic/technological impacts and impact on SMEs

- EU validates its ability to deploy economically viable hydrogen generation at scale
- EU validates its ability to deploy hydrogen infrastructures at scale
- ➤ EU validates its ability to scale-up clean economically viable hydrogen end-use applications in heavy-duty transport and energy-intensive industries maintaining global competitiveness
- > EU growth in the hydrogen economy, especially for SMEs

Successful realisation of the objectives would result in a strengthened EU hydrogen industry. The EU would be able to pursue its climate targets while protecting the competitiveness of its energy intensive industries and heavy transport sectors. SMEs which have developed innovative hydrogen technologies would be likely to thrive and receive increased investment. There is also potential for localised economic growth in areas where hydrogen hubs or valleys are developed. This would impact stakeholders across the EU;

Member States which can capitalise on hydrogen development and uptake could incorporate a new, competitive industry into their economies. Across industrial and transport sectors, companies will be equipped to comply with climate standards without sacrificing competitiveness. There are substantial opportunities for SMEs to grow successful businesses and position themselves strongly within the hydrogen supply chain.

Societal impacts

- The EU's maritime, aviation, rail and heavy-duty transport sectors, as well as its gas grid, can progressively decarbonize so the EU can meet its climate targets
- > Reduction of carbon emissions and pollution to air, water and soil
- ➤ Knowledge capacity built up to support the hydrogen transition while increasing public support for additional hydrogen policy and regulatory frameworks increases

Environmental impacts

If executed in full, the initiative could lead to a substantial environmental impact. Especially in sectors that are difficult to decarbonise, increased support for and investment in hydrogen applications would enable energy-intensive industries and heavy-duty transport to fully decarbonise. In turn, this would strengthen the EU low carbon society and enable the EU to meet its climate targets. This would impact a wide range of stakeholders in the long-term, from company owners to citizens and local, Member State, and EU-level policy makers. In addition to decarbonisation goals, a clean hydrogen economy can significantly contribute to decrease outdoor pollution, thanks to the replacement of fossil-based fuels and feedstock.

Social impacts

Additional demonstration projects are likely to generate further public interest in hydrogen. At the same time, increased public outreach and education on hydrogen would likely create a basis of public support for hydrogen applications. Getting citizens' engagement and cocreating solutions, starting from the users' needs would facilitate the integration of innovative solutions into societies, from local to national to international levels. Proof of hydrogen solutions' feasibility would also likely prompt policy makers to act quickly and develop regulatory frameworks that can effectively govern applications' uses.

Increased public outreach on hydrogen would in turn increase public support for hydrogen; in a best case scenario, policy makers would receive public mandates/public pushes for developing policies that enable hydrogen's integration into existing systems, similar to how public support for renewables integration bolstered EU policymakers' support for renewable power in recent years. Finally, the deployment of hydrogen produced from renewable electricity would significantly facilitate and enable the deployment of renewable electricity production at scale.

Based on the interviews and as shown from the result of the Open Public Consultation, the results and impacts of the initiative can best be achieved if industry and research are involved at all stages, starting from basic research up to ready-to-market level, in order to develop and bring hydrogen technologies to large deployment scales. This would ensure that research and development are in line with the overarching goals, and also avoid fragmentation and duplication of efforts.

4.3. What is needed to achieve the objectives – Key functionalities needed

Given the focus of the impact assessment on comparing different forms of implementation, the identification of "key functionalities needed" allows making the transition between the

definition of the objectives and what would be crucial to achieve them *in terms of implementation*. These functionalities relate to the type and composition of actors that have to be involved, the type and range of activities that should be performed, the degree of directionality needed and the linkages needed with the external environment.

4.3.1. Type and composition of actors to be involved

To be able to achieve the scientific objectives of the proposed clean hydrogen initiative, all sectors concerned by the hydrogen economy should be given the possibility to get involved in preparing and implementing the Research and Innovation Agenda, in particular priority should be given to solutions and actors that can contribute most to the energy and climate objectives of the EU. The concerned sectors (involving industry and SMEs), in addition to the hydrogen manufacturing actors, should comprise of at least heavy industry using hydrogen as feedstock, the biomass/biogas sector, the power sector, where hydrogen can act as long-term storage for renewables generation, the gas and grid operators, the transport sector, the building and heating sector and project developers who can coordinate efforts in project implementation, especially to facilitate sector coupling. In addition, the public sector should also be involved, especially regional and national authorities, the latter being responsible to set up climate policies (ideally by integrating hydrogen into the NECP 2030) and measures (market mechanisms) to fill in the huge gap between ready-to-market technology development and large-scale uptake. National authorities should also address cross-border issues like infrastructure and corridors (pipelines, hydrogen refuelling stations ...), norms and standards.

Despite the potential of hydrogen to contribute to the decarbonisation of many different sectors, one has to acknowledge that the deployment of hydrogen and fuel cells is only marginal today (see Annex 6). As a consequence, there is no evidence of anti-competitive behaviour from the side of partners or in product markets. To accelerate the commercial readiness of hydrogen technologies, the proposed Clean Hydrogen Partnership is building on the work of FCH 2 JU which made the start of commercialisation of a first series of applications possible. It will aim at bringing a second series of applications to commercial level in particular in industry heat and feedstock, power generation and hard to abate transport sectors.

This increased collaboration between researchers, SMEs and industrial players will also be critical to achieve the economic/technological objectives by facilitating the entry of hydrogen into multiple markets. It will also enable the development of a more cohesive, complete hydrogen ecosystem with strongly linked value chains from clean production to efficient end-use. 175

Finally, the initiative would benefit from involving non-EU market players with their own strengths that can complement EU R&I actors and from the coordination of well-established partnerships with international actors e.g., the International Partnership for Hydrogen and Fuel Cells in the Economy (IPHE); Mission Innovation – Renewable and Clean Hydrogen Challenge, Clean Energy Ministerial (CEM) Hydrogen Initiative, Hydrogen Energy Ministerial (HEM), and so on.

All categories of respondents to the Open Public Consultation clearly see stakeholders from industry as the most relevant in setting a joint long-term agenda, followed by academia and governments (Member States and Associated Countries).

4.3.2. Type and range of activities needed

For hydrogen, we are talking today about a very dynamic sector and community. Responsiveness to new technological developments will be a must, meaning that it should be ensured that the partnership will be able to react quickly and efficiently in particular considering the proposed substance of cooperation with the partnership seeking now to address broader research and innovation aspects related to production, distribution, infrastructure and storage of hydrogen. As such, it is open to newcomers as mentioned in paragraph 4.3.1.

A number of activities have been identified to ensure flexibility of implementation and create the expected impacts such as:

- (i) Seek synergies with R&I programmes of other sectors and initiatives strong links are already identified with the candidate European Partnerships on: towards zero emission road transport transforming EU's railway system, clean aviation, clean steel, zero emission waterborne transport and processes 4 planet;
- (ii) Coordinating R&I actions ranging from concept to demonstration and validation activities (covering all Technology Readiness Levels), ensuring inclusion of new actors and integration of extended value chains;
- (iii) Developing deployment and piloting activities to ensure flexibility over time across the range of applications implemented;
- (iv) Communication and dissemination activities to ensure societal and political support for envisaged developments and overseeing actions fostering regulation or standardisation
- (v) Co-creating solutions with end-users, emphasising the importance of flexibility in addressing different target groups over time, including industrial end users for which low carbon alternatives are not evident.

4.3.3. Priority setting system and level of directionality required

A common vision for the initiative addressing an integrated research and innovation agenda cannot be achieved in the absence of a strong commitment of industry, the research organisations and the public sector in Europe. It is critical that stakeholders with long-term commitments in the hydrogen sector remain involved in the initiative. Industry should be ready to continuously improve technologies and applications, once uptake is starting, in order to constantly improve efficiency, cost, reliability and performance. Clean hydrogen R&I activities (under Horizon Europe) should be based on cooperation between consortia of

In the Open Public Consultation, the following activities were considered the most relevant: deployment and piloting activities, joint R&D programme, collaborative R&D projects, whereas input to regulatory aspects and co-creation of solutions with end-users scored less.

stakeholders, working together on the basis of consented multi-annual (and possibly multi-projects) actions targeted at specific technological goals.

Less mature applications still need to be improved and will need to involve research and industry players in the long-term. Political commitment from both Member States' and the

¹⁷⁶ The Strategic Research and Innovation Agenda, Hydrogen Europe, December 2019, p 7

EC is of utmost importance — as hydrogen technologies are not yet economically competitive. Strong signalling and support from governments is necessary to ensure that hydrogen applications will play a long-term role in future energy/industry/transport landscapes. To conclude, the level of directionality should be as high as possible for the initiative to reach its objectives. The strategic vision should be shared and implemented as much as possible by the key stakeholders along the whole value chain.

4.3.4. Coherence needed with the external environment

Due to its versatility and cross-sectoral integration, clean hydrogen should be addressed through close collaboration frameworks with other programmes and initiatives to create synergies and limit duplications. Regarding other initiatives, it is crucial to share views on the ways to integrate hydrogen into the concerned sectors (e.g. trucks, coaches, rail, maritime, gas and power, grids, aviation, building, ...) and ideally to share a common vision to define where to concentrate efforts. Complementary calls, including their funding and management, would be the next step to ensure full coherence with other initiative's agendas.

Other key elements related to the framework conditions will play a role in the ability of the initiative to reach its objectives. This concerns in particular the next steps after R&I activities, namely scaling up, market deployment, regulatory frameworks, infrastructure deployment, customer acceptance, etc. For supportive framework conditions, the initiative should ensure close collaboration and engagement with end users, citizen, policy makers and regulators. Furthermore there is a need to link with other crucial funding and financing mechanisms, in particular articulation with the Connecting Europe Facility; ETS Innovation fund; IPCEI and risk capital players to finance scaling up and deployment activities and financing institutions to bring solutions to the market will be considered.

5. WHAT ARE THE AVAILABLE POLICY OPTIONS?

This section describes the specific functionalities that could be provided under the baseline scenario of traditional calls and the different options of different types of European partnerships.

5.1. What is the baseline from which options are assessed?

The baseline scenario used in this impact assessment is a situation without a Partnership and only traditional calls of Horizon Europe. Given that there is a predecessor Partnership as well as other funding sources in the area, these will continue generating effects even if there is no new Partnership. In particular it is expected that these already existing initiatives will still have an impact in the coming years.. This is taken into account in the effectiveness assessment.

In parallel, the baseline situation means that the current implementation structure of the Article 187 would be closed, which bears winding down and social discontinuation costs. There would also be financial cost-savings related to the closing of the structure, related to operations, staff and coordination costs in particular. This is taken into account in the efficiency assessment.

Table 1: Key characteristics of the baseline situation - Horizon Europe calls

What is feasible under this option - Functionalities of option

Enabling appropriate profile of participation

- The Commission would need to prepare the Strategic Research and Innovation Agenda (SRIA) by consulting a wide range of actors, i.e. hydrogen equipment manufacturers, end-use sectors (energy intensive and hydrogen feedstock industry, heavy transportation, building) and their equipment manufacturing industry, gas operators and industries, the gas and power sectors (including renewable), related research organisations and academia and representatives of local and regional authorities or communities (as key player to build ecosystems). This could be challenging, considering the current evolution of the hydrogen economy and the early stage of building up a clean hydrogen EU strategy (not existing at the moment).
- The implementation of the SRIA would need further consultation with research and industrial organisations to deal with technical, economical and industrial knowledge as expertise is needed to address hydrogen versatility in an evolving landscape.
- The specification of calls over the period of the Framework Programme will reflect the need for an evolving profile of participation, with different consortia forming at different stages to take different types of activity forward.

Supporting implementation of R&I agenda

- Implementation would rely on standard infrastructure underpinning the open calls procedure, drawing on resources of relevant executive agencies and Commission IT systems.
- Administrative costs for the European Commission would be significantly reduced.
- Calls for proposals would be published in the work programmes of Horizon Europe.
- Transparency and open publication of results would ensure their availability to interested parties.
- Dissemination of knowledge and share of practice would happen predominantly among partners within the calls consortia.

Ensuring alignment with R&I agenda

- Work programmes would need to reflect the requirement for R&I activity across TRLs, with input from representatives of all relevant stakeholders.
- Specification of calls for activity at higher TRLs, particularly demonstration projects, would need substantial input from industry.
- R&I activity would focus on the short to medium term needs of industry and fundamental research, although it would also include long term applications and trends.
- Commission input into specification and oversight of calls would ensure alignment with overarching policy objectives as well as integration with other programmes.
- Selection of high TRL projects would require provision of external expert (and independent) advice to the Commission.

Securing effective leveraging of resources

- Progress of R&I effort would depend on EU funding, with leveraging of industry support coming mainly from their financial contributions determined by Horizon Europe rules.
- Demonstration programmes would require significant in-kind support and collaboration from industry.

Key differences compared to the current situation

The commission would need to complete the SRIA and recruit new resources i.e. Policy Officers to design, implement and monitor the research programme. There would be significantly weakened contacts with industry & research, since in the absence of a partnership Hydrogen Europe and Hydrogen Europe Research Organisations may well cease operation. Dissemination of results, promotion of safety and standards through the partnership would no longer occur.

5.2. Description of the policy options

Table 2: Key characteristics of Option 1 – Co-Programmed European Partnership

	What is feasible under this option - Functionalities of option
Enabling appropriate profile of participation	 The partnership would enable participation by all key stakeholders contributing to the specification and delivery of the SRIA. It would need to consult with a wide range of stakeholders, within its membership to ensure that the SRIA, and ultimately the work programme, is aligned with industry, research and market needs. At the same time, it would offer the flexibility to change the profile of participation over time, with new partners joining to support new areas of activity in response to emerging results and changing priorities.
Supporting implementation of R&I agenda	 Implementation would rely on standard administrative infrastructure underpinning the open calls procedure, drawing on resources of relevant executive agencies and Commission IT systems. Calls for proposals would be published in the work programmes of Horizon Europe.

	- Transparency and open publication of results would ensure their availability to interested parties.
Ensuring alignment with R&I agenda	 Work programmes would need to reflect the requirement for R&I activity across TRLs, with input from the various partners to achieve an appropriate balance of activity directed towards different markets. The partnership would be responsible for ensuring that priorities for calls were specified in line with R&I priorities, including demonstration projects. R&I activity would be likely to focus on the medium-term needs of industry and research. Programme Committee would ensure alignment with overarching policy objectives and coordination with related programmes.
Securing effective leveraging of resources	 Aspirations for partner contributions would be clearly defined at the outset. Industry or research commitments would not be legally binding. Expected in-kind contributions from the private sector would be identified in the work programme.

Table 3: Key characteristics of Option 2 – Institutionalised European Partnership (Article 187 TFEU)

	What is feasible under this option - Functionalities of option
Enabling appropriate profile of participation	 The partnership would enable participation by all key stakeholders contributing to the specification and delivery of the SRIA. The implementation of the agenda would not need further consultation, as the structure, thanks to its technical, economical and industrial knowledge and acquired expertise, allows self-management. It would provide a forum or even a platform for consulting stakeholders on R&I priorities and the work programme, ensuring that they are aligned with industry, research and market needs and with the agenda of other partnerships and sectoral programmes. Participation would be less flexible than under other options, but it might nevertheless be possible to change the profile of participation over time, with new partners joining to support new areas of activity in response to emerging challenges and evolving priorities.
Supporting implementation of R&I agenda	 A dedicated administrative structure would be established to coordinate the specification of R&I activity, manage implementation and report on the results (with administrative expenditure limited to a percentage of the budget). Calls for proposals would be published broadly by the administrative structure. Transparency and open publication of results would ensure their availability to interested parties. Dissemination of knowledge and share of practices would happen among the stakeholders of the community, with potential diffusion activities managed by the partnership structure.
Ensuring alignment with R&I agenda	 The partnership would be responsible for specifying a work programme fully in line with the R&I priorities identified by industry and research organisations to fulfil the European policy needs, combining activities across low and high TRLs and in different areas. The work programme would reflect the medium- and long-term needs of industry, the research organisations and society in adopting clean hydrogen solutions. Commission participation in the partnership governance arrangements and approval of the work programme would help to ensure alignment with overarching policy objectives and enable integration with other programmes and initiatives.
Securing effective leveraging of resources	 Legally binding funding requirements would be clearly defined at the outset, with private sector partners expected to provide between 50% and up to 75% of partnership resources through in-kind and/or financial commitments.

5.3. Options discarded at an early stage

The co-funded partnership and an institutional partnership created under Article 185 of the TFEU are not considered relevant for the impact assessment on the Clean Hydrogen initiative. In a co-funded partnership option, the partners do not include private sector companies or private research organisations and instead include only public authorities with

research funders (or governmental research organisations) and other public authorities at the core of the consortium. These types of partnerships rely on pooling and/or coordinating national programmes and policies with Union policies and investments, to help overcome fragmentation. This form of implementation only allows to address public partners at its core (comparable to the Article 185 initiatives), with Member States that are partners in this partnership becoming the 'owners' of the priority and taking sole responsibility for its funding. Industry and research RD&I can nevertheless be addressed by the activities of the partnerships, but it does not make formal commitments and financial contributions, or decide the R&I priorities. In the context of a Clean Hydrogen initiative, industry and research involvement is vital as there is a definite need for industry and research to plan, deliver and fund research and innovation.

6. HOW DO THE DIFFERENT POLICY OPTIONS COMPARE?

Based on the objectives pursued by the initiative and the key functionalities identified to be able to achieve them, each option for implementation is assessed in terms of effectiveness, efficiency and coherence compared to the baseline scenario of traditional calls. The analysis is primarily based on the degree to which the different options would cater for the key needed functionalities. All options are compared to the baseline situation of traditional calls, which is thus consistently scored at 0 to serve as reference point.

6.1. Effectiveness

To be in line with the Horizon Europe impact framework, the fulfilment of the specific objectives of the initiative is translated into 'expected impacts' - how success would look like -, differentiating between scientific, economic/ technological, and societal (including environmental) impacts. This section considers to which extent the different policy options would allow delivering these expected impacts - confronting what is needed (functionalities) with what each form of implementation can provide in practice. The assessments in this section set the basis for the comprehensive comparative assessment of all retained options against all dimensions in Section 6.4, based on a scoring system 177.

Scientific impacts

Concerning the efficiency and reliability of hydrogen applications and equipment, without a long-term focus and commitment from both the research and the industry communities, Europe's hydrogen sector will not be able to adapt quickly enough to changing competitive forces, to the delivery of new low carbon solutions and the emergence of low carbon challenges.

The baseline option is unlikely to contribute to the emergence of new applications for clean hydrogen as it will struggle to reach new sectors and to prepare and implement a long-term agenda. This option could easily manage fundamental R&I activities (and could be complementary to any type of partnership) if there was a clear centralised agenda pinpointing the climate and industrial priorities. Activities which need more coordination (including the demonstration of complex projects, technology comparison, increasing public awareness, and developing new business models) would need closer collaboration between research, industry and decision-makers to define cohesive work plans. This option does not

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¹⁷⁷ A more in depth and detailed analysis of each policy option is provided in Technopolis Group (2020)

Boston Consulting Group (2019), The Real Promise of Hydrogen – available at https://www.bcg.com/publications/2019/real-promise-of-hydrogen.aspx

provide such a framework or ecosystem of actors. However, this option could deliver improvements for low and medium TRL applications if a clear agenda is set up.

Option 1 could deliver more impact than the baseline option when it comes to higher TRL applications where a strong community with all actors is needed in order for all potential partners to liaise on complex projects. Its score would therefore be good compared to the baseline with +.

Option 2, by most fully involving research and industry with a long-term commitment, could contribute to the emergence of new applications and to continuous efficiency, quality and reliability improvements in applications and equipment. Its score would therefore be high compared to the baseline with ++.

With regard to the second scientific impact e.g. EU maintains its leading position for cutting edge research and innovation in hydrogen applications, **the baseline option** may allow some European organisations to maintain market-leading positions and cutting-edge research initiatives. However, without the deep involvement of industry in developing a roadmap and providing directionality, or without openness to a wide range of stakeholders, and given that the clean hydrogen economy and market are evolving constantly, it would be difficult to properly seize emerging market opportunities.

Compared to the baseline, **Option 1** could also help European organisations to maintain their leading positions because some industry involvement would be maintained and is therefore given a score of +. ¹⁷⁹

However, **Option 2** through strong involvement of the research and the industrial community, would be more efficient than Option 1 and provide greater possibilities to adapt to the evolving hydrogen economy and to anticipate and seize emerging opportunities. It would also support increased knowledge diffusion between industrial players, public sector authorities and members of the public thanks to its broad community and internal expertise. ¹⁸⁰ Its score would therefore be higher with ++.

Stakeholder opinion (from interviews)

A long-term shared vision, financial and structural commitment and the existence of a strong community are the 3 key pillars to tackle the evolving challenges of the clean hydrogen economy, not only from an RD&I perspective, but also more broadly to address regulatory, policy and awareness issues. The existing FCH 2 JU does provide these three pillars.

Knowledge of global market trends and industrial developments for clean hydrogen is essential to follow up and strengthen the leading position of EU organisations and is properly handled by the existing FCH 2 JU.

Around 70% of respondents to the Open Public Consultation indicated that the Institutionalised Partnership would significantly (positively) impact all listed categories in the area of science. The respondents who have indicated that the scope and coverage are not right, have indicated that it was too narrow more often than they viewed it as too broad.

¹⁸⁰ As affirmed comprehensively in interviews with stakeholders from both research and industry institutions, Impact Assessment Study for Institutionalised European Partnerships under Horizon Europe – Candidate Institutionalised European Partnership on Clean Hydrogen

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Thomas Reiss for the European Commission and Fraunhofer ISI (2016), Study on EU Positioning: An Analysis of the International Positioning of the EU Using Revealed Comparative Advantages and the Control of Key Technologies, https://ec.europa.eu/info/sites/info/files/research_and_innovation/groups/rise/final-report_eu-positioning.pdf

Economic/Technological impacts

The baseline option could contribute to achieve technological impacts, for example by reducing the cost of hydrogen production. However, the lack of a community structure beyond the project consortia might limit the sharing and diffusion of experience among the key actors involved in hydrogen R&I¹⁸¹ and limit the coordination and collaboration necessary to address cross-border issues.¹⁸² In addition, this option will not significantly support the scaling up of ready-to-market applications as there is no clear mechanism to facilitate the bridge from R&D to market deployment¹⁸³ and it is assessed as more difficult for SMEs to access funding. This option would probably be less efficient in creating new networks or linking hydrogen and non-hydrogen players to potential partners dealing with complex projects than options with a community (e.g. energy intensive industry as potential end users, public transport operators, building owners and local or regional communities)..

A research agenda could be centrally defined under **Option 1**, so this Option could contribute to deploy hydrogen generation and infrastructures at scale. With a broader community than in the baseline option, this option can provide a collaborative framework which will contribute to bolster EU industry and can contribute to maintaining the competitiveness of industry and decarbonising heavy transport. ¹⁸⁴ (score of +, see Table 5).

Thanks to the long term industrial commitment, **Option 2** allows high leverage of the private sector which is needed to finance expensive demonstrations. With a broad community, this option can contribute to maintaining the competitiveness of industry and to the decarbonisation of heavy transport. The community structure will also ensure the sharing and diffusion of experience among the key actors involved in hydrogen R&I. If well-coordinated with other funding and financing sources, this option can provide help for scaling up hydrogen applications ready-to-market (score of ++, see Table 5).

Stakeholder opinion

A thriving hydrogen economy can only be developed in Europe with the full backing of the European Commission and Member States. Stakeholders doubt whether hydrogen can be integrated into the EU's power, industry, and transport sectors if it loses institutionalised R&D support.

SMEs and research organisations in particular note the value of an institutionalised partnership in the hydrogen sector. The partnership allows smaller companies, which have developed niche products to serve growing hydrogen markets, to connect with larger industrial players that can support their development. The partnership allows research organisations to liaise with all potential partners, from research or from industry.

Around 80% of the respondents to the Open Public Consultation suggested the Institutionalised Partnership would have a significant (positive) effect on or be 'very relevant' for increasing industrial leadership in hydrogen technologies and the uptake of new technologies, for the provision of a solution for storing renewable energy for later use, and for the provision of low-carbon and competitive solutions for heavy duty and long-distance transport.

¹⁸¹ As affirmed comprehensively in interviews with stakeholders from both research and industry institutions.

As affirmed comprehensively in interviews with stakeholders from both research and industry institutions.

Fuel Cell and Hydrogen 2 Joint Undertaking (2019), Hydrogen Roadmap Europe, available at

https://www.fch.europa.eu/news/hydrogen-roadmap-europe-sustainable-pathway-european-energy-transition

184 Joint Research Centre (2016), 4th International Workshop on Hydrogen Infrastructure and Transportation

Report,https://publications.jrc.ec.europa.eu/repository/bitstream/JRC103586/4%20int%20workshop%20on%2

0h2%20infra%20final%20pdfonline.pdf

Societal impacts (including environmental, social, fundamental rights)

Continuous collaboration is needed to increase the maturity levels of transportation, industrial and building applications. **The baseline option,** given the short-term perspective of the calls, tends to support applications with short development timelines, meaning it could not enable all the opportunities the hydrogen economy could offer to support EU's climate goals. The capacity to reduce carbon emissions and pollution to air, water and soil would be rather limited under the baseline option since this is directly dependent on the ability to deploy at scale. Without knowledge management capacities to provide support to national, regional and local authorities, without the ability to support the increase of awareness and without the support to coordinate many stakeholders, this option would not be able to support the growth of a strong hydrogen ecosystem.

Compared to the baseline, Option 1, having a medium term perspective, would bring some of the opportunities the hydrogen economy offers to support EU's climate goals. Option 1 can contribute to build up knowledge capacity to support the hydrogen transition and can contribute to decarbonising hydrogen feedstock use by funding demonstration projects aiming to couple large renewable electricity production plants with hydrogen generation. (score of +)

Under **Option 2**, the strong community and network could bring together the required actors to build local or regional ecosystems, large transportation corridors and the related infrastructure that would connect producers and consumers¹⁸⁷. These efforts need a long-term commitment and vision for the hydrogen economy so that the EU can meet its climate targets. This option can support the building of capacities, by capitalising on experience, knowledge and expertise of a dynamic community of researchers and industrials from different sectors and on skills of an internal structure. Option 2 can also contribute to decarbonising hydrogen feedstock and it could also have an important impact regarding the market uptake (as explained under the economic impact) (score of ++).

None of the above options is expected to impact fundamental rights in the EU or abroad.

Directionality and additionality required

As regards the level of directionality and additionality required, **the baseline option** would not be able to facilitate the synchronised actions necessary to support policy objectives, Even if this option could ensure partial alignment with EU strategies, it would not be effective enough to significantly contribute to achieving them.

With the ability to prepare and implement a medium term plan **Option 1** could ensure compliance with EU and Member States strategies. However, a medium term clean hydrogen R&I agenda could only partially fit with the broader framework of a low carbon roadmap.

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¹⁸⁵ European Commission and Hydrogen Europe (2019), Hydrogen for Climate Action: How to kick start the EU Hydrogen Industry to achieve the EU climate goals? –available at https://static1.squarespace.com/static/5d3f0387728026000121b2a2/t/5d9f23c486e0ee312c6380a7/1570710475 <a href="https://static1.squarespace.com/static/5d3f0387728026000121b2a2/t/5d9f23c486e0ee312c6380a7/t/5d9f23c486e0ee312c6380a7/t/

European Commission and Joint Research Centre (2019), Hydrogen use in EU decarbonisation scenarios, available at https://ec.europa.eu/jrc/sites/jrcsh/files/final_insights_into_hydrogen_use_public_version.pdf

¹⁸⁷ The <u>Green Hydrogen@Blue Danube IPCEI</u> project is a very good example of bringing together all actors along the whole value chain, involving many different actors. The institutionalised partnership is not an absolute necessity, but would be very helpful in networking

A long-term vision and strategy will be essential for hydrogen which is a versatile solution addressing many different sectors with continuously emerging applications. By involving research organisations, industry and the public sector, **Option 2** is considered as the most appropriate since it ensures a long-term commitment. Integrating the Strategic R&I Agenda into a broader spectrum is also essential. Option 2 will ensure a coherent approach for the whole hydrogen economy from R&I to market uptake, addressing in particular the "valley of death" challenge.

Stakeholder opinion

Hydrogen's capacity to facilitate the decarbonisation of heavy industry and heavy transport within the EU is seen as its core strength. In order to fully decarbonise these sectors through hydrogen use, however, extensive development is still required. Stakeholders continuously argued that the partnership which most quickly and effectively can prompt the large-scale integration of hydrogen applications into Member States' societies will be best positioned to contribute to the vital environmental goal of full decarbonisation of the EU by 2050.

The large majority of respondents to the Open Public Consultation considered the Institutionalised Partnership would be 'very relevant' to deliver on societal impacts with the exception for the category "improved working conditions".

Table 5 summarises the scores assigned for each policy option, based upon the assessments above, as well as taking into account the support expressed by the different stakeholders.

Table 5: Overview of the options' effectiveness compared to the baseline

	Baseline: Horizon Europe calls	Option 1: Co- programmed	Option 2: Institutionalised Article 187 TFEU
Scientific impac	t		
Hydrogen applications are more competitive, efficient and reliable	0	+	++
The EU maintains its leading position for cutting edge research and innovation in hydrogen applications	0	+	++
Economic/technologica	al impact		
Through demonstration EU validates its ability to deploy economical hydrogen generation at scale	0	0	+
EU demonstrates its ability to deploy hydrogen infrastructures at scale	0	+	++
EU validates its ability to scale-up clean economical hydrogen end- use applications in heavy-duty transport and energy-intensive industries – maintaining global competitiveness	0	+	++
EU growth in hydrogen economy, especially for SMEs	0	+	++
Societal impac	t		
The EU's maritime, aviation, rail and heavy-duty transport sectors, as well as its gas grid, can progressively decarbonise so the EU can meet its climate targets	0	+	++
Outdoor pollution can progressively decrease while reducing carbon emissions	0	+	++
Knowledge capacity built up to support the hydrogen transition, while increasing public support for additional hydrogen policy and regulatory frameworks	0	+	++

Notes: Score ++: Option presenting a *high* potential compared to baseline; Score +: Option presenting a *good* potential compared to baseline; Score 0: Potential of the baseline.

6.2. Efficiency

In order to compare the policy options consistently in terms of their efficiency, a standard cost model was developed for the external study supporting the impact assessment for the set of candidate Institutionalised Partnerships. The model and the underlying assumptions and analyses are set out in the Common Part of this impact assessment, Section 2.3.2 and in the Methodology Annex 4. A dedicated Annex 3 also provides more information on who is affected and how by this specific initiative in line with the Better Regulation framework. The scores related to the costs set out in this context allow for a "value for money" analysis (cost-effectiveness) in the final scorecard analysis in Section 6.4.

In addition, for this specific initiative under the baseline scenario of traditional calls, there would be winding down and social discontinuation costs for the existing implementation structure of the current Article 187 initiative. The impact assessment and Annex 3 in particular have estimated the costs of running an Institutionalised Partnership under Article 187 at \in 2.9 million, corresponding to 27 full time equivalent staff. In contrast, the baseline (Horizon Europe calls) would rely on Horizon Europe structures and also require winding down the current JU Secretariat. Winding down costs would essentially be linked to the termination of existing contracts. As most of these contracts were already tied to the foreseen initial duration of the existing JU, the winding down costs are expected to be limited and much lower than the \in 2.9 million recurring costs for the proposed Institutionalised Partnership. Overall it is estimated that the overall longer term cost savings from using traditional calls instead of an existing Article 187 initiative would considerably exceed the costs incurred for winding down operations. This overall situation is set as the starting point for the comparison of options. The score of this baseline scenario (traditional Horizon Europe calls) is set to 0 to be used as a reference point.

On this basis, the scores for the costs of the different options range from a value of 0, in case an option does not entail any additional costs compared to the baseline, to a score of (-) when an option introduces limited additional costs when compared to the baseline and a score of (-)(-) when substantial additional costs are expected in comparison with the baseline. In case the scores are lower than for the baseline scenario, (+) and (+)(+) are used.

It is considered that while there is a clear gradation in the overall costs of the policy options, the cost differentials are less marked when one takes into account the expected co-financing rates and the total budget available for each of the policy options, assuming a common Union contribution. From this perspective, there are only one or two percentage points that split the most cost-efficient policy options – the baseline (traditional calls) and the Co-Programmed policy option – and the least cost-efficient – the Institutionalised Partnership option. Indeed, in terms of cost-efficiency, the Co-Programmed Partnership (Option 1) is 2 percentage points more efficient than the baseline and an Article 187 Partnership is 2 percentage points less cost-efficient than the baseline. This refers to the proportion of "total costs and investments" that is available to be spent on "R&I investment". These figures were estimated for the different forms of implementation, as described in the common part of the impact assessment. On the basis of this ratio, the baseline appears to be 2% more efficient than the Article 187 Institutionalised Partnership. The main differences between the costs structures of the various implementation forms are described in Annex 4, p. 52. A score of

(+) is therefore assigned for **cost-efficiency** to the Co-Programmed options and a score of (-) for the Institutionalised Partnership policy option ¹⁸⁸.

Looking at cost-efficiency on the broader perspective of attracting higher level of investments from stakeholders, **Option 2 may appear much more cost-efficient**. The reason is a much higher total investment in R&I and a much higher contribution from the private actors (fact identified within the current FCH 2 JU, where for a flagship large-scale project like the "Hydrogen Valley" the contribution from the partners is three times higher than the Union contribution).

In the case of the current FCH 2 JU, the assessment of the contributions can be considered as an indication of the leverage achieved by EU funds and is clearly a strong sign that the JU is successfully aligned on industrial priorities¹⁸⁹. As mentioned in the Annual Activity report 2019, the FCH 2 JU has generated 2.24 of total leverage.

The majority of respondents to the Open Public Consultation indicated that it was very relevant to set up a specific legal structure for the partnership to achieve a more effective implementation of activities and to increase financial leverage, which is considered as a key element for the demonstration phase.

It should be noted that the potential for the creation of crowding-in effects for industry has been taken into account when assessing the effectiveness of the policy options.

Financial management of the existing FCH 2 JU, as stated in its interim evaluation, appears to be robust and the views of the public and beneficiaries sought in the consultations are strongly positive. The overall operational efficiency of the FCH 2 JU has improved as the institution has matured¹⁹⁰ in particular on budget execution level, commitment and payment appropriations, time to contract and time to payment. The proposed initiative will build on this strength.

Table 6: Matrix on 'overall costs' and 'adjusted cost scoring'

	Baseline: Horizon Europe calls	Option 1: Co- programmed	Option 2: Institutionalised Article 187 TFEU
Administrative, operational and coordination costs	0	(0)	(-)(-)
Administrative, operational and coordination costs adjusted per expected co-funding (i.e. cost-efficiency)	0	(+)	(-)

Notes: Score 0 = same costs as for the baseline; score (-) = limited additional costs compared with the baseline; score (-)(-) = substantial additional costs compared with the baseline.

¹⁹⁰ See section 1.3.3 of the present report

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¹⁸⁸ The baseline (traditional calls) is scored 0, as explained above.

¹⁸⁹ See section 1.3.3 of the present report

6.3. Coherence

6.3.1. Internal coherence

In this section we assess the extent to which the policy options show the potential of ensuring and maximising coherence with other actions, programmes and initiatives under Horizon Europe, in particular European Partnerships (internal coherence).

Baseline: Horizon Europe calls

Under this option, coherence between activities in the area of Clean Hydrogen with activities under Cluster 5 of Horizon Europe and the other initiatives presented in Figure 1 are ensured by the European Commission. However, exploitation of synergies between Clean Hydrogen and other initiatives, including exchanges of knowledge and experience between project teams and stakeholders, would require an additional level of coordination beyond Programme Committees. Option 0 could easily manage fundamental R&I activities. However, it is considered sub-optimal to address activities which need more coordination (for example demonstration activities) and closer collaboration between research, industry and decision-makers to define cohesive work plans.

Option 1: Co-Programmed European Partnership

Under the Co-Programmed option, synergies could be exploited more easily than under the baseline option. The European Commission could ensure coordination at the level of research agendas, while the Clean Hydrogen associations could proactively bring together projects and stakeholders from various initiatives to work together on common problems or tackle common challenges. However, as the Co-Programmed option does not promote a strong community or a network framework outside of project consortia, it is unlikely that it will establish an effective long-term framework and vision, nor increase cross-sector collaboration. Option 1 could better manage all types of R&I activities thanks to a better agenda setting pinpointing the climate and industrial priorities. However, Option 1 is not considered optimum to address the complex supply chains of hydrogen applications and the spread of actors. Its score would therefore be good compared to the baseline with +.

Option 2: Institutionalised European Partnership under Article 187 TFEU

The Institutionalised Article 187 partnership could provide for the highest level of coordination. The structure provides roles for the European Commission and for Clean Hydrogen associations, but it is built on a central coordination layer which can increase the effectiveness of its efforts. Since its management body organises the funding and implementation of projects, the Clean Hydrogen partnership could (together with other institutionalised partnerships) set concrete objectives and lay out a roadmap of activities and projects that can be implemented.

A dedicated management team responsible for the development of a long-term strategy and supporting work programmes for clean hydrogen RD&I would ensure that these are fully aligned with relevant strategies and programmes developed by other partnerships and initiatives within the EU research and innovation landscape. This would also enable the development of a shared vision and better exploitation of synergies from joint programmes and calls, in areas such as Clean Aviation, Battery Technology, Transforming EU's rail system, Clean Steel, Sustainable Process Industry (Process4Planet), waterborne sector (ZEWT), towards zero-emission road transport (2ZERO), Clean Energy Transition, and the power and the gas sectors. Option 2 would manage all TRLs related activities, from fundamental R&D up to market-readiness. Good knowledge management is also an asset

under this option - to allow the initiative to adequately assess projects in the selection process, to provide technical assistance where needed and even to challenge the industries in order to increase the speed of development. This would translate into a high score compared to the baseline set at ++.

Stakeholder opinion

Stakeholders overwhelmingly argue that only through an institutionalised partnership can all necessary actors be involved, the ideal range of activities undertaken, and the strategic directionality be designed and implemented as required. They agree that if an institutionalised partnership were not pursued, vital stakeholders would be left out of important conversations, an inadequate/partial range

Respondents to the Open Public Consultation, when asked if it would be possible to rationalise the candidate European Institutionalised Partnership and its activities and/or better link it with other comparable initiatives, indicated that they think rationalisation and linking with other sectors are important. The respondents think the initiative could be linked with other comparable initiatives related to hydrogen, renewable energy and the application of hydrogen as well as clean aviation and rail systems.

of activities and projects would be funded, and the strategic directionality established would lack clarity and vision.

6.3.2. External coherence

In this section we assess the extent to which the policy options show the potential of ensuring and maximising coherence with their external environment, including EU-level programmes and initiatives beyond the Framework Programme and/or national and international programmes and initiatives, but as well as with overarching framework conditions, such as regulation, standardisation, etc. (external coherence).

Baseline: Horizon Europe calls

In absence of a clear engagement with relevant stakeholders, this option would not be helpful for putting together market uptake mechanisms outside the R&I sphere for the applications developed to market readiness where these are needed (e.g. buses, fuel cells, electrolysers, ...). Despite that under this option, some coordination with other European Commission activities is possible at the level of priorities, coordination at the level of implementation is somewhat limited or even not feasible. In addition, this option typically remains focused on the EU27 alone. International organisations play an important role in the development of clean hydrogen. However, the baseline option does not allow for implementation of a coherent international cooperation strategy. In addition, this option would not support motivating additional Member State participation, where increasing their involvement to ensure alignment with their own R&D agendas and low carbon roadmaps is essential. Finally, collaboration with national or regional initiatives such as national programmes for the support of Clean Hydrogen or the coordination with regional clusters is not feasible under this option.

Option 1: Co-Programmed European Partnership

Under this option, the European Commission can contribute to some extent to the coordination with European non-FP initiatives at the level of the strategy. The non-

¹⁹¹Fuel Cell and Hydrogen 2 Joint Undertaking (2019), Hydrogen Roadmap Europe, available at https://www.fch.europa.eu/news/hydrogen-roadmap-europe-sustainable-pathway-european-energy-transition

systematic participation of Member States provides the opportunity for coordination with the national programmes and initiatives and the regional clusters. Member States and Clean Hydrogen associations could coordinate with the national and industry efforts to ensure alignment with their own R&D agendas and low carbon roadmaps and fully engage in the Clean Hydrogen IPCEI. Score would therefore be good compared to the baseline with +.

Option 2: Institutionalised European Partnership under Article 187 TFEU

This option ensures continuous dialogue among all players, including international, national, regional and local authorities and therefore does provide a clear global framework which would be necessary to mainstream clean hydrogen RD&I efforts into a global low carbon roadmap. But this option does not focus on the engagement of Member States and will need to take care to involve them all. MS should not be forced to join the hydrogen R&D dynamic but should be convinced of its strategic importance. Experience-sharing platforms would therefore be relevant and powerful. This option would be the most relevant to set up such a framework and ensure its large diffusion. Furthermore, this option, with the direct involvement of the EC and Member States, could facilitate the development of an effective, cross-sectoral, cross-border governance model necessary to enable agile rollout of hydrogen applications, and to open broader markets to these technologies. Finally, under this option, the possibilities of coordination and exploitation of synergies offered by the Co-Programmed option are expanded by the existence of the central coordination level which can improve and extend the collaboration at the level of projects. This would translate into a high score compared to the baseline with ++.

Stakeholder opinion

Many stakeholders who are also interested in/involved with other candidate partnerships believe that strongly coordinated efforts between partnerships and other EU programmes will be required to ensure external coherence. They argue that an institutionalised partnership with a dedicated coordination function is the best way to ensure that unnecessary overlap is avoided while potential synergies are properly exploited.

The initiative should operate at a global level, or at least be connected to all relevant counterparts to ensure compliance with international standards, to secure the role of EU industry in different hydrogen spaces, and to ensure that regulatory issues are addressed properly. As affirmed comprehensively in interviews with stakeholders from both research and industry, an institutionalised partnership is probably the most appropriate initiative to foster collaboration at international levels, given its expertise and knowledge management.

For some **EU13 national associations interviewed**, Member States would expect more international collaboration and more involvement in EU calls in order to align Clean Hydrogen with their national low carbon strategies, including funding policies.

Table 7, below, lists the scores assigned for each of the policy options, based upon the assessments above, as well as taking into account the views expressed by the different stakeholders.

Regarding **internal coherence**, synergies and coherence (ensured by the European Commission) between Clean Hydrogen and other initiatives would require an additional level of coordination than provided by the baseline option. The Co-Programmed option

 $\frac{https://static1.squarespace.com/static/5d3f0387728026000121b2a2/t/5d9f23c486e0ee312c6380a7/1570710475026/Framework_H2+for+Climate+Action final.pdf$

¹⁹² European Commission and Hydrogen Europe (2019), Hydrogen for Climate Action: How to kick start the EU Hydrogen Industry to achieve the EU climate goals? –available at

would be able to provide this coherence, but it will unlikely establish an effective long-term framework and vision, nor increase cross-sector collaboration. Therefore, the institutionalised partnership would allow for greater internal coherence than the two other options, expanding the possibilities of coordination and exploitation of synergies offered by the Co-Programmed option by the existence of the central coordination level.

Regarding the **external coherence**, the baseline option and the co-programmed partnership are assessed to be less successful than an institutionalised partnership in creating the required systemic effects. This is due to their weaknesses in addressing the international community, ensuring adequate coordination with other programmes, third countries and international organisations, aligning with their own R&D agendas and low carbon roadmaps, and for facilitating market uptake support to be put in place. Therefore, the institutionalised from of partnership would allow for greater external coherence than the two other options.

Table 7: Overview of the options' potential for ensuring and maximizing coherence

	Option 0: Horizon Europe calls	•	Option 2: Institutionalised Article 187 TFEU
Internal coherence	0	0/+	++
External coherence	0	+	++

Notes: Score ++: Option presenting a *high* potential compared to baseline; Score +: Option presenting a *good* potential compared to baseline; Score 0: Potential of the baseline.

6.4. Tabular comparison of options and identification of preferred option

Building upon the outcomes of the analysis, this section presents a comparison of the options' 'performance' against the dimensions of effectiveness, efficiency and coherence.

Table 8: Overall scorecard of the policy options for all criteria

	Criteria	Baseline: Horizon Europe calls	Option 1: Co- programmed	Option 2: Institutionalised Article 187 TFEU
	Scientific impacts			
	Hydrogen applications are more competitive, efficient and reliable	0	+	++
	The EU maintains its leading position for cutting edge research and innovation in hydrogen applications	0	+	++
	Economic/technological impacts			
	Through demonstration EU validates its ability to deploy economical hydrogen generation at scale	0	0	+
ess	EU demonstrates its ability to deploy hydrogen infrastructures at scale	0	+	++
Effectiveness	EU validates its ability to scale-up clean economical hydrogen enduse applications in heavy-duty transport and energy-intensive industries – maintaining global competitiveness	0	+	++
	EU growth in hydrogen economy, especially for SMEs	0	+	++
	Societal impacts			
	The EU's maritime, aviation, rail and heavy-duty transport sectors, as well as its gas grid, can progressively decarbonize so the EU can meet its climate targets	0	+	++
	Outdoor pollution can progressively decrease while reducing carbon emissions	0	+	++
	Knowledge capacity built up to support the hydrogen transition while increasing public support for additional hydrogen policy and regulatory frameworks increases	0	+	++

Coherence	Internal coherence	0	0/+	++
	External coherence	0	+	++
Efficiency	Overall cost	0	0	
	Adjusted cost-scoring	0	+	-

Notes: Scores for effectiveness and coherence: Score ++: Option presenting a *high* potential compared to baseline; Score +: Option presenting a *good* potential compared to baseline; Score 0: Potential of the baseline. Scores for efficiency: Score 0 = same costs as for the baseline; score (-) = limited additional costs compared with the baseline; score (-)(-) = substantial additional costs compared with the baseline

Box 2 Comparison between the preferred option & the current partnership existing in the area taking into account lessons from past evaluations

What continues	What is different
 Art 187 Union Body, with EC, Hydrogen Europe and Hydrogen Europe Research as founding members Blending of funds for large demonstration projects: Horizon, CEF Members contributing to running costs of the JU Preparation of Multiannual and Annual Work Programmes based on Strategic Research and Innovation Agenda Management of evaluation calls and running projects 	 Enlargement of the scope of the initiative addressing the entire value-chain from production to end-use of hydrogen Better member state involvement/ renewed role of state representative group Actions to increase wider participation from all EU 27 Potentially higher leverage of private investment Higher impact of investments due to closer links with industrialisation/ market uptake (e.g. the proposed Clean Hydrogen Alliance) Better synergies with other Horizon Europe, national and regional initiatives

Overall the implementation of the Clean Hydrogen initiative through an **institutionalised** partnership established under Article 187 of TFEU is the preferred option as it would best ensure that private and public sectors remain fully engaged in the development and implementation of a long-term strategy for clean hydrogen R&I. It is also consistent with the aim of leveraging industrial financial and in-kind resources, such that the impact of funding provided by the Commission is maximised. This form of partnership would continue to provide a stable framework for encouraging the participation of organisations from all concerned sectors (including those outside the hydrogen industry), securing and allocating resources, managing a wide range of RD&I projects across all TRLs and creating synergies with other partnerships and initiatives within and outside the Climate, Energy and Mobility cluster. It is also considered appropriate to develop a strategy for hydrogen that is fully aligned with European Green Deal priorities, and especially the European climate commitment, and with several sustainable development goals.

7. THE PREFERRED OPTION - HOW WILL ACTUAL IMPACTS BE MONITORED AND EVALUATED?

7.1. The preferred option

- In Table 9, below, the alignment of the preferred option of Institutionalised European Partnership under Article 187 TFEU with the selection criteria for European Partnerships defined in Annex III of the Horizon Europe Regulation is depicted.

Seeing that the design process of the candidate Institutionalised Partnerships is not yet concluded and several of the related topics are still under discussion such as finalisation of Strategic Research and Innovation Agenda, Governance of the proposed partnership, partners signing up to final, commonly agreed objectives and committing the resources and investments needed from their side to achieve them, e.g. partners' financial contribution, the criteria of additionality/directionality and long-term commitment are covered in terms of *expectations* rather than ex-ante demonstration.

Table 9: Alignment with the selection criteria for European Partnerships

Criterion	Alignment of the preferred option
Higher level of effectiveness	As demonstrated in Chapter 6, an institutionalised partnership would be considerably more effective in addressing global challenges and delivering research and innovation objectives, in securing EU competitiveness and, where relevant, in contributing to international commitments (e.g. on standards).
	The institutionalised partnership would also be effective in securing sustainability (the final goal of "clean" hydrogen) and in strengthening the European Research and Innovation Area.
Coherence and synergies	A dedicated management structure similar to the Programme Office in current FCH 2 JU, responsible for the development of a long-term strategy and supporting work programmes for clean hydrogen RD&I, would ensure that these are fully aligned with relevant strategies and programmes developed by other partnerships and initiatives within the EU research and innovation landscape. This would also enable the development of a shared vision and better exploitation of synergies from joint programmes and calls, in areas such as Clean Aviation, Transforming EU's rail system, Clean Steel, Sustainable Process Industry (Process4Planet), waterborne sector (ZWET), towards zero-emission road transport (2ZERO), Clean Energy Transition, and the power and the gas sectors.
	A dedicated management structure would also ensure proper coordination and complementarity with European Union, local, regional, national and, where relevant, international initiatives on hydrogen or other partnerships and missions.
Transparency and openness	As demonstrated in Chapter 6, an institutionalised partnership would be better placed to identify priorities and objectives in terms of expected results and impacts, in involving partners and stakeholders from across the entire clean hydrogen value chain, from different sectors, backgrounds and disciplines, including international ones when relevant.
	SMEs would have the most appropriate support from the partnership. A dedicated management structure would also be able to put into place clear modalities for promoting participation of SMEs and for disseminating and exploiting results,
	An institutional partnership would ensure that the outputs of RD&I programmes are transparent and available to stakeholders inside and outside the hydrogen community. The framework governing participation would allow any organisation meeting defined criteria to participate, in an open and transparent way. This framework could provide support and guidance, help networking and build up consortia when addressing complex projects throughout the whole value chain.
Additionality and directionality	As demonstrated in chapter 6, an institutionalised partnership would be much better placed to define a common strategic vision of the purpose of the European Partnership, in demonstrating expected qualitative and significant quantitative leverage effects, including a method for the measurement of key performance indicators and in creating synergies within the EU research and innovation landscape.
	An institutionalised partnership would be able to adjust to changing policy, societal and/or market needs, or scientific advances, to increase policy coherence between regional, national and EU level.
Long-term commitment	In the case of institutionalised European Partnerships, established in accordance with article 187 TFEU, the financial and/or in-kind, contributions from partners other than the Union, will at least be equal to 50% and may reach up to 75% of the aggregated European Partnership budgetary commitments

7.2. Objectives and corresponding monitoring indicators

7.2.1. *Operational objectives*

Several operational objectives have been identified which would enable the partnership to achieve its specific objectives, as shown in Figure 10 below.

The figure also lists a range of actions and activities, going beyond R&I that can be implemented under Horizon Europe (which are highlighted in yellow). This reflects the definition of European Partnerships in the Horizon Europe Regulation as initiatives whereby the Union and its partners "commit to jointly support the development and implementation of a programme of research and innovation activities, including those related to market, regulatory or policy uptake."

Actions fostering regulation & Actions supporting access to validation projects support actions standardisation financing and funds Activities Contribute to proposals on se, prioritizing cross regulatory and frameworks and support access to Operational objectives elerate through nonstration the co-Increase public & Foster close collaboration with regulators, policy and innovation the costscientific and scale-up clean effectiveness, reliability and quality of clean industrial deployment of EU hydrogen to provide long-term acceptance, nate neutral innovative utions across the power demand and uptake of clean makers, and investors to develop a global hydrogen applications innovative clean stimulate large-scale framework for enabling and gas, maritime, aviation hydrogen rollout Specific objectives Societal Objective (incl. environmental and Scientific Objective: Strengthen and integrate EU the development and improvement of advanced clean contribute to the greening of hydrogen generation deployment and use through innovative solutions General objectives

Figure 10: Operational objectives of the initiative

7.2.2. Monitoring indicators

In addition to Key Impact Pathways indicators set centrally in the Regulation of Horizon Europe, additional monitoring indicators have been identified to enable the tracking of progress of the partnership towards meeting its objectives. These are shown in Table 9.

Table 9: Monitoring indicators in addition to the Horizon Europe key impact pathway indicators

	Short-term (typically as of year 1+)	Medium-term (typically as of year 3+)	Long-term (typically as of year 5+)
Scientific impact	Number of projects resulting in one or more journal citations	Number of times that journal citations generated by the partnership are cited in the global literature	Number of publications registered by the clean hydrogen industry and research organisation located in Europe Number of staff transferring between research-based institutions & industry
Technological / economic impact	Number of projects involving organisations outside the hydrogen industry Number of projects with a documented strategy identifying the potential application of results to	Number of projects leading to validated demonstration of clean hydrogen applications Number of clean hydrogen pilots demonstrating readiness	Number of patents registered by the clean hydrogen industry and research organisation located in Europe Number of projects conducting market uptake Time for clean hydrogen pilots demonstrating readiness for market

	defined market needs	for market uptake	uptake
	Number of projects resulting in increasing clean hydrogen application's TRLs	Number of years for programmed projects to reach TRL 8	Value of exports generated by the European hydrogen sector Direct and indirect employment
	Number of individuals working on projects initiated by the	Number of mature clean hydrogen applications	generated by the European clean hydrogen economy
	partnership	Number of occupied and	Costs of clean hydrogen production
		advertised jobs in clean hydrogen	Costs of clean hydrogen distribution
		nydrogen	Price of hydrogen based solutions compared to alternatives
Societal	Number of projects developing	Level and intensity of the	Changes in local outdoor air pollution
impact Incl. Environmental	sector specific low carbon solutions, including the large	hydrogen-related R&I (in percentage of turn-over)	Changes in public acceptance of clean hydrogen solutions
impact	public	Number of projects focussing on hard to decarbonise sectors	Evolution in CO_{2} , emissions reduction in relevant sectors

7.2.3. Evaluation framework

The evaluation of the Partnership will be done in full accordance with the provisions laid out in Horizon Europe Regulation Article 47 and Annex III, with external interim and ex-post evaluations feeding into the overall Horizon Europe evaluations. As set in the criteria for European Partnerships, the evaluations will include an assessment of the most effective policy intervention mode for any future action; and the positioning of any possible renewal of the Partnership in the overall European Partnerships landscape and its policy priorities. In the absence of renewal, appropriate measures will be developed to ensure phasing-out of Framework Programme funding according to conditions and timeline agreed with the legally committed partners ex-ante.



Brussels, 23.2.2021 SWD(2021) 37 final

PART 19/19

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT REPORT Accompanying the document

Proposal for a COUNCIL REGULATION establishing the Joint Undertakings under Horizon Europe

European Partnership for Clean Hydrogen

{COM(2021) 87 final} - {SEC(2021) 100 final} - {SWD(2021) 38 final}

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Annex 1 Procedural information

1. LEAD DG, DECIDE PLANNING REFERENCES

Lead DG: Directorate General Research and Innovation (RTD)

Decide number: PLAN/2019/5306

2. ORGANISATION AND TIMING

Institutionalised partnerships are foreseen in Articles 185 and 187 of the Treaty on the Functioning of the European Union (TFEU). The preliminary agreement on Horizon Europe contained a list of possible areas for institutionalised partnerships based on Article 185 and 187. For each of these areas the Commission considered 12 potential institutionalised partnerships. Their set up involves new EU legislation and the establishment of dedicated implementing structures and therefore an impact assessment for each of these initiatives.

Following political validation in June 2019, the impact assessment process started with the publication of inception impact assessments for each initiative in August 2019.

An inter-service steering group (ISSG) on research and innovation partnerships under Horizon Europe was set up in May 2019 and held 4 meetings before submission of the Staff Working Document to the Regulatory Scrutiny Board (7 May 2019, 19 June 2019, 5 December 2019, 20 January 2020). The ISSG consisted of representatives of the Secretariat-General, Directorate-General for Budget, Directorate-General for Research and Innovation, Directorate-General for Communications Networks, Content and Technology, Directorate-General for Mobility and Transport, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, Directorate-General for Energy, Directorate-General for Environment, Directorate-General for Climate Action, and the Legal Service.

An online public stakeholder consultation was launched between September and November 2019, gathering 1635 replies for all 12 initiatives.

3. CONSULTATION OF THE RSB

Two upstream meetings with the Regulatory Scrutiny Board were held on 10 July 2019 and 30 September 2019.

In accordance with the feedback received from the Regulatory Scrutiny Board on 27.03.2020 the Staff Working Document has been revised as presented in Figure 1. The impact assessment was endorsed by the Inter Service Steering Group on 20.01.2020.

4. EVIDENCE, SOURCES AND QUALITY

To ensure a high level of coherence and comparability of analysis for all candidate initiatives, an external study was procured to feed into the impact assessments of the 12 candidate institutionalised partnerships¹. It consisted of an horizontal analysis and individual thematic analyses for each of the initiatives under review.

-

¹ Technopolis Group, 2020, forthcoming.

For all initiatives, the evidence used includes desk research partly covering the main impacts and lessons learned from previous partnerships. A range of quantitative and qualitative data sources complement the evidence base, including evaluations; foresight studies; statistical analyses of Framework Programmes application and participation data and Community Innovation Survey data; analyses of science, technology and innovation indicators; reviews of academic literature; sectoral competitiveness studies and expert hearings. The analyses included a portfolio analysis, a stakeholder and social network analysis in order to profile the actors involved as well as their co-operation patterns, and an assessment of the partnerships' outputs (bibliometrics and patent analysis). A cost modelling exercise was performed in order to feed into the efficiency assessments of the partnership options. Public consultations (open and targeted) supported the comparative assessment of the policy options. For each initiative up to 50 relevant stakeholders were interviewed by the external contractor (policymakers, business including SMEs and business associations, research institutes and universities, and civil organisations, among others). In addition, the analysis was informed by the results of the Open Public Consultation (Sep – Nov 2019), the consultation of the Member States through the Strategic Programme Committee and the online feedback received on the Inception Impact Assessments of the set of candidate Institutionalised European Partnerships.

A more detailed description of the methodology and evidence base used, completed by thematic specific methodologies, is provided in Annexes 4 and 6.

Figure 1 Modifications to the draft Staff Working Document based on comments received from the Regulatory Scrutiny Board

Comments	from	the	Regulatory	Scrutiny	
Board					

(1) The report does not adequately explain how greater flexibility in implementation of research projects relates to the desire to focus research. It does not sufficiently describe the competition aspects of the partnership.

Actions taken for the Staff Working Document

For hydrogen, we are talking today about a verv dynamic sector and community. Responsiveness to new technological developments is essential, meaning that it should be ensured that the partnership would be able to react quickly and efficiently and that the Clean Hydrogen initiative is empowered enough to deliver.

Explanations are provided in p.44 and p.45. A number of activities have been mentioned IA to ensure flexibility implementation and create the expected impacts such as (i) Seek synergies with R&I programmes of other sectors and initiatives (ii) Coordinate R&I actions ranging from concept to demonstration and validation activities (covering all Technology Readiness Levels), ensuring inclusion of new actors and integration of extended value chains (iii) Develop deployment and piloting activities to ensure flexibility over time across the range of applications implemented and (IV) Co-

create solutions with end-users, emphasising the importance of flexibility in addressing different target groups over time, including industrial end users for which low carbon alternatives are not evident.

The request of flexibility or responsiveness in terms of implementation of the Clean Hydrogen Partnership is fully aligned with the call for an enlarged research agenda, addressing production, distribution and storage as indicated in p.40.

The calls for research and innovation proposals in the partnership will be open to all and not restricted to just members of the associations Hydrogen Europe and Hydrogen Europe Research. The partnership will fund and manage cooperative research projects where different industrial and research entities will conclude a consortium agreement on how they will share foreground and background IPR.

(2) The report should explain in more detail the current partnership, its objectives and its structure. Additional information is provided on p.26.

The objectives of FCH 2 JU, organised around the energy and transport pillars were the following:

- <u>Clean Transport</u>: reduce fuel cell system costs for transport applications
- Green hydrogen production: increase efficiency and reduce costs of hydrogen production, mainly from water electrolysis and renewables
- <u>Heat & electricity production</u>: increase fuel cell efficiency and lifetime
- Hydrogen storage for grid balancing: demonstrate on a large-scale hydrogen's capacity to harness power from renewables and support its integration into the energy system
- <u>Minimal use of critical raw materials</u>: reduce platinum loading

FCH 2 JU is a public-private partnership with 3 members: the industry grouping Hydrogen Europe, the research grouping Hydrogen

Europe Research and the European Commission.

(3) The report does not adequately describe the existing partnership, including its strengths and weaknesses.

The report should use the findings of the evaluation of the existing Joint Undertaking to explain the need for change. It should justify the shift of focus to hydrogen production, distribution and storage in the new partnership.

Information is provided on p.26 and p.27. Strengths under the new headings "What has or is being achieved so far" and weaknesses under "What are the key areas for improvement & unmet challenges".

Explanation is provided on p.40. The shift of focus to hydrogen production, distribution and storage in the new partnership is justified by the evolution of the political context with the role of hydrogen likely to become more prominent in a fully decarbonised energy system and the European Green Deal, the new growth strategy that aims to transform the EU into a fair and prosperous society, with a modern, resource-efficient and competitive economy, where there are no net emissions of greenhouse gases in 2050 and where economic growth is decoupled from resource use.

Reaching this long term vision means capacity to supply hydrogen at scale and simultaneously boosting demand.

(4) The report does not clearly identify which problems and problem drivers the initiative would address.

The report should limit the problems and problem drivers to what research and innovation actions can address. It could clarify how wider problems are addressed by other initiatives.

On Figure 8 p. 30 "Problem tree behind an initiative for European research and innovation on Clean Hydrogen", issues relevant to research and innovation actions are highlighted in boxes in blue.

Chapter 2 of the report, in particular sections 2.1 and 2.2 now better define what research and innovation actions will address.

Inadequate or not fit for purpose regulatory, policy and financial framework for clean hydrogen are addressed in the Hydrogen Strategy and the global framework for enabling hydrogen rollout will be central to the Clean hydrogen Alliance to be launched as announced in the New Industrial Strategy.

(5) In this framework, the report should justify why continuation of the current partnership is not the baseline. The report should use its selected baseline (Horizon

See p.14, In line with the Better Regulation Framework, the assessment of the effectiveness, efficiency and coherence of each option is made compared to the Europe calls) consistently throughout the report, notably in the impact analysis and in the comparison of the policy options. The report sometimes takes the absence of any research programme as a baseline. The selected baseline should consistently be scored as zero, while the scoring of the other options should be adjusted to reflect their impacts as compared to the baseline.

baseline. Therefore, for each of these aspects the performance of using traditional calls under Horizon Europe is first estimated and scored 0 to serve as a reference point.

A new Table 5: Overview of the options' effectiveness compared to the baseline is provided on p.53.

(6) The report should clarify how the flexibility of a partnership, in particular via changes to its membership, is compatible with the narrower focus on research areas and with potential risks of excluding competitors. It should reflect on the consequences of partners not being willing to accept newcomers to avoid that competitors take advantage of their earlier investments. The report should clarify the changes in the substance of cooperation by moving from research to production and distribution. It should reflect on how to avoid anticompetitive behaviour in product markets.

See point (1) above and paragraphs 4.3.1 and 4.3.2 on p.44 and p.45

Despite the potential of hydrogen to contribute to the decarbonisation of many different sectors, one has to acknowledge that the deployment of hydrogen and fuel cells is only marginal today (see Annex 6). As a consequence, there is no evidence of anticompetitive behaviour from the side of partners or in product markets. To accelerate the commercial readiness of hydrogen technologies, the proposed Clean Hydrogen Partnership is building on the work of FCH 2 JU which made the start of commercialisation of a first series of applications possible. It will aim at bringing a second series of applications to commercial level in particular in industry heat and feedstock, power generation and hard to abate transport sectors.

Considering the substance of cooperation, the partnership seek to address **research and innovation aspects related to production, distribution, infrastructure and storage of hydrogen**. As such, it is open to newcomers as mentioned in p.44, paragraph 4.3.1 "Type and composition of actors to be involved". Clean hydrogen partnership is the R&I pillar of the overall hydrogen strategy.

(7) The report should provide – as far as possible – quantified estimates of the cost of the different partnership types. This would provide evidence for the assessment that cost differences between policy options matter less than differences in benefits. The report should also take into account savings or costs stemming from the continuation or

See revised paragraph 6.2 Efficiency in p.53 and p.54.

A common approach was taken to assess the costs of the various policy options in general terms. The main purpose of this common approach was to show – in relative terms - how the costs of e.g. traditional calls compare

discontinuation of various elements of the already existing partnership in the baseline and policy options. with those of an institutionalised partnership in general.

Further refinements in these costs are made in the individual assessment, for instance if one would have to hypothesize discontinuation costs for an existing Partnership. Conversely, the benefits are specific to each case and reflect the expected impacts of the Partnership. Where some monetised figures were available, these have been included in Annex 3.

The overall message however, is that the costs difference are not the driving factors for choosing between the various options, but it is rather the type of benefits that the different forms of implementation could bring about that justify the choice.

(8) The report should explain the choice of the specific objectives (in particular the origin of the quantified targets) and clarify the relation between the objectives, the "expected impacts" and the "functionalities". Impacts should be assessed with respect to the specific objectives.

Due to the flexibility and versatility of hydrogen and multitude of hydrogen end-use applications, defining overall time-bound targets was not straightforward. In order to achieve the general objectives, seven specific objectives were defined in the IA from which three "time-bound targets" were mentioned on p.40 and p.41:

- Deliver hydrogen based solutions at a price equivalent to the alternatives by 2030.
- Produce clean hydrogen at a cost of ~€1.5-3/kg by 2030, allowing penetration into mass markets.
- Reduce the distribution costs to less than €1/kg of hydrogen at scale by 2030

These time-bound targets can already be considered as operational objectives.

These objectives in terms of costs are very ambitious considering in particular that the actual cost of clean hydrogen delivered today at Hydrogen refuelling station is on average close to € 9-12/kg. Similar comments could be made for fuel cells components and stacks which are today still very expensive -

meaning that efforts should be made to reduce costs by funding R&I activities seeking for example to reduce the amount of critical elements (Platinum group metals) while improving energy density, efficiency and durability.

Production costs of clean hydrogen are linked to Electrolyser costs. Those have already been reduced by 60% in the last ten years, and are expected to halve by 2030 compared to today with economies of scale.² In areas with low-cost renewable electricity, electrolysers are expected to be able to compete with fossil-fuel hydrogen in 2030.

On distribution costs, transport costs can vary dramatically between transport means (e.g. pipeline (15 cents/kg) versus trucks versus liquid carriers, etc....) and context of usage. The figure of "less than 1 euro" is for the specific case of transport by truck for mobility application.

Given the focus of the impact assessment on comparing different forms implementation, the identification of "key functionalities needed" allows making the transition between the definition of the objectives and what would be crucial to achieve them in terms of implementation. These functionalities relate to the type and composition of actors that have to be involved, the type of range of activities that should be performed, the degree directionality needed and the linkages needed with the external environment. A paragraph is inserted in 4.4.

(9) The report should be more transparent about what issues remain open after the impact assessment and will be decided at a later stage, because of the particularities of this exercise where some contextual elements,

Issues that remain open after the impact assessment are now listed on p. 60.

These are the followings:

- Finalisation of Strategic Research and

9

² Based on cost assessments of IEA, IRENA and BNEF. Electrolyser costs to decline from EUR 900/kW to EUR 450/KW or less in the period after 2030, and EUR 180/kW after 2040. Costs of CCS increases the costs of natural gas reforming from EUR 810/kWh2 to EUR 1512/kWh2. For 2050, the costs are estimated to be EUR 1152/kWh2.

such as the budget, remain undecided. For example, the report refers to certain selection criteria that will be addressed later.

The Board notes the estimated costs and benefits of the preferred option in this initiative, as summarised in the attached quantification tables.

- Innovation agenda which will provide a detailed description of activities to be performed in the partnership.
- Governance of the proposed partnership
- Partners signing up to final, commonly agreed objectives and committing the resources and investments needed from their side to achieve them, e.g. partners' financial contribution.
- Finalisation of the Basic Legal Act.

Annex 2 Stakeholder Consultation

1. OVERVIEW FOR ALL CANDIDATE INSTITUTIONALISED EUROPEAN PARTNERSHIPS

1.1. Introduction

In line with the Better Regulation Guidelines,³ the stakeholders were widely consulted as part of the impact assessment process of the 12 candidates for institutionalised partnerships, including national authorities, the EU research community, industry, EU institutions and bodies, and others. These inputs were collected through different channels:

- A feedback phase on the inception impact assessments of the candidate initiatives in August 2019, gathering 350 replies for all 12 initiatives on the "Have your say" web portal during a period of 3 weeks;
- A structured consultation of Member States performed by the EC services over 2019 through the Shadow Strategic Configuration of the Programme Committee of Horizon Europe (in line with the Article 4a of the Specific Programme of Horizon Europe). This resulted in 44 possible candidates for European Partnerships identified as part of the first draft Orientations Document towards the Strategic Plan for Horizon Europe (2021-2024), taking into account the areas for possible institutionalised partnerships defined in the Regulation.
- An online public stakeholder consultation administered by the EC, based on a structured questionnaire, open between September and November 2019, gathering 1635 replies for all 12 initiatives;
- A targeted consultation run by the external study contractors with a total of 608 interviews performed as part of the thematic studies by the different study teams between August 2019 and January 2020.

1.2. Horizontal results of the Open Public Consultation

The consultation was open to everyone via the EU Survey online system.⁴ The survey contained two main parts to collect views on general issues related to European partnerships (in Part 1) and specific responses related to one or more of the 12 candidate initiatives (as selected by a participant). The survey was open from 11 September till 12 November 2019. The consultation was available in English, German and French and advertised widely through the European Commission's online channels as well as via various stakeholder organisations.

1.2.1. Profile of respondents

In total, 1635 respondents filled in the questionnaire of the open public consultation. Among them, 272 respondents (16.64%) were identified to have responded to the consultation as part of a campaign (coordinated responses). Based on the Better Regulation Guidelines, the groups of respondents where at least 10 respondents provided coordinated answers were labelled as 'campaigns', segregated and analysed separately and from other responses. In total 11

⁴ https://ec.europa.eu/eusurvey/runner/ConsultationPartnershipsHorizonEurope

11

³ https://ec.europa.eu/info/files/better-regulation-guidelines-stakeholder-consultation_en

campaigns were identified, the largest of them includes 57 respondents⁵. In addition, 162 respondents in the consultation also display similarities in responses but in groups smaller than 10 respondents. Hence, these respondents were not labelled as campaigns and therefore were not excluded from the general analysis.

Table 1: Country of origin of respondents (N=1635)

Country	Number of	Percentage of
Country	respondents	respondents
Germany	254	15.54%
Italy	221	13.52%
France	175	10.70%
Spain	173	10.58%
Belgium	140	8.56%
The Netherlands	86	5.26%
Austria; United Kingdom	61	3.73%
Finland	49	3.00%
Sweden	48	2.94%
Poland	45	2.75%
Portugal	32	1.96%
Switzerland	28	1.71%
Czechia	24	1.47%
Greece	23	1.41%
Norway; Romania	22	1.35%
Denmark	20	1.22%
Turkey	19	1.16%
Hungary	14	0.86%
Ireland	12	0.73%
United States	11	0.67%
Estonia; Slovakia; Slovenia	10	0.61%
Bulgaria; Latvia	9	0.55%
Bosnia and Herzegovina	7	0.43%
Lithuania	4	0.24%
Canada; Croatia; Israel	3	0.18%
China; Ghana; Iceland; Japan; Luxembourg; Morocco	2	0.12%
Bhutan; Botswana; Cyprus; Iran; Malta; Mexico; Moldova; Mongolia; Palestine; Russia; Serbia; South Africa; Tunisia; Ukraine; Uruguay	1	0.06%

As shown in Figure 2, the three biggest categories of respondents are representatives of companies and business organisations (522 respondents or 31.9%), academic and research institutions (486 respondents or 29.7%) and EU citizens (283 respondents or 17.3%). Among the group of respondents that are part of campaigns, most respondents are provided by the same groups of stakeholders, namely company and business organisations (121 respondents or 44.5%), academic and research institutions (54 respondents or 19.8%) and EU citizens (42 respondents or 15.4%).

⁵⁵ The candidate Institutionalised Partnership Clean Hydrogen has the highest number of campaigns, namely 5. A few initiatives, such as Innovative SMEs, Smart Networks and Systems, were not targeted by campaigns. Some campaign respondents decided to provide opinions about several partnerships.

522 486 283 99 97 78 53

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

© Company/business organisation Academic/research institution EU citizen

Business association Public authority Other

Non-governmental organisation (NGO) Non-EU citizen

Environmental organisation

Figure 2 Type of respondents (N=1635) - For all candidate initiatives

Among all consultation respondents, 1303 (79.69%) have been **involved in the on-going research and innovation framework programme** Horizon 2020 or the preceding Framework Programme 7, while 332 respondents (20.31%) were not. In the group of campaign respondents, the share of those who were involved in these programmes is higher (245 respondents out of 272 or 90.07%) than in the group of non-campaign respondents (1058 out of 1363 or 77.62%). When respondents that participated in the Horizon 2020 or in the preceding Framework Programme 7 were asked to indicate in which capacity they were involved in these programmes, the majority stated they were a beneficiary (1033 respondents) or applicant (852 respondents). The main stakeholder categories, e.g. companies/business organisation, academic/research institutions, etc., show a similar distribution across the capacities in which they 'have been involved in Horizon 2020 or in the Framework Programme 7' as the overall population of consultation respondents.

Among those who have been involved in Horizon 2020 or the preceding Framework Programme 7, 1035 respondents (79.43%) are/were involved in a partnership. The share of respondents from campaigns that are/were involved in a partnership is higher than for noncampaign respondents, 89.80% versus 77.03% respectively. The list of partnerships under Horizon 2020 or its predecessor Framework Programme 7 together with the numbers, percentages of participants is presented in Table 4Error! Reference source not found., the table also show the key stakeholder categories for each partnership. Most consultation respondents participated in the following partnerships: Fuel Cells and Hydrogen 2 (FCH2) Joint Undertaking, Clean Sky 2 Joint Undertaking, European Metrology Programme for Innovation and Research (EMPIR) and in Bio-Based Industries Joint Undertaking. The comparison between the non-campaign and campaign groups of respondents shows that the overall distribution is quite similar. However, there are some differences. For the campaign group almost a half of respondents is/was involved in the Fuel Cells and Hydrogen 2 (FCH2) Joint Undertaking, a higher share of campaign respondents is/was participating in Clean Sky 2 Joint Undertaking and in Single European Sky Air Traffic Management Research (SESAR) Joint Undertaking.

When respondents were asked in which **role**(s) **they participate**(d) in a **partnership**(s), over 40% indicated that they act(ed) as partner/member/beneficiary in a partnership. The second largest group of respondents stated that they applied for funding under a partnership. The roles selected by non-campaign and campaign respondents are similar.

Table 4: Partnerships in which consultation respondents participated (N=1035)

Name of the partnership	Number and % of respondents from both groups (n=1035)	Number and % of respondents from a non-campaign group (n=815)	Academic/researc h institutions	Business associations	Company/busines s organisations	Company/busines s organisations	EU citizens	NGOs	Public authority
Fuel Cells and Hydrogen 2 (FCH2) Joint Undertaking	354 (33.33%)	247 (30.31%)	97	9	37	43	41	8	5
Clean Sky 2 Joint Undertaking	195 (18.84%)	145 (17.79%)	57	2	10	27	37	1	7
European Metrology Programme for Innovation and Research (EMPIR)	150 (14.49%)	124 (15.21%)	64	0	13	9	14	2	19
Bio-Based Industries Joint Undertaking	142 (13.72%)	122 (14.97%)	39	8	20	27	14	1	6
Shift2Rail Joint Undertaking	124 (11.98%)	101 (12.40%)	31	7	5	31	14	3	7
Electronic Components and Systems for European Leadership (ECSEL) Joint Undertaking	111 (10.72%)	88 (10.80%)	42	2	7	20	12	0	5
Single European Sky Air Traffic Management Research (SESAR) Joint Undertaking	66 (6.38%)	46 (5.64%)	10	3	3	20	3	2	3
5G (5G PPP)	53 (5.12%)	47 (5.77%)	20	1	6	14	5	0	1
Eurostrars-2 (supporting research-performing small and medium-sized enterprises)	44 (4.25%)	40 (4.91%)	17	0	6	1	7	0	6
Innovative Medicines Initiative 2 (IMI2) Joint Undertaking	37 (3.57%)	35 (4.29%)	18	2	3	3	2	4	3
Partnership for Research and Innovation in the Mediterranean Area (PRIMA)	28 (2.71%)	26 (3.19%)	15	0	3	1	2	0	2
European and Developing Countries Clinical Trials Partnership	25 (2.42%)	24 (2.94%)	12	0	1	2	3	3	2
Ambient Assisted Living (AAL 2)	22 (2.13%)	21 (2.58%)	11	2	1	1	3	0	3
European High- Performance Computing Joint Undertaking (EuroHPC)	22 (2.13%)	18 (2.21%)	6	0	2	3	5	0	2

For the remaining of the consultation, respondents could provide their views on each/several of the candidate initiatives. The majority of respondents (31.4%) provided their views on the Clean Hydrogen candidate partnership. More than 45% of respondents from the campaigns selected this partnership. Around 15% provided their views for European Metrology, Clean Aviation and Circular Bio-based Europe. The share of respondents in the campaign group that chose to provide views on the Clean Aviation candidate partnership is of 20%. The smallest number of respondents provided opinions on the candidate initiative 'EU-Africa research partnership on health security to tackle infectious diseases – Global Health'.

Table 5: Candidate Institutionalised Partnerships for which consultation respondents provide responses (N=1613)

Name of the candidate Institutionalised European partnership	Number and % of respondents from both groups (n=1613)	Number and % of respondents from a non-campaign group (n=1341)
Clean Hydrogen	506 (31.37%)	382 (28.49%)
European Metrology	265 (16.43%)	225 (16.78%)
Clean Aviation	246 (15.25%)	191 (14.24%)
Circular bio-based Europe	242 (15%)	215 (16.03%)
Transforming Europe's rail system	184 (11.41%)	151 (11.26%)
Key Digital Technologies	182 (11.28%)	162 (12.08%)
Innovative SMEs	111 (6.88%)	110 (8.20%)
Innovative Health Initiative	110 (6.82%)	108 (8.05%)
Smart Networks and Services	109 (6.76%)	107 (7.98%)
Safe and Automated Road Transport	108 (6.70%)	102 (7.61%)
Integrated Air Traffic Management	93 (5.77%)	66 (4.92%)
EU-Africa research partnership on health security to tackle infectious diseases – Global Health	49 (3.04%)	47 (3.50%)

1.2.2. Characteristics of future candidate European Partnerships

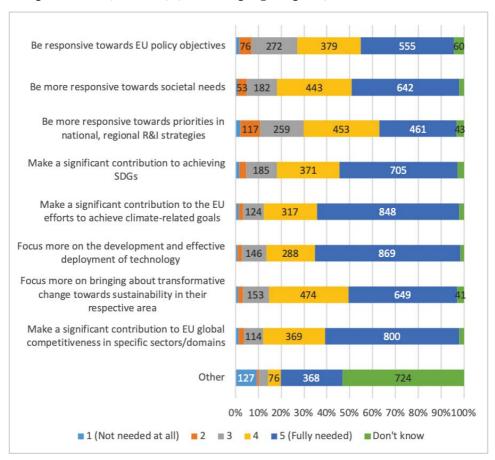
Respondents were asked to assess what areas, objectives, aspects need to be in the **focus of the future European Partnerships** under Horizon Europe and to what extent. According to Figure 6, a great number of respondents consider that a significant contribution by the future European Partnerships is 'fully needed' to achieve climate-related goals, to the development and effective deployment of technology and to EU global competitiveness in specific sectors/domains. Overall, respondents' views reflect that many aspects require attention of the Partnerships. The least attention should be paid to responding towards priorities of national, regional R&D strategies, including smart specialisation strategies, according to respondents.

Overall, only minor differences can be found between the main stakeholder categories. Academic/research institutions value the responsiveness towards EU policy objectives and focus on development and effective deployment of technology a little less than other respondents. Business associations, however, find that the future European Partnerships under Horizon Europe should focus a little bit more on the development and effective deployment of

technology than other respondents. Furthermore, business associations, large companies as well as SMEs value the role of the future European Partnerships for significant contributions to EU global competitiveness in specific sectors domains a little higher than other respondents. Finally, both NGOs and Public authorities put a little more emphasis on the role of the future European Partnerships for significant contributions to achieving the UN SDGs. The views of citizens (249, or 18.3%) do not reflect significant differences with other types of respondents. However, respondents that are/were directly involved in a partnership under Horizon 2020 or its predecessor Framework Programme 7 assign a higher importance of the future European Partnerships to be more responsive towards EU policy objectives and to make a significant contribution to achieving the UN's Sustainable Development Goals.

A qualitative analysis of the "other" answers highlights the importance of collaboration and integration of relevant stakeholders to tackle main societal challenges and to contribute to policy goals against which fragmentation of funding and research efforts across Europe should be avoided. Additionally, several respondents suggested that faster development and testing of technologies, acceleration of industrial innovation projects, science transfer and market uptake are needed. Next to that, many respondents provided answers related to the hydrogen and the energy transition, which corresponds to the high number of respondents that provided answers to the candidate initiative on this topic.

Figure 6: To what extent do you think that the future European Partnerships under Horizon Europe need to (N=1363) (non-campaign replies) For all candidate initiatives



1.2.3. Main advantages and disadvantages of Institutionalised European Partnerships

An open question asked to outline the main advantages and disadvantages of participation in an Institutionalised European Partnership (as a partner) under Horizon Europe (1551 respondents). The advantages mentioned focus on the development of technology, overall collaboration between industry and research institutions, and the long-term commitment. Disadvantages mentioned are mainly administrative burdens. An overview is provided below.

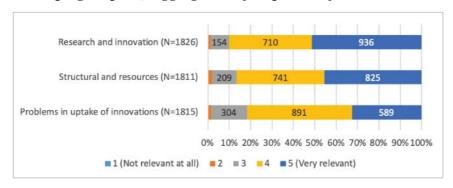
Advantages mentioned: Long term commitment, stability, and visibility in financial, legal, and strategic terms; Participation of wide range of relevant stakeholders in an ecosystem (large/small business, academics, researchers, experts, etc.); Complementarity with other (policy) initiatives at all levels EU, national, regional; Efficient and effective coordination and management; High leverage of (public) funds; Some innovative field require high levels of international coordination/standardisation (at EU/global level); Ability to scale up technology (in terms of TRL) through collaboration; Networking between members; Direct communication with EU and national authorities

Disadvantages mentioned: Slow processes; System complexity; Continuous openness to new players should be better supported as new participants often bring in new ideas/technologies that are important for innovation; Lower funding percentage compared to regular Horizon Europe projects; Cash contributions; Administrative burdens; Potential for IPR constraints.

1.2.4. Relevance of EU level to address problems in Partnerships' areas

Respondents were asked to rate the **relevance of research and innovation efforts at EU level efforts to address specific problems in the area of partnerships**. Research and innovation related problems were rated as most relevant across all candidate initiatives, followed by structural and resources problems and problems in the uptake of innovations. Overall, all three areas were deemed (very) relevant across the partnerships, as more than 80% of respondents found these challenges (very) relevant. Only minor differences were found between stakeholder categories. Research and innovation problems were found slightly more relevant by academic/research institutions, yet slight less relevant by large companies and SMEs. Structural and resource problems were indicated as slightly more relevant by NGOs, but slightly less by academic/research institutions. While both NGOs and public authorities find slightly more relevant to address problems in uptake of innovation than other respondents. The views of citizens are not differing significantly. Respondents that are/were directly involved in a current/preceding partnership find, however, the need to address problems related to the uptake of innovations slightly more relevant than other respondents.

Figure 9: To what extent do you think this is relevant for research and innovation efforts at EU level to address the following problems in relation to the candidate partnership in question? (non-campaign replies) Aggregation of responses of all candidate initiatives



1.2.5. Horizon Europe mode of intervention to address problems

Respondents were asked to indicate how these challenges could be addressed through Horizon Europe intervention. Just over 50% of all respondents indicated that institutionalised partnerships were the best fitting intervention, with relatively strong differences between stakeholder categories. The use of Institutionalised Partnership was indicated more by business associations and large companies, but less by academic/research institutions and SMEs. While academic/research institutions valued traditional calls more often, this was not the case for business associations, large companies and public authorities. Public authorities indicated a co-programmed intervention more often than other respondents. Citizens indicated slightly less often that institutionalised partnerships were the best fitting intervention. Respondents that are/were directly involved in a current/preceding partnership, selected the institutionalised partnership intervention in far higher numbers (nearly 70%).

Figure 10: In your view, how should the specific challenges described above be addressed through Horizon Europe intervention? (non-campaign replies) For all candidate initiatives



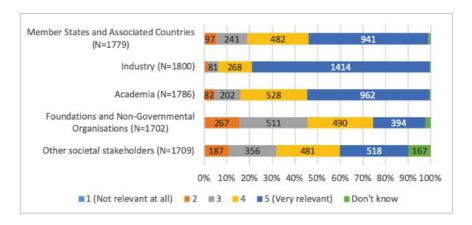
When asked to reflect on their answers, respondents that pointed to the need for using institutionalised partnership mentioned the long-term commitment of collaboration, a common and ambitious R&I strategy as well as the overall collaboration between industry and research institutions. Others shared positive experiences with other modes of interventions:

- Traditional calls, because of their flexibility and integration of a wide range of actors, as long as the evaluation panels do not deviate from the policy focus. This was mentioned by 94 participants, including companies (25), academics (26) and EU citizens (25).
- Co-funded partnership, as a mechanism to ensure that all participants take the effort seriously, while allowing business partnerships to develop. This approach was deemed suitable based on previous experiences with ERANETs. This was raised by 84 participants, 36 of them academic respondents, 18 companies and 16 EU citizens.
- Co-programmed partnerships, to tackle the need to promote and engage more intensively with the private sector. This was mentioned by 97 participants, most of them companies (34), followed by academics (22), business associations (15) and EU citizens (11).
 - 1.2.6. Relevance of a set of elements and activities to ensure that the proposed European Partnership would meet its objectives

Setting joint long-term agendas

Respondents were asked how relevant it is for the proposed European Partnerships to meet their objectives to have a strong involvement of specific stakeholder groups in setting joint long-term agenda. All respondents see stakeholders from industry as the most relevant, followed by academia and governments. The involvement of foundations and NGOs as well as other societal stakeholders were, however, still found to be (very) relevant by more than 50% of the respondents. Most respondents indicated the stakeholder group they belong to themselves or that represent them as relevant to involve.

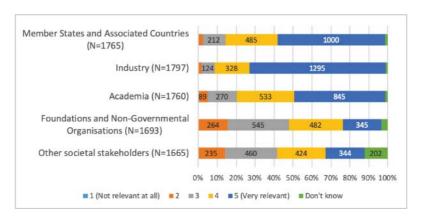
Figure 11: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives - Setting joint long-term agenda with strong involvement of: (non-campaign replies) For all candidate initiatives



<u>Pooling and leveraging resources through coordination, alignment and integration with stakeholders</u>

Respondents were asked how relevant it is for the proposed European Partnership to meet its objectives to pool and leverage resources (financial, infrastructure, in-kind expertise, etc.) through coordination, alignment and integration with specific groups of stakeholders. Respondents see stakeholders from industry as the most relevant, followed by academia and governments (Member States and Associated Countries). The involvement of foundations and NGOs as well as other societal stakeholders are also still found to be (very) relevant for more than 50% of the respondents. Similarly as described for the question on setting joint long-term agendas, most stakeholder categories valued their own involvement higher than other respondents – although also here differences between stakeholder categories were minor.

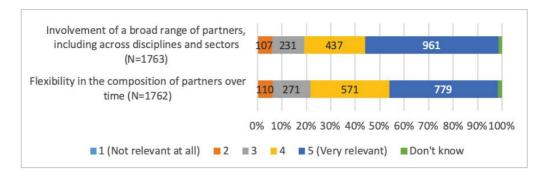
Figure 12: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives – Pooling and leveraging resources (financial, infrastructure, in-kind expertise, etc.) through coordination, alignment and integration with: (non-campaign replies) For all candidate initiatives



Composition of the partnerships

Regarding the composition of the partnership most respondents indicated that for the proposed European Partnership to meet its objectives the composition of partners needs to be flexible over time and that a broad range of partners, including across disciplines and sectors, should be involved (see Figure 13). When comparing stakeholder groups only minor differences were found. Academic/research institutions and public authorities found the involvement of a broad range of partners and flexibility in the composition of partners over time slightly more relevant than other respondents, while large companies found both less relevant. SMEs mainly found the flexibility in the composition of partners over time less relevant than other respondents, while no significant differences were found regarding the involvement of a broad range of partners. Citizens provided a similar response to non-citizens. Respondents that are/were directly involved in a current/preceding partnership, when compared to respondents not involved in a current/preceding partnership, indicated a slightly lower relevance of the involvement of a broad range of partners and flexibility in the composition of partners over time.

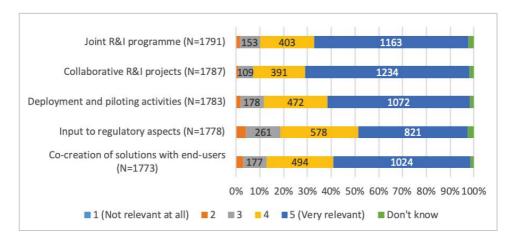
Figure 13: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives – Partnership composition (non-campaign replies) Aggregation of responses of all candidate initiatives



Implementation of activities

Most respondents indicated that implementing activities like a joint R&I programme, collaborative R&I projects, deployment and piloting activities, providing input to regulatory aspects and the co-creation of solutions with end-users are all (very) relevant for the partnerships to be able to meet its objectives. Minor differences were found between the main stakeholder categories, the differences found were in line with their profile. As such, academic/research institutions found joint R&I programme & collaborative R&I projects slightly more relevant and deployment and piloting activities, input to regulatory aspects and co-creation with end-users slightly less relevant than other respondents. For SMEs an opposite pattern is shown. Large companies, however, also found collaborative R&I projects slightly more relevant than other respondents, as well as input to regulatory aspects. The views of citizens are similar to non-citizens. Respondents that are/were directly involved in a current/preceding partnership, when compared to respondents not involved in a current/preceding partnership, show a slightly higher relevance across all activities.

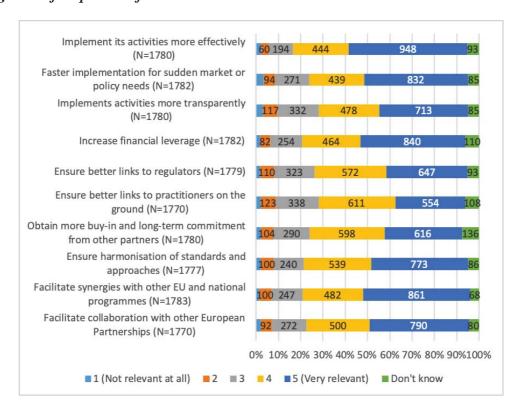
Figure 14: In your view, how relevant are the following elements and activities to ensure that the proposed European Partnership would meet its objectives – Implementing the following activities (non-campaign replies) For all candidate initiatives



1.2.7. Relevance of setting up a legal structure (funding body) for the candidate European Partnerships to achieve improvements

Respondents were asked to reflect on the relevance of setting up a legal structure (funding body) for achieving a set of improvements, as shown in the Figure below. In general, 70%-80% of respondents find a legal structure (very) relevant for these activities. It was found most relevant for implementing activities in a more effective way and least relevant for ensuring a better link to practitioners on the ground, however differences are small.

Figure 15: In your view, how relevant is to set up a specific legal structure (funding body) for the candidate European Partnership to achieve the following? (non-campaign replies) Aggregation of responses of all candidate initiatives

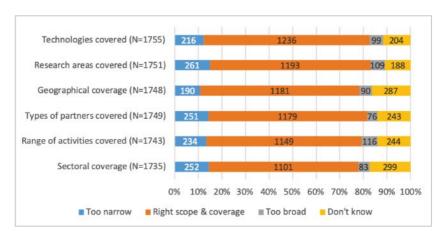


When comparing stakeholder categories there are only minor differences. Academic/research institutions indicated a slightly lower relevance for transparency, better links to regulators as well as obtaining the buy-in and long-term commitment of other partners. SMEs also indicated a lower relevance regarding obtaining the buy-in and long-term commitment of other partners. Large companies showed a slightly higher relevance for implementing activities effectively, ensure better links to regulators, obtaining the buy-in and long-term commitment of other partners, synergies with other EU/MS programmes and collaboration with other EU partnerships. NGOs find it slightly more relevant to implement activities faster for sudden market or policy needs. Public authorities, however, find it slightly less relevant to facilitate collaboration with other European Partnerships than other respondents. The views of citizens show a slightly lower relevance for a legal structure in relation to implementing activities in an effective way. Respondents that are/were directly involved in a current/preceding partnership indicated a higher relevance across all elements presented.

1.2.8. Scope and coverage of the candidate European Partnerships based on their inception impact assessments

Consulted on the scope and coverage for the partnerships, based on their inception impact assessments, the large majority feels like the scope and coverage initially proposed in the inception impact assessments is correct. However, about 11% to 15% of the respondents indicated the scope and coverage to be too narrow. About 11%-17% of respondents answered "Don't know". Overall, differences between the main stakeholder categories were found to be minor. Academic/research institutions indicated slightly more often that the research area was "too narrow" then other respondents. SMEs on the other hand indicated slightly more often that the research area and the geographical coverage were "too broad". NGOs and public authorities, however, found the geographical coverage slightly more often "too narrow". Large companies found the range of activities slightly more often "too broad" and the sectoral focus slightly more often "too narrow" when compared to other respondents. The views of citizens are the same as for other respondents. Respondents that are/were directly involved in a current/preceding partnership more often indicated that the candidate institutionalised European Partnership have the "right scope & coverage".

Figure 16: What is your view on the scope and coverage proposed for this candidate institutionalised European Partnership, based on its inception impact assessment? (non-campaign replies) Aggregation of responses of all candidate initiatives



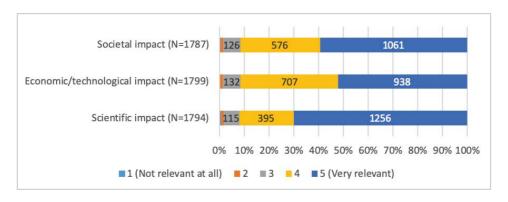
1.2.9. Scope for rationalisation and alignment of candidate European Partnerships with other initiatives

When asked whether it would be possible to rationalise a specific candidate European Institutionalised Partnership and its activities, and/or to better link with other comparable initiatives, nearly two thirds of respondents answered "Yes" (1000, or 62%), while over one third answered "No" (609, or 39%). Nearly no differences were found between stakeholder categories, only large companies and SMEs indicated slightly more often "Yes" in comparison to other respondents. The views of citizens are the same as for other respondents. Respondents that are/were directly involved in a current/preceding partnership, indicated "No" more often, the balance is about 50/50 between "Yes" and "No" for this group.

1.2.10. Relevance of European Partnerships to deliver targeted scientific, economic/technological and societal impacts

Finally, respondents were asked to rate the relevance of partnership specific impacts in three main areas: Societal; Economic/technological; and Scientific impacts. All three areas were deemed (very) relevant across the candidate partnerships. Scientific impact was indicated as the most relevant impact, more than 90% of respondents indicated that this as (very) relevant. Only minor difference between stakeholder groups were found. Academic/research institutions found scientific impacts slightly more relevant, while large companies found economic and technological impacts slightly more relevant than other respondents. NGOs found societal impact slightly more relevant, while SMEs found this slightly less important. Citizens did not a significantly different view when compared to other respondents. Respondents that are/were directly involved in a current/preceding partnership find all impacts slightly more relevant than other respondents.

Figure 17: In your view, how relevant is it for the candidate European Institutionalised Partnership to deliver on the following impacts? (non-campaign replies) Aggregation of responses of all candidate initiatives



1.3. Stakeholder consultation results for the Clean Hydrogen Initiative

1.3.1. Feedback to the inception impact assessment on candidate initiatives for Institutionalised Partnerships

Following the publication of the inception impact assessment, a feedback phase of 3 weeks allowed any citizen to provide input on the proposed initiatives on the "Have your say" web portal. In total 350 feedbacks were collected for all initiatives.

For the initiative "Clean Hydrogen" 38 individual feedbacks were collected, mainly from company/business organisations (15) and business associations (12).⁶ Among the elements mentioned were:

- This new partnership should build on the progress made by the FCH 2 JU ("Fuel Cells and Hydrogen 2 Joint Undertaking) during the last decade which has demonstrated effectiveness especially for the coordination of the programme and alignment of priorities between the various stakeholders;
- 14 respondents clearly wrote that the institutionalised European Partnership based on Article 187 TFEU (option 2) offers the most effective way of delivering the objectives of the initiative:
- Uptake of the production and consumption of renewable or decarbonised hydrogen is slowed down by a lack of political commitment, perfectible market design, important costs and varying technology readiness levels (TRL);
- Coordination between economic actors and between sectors, such as mobility, energy, heating and industry, is key and can be better achieved within an iPPP;
- Openness to EU-13 MS is essential and needs to be improved;
- Key components: gas infrastructure & underground storage (to transport and store renewable hydrogen) to meet demand from the power, industry, land and marine transportation and heating sectors;
- The overall leverage achieved in the FCH JU (i.e. level of private investment compared with EU finding) to date stands at 1.96, compared to 1.09 during the FP7 programme. This leverage effect is forecasted to rise to 3.0.

Beyond the cooperation expected from an R&D programme, the creation of an Institutionalised Partnership has led to many additional coordination efforts: MoUs with 90+ regions and cities; various hydrogen mobility initiatives across MS; better synergies with other European programmes (CEF, ETS Innovation Fund, etc.); co-funding with national and regional programmes; and more.

Whilst this Institutionalised Partnership would support and enable cooperation between the actors of the wider Hydrogen Value Chain, it needs to be complemented: first, by sector-specific Hydrogen activities; secondly, by activities focusing specifically on aspects of industrial cross-sectoral nature; third, by Hydrogen-related infrastructural investment; as well as, fourth, the regulatory environment, which would provide access to the CO2-lean electricity (needed to operate the Hydrogen Value Chain) at costs, which do not undermine the global economic feasibility of this value chain.

A structured consultation of Member States through the Shadow Strategic Configuration of the Programme Committee Horizon Europe in May/June 2019 provided early input into the preparatory work for the candidate initiatives (in line with the Article 4a of the Specific Programme of Horizon Europe). This resulted in 44 possible candidates for European Partnerships identified as part of the first draft Orientations Document towards the Strategic Plan for Horizon Europe (2021-2024), taking into account the areas for possible institutionalised partnerships defined in the Regulation.

The feedback provided by 30 countries (all Member States, Iceland and Norway) has been analysed and summarised in a report, with critical issues being discussed at the Shadow Strategic Programme Committee meetings.

For the initiative "Clean Hydrogen" the following overall feedback was received from Member States: "countries support the proposed partnership, and its objectives. Key issues raised by delegations and that may need further discussion include the need to ensure systems aspects and sectoral coupling for the use of hydrogen technologies, and agreeing on the areas for applications".

"Overall there is a good agreement on the use of a partnership approach in addressing energy transition through clean hydrogen technologies (64% consider it very and 11% somewhat relevant). There is broad agreement (71%) that the partnership is more effective in achieving the objectives and delivering clear impacts for the EU and its citizens, but to a lesser degree (43%) that it would contribute to improving the coherence and synergies within the EU R&I landscape."

Delegations identified further of aspects that could be reinforced in the proposal a partnership "that would increase its relevance for national priorities, e.g." ensure synergies with other related partnerships (e.g. Clean Hydrogen)"... Other comments were related to "avoiding duplications with other Partnerships (notably on Integrated Air Traffic Management and Hydrogen), and clarifying objectives".

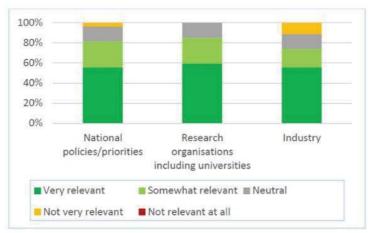
Section on "clean hydrogen"

"Overall the results of the consultation confirm the relevance of the proposed European Partnership on Clean Hydrogen, with 82% considering it very or somewhat relevant for their research organisations, including universities, 79% for their national policies and priorities, and 72% of respondents found the proposed partnership to be relevant for their industry".

Figure 1: Relevance of the European Partnership for Clean Hydrogen in the national context

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⁷ Comments on scope and content have to be assessed in the context of the overall priority setting to ensure coherence.



On the question of existing national/regional R&I strategies, plans and/ or programmes in support of the proposed Partnership for Clean Hydrogen, 25 countries report to have relevant elements in place. National economic sectoral strategies and/or plans with a strong emphasis on research and innovation (54%, AT, CZ, DE, DK, EE, FR, HR, IT, LUC, LV, NL, SE, SI, SK, NO) and regional R&I and/or smart specialisation strategies (54%, AT, BE, DE, DK, EL, ES, FR, HR, NL, PL, PT, SE, SI, SK, UK) were identified most frequently, followed by national R&I strategies or plans (50%, DE, DK, EE, FR, HR, LV, NL, PT, RO, SE, SI, SK, IS, NO), dedicated R&I funding programmes or instruments (46%, AT, DE, DK, ES, FR, HR, NL, RO, SE, SI, SK, UK, NO). Eight countries (FR, HR, HU, IE, NL, PT, SE, SK) reported other policies/ programmes, such as national /state support plans and cross-sectoral roadmaps.

Delegations identified a number of aspects that could be reinforced in the proposal for this partnership that would increase its relevance for their national priorities. Several delegations emphasise the need to ensure systems aspects and sectoral coupling, notably by developing demonstrators for the use of hydrogen technologies in energy, transport and industry. In a similar manner, several countries indicated specific areas of interest for applications, e.g.: all types of road transport (not just heavy-duty transport), the maritime sector, small-scale hydrogen usage, transportation and storage. Various comments also pointed out the need to ensure alignment with national activities, as well as the complementarity and synergies with other related partnerships/initiatives/programmes to cover the entire Hydrogen value chain. Other individual comments suggest to, e.g.:

- Include infrastructure for heavy-duty and FCEVs
- Ensure R&I activities among the whole value chain
- Extend the scope to the development of fuels with high energy density
- Include hydrogen sensor as an important field of application
- Assess the role of Carbon Capture & Storage as a means of achieving the scale required both for volume and cost
- Include technologies for distribution of hydrogen through pipelines
- Focus on near-zero carbon hydrogen production pathways

Many countries (64%) are undecided concerning their interest to participate in an initiative. At this stage 9 countries (BE, DE, EE, ES, FR, IT, MT, RO, NO) expressed interest to join as a partner, and only one country (CY) indicated that there is no national interest to participate. Governmental research organisations (61%), research infrastructures (50%), and planned

national R&I programmes (50%) are most frequently identified as potential partners or contributors.

While many are undecided concerning their participation, all countries show interest in having access to results produced in the context of the partnership.

Feedback on objectives and impacts

Overall there is a good agreement on the use of a partnership approach in addressing energy transition through clean hydrogen technologies (64% consider it to be very relevant and 11% see it as somewhat relevant). There is broad agreement (71%) that the partnership is more effective in achieving the objectives and delivering clear impacts for the EU and its citizens, but to a lesser degree (43%) that it would contribute to improving the coherence and synergies within the EU R&I landscape.

Countries indicate strong agreement with the proposed short, medium and long term objectives, as well as with the expected scientific, economic and societal impacts at the European level (79%). Slightly fewer MS (75%) consider the impacts to be relevant in the national context. Three-quarters (75%) of the countries find the envisaged duration of the proposed partnership to be adequate, although some delegations point out that there is insufficient information to assess the appropriate timeframe. In additional comments, delegations reiterated some of the points made regarding elements to be reinforced, notably sector coupling and inclusion of all transport modes. Additional individual comments highlighted the need to allow technology-neutral solutions (in this context, one delegation suggested a merger with 2ZERO), to consider international initiatives in the field, and to include H2 production from renewables through water electrolysis, water thermochemical splitting and biomass gasification, and photochemical water splitting.

Views on partners, contributions and implementation

Around two-thirds (64%) of the countries agree on the type and composition of partners, whilst 18% remain neutral and 7% disagree. In additional comments, several countries' delegates emphasised the need to ensure stronger involvement of Member States and local authorities in the partnership to guarantee alignment with national activities. Other comments stressed the need to ensure a more balanced participation from other countries, stakeholders and actors compared to the current set-up of the Fuel Cells and Hydrogen Joint Undertaking, notably by ensuring increased involvement of smaller suppliers for the hydrogen industry.

At this stage, the majority of the countries' respondents (79%) indicated that they would need more information on the contributions and level of commitments expected from partners.

More than half (61%) of the countries needed more information to assess the proposed mode of implementation based on Article 187 TFEU, while 8 countries are in favour and 3 against. In the additional comments, three countries favour explicitly implementation through a coprogrammed model, and two countries stress the need for comprehensive assessments as to whether a co-programmed or institutionalised model is more effective. One country supported implementation through competitive calls in Horizon Work Programmes."

1.4. Targeted consultation of stakeholders

In addition to the consultation exercises coordinated by EC services, the external study thematic teams performed targeted consultations with businesses, research organisations and other partners on different aspects of potential European Partnerships.

1.4.1. Approach to the targeted consultation

Few actors have experience with different types of initiatives (usually actors involved in H2 funding have only experience with either standard EU programme calls or with the FCH JU, but not with a co-programmed or co-funded scheme). Therefore, it was difficult to ask them for their opinions on the "best option." With each topic, the main objective for the interviewers was to collect data that would allow for distinguishing between the options to determine which was best, given their characteristics. The co-funded initiative and Article 185 were quickly deemed out of scope, so that interviewers focused on the baseline, the co-programmed and the existing Article 187 options. It was obvious that all interviewees – even the five actors that were not currently involved in FCH JU calls – favoured an IP (some strongly, others with some nuances). These actors favoured an IP due to the increasing scope of applications in the hydrogen field, and the growing need for coordination and a strong community within the sector.

The partnership in Clean Hydrogen would require engagement not only with stakeholders from across the European Hydrogen community, but also from across new non-H2 sectors, in order to fulfil low carbon objectives. An outline of stakeholders targeted for interviews is presented in the table below; it was drafted by taking into account current trends in the field of H2.

1.4.2. Overview of respondents to the targeted consultation

The table below shows that targeted interviewees were well-distributed across categories, with strong representation from Research and Academia, End-use industry and Manufacturing industry. The subsequent figure illustrates how interviewees were primarily based in areas with strong national hydrogen programmes, including Germany, France, the Netherlands and Spain. Efforts were also made to reach out to relevant Eastern and Southern European countries in order to collect a diversity of perspectives.

Table 1 – Number of interviews per stakeholder category

Stakeholder category	Number	Share (%)
Manufacturing industry	7	15%
Association	4	8%
Grid operator	2	4%
Research & academia	13	27%
Civil society	1	2%

Stakeholder category	Number	Share (%)
National associations	3	6%
End use industry	8	17%
MS and EU Commission	6	13%
Industry (utilities)	2	4%
Local authority representatives	1	2%
Integrators / developers	1	2%
TOTAL	48	100%

1.4.3. Key results/messages from the targeted consultation

Scope of the initiative

- Focus on Clean Hydrogen complete chains: the focus of a partnership should be on hydrogen generation, delivery (transport, distribution and storage) and end-use, covering all relevant sectors and applications.
 - The partnership should only support the scale-up of clean hydrogen applications, i.e., technologies that produce and use hydrogen from low carbon sources (like renewable or other low carbon electricity, or SMR combined with CCUS).
- Technology neutral: the initiative should not focus on specific technologies or applications but should remain open to all potential developments.
- Sector coupling & infrastructure development: the coupling of renewable electricity production and hydrogen generation is seen as a key technology route for propagating clean hydrogen and a key enabler for the deployment of renewables. The FCH JU has been instrumental in reaching out to renewables companies and other potential end-users to increase their interest in hydrogen applications many new organisations across several different sectors have incorporated hydrogen into their long-term strategies (e.g., power companies, gas distributors) largely due to FCH JU outreach.
 - The development of infrastructure (gas pipelines and refuelling stations) is considered as a key enabler to deploy clean hydrogen at scale. There is also a need to define the form in which hydrogen will be transported (e.g., compressed, liquid). The initiative should provide support to ensure that infrastructure investments are encouraged, even if they must be realised by the industry with private capitals (connections to receive support from the CEF could help).
- Continuous improvement: through further RD&I, there is need to spur further cost decreases, quality improvements and performance enhancements of all technologies, applications and stacks. There is still room for improvement in all sectors and for all applications, even for applications that are ready-to-market. The JU has demonstrated its ability to develop technologies to expected maturity levels in the direction of market uptake, and has proven its ability to strengthen the hydrogen community and encourage shared practices and knowledge at all TRLs.

• Coordination with other sectors and/or initiatives: the initiative will have to ensure coordination with other initiatives in concerned sectors. The need for strong coordination can be better handled with an IP than with any other option. For example, the gas sector will play a key role in hydrogen's rollout, but there is no existing initiative on decarbonising gas grids, so it will be important for the partnership to involve gas sector stakeholders. This is true for several "end use" sectors.

Collaboration between all sectors relevant to clean hydrogen is of paramount importance, as they complement one another while sharing a broad low-carbon vision and the scientific knowledge and skills necessary to adapt existing technologies appropriately.

Policy and regulatory vacuum

- No market conditions: there is a need for market uptake of several technologies considered ready-to-market (including FC buses, FC forklifts, stationary FCs, microgrids, and certain types of electrolysers). Further improvement of these applications could prompted by industry deploying technologies at scale. However, necessary market conditions are missing, jeopardising their deployment. The risk of losing the benefits of past years' RD&I efforts is high, if market uptake does not increase within the EU. While it is no longer the role of RD&I to support market uptake, an IP could provide vital support to foster requisite market conditions (both regulatory and policy).
- Absence of regulation: as H2 applications are maturing within all sectors, the need for regulation is increasing. An optimal first space for addressing regulatory requirements is within the RD&I sphere, as it contains actors with the required knowledge (both industry- and research-based actors) and with views on market constraints (industry actors).
 - In addition, the dominance of a strong hydrogen community at an EU level would make discourse with other global regions more efficient, as the EU could address international norms and standards with a single voice. A strong community would also support the leading position of EU organisations.
- Missing vision: the lack of a cohesive European hydrogen policy is a big issue. Without a long-term vision on hydrogen rollout, stakeholders are confident there will be insufficient commitment to launch new markets and secure investors.
 - The JU is the most appropriate framework for proposing and implementing a clear vision on sequential next steps for hydrogen uptake: design, develop, improve, integrate and deploy at scale.

Coordination and cooperation

- There is a need for strong coordination between Research and Industry as the former has knowledge/views on fundamental R&D and emerging technologies and the latter is well-versed in market needs and trends. A community that gathers both types of stakeholders is very important and should be strengthened to ensure complementarity along the entire hydrogen value chain. An IP is the most appropriate option for maintaining and reinforcing the strong, existing European hydrogen community.
- A community addressing all related topics: community coordination is essential in order to help establish a clear agenda that identifies priorities and necessary activities in the clean hydrogen space. This community can most effectively be hosted by an IP.

Involving authorities

- MS involvement: for some stakeholders, sharing best practices will bring MS on board "naturally." But for others, outreach is still needed in order to increase interest. At the MS-level, the European HyENet initiative has made a very good start in engaging with authorities, as it plans to support exchanges on market trends, to present best practices and leverage downstream development.
- Local authorities involvement: local authorities have an important role to play in enabling clean hydrogen uptake; they are involved with public awareness, permitting, coordination, setting low carbon roadmaps, creating early market conditions, responding to local needs, and bringing funds for projects. Therefore, depending on the specific needs of a project or an application that can be deployed at the local level, their involvement in a partnership could become essential. An IP would be the most appropriate structure to support knowledge-sharing and to liaise with important local actors and develop local hydrogen communities.

Awareness

- Specific vs general: awareness must be properly fostered. Outreach on hydrogen should correctly explain the technical, economic and environmental characteristics of different hydrogen applications.
- Extensive diffusion: established best practices should be encouraged and propagated in all concerned industries.

EU positioning

- Relevant for all applications: the supply chain for clean hydrogen applications is dispersed across sectors and industries; knowledge management encourages collaboration and linkages between potential partners. An appropriate IP provides such effective knowledge management.
 - Targeted areas for R&D should be determined based on identified needs (among endusers) rather than on established practices (what EU industry is doing). Therefore, even in segments and with technologies where other regions are gaining prominence (e.g., Asia, which leads in FCEV rollout), it is still important to support R&I, given the need for building blocks and considering that assemblers play a role within hydrogen value chains as well.
- Vital for SMEs: FCH JU plays a **vital role in supporting SMEs**. Within national governments, there is a feeling that larger industrial players dominate the conversations on the strategies for hydrogen, and that they steer national funding towards their own organisations. But the FCH JU provides a forum for SMEs to substantially contribute to/engage in strategic discussions, and there is more of a sense that funding is allocated to projects which really merit it.

Market uptake

- Demonstration: there is a consensus among stakeholders that hydrogen applications are entering a phase of real demonstration. Many demonstration projects will be managed at the MS level, with important industry leverage. EU level intervention and monitoring will remain important to ensure that coordination addresses cross-border projects and linkages between different actors throughout Europe.
- Industrialisation: There is still a strong need for R&D efforts in developing hydrogen applications; whereas in the past R&D mainly focused on scientific and technological development, there is now a much stronger need for research focused on production processes and commercial deployment. The industrialisation phase of hydrogen

- applications will depend on market uptake. R&D funds can go into validating the applications (as the phase of industrialisation remains outside the R&D sphere). Complementarity could be developed with the Innovation Fund (from ETS) to support this phase of industrialisation. This is where an IP, with good knowledge management, could also provide some support (in preparing calls or screening projects).
- Financing: where competitiveness of end use applications is market volume-dependent, an effective market launch will be possible only with policy incentives. Decision makers should therefore seize all opportunities of an H2 economy by setting up adequate support frameworks. An IP, with deep expertise, can provide support in developing and deploying incentives.

Strategic Research & Innovation Agenda

- As H2 is versatile and can be integrated into various sectors using many different applications, it is vital to prepare a coherent SRIA, which is able to draw from current efforts and results to develop a longer term vision. The SRIA should ideally ensure that there is a proper articulation between the long-term CO2 strategy objectives AND the applications where we can expect cost decreases. Coupling the SRIA and H2 strategy is essential and could be best managed by an IP.
- Balance between low and high TRLs. It is important to address all levels of technological readiness in the RD&I agenda. Most stakeholders agree that over the next ten years, RD&I should be concentrated on technologies at high, nearly market-ready levels and at low, potentially innovative levels. EU contributions should decrease when addressing higher TRL projects, to ensure higher private contributions for demonstration projects. An IP is the most appropriate structure through which to prompt increasing industry leverage.

Openness

- The initiative should work at a global level, or at least be connected to all relevant counterparts to ensure compliance with international standards, to secure the role of EU industry in different hydrogen spaces, and to make sure that regulatory issues are addressed properly. An IP is probably the most appropriate initiative to foster collaboration at international levels, given its expertise and knowledge management.
- Open calls: there is a consensus among the interviewees that calls for funding should remain open, but it is considered important (strategically and financially) to ensure that there are incentives that keep members of the IP community consistently interested in its efforts.

Long term commitment

- Public / private collaboration on long term is key. An IP is considered the most appropriate structure for ensuring follow-up and engaging both public and private players in the long run.
 - Fundamental R&D could be facilitated and reinforced by providing structural funding to centres and academia in a more programmatic ways, avoiding the need to regularly submit new project proposals. With clear and strict monitoring, programming could ensure a longer-term and coherent vision of the R&D agenda, and alleviate the process of launching new calls.
- Long-term application selection: for some applications (e.g. in the maritime or aviation sectors), there is need to test out different technologies and alternatives in order to be

able to later see which is the most appropriate for deployment at scale. It takes years to test applications and requires long-term commitments to carbon emission reduction at large scales.

1.5. Open Public Consultation

1.5.1. Characteristics of respondents

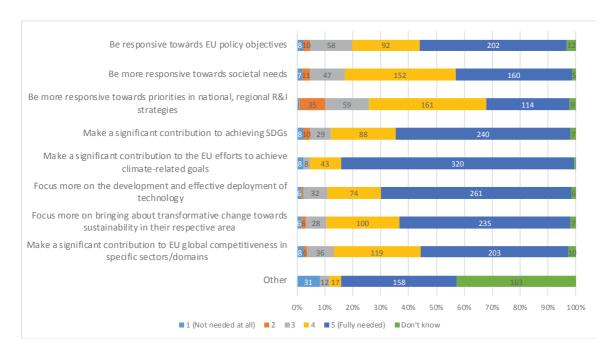
There are 382 respondents who have answered (part of) the consultation for the Clean Hydrogen Partnership. Of these respondents, 76 (19.90%) were citizens. The largest group of respondents were businesses and academic and research institutions both with 123 respondents (32.20%). There were 21 respondents from business associations (5.50%). The other respondents were representatives of public authorities (13, 3.4%), non-governmental organisations (8, 2.09%) or other (17, 4.45%). Over 3/4s of respondents, namely 293 (76.70%), have been involved in the on-going research and innovation framework programme, of which 245 respondents (83.62%) were directly involved in a partnership under Horizon 2020 or its predecessor Framework Programme 7.

1.5.2. Results on general questions

Relevance of efforts of the candidate European Partnership to address problems

At the beginning of the consultation, the respondents of this partnership were asked to indicate their views on the needs of the future European Partnerships under Horizon Europe. All 382 respondents answered these questions. Overall, the respondents indicated that many of the options presented were very relevant. The option where most respondents indicated this, was making a significant contribution to the EU efforts to achieve climate-related goals (320, 83.77%), which is not surprising considering the focus of this partnership. The option where the least amount of respondents indicated that improvements were very relevant, being more responsive towards priorities in national and/or regional R&I strategies (114, 29.84%). No statistical differences were found between the views of citizens and other respondents.

Figure 1: Views of the respondents in regard to the needs of future European Partnerships under Horizon Europe (N=382)



The respondents also had the option to indicate other needs. The results show that respondents have indicated needs around international policy and industrial competition as well as the development of technology for clean hydrogen fuels and cells.

Main advantages and disadvantages of participation in the Institutionalised European Partnership

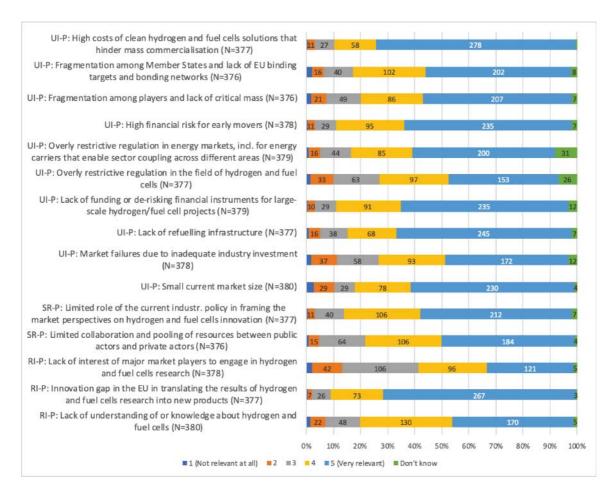
The respondents were asked what they perceived to be the main advantages and disadvantages of participation in an Institutionalised European Partnership (as a partner) under Horizon Europe. This analysis showed the respondents mentioned long term commitment and collaboration in relation to advantages and efficient management and higher visibility in relation to disadvantages.

1.5.3. Results on candidate European Partnership specific questions

Relevance of research and innovation efforts at the EU level to address problems

In the consultation, respondents were asked to provide their view on the relevance of research and innovation efforts at EU level to address the following problems in relation to hydrogen and fuel cells, specifically on three types of problems: problems in uptake of hydrogen and fuel cells innovations (UI-P), structural and resource problems (SR-P) and research and innovations problems (RI-P). In Figure 2 the responses to these answers are presented.

Figure 2: Views of respondents on relevance of research and innovation efforts at the EU level to address problems in relation to hydrogen and fuel cells



With regard to the uptake in innovation problems, 278 respondents have indicated that it is very relevant for research and innovation efforts at EU level to address the problem of high costs of clean hydrogen and fuel cells solutions that hinder mass commercialisation until serial production is achieved, factoring-in economies of scale (73.74%). Of the uptake in innovation problems, market failures due to inadequate industry investment has the least amount of very relevant answers (45.50%), while most respondents still have indicated that they view this issue as very relevant.

There were only two structural and resource problems that the respondents were asked to reflect on. Of these the limited role of current industrial policy in framing the market perspectives related to hydrogen and fuel cells innovation, received more 5 (very relevant) answers, namely 60.53% of responses.

The research and innovation problem that most people have indicated as very relevant is the innovation gap in the EU in translating the results of hydrogen and fuel cells research into new products, with 267 respondents choosing this answer (70.82%). The problem that was least often indicated as very relevant, is also a research and innovation problem, namely: lack of interest of major market players to engage in hydrogen and fuel cells research (121, 32.01%).

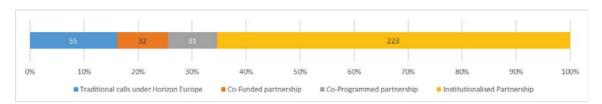
No statistical differences were found between the views of citizens and other respondents. Respondents that are/were involved in a current/preceding partnership (Horizon 2020 or Framework Programme 7) found all uptake in innovation problems more relevant than other respondents.

Horizon Europe interventions to address problems

After providing their views on the relevance of problems, respondents were asked to indicate how these challenges could be addressed through Horizon Europe intervention. As shown in Figure 3, just over 65% of respondents indicated that institutionalised partnerships were the best fitting intervention.

No statistical differences were found between the views of citizens and other respondents.

Figure 3: Assessment of Horizon Europe intervention



The respondents were asked to briefly explain their answers to the question above. People who stated that an institutionalised partnerships was the best fitting answer, mentioned long term, research and innovation and private funding.

Relevance of involvement of actors in setting joint long-term agenda

Respondents were asked how relevant the involvement of actors is in setting a joint long-term agenda to ensure that the proposed European Partnership would meet its objectives (see Figure 4). The highest amount of respondents indicated that the involvement of Industry is very relevant (323 respondents or 86.13%). A large part of respondents also indicated that the involvement of Academia (215, 58.58%) and Member States and Associated Countries (201, 53.46%) is very relevant. With regard to Foundations and NGO's, respondents indicate that their involvement is seen as less relevant, with only 70 (19.23%) respondents indicating that their involvement is very relevant and a 135 respondents (37.09%) indicating that their involvement is a 3 on the relevance scale.

No statistical differences were found between the views of citizens and other respondents.

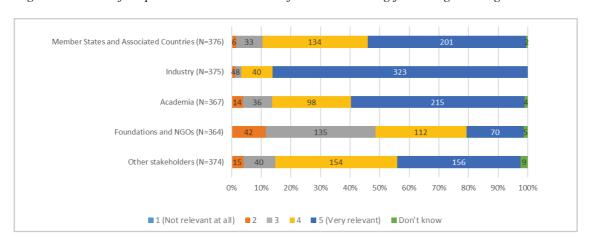


Figure 4: Views of respondents on relevance of actors in setting joint long-term agenda

Relevance of elements and activities in pooling and leveraging resources

With respect to the relevance of actors in pooling and leveraging resources, such as financial, infrastructure, in-kind expertise etc.), to meet Partnership objectives, the patterns are similar. First, 301 respondents (80.05%) indicated that industry was very relevant, which is much

larger than for any of the other stakeholders. 205 (54.14%) respondents felt that Member States and Associated Countries were very relevant and 188 (51.37%) of respondents indicated that Academia were very relevant. Foundations and other stakeholders were deemed less relevant, since only 68 (18.68%) and 89 (24.31%) respondents respectively indicated that these stakeholders were very relevant. No respondents indicated that any of the categories was not relevant at all.

No statistical differences were found between the views of citizens and other respondents.

Member States and Associated Countries (N=373)

Industry (N=376)

Academia (N=366)

Foundations and NGOs (N=364)

Other stakeholders (N=366)

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

1 (Not relevant at all)

2 3 4 5 (Very relevant)

Don't know

Figure 5: Views of respondents on relevance of actors for pooling and leveraging resources

Relevance of elements and activities for the partnership composition

Respondents were asked about the relevance of the Partnership composition, such as flexibility in the composition of partners over time and involvement of a broad range of partners (including across disciplines and sectors), to reach Partnership objectives. As it is visible in Figure 6, ensuring involvement of a broad range of partners has more 'very relevant' answers (143, 38.96%) than the flexibility in the composition of partners (112, 30.60%). Almost 17% (16.94%) of respondents has indicated that flexibility in composition is worth a 2 on the relevancy scale, for ensuring involvement of a broad range of partners, this is the case for 47 respondents (12.81).

No statistical differences were found between the views of citizens and other respondents. Respondents that are/were directly involved in a current/preceding partnership found flexibility in the composition of partners less relevant.

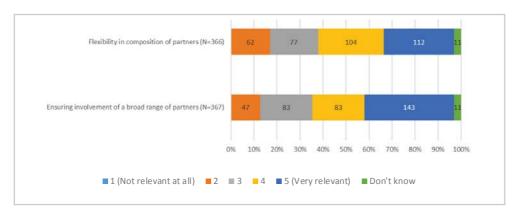


Figure 6: Views of respondents on relevance of partnership composition elements

Relevance of implementation of activities

Respondents were asked to provide opinions on the relevance of implementation of several activities for meeting objectives of the Clean Hydrogen Partnership. Among activities were

listed – joint R&D programme, collaborative R&D projects, deployment and piloting activities, input to regulatory aspects and co-creation of solutions with end-users. Out of 375 respondents, 292 (77.86%) indicated that deployment and piloting activities are very relevant to ensure that the Partnership would meet its objectives. For all the other options, the majority (over 60%) of all respondents have indicated that these are very relevant. See Figure 7.

No statistical differences were found between the views of citizens and other respondents. Respondents that are/were directly involved in a current/preceding partnership found most activities slightly more relevant than other respondents.

Joint R&I programme (N=378) 11 27 79 253 8

Collaborative R&I projects (N=375) 5 23 80 260 6

Deployment and piloting activities (N=375) 613 61 292 3

Input to regulatory aspects (N=372) 8 35 88 235 6

Co-creation of solutions with end-users (N=374) 8 31 103 227 5

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

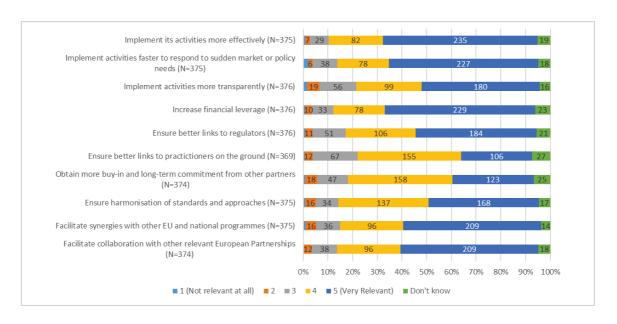
Figure 7: Views of respondents on relevance of implementation of the following activities

Relevance of a legal structure (funding body) to achieve specific objectives

Respondents were also asked to assess the relevance of a specific legal structure (funding body) for the candidate European Partnership to achieve several activities. According to Figure 8, respondents indicated that it was very relevant to set up a specific legal structure for the partnership to achieve a more effective implementation of activities (235, 62.67%) and to increase financial leverage (229, 60.90%). Although 'to ensure better links to practitioners on the ground' and 'to obtain more buy-in and long term commitment from other partners, have received the least 5 (very relevant) answers (106 and 123 respectively), they have received the most 4 answers. Which could indicate that they are still seen as important, just slightly less important than the other options.

No statistical differences were found between the views of citizens and other respondents. Respondents that are/were directly involved in a current/preceding partnership found a legal structure slightly more relevant for most objectives.

Figure 8: Views of respondents on relevance of a specific legal structure

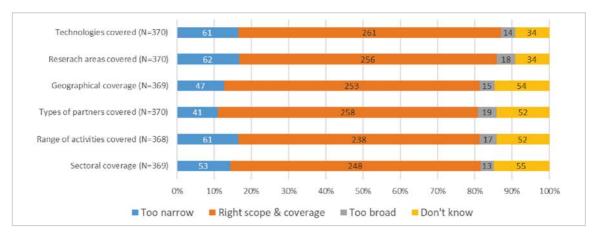


Scope and coverage of the candidate European Partnership

Respondents were asked to assess the scope and coverage of the proposed Clean Hydrogen Partnership, based on its inception impact assessment. The clear majority of the respondents have indicated that the partnership has the right scope and coverage across all areas. The respondents have been the most positive with regard to technologies covered, where 261 respondents (70.54%) have indicated the partnership has the right scope and coverage. The respondents who have indicated that the scope and coverage are not right, have indicated that it was too narrow more often than they viewed it as too broad.

No statistical differences were found between the views of citizens and other respondents.

Figure 9: Views of respondents on the scope and coverage proposed for the Clean Hydrogen partnership



Aside from this multiple choice question, the respondents were also asked to provide any comment that they may have on the proposed scope and coverage for this candidate Institutionalised Partnership. This analysis showed the respondents used this question to talk about low TRL levels, flagship projects and the production and distribution of hydrogen technology.

Alignment of the European Partnership with other initiatives

The respondents were also asked if it they thought it would be possible to rationalise the candidate European Institutionalised Partnership and its activities, and/or to better link it with

other comparable initiatives. 165 respondents (48.53%) have indicated that they think this is the case.

No statistical differences were found between views of citizens and other respondents.

The respondents who answered affirmative, where asked which other comparable initiatives it could be linked with. The results show that respondents think the initiative could be linked with other comparable initiatives related to hydrogen, renewable energy and the application of hydrogen as well as clean aviation and rail systems.

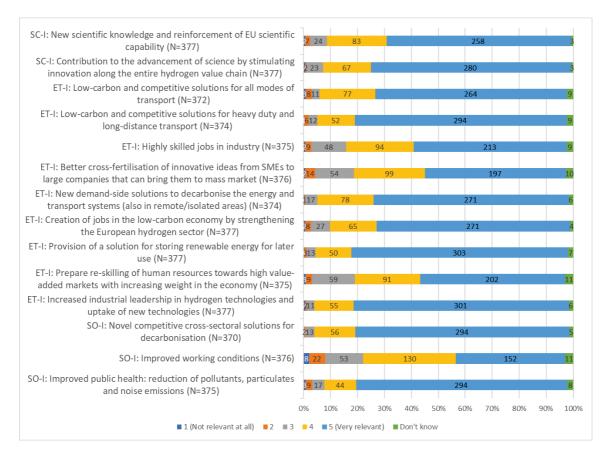
For the respondents who answered negatively on the previous question, The results show that respondents mention key success factors, other initiatives, other partnerships and the energy system and energy transport.

Relevance of the Candidate European Partnership to deliver impacts

Based on Figure 10, among presented societal impacts, only the category "improved working conditions" has a relatively low number of respondents that consider that the Partnership would be 'very relevant' for this impact category. In other categories, around 80% of respondents consider that the Partnership would be 'very relevant' to deliver on those impacts. Similarly, among listed economic/technological impacts, around 80% of respondents suggest that the Partnership would have a significant effect on/be 'very relevant' for increasing industrial leadership in hydrogen technologies and uptake of new technologies, for provision of a solution for storing renewable energy for later use, and for provision of low-carbon and competitive solutions for heavy duty and long-distance transport. In contrast, the least number of respondents, namely 197 out of 376 (52.39%), expect a significant impact of the candidate Partnership on better cross-fertilisation of innovative ideas from SMEs to large companies. Around 70% of respondents indicated that the Partnership will have a significant impact on all listed categories in the area of science.

No statistical differences were found between the views of citizens and other respondents. Respondents that are/were involved in a current/preceding partnership found most economic/technological and scientific impacts more relevant than other respondents.

Figure 10: Views of respondents on the relevance of the candidate European Institutionalised Partnership to various impacts



1.5.4. Summary of campaigns results

Five campaigns were identified among respondents that provided answers for the current candidate Partnership:

- 1. campaign #1 includes 57 respondents
- 2. campaign #2 includes 25 respondents
- 3. campaign #7 includes 18 respondents
- 4. campaign #9 includes 13 respondents
- 5. campaign #11 includes 9 respondents

Only the overview for campaign #1 is presented.

Table 1: Overview of responses of the first campaign (campaign #1) (N=57)

Question category	Summary of responses
Research and innovation problems	The answer category "Innovation gap in the EU in translating the results of hydrogen and fuel cells research into new products" was assessed as 'very relevant' by all respondents. Other categories have mixed and lower scores, on average.
Structural and resource problems	With exception of three respondents, all respondents gave a high score (5 'very relevant') for both answer categories.
Problems in uptake of digital innovations	Across all answer categories, most respondents selected the option 5 'very relevant'.

Preferred Horizon Europe intervention	Institutionalised Partnership was selected by all respondents. When respondents were asked to explain their choice, all of them used the following quote: "IPPP with its specific governance and 7 years budget enables the sector to define and implement a common ambitious R&I strategy. IPPP unique in coordinating innovation effort beyond industry and research with regions, end-users, members states, other industrial sectors, other EU programmes. IPPP superior in leveraging EU funding with private contributions and other funding sources".
Relevance of actors for setting join long-term agenda	A higher number of respondents consider that the involvement of industry and academia is 'very relevant'. Foundation and NGOs received the lowest score (3.21), on average.
Relevance of actors for pooling and leveraging resources	A higher number of respondents consider that the involvement of industry and academia is 'very relevant'. Foundation and NGOs received the lowest score (3.30), on average.
Partnership composition	Both categories received a relatively low score (between 2 and 3), on average.
Implementation of activities	Across all categories, the majority of respondents indicated that listed activities are 'very relevant'.
Relevance of the legal structure	On average, across all categories, respondents indicated that the legal structure would be 'very relevant'. The exceptions include the following categories "ensure better links to practitioners on the ground", "obtain more buy-in and long-term commitment from other partners" and "ensure harmonisation of standards and approaches". In these categories, on average, respondents gave a score of 4 'relevant'.
Scope and coverage of the candidate Partnership	Across all answer categories, most respondents consider that the elements are of right scope and coverage. Respondents were offered an opportunity to provide comments on the proposed scope and coverage of the Institutionalised Partnership. Most of them included the following quote: "Inception impact assessment says little. PPP infosheet for member states included excellent description with three pillars: 1. Near-zero carbon hydrogen production + 2. Technologies distribution and storage + 3. Demand side technologies for (a) power and/or heat in industry, (b) and building and the (c) In the transport sector with focus on heavy duty road freight, rail, and water-borne. Programme to include adapted instruments to support low TRL, flagship projects and EU supply chain".
Rationalisation of the candidate Partnership and linking to other initiatives	Out of 57 respondents, 53 (92.98%) consider that it would not be possible to rationalise the candidate Partnership and its activities, and/or to better link it with other comparable initiatives. Respondents were asked to explain their answer. Regardless of the answer option, all of them inserted a following quote: "We believe that Hydrogen should have its proper partnership and there is no value in merging it with another partnership. It would increase complexity and lose the focus which is key success factor of an IPPP. Nevertheless we value focussed cooperation with a number of partnerships in particular Clean Aviation, Transforming EU Rail, Waterborne, Built Environment, Clean and Low Carbon Steel, Clean and Circular Industry, Batteries and 2Zero".

Societal impact	Almost all respondents consider that the Partnership would be 'very relevant' to deliver on the following results: "improved public health, reduction of pollutants etc." and "novel competitive cross-solutions for decarbonisation". The other suggested impact is considered 'relevant', on average, by respondents.
Economic/technological impact	Across all listed categories, majority of respondents indicated that impacts are 'very relevant'.
Scientific impact	Across all listed categories, majority of respondents indicated that impacts are 'very relevant'.

Annex 3 Who Is Affected And How?

1. PRACTICAL IMPLICATIONS OF THE INITIATIVE

The proposed Clean Hydrogen Partnership focuses on areas where there is a demonstrable advantage in acting at the EU-level due to the scale, speed and scope of the efforts needed for the EU. It will produce quantifiable contributions towards the achievement of climate targets in 2030 and for climate neutrality by 2050. The following stakeholder groups are affected by the proposed initiative, as explained below:

- Academia and the scientific community play a pivotal role in strengthening and integrating scientific capacity to accelerate the development and improvement of advanced clean hydrogen applications ready for market, across energy, transport, building and industrial end-uses;
- The private sector, by having a central role in the proposed Clean Hydrogen Partnership, will benefit from the long-term vision and financial certainty required for its businesses and industries to grow and to strengthen the competitiveness of the EU clean hydrogen value chain (notably SMEs);
- Civil society as a whole is mainly affected by the climate change issue. The proposed Clean Hydrogen Partnership provides the right framework to increase public awareness, acceptance and trust of Hydrogen solutions and services. Having civil society on board is a prerequisite for the clean energy transition to happen, in particular for the development of a highly transformative sector such as Hydrogen;
- Finally, in an increasingly globalized and interlinked world, governments are required to enhance their role in the fight against climate change. New evidence on this issue should be incorporated in every level of policy-making and in every sector. Governments are responsible for the development, implementation and enforcement of environmental clean energy and climate change regulation that addresses current and future problems. The proposed Clean Hydrogen Partnership will be instrumental in providing a relevant scientific and technology evidence base.

For the preferred option

I. Overview of Benefits (total for all provisions) – Preferred Option						
Description	Estimation (quantitative or qualitative)	Comments				
Direct benefits						
More competitive hydrogen industry	Hydrogen applications are more competitive, efficient and reliable.					
Clean Hydrogen scale up	EU validates its ability to scale-up clean economical hydrogen end-use applications in heavy-duty transport and energy-intensive					

	industries – maintaining global competitiveness.	
Economic growth particularly for SMEs	EU growth in hydrogen economy, especially for SMEs.	When the clean hydrogen value chain develops, it will be possible to monitor the number of SMEs operating in the sector.
	Indirect benefits	
Decarbonisation of heavy industry	The EU's maritime, aviation, rail and heavy-duty transport sectors, as well as their gas grid, can progressively decarbonize so the EU can meet its climate targets.	
Reduction in pollution and CO2 emissions	Outdoor pollution can progressively decrease while reducing carbon emissions at the same time.	
Incorporation of larger shares of renewable energy in European electricity grids.	The European electricity grid can accommodate larger shares of renewable energy, thanks to flexibility services provided by power to gas installations.	

⁽¹⁾ Estimates are relative to the baseline for the preferred option as a whole (i.e. the impact of individual actions/obligations of the <u>preferred</u> option are aggregated together); (2) Please indicate which stakeholder group is the main recipient of the benefit in the comment section;(3) For reductions in regulatory costs, please describe details as to how the saving arises (e.g. reductions in compliance costs, administrative costs, regulatory charges, enforcement costs, etc.; see section 6 of the attached guidance).

II. Overview of direct and indirect costs – Preferred option								
		Citizens/Consum ers		Businesses		Administrations		
		One- off	Recurren t	One- off	Recurr	One-off	Recurrent	
Management/ Administrative costs	Direct costs						Other cost €2.1 million ⁸ .	
	Indirect costs							
Personnel costs	Direct costs						€ 2.9 million corresponding to 27 full time equivalent staff ⁹	
	Indirect costs							
Coordination costs (or transaction costs)								

 $^{^{\}rm 8}$ These are the costs of running the FCH JU from the 2018 Annual report.

⁹ These are the costs of running the FCH JU from the 2018 Annual report.

Budget expenditure/investment costs				

⁽¹⁾ Estimates to be provided with respect to the baseline; (2) costs are provided for each identifiable action/obligation of the <u>preferred</u> option otherwise for all retained options when no preferred option is specified; (3) If relevant and available, please present information on costs according to the standard typology of costs (compliance costs, regulatory charges, hassle costs, administrative costs, enforcement costs, indirect costs; see section 6 of the attached guidance).

REFIT Cost savings table

Not applicable for the proposed Clean Hydrogen Partnership. The initiative will benefit from the existing organisation/structure (e.g. the Programme Office) already in place for the FCH 2 JU. There are no additional regulatory costs associated, and no specific simplification measures apply in this case.

Annex 4 Analytical Methods

The methodology for each impact assessment is based on the Commission Better Regulation Guidelines¹⁰ to evaluate and compare options with regards to their **efficiency**, **effectiveness** and **coherence**. This is complemented by integrating the **conditions and selection criteria** for European Partnerships, as well as requirements for setting up Institutionalised Partnerships.¹¹

1. OVERVIEW OF THE METHODOLOGIES EMPLOYED

In terms of **methods and evidence used**, the set of impact assessments for all candidate Institutionalised European Partnerships draw on an external study covering all initiatives in parallel to ensure a high level of coherence and comparability of analysis¹².

All impact assessments mobilised a mix of qualitative and quantitative data collection and analysis methods. These methods range from desk research and interviews to the analysis of the responses to the Open Consultation, stakeholder analysis and composition/portfolio analysis, bibliometric/patent analysis and social network analysis, and a cost-effectiveness analysis.

The first step in the impact assessment studies consisted in the definition of the context and the problems that the candidate partnerships are expected to solve in the medium term or long run. The main data source in this respect was desk research. This includes grey and academic literature to identify the main challenges in the scientific and technologic fields and in the economic sectors relevant for the candidate partnerships, as well as the review of official documentations on the policy context for each initiative.

In the assessment of the problems to address, the lessons to be learned from past and ongoing partnerships were taken into account, especially from relevant midterm or ex-post evaluations.

The description of the context of the candidate institutionalised European Partnerships required a good understanding of the corresponding research and innovation systems and their outputs already measured. Data on past and ongoing Horizon 2020 projects, including the ones implemented through Partnerships, served as basis for descriptive statistic of the numbers of projects and their respective levels of funding, the type of organisations participating (e.g. universities, RTOs, large enterprises, SMEs, public administrations, NGOs, etc.) and how the funding was distributed across them. Special attention was given to analysing the participating countries (and groups of countries, such as EU, Associated Countries, EU13 or EU15) and industrial sectors, where relevant. The sectoral analysis required enriching the eCORDA data received from the European Commission services with sector information extracted from ORBIS, using the NACE codification up to level 2. These data enabled the identification of the main and, where possible, emerging actors in the relevant systems, i.e. the organisations, countries and sectors that would need to be involved (further) in a new initiative.

¹⁰ European Commission (2017), Better Regulation Guidelines (SWD (2017) 350)

¹¹ A pivotal element of the present analysis is the so-called two-step 'necessity test' for European Partnerships, used to establish: step 1) the need for a partnership approach in the first place, followed by step 2) a justification for the form of Institutionalised Partnership. The necessity test is described in Annex 6. This impact assessment focuses on the second step of the test.

¹² Technopolis Group (2020), Impact Assessment Study for Institutionalised European Partnerships under Horizon Europe.

A Social Network Analysis was performed by the contractors using the same data. It consisted in mapping the collaboration between the participants in the projects funded under the ongoing R&I partnerships. This analysis revealed which actors – broken down per type of stakeholders or per industrial sector – collaborate the most often together, and those that are therefore the most central to the relevant research and innovation systems.

The data provided finally served a bibliometric analysis run by the contractor aimed at measuring the outputs (patents and scientific publications) of the currently EU-funded research and innovation projects. A complementary analysis of the Scopus data enabled to determine the position and excellence of the European Union on the international scene, and identify who its main competitors are, and whether the European research and innovation is leading, following or lagging behind.

A cost modelling exercise was performed in order to feed into the efficiency assessments of the partnership options.

The conclusions drawn from the data analysis were confronted to the views of experts and stakeholders collected via three means:

- The comments to the inception impact assessments of the individual candidate institutionalised European Partnerships;
- The open public consultation organised by the European Commission from September to November 2019;
- The interviews (up to 50) conducted by each impact assessment study team conducted between August 2019 and January 2020 (policymakers, business including SMEs and business associations, research institutes and universities, and civil organisations, among others).

The views of stakeholders (and experts) were particularly important for determining the basic functionalities (see further below) that the future partnerships need to demonstrate to achieve their objectives as well as their most anticipated scientific, economic and technological, and societal impacts. The interviews allowed more flexibility to ask the respondents to reflect about the different types of European Partnerships. Furthermore, as a method for targeted consultation, it was used to get insights from the actors that both the Study Teams and the European Commission were deemed the most relevant. For the comparative assessment of impacts, the external contractors confronted the outcomes of the different stakeholder consultation exercises to each other with a view of increasing the validity of their conclusions, in line with the principles of triangulation.

Annex 2 includes also the main outcomes of the stakeholder consultation exercises.

2. METHOD FOR ASSESSING THE EFFECTIVENESS, EFFICIENCY AND COHERENCE OF EACH OPTION - THE USE OF FUNCTIONALITIES

Given the focus of the impact assessment on comparing different forms of implementation, the Better Regulation framework has been adapted to introduce "**key functionalities needed**" – so as to link the intended objectives of the candidate European Partnerships and what would be crucial to achieve them *in terms of implementation*. The identification of "key functionalities needed" for each initiative as an additional step in the impact assessment is based on the distinguishing factors between the different options (see Section 2.2.1 in the main body of the impact assessment). In practical terms, each option is assessed on the basis

of the degree to which it would allow for the key needed functionalities to be covered, as regards e.g. the type and composition of actors that can be involved ('openness'), the range of activities that can be performed (including additionality and level of integration), the level of directionality and integration of R&I strategies; the possibilities offered for coherence and synergies with other components of Horizon Europe, including other Partnerships (internal coherence), and the coherence with the wider policy environments, including with the relevant regulatory and standardisation framework (external coherence). This approach guides the identification of discarded options. It also allows for a structured comparison of the options as regards their effectiveness, efficiency and coherence, and also against a set of other key selection criteria for European Partnerships (openness, transparency, directionality)¹³.

Figure 3 Overview of key functionalities of each form of implementation of European Partnerships

Baseline: Horizon Europe calls	Option 1: Co- programmed	Option 2: Co- funded	Option 3.1: Institutionalised Article 185	Option 3.2: Institutionalised Article 187				
Type and composition of actors (including openness and roles)								
Partners: N.A., no common set of actors that engage in planning and implementation Priority setting: open to all, part of Horizon Europe Strategic planning Participation in R&I activities: fully open in line with standard Horizon Europe	Partners: Suitable for all types: private and/or public partners, foundations Priority setting: Driven by partners, open stakeholder consultation, MS in comitology Participation in R&I activities: fully open in line with standard Horizon Europe rules	Partners: core of national funding bodies or governmental research organisations Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: limited, according to national rules of partner countries	Partners: National funding bodies or governmental research organisation Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: fully open in line with standard Horizon Europe rules, but possible derogations	Partners: Suitable for all types: private and/or public partners, foundations Priority setting: Driven by partners, open stakeholder consultation Participation in R&I activities: fully open in line with standard Horizon Europe rules, but possible				
rules		partifer countries	derogations	derogations				
Type and range of a	ctivities (including add	itionality and level of	integration)					
Activities: Horizon Europe standards that allow broad range of individual actions Additionality: no additional activities and investments outside the funded projects Limitations: No systemic approach beyond individual actions Directionality	Activities: Horizon Europe standard actions that allow broad range of individual actions, support to market, regulatory or policy/ societal uptake Additionality: Activities/investment s of partners, National funding Limitations: Limited systemic approach beyond individual actions.	Activities: Broad, according to rules/programmes of participating States, State-aid rules, support to regulatory or policy/ societal uptake Additionality: National funding Limitations: Scale and scope depend on the participating programmes, often smaller in scale	Activities: Horizon Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to systemic approach Additionality: National funding	Activities: Horizon Europe standards that allow broad range of individual actions, support to regulatory or policy/societal uptake, possibility to systemic approach (portfolios of projects, scaling up of results, synergies with other funds. Additionality: Activities/investments of partners/ national funding				

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¹³ The criterion on the ex-ante demonstration of partners' long term commitment depends on a series of factors that are unknown at this stage, and thus fall outside the scope of the analysis.

Baseline: Horizon Europe calls	Option 1: Co- programmed	Option 2: Co- funded	Option 3.1: Institutionalised Article 185	Option 3.2: Institutionalised Article 187
Priority setting: Strategic Plan and annual work programmes, covering max. 4 years. Limitations: Fully taking into account existing or to be	Priority setting: Strategic R&I agenda/ roadmap agreed between partners and COM, covering usually 7 years, including allocation of Union contribution	Priority setting: Strategic R&I agenda/ roadmap agreed between partners and COM, covering usually 7 years, including allocation of Union contribution	Priority setting: Strategic R&I agenda/ roadmap agreed between partners and COM, covering usually 7 years, including allocation of Union contribution	Priority setting: Strategic R&I agenda/ roadmap agreed between partners and COM, covering usually 7 years, including allocation of Union contribution
developed SRIA/ roadmap Input to FP annual work programme drafted by partners finalised by COM (comitology) Objectives and	drafted by partners, finalised by COM (comitology)	Annual work programme drafted by partners, approved by COM Objectives and commitments are set in the Grant	Annual work programme drafted by partners, approved by COM Objectives and commitments are set	Annual work programme drafted by partners, approved by COM (veto-right in governance)
	in the contractual arrangement.	Agreement.	in the legal base.	Objectives and commitments are set in the legal base.
Coherence: internal industrial strategies	(Horizon Europe) and	external (other Union	programmes, national	programmes,
Internal: Between different parts of the Annual Work programme can be ensured by COM External: Limited for other Union programmes, no synergies with national/regional programmes and activities	Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Limited synergies with other Union programmes and industrial strategies If MS participate, with national/	Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Synergies with national/ regional programmes and activities	Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Synergies with national/ regional programmes and activities	Internal: Coherence among partnerships and with different parts of the Annual Work programme of the FP can be ensured by partners and COM External: Synergies with other Union programmes and industrial strategies If MS participate, with national/
	regional programmes and activities			regional programmes and activities

In line with the Better Regulation Framework, the assessment of the effectiveness, efficiency and coherence of each option is made in comparison to the baseline. Therefore, for each of the above criteria, the performance of using traditional calls under Horizon Europe is first estimated and scored 0 to serve as a reference point. When relevant, this estimation also includes the costs/benefits of discontinuing existing implementation structures. The policy options are then scored compared to the baseline with a + and – system along a two-point scale, to indicate limited (+ or -) or high (++ or --) additional/lower performance compared to the baseline. When a policy option is scored 0, this means that its impact is expected to be roughly equal to the baseline option.

On the basis of the evidence collected, the intervention logic of each initiative and the key functionalities needed, the impact assessments first evaluate the **effectiveness** of the various policy options to deliver on their objectives. To be in line with the Horizon Europe impact

framework, the fulfilment of the specific objectives of the initiative is translated into 'expected impacts' - how success would look like -, differentiating between scientific, economic/ technological, and societal (including environmental) impacts. Each impact assessment considers to which extent the different policy options provides the 'key functionalities needed' to achieve the intended objectives. The effectiveness assessment does not use a compound score but shows how the options would deliver on the different types of expected impacts. This is done to increase transparency and accuracy in the assessment of options¹⁴.

A similar approach is followed to evaluate the coherence of options with the overarching objectives of the EU's R&I policy, and distinguishes between **internal** and **external coherence**. Specifically, internal coherence covers the consistency of the activities that could be implemented with the rest of Horizon Europe, including European Partnerships (any type). External coherence refers to the potential for synergies and/or complementarities (including risks of overlaps/gaps) of the initiative with its external environment, including with other programmes under the MFF 2021-27, but also the framework conditions at European, national or regional level (incl. regulatory aspects, standardisation).

To compare the expected costs and benefits of each option (efficiency), the thematic impact assessments broadly follow a cost-effectiveness approach 15 to establish to which extent the intended objectives can be achieved for a given cost. A preliminary step in this process is to obtain a measure of the expected costs of the policy options, to be used in the thematic assessments. As the options correspond to different implementation modes, relevant cost categories generally include the costs of setting-up and running an initiative. For instance, setup costs includes items such as the preparation of a European Partnership proposal and the preparation of an implementation structure. The running costs include the annual work programme preparation costs. Where a Partnership already exists, discontinuation costs are also taken into account 16. The table below provides an overview of the cost categories used in the impact assessment and a qualitative scoring of their intensity when compared to the baseline option (traditional calls). Providing a monetised value for these average static costs would have been misleading, because of the different features and needs of each candidate initiative. 17 Where possible however, Annex 3 to the thematic impact assessments provides additional quantification and details. The cost categories are then used to develop a scorecard analysis and further refine the assessment of options for each of the 12 candidate Institutionalised Partnerships. Specifically, the scores related to the set-up and implementation costs are used in the thematic impact assessments to consider the scale of the expected benefits and thereby allow a simple "value for money" analysis (cost-effectiveness)¹⁸. In carrying out the scoring of options, the results of fieldwork, desk research and stakeholder consultation undertaken and taken into account.

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¹⁴ In the thematic impact assessments, scores are justified in a detailed manner to avoid arbitrariness and spurious accuracy. A qualitative or even quantitative explanation is provided of why certain scores were given to specific impacts, and why one option scores better or worse than others.

¹⁵ For further details, see Better Regulation Toolbox # 57.

¹⁶ While monetised cost figures are available for existing European Partnerships, they widely differ between each case, thus limiting meaningful comparability. Moreover, they are not readily applicable for new candidate initiatives. Instead, the analysis uses a static, common model of average real costs as a means to show the order of magnitude of efforts and reveal the principal differences between the options.

¹⁷ A complete presentation of the methodology developed to assess costs as well as the sources used is described in the external study supporting this impact assessment (Technopolis Group, 2020).

¹⁸ More details on the methodology can be found in Annex 4.

Figure 4 - Intensity of additional costs compared with Horizon Europe Calls (for Partners, stakeholders, public and EU)

Cost items	Baseline: traditional calls	Option 1: Coprogrammed	Option 2 Co-funded	Option 3a - Art. 185	Option 3b - Art. 187					
Preparation and set-up costs	Preparation and set-up costs									
Preparation of a partnership proposal (partners and EC)	0		↑ ↑							
Set-up of a dedicated implementation structure		0		Existing: ↑ New: ↑↑	Existing: ↑↑ New: ↑↑↑					
Preparation of the SRIA / roadmap	0		↑ ↑							
Ex-ante Impact Assessment for partnership		0		1	$\uparrow \uparrow$					
Preparation of EC proposal and negotiation		0		1	$\uparrow \uparrow$					
Running costs (Annual cycle of implement	ation)									
Annual Work Programme (AWP) preparation	0		1							
Call and project implementation	0	0 In case of MS contributions: ↑	↑	↑	\uparrow					
Cost to applicants	Comparable, oversubscript	unless there are	strong argume	ents of major	differences in					
Partners costs not covered by the above	0	\uparrow	0	↑	↑					
Additional EC costs (e.g. supervision)	0	1	1	↑	$\uparrow \uparrow$					
Winding down costs	Winding down costs									
EC		0			$\uparrow \uparrow \uparrow$					
Partners	0	\uparrow	0	↑	1					

Notes: 0: no additional costs, as compared with the baseline; \uparrow : minor additional costs, as compared with the baseline; $\uparrow \uparrow$: medium additional costs, as compared with the baseline; $\uparrow \uparrow \uparrow$: higher costs, as compared with the baseline.

3. METHOD FOR IDENTIFYING THE PREFERRED OPTION – THE SCORECARD ANALYSIS

For the **identification of the preferred option**, a scorecard analysis is used to build a hierarchy of the options by individual criterion and overall in order to identify a single preferred policy option or in case of an inconclusive comparison of options, a number of 'retained' options or hybrid. This exercise supports the systematic appraisal of alternative options across multiple types of monetary, non-monetary and qualitative dimensions. It also allows for easy visualisation of the pros and cons of each option. Each option is attributed a score of the adjudged performance against each criterion with the three broad appraisal dimensions of effectiveness, efficiency and coherence.

This scorecard approach also relies on a standard cost model developed for the external study supporting the impact assessment, as illustrated in **Error! Reference source not found.** These costs essentially refer to the administrative, operational and coordination costs of the various options. The figure shows how the scoring of costs range from a value of 0, in case an option does not entail any additional costs compared to the baseline (traditional calls), to a score of (-) for options introducing limited additional costs relative to the baseline and a score of (--) when substantial additional costs are expected in comparison with the baseline. Should the costs of a policy option be lower than those of the baseline, (+) and (+ +) are used.

Figure 5: Matrix on 'overall costs' and 'adjusted cost scoring'

	Baseline: Horizon Europe calls	_	Option 2: Cofunded	Option 3: Institutionalised
Administrative, operational and coordination costs	0	(-)	()	()
Administrative, operational and coordination costs adjusted per expected co-funding (i.e. cost-efficiency)	0	0	(-)	(-)

Notes: Score 0 = same costs as for the baseline; score (-) = limited additional costs compared to baseline; score (- -) = substantial additional costs compared to baseline.

The **baseline** (**regular calls**) has the lowest administrative, operational and coordination costs. This is based on two facts: firstly, that Horizon Europe traditional calls will not entail any additional one-off costs to be set up or discontinued at the end, where each of the other policy options will require at least some additional set-up and phasing out costs; and secondly, that Horizon Europe will not require any additional running costs, where each of the other policy options will involve additional efforts by the Commission and partners in the carrying out of necessary additional tasks (e.g. preparing annual work programmes).

A **co-programmed partnership** (Option 1 - CPP) will entail slightly higher overall costs as compared with the baseline. There will be some additional set-up costs linked for example with the creation of a strategic research and innovation agenda (SRIA) and additional running costs linked with the partners role in the creation of the annual work programmes and the Commission's additional supervisory responsibilities. A CPP will have lower overall costs than each of the other types of European Partnership, as it will function with a smaller governance and implementation structure than will be required for a Co-Funded Partnership or an Institutionalised Partnership and – related to this – its calls will be operated through the existing HEU agencies and RDI infrastructure and systems.

The **Co-Funded Partnership** (Option 2 – CFP) has been **scored** (- -) on overall cost. This reflects the additional set-up costs of this policy option and the substantial additional running costs for partners, and the Commission, of the distributed, multi-agency implementation model.

The **Institutionalised Partnership** (Option 3 - IP) has been **scored** (--) on overall cost. This reflects the substantial additional set-up costs of this policy option – and in particular the high costs associated with preparing the Commission proposal and negotiating that through to a legal document – and the substantial additional running costs for the Commission associated with the supervision of this dedicated implementation model.

It is considered that while there is a clear gradation in the overall costs of the policy options, the cost differentials are less marked when one takes into account the expected co-financing rates and the total budget available for each of the policy options, assuming a common Union contribution. From this perspective, there are only one or two percentage points that split the most cost-efficient policy options – the baseline (traditional calls) and the Co-Programmed policy options – and the least cost-efficient – the Institutionalised Partnership option. A score of 0 is therefore assigned for **cost-efficiency** to the Co-Programmed option and a score of (-) for the Co-Funded and the Institutionalised Partnership policy options ¹⁹.

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¹⁹ The baseline (traditional calls) is scored 0, as explained above.

Annex 5 Subsidiarity Grid

1. Can the Union act? What is the legal basis and competence of the Unions' intended action?

1.1 Which article(s) of the Treaty are used to support the legislative proposal or policy initiative?

This proposal is based on (1) Article 185 TFEU which stipulates that in implementing the multiannual framework programme, the Union may make provision, in agreement with the Member States concerned, for participation in research and development programmes undertaken by several Member States, including participation in the structures created for the execution of those programmes; and (2) Article 187 TFEU according to which the Union may set up joint undertakings or any other structure necessary for the efficient execution of Union research, technological development and demonstration programmes (both Articles are under Title XIX of the TFEU - Research and Technological Development and Space).

The proposal aims to implement Article 8 of the Commission proposal for Horizon Europe the future EU research and innovation (R&I) programme for 2021-2027, according to which, "European Partnerships shall be established for addressing European or global challenges only in cases where they will more effectively achieve objectives of Horizon Europe than the Union alone and when compared to other forms of support of the Framework programme". The Horizon Europe proposal has received the political agreement of the Council and the European Parliament.

1.2 Is the Union competence represented by this Treaty article exclusive, shared or supporting in nature?

Research is a shared competence between the EU and its Member States according to the TFEU. Article 4 (3) specifies that in the areas of research, technological development and space, the European Union can carry out specific activities, including defining and implementing programmes, without prejudice to the Member States' freedom to act in the same areas.

Subsidiarity does not apply for policy areas where the Union has **exclusive** competence as defined in Article 3 TFEU²⁰. It is the specific legal basis which determines whether the proposal falls under the subsidiarity control mechanism. Article 4 TFEU²¹ sets out the areas where competence is shared between the Union and the Member States. Article 6 TFEU²² sets out the areas for which the Unions has competence only to support the actions of the Member States.

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²⁰ https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12008E003&from=EN

https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12008E004&from=EN https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12008E006:EN:HTML

2. Subsidiarity Principle: Why should the EU act?

2.1 Does the proposal fulfil the procedural requirements of Protocol No. 2^{23} :

- Has there been a wide consultation before proposing the act?
- Is there a detailed statement with qualitative and, where possible, quantitative indicators allowing an appraisal of whether the action can best be achieved at Union level?

This proposal and the accompanying impact assessment were supported by a wide consultation of stakeholders, both during the preparation of the Horizon Europe proposal and - later on, all the candidates for European Partnerships. Member States were consulted via the Shadow Strategic configuration of the Horizon Europe Programme Committee. On candidates for institutionalised Partnerships based on Article 185/187 of the TFEU, an Open Public Consultation (OPC) was held between 11 September and 6 November 2019. Over 1 600 replies were received. In addition, targeted consultation activities were undertaken to prepare the present impact assessment. In particular, for each of the candidate partnerships, an external consultant interviewed a representative sample of stakeholders. The need for EU action as well as its added value were covered in those interviews.

The explanatory memorandum and the impact assessment (horizontal part, Section 3) contain a dedicated section on the principle of subsidiarity, as explained in question 2.2 below.

2.2 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the conformity with the principle of subsidiarity?

The impact assessment accompanying the proposal features a horizontal part on relevant common elements to all the candidate partnerships, including the conformity of the proposed initiative with the principle of subsidiarity (Section 3). Moreover, the individual assessments of each candidate partnership include additional details on subsidiarity, touching in particular on the specificities of a candidate partnership that could not be adequately reflected in the horizontal part of the impact assessment. This will also be reflected in the explanatory memorandum.

2.3 Based on the answers to the questions below, can the objectives of the proposed action be achieved sufficiently by the Member States acting alone (necessity for EU action)?

National action alone cannot achieve the scale, speed and scope of support to R&I needed for the EU to meet its long-term Treaty objectives, to deliver on the EU's strategic policy priorities (including the climate and energy goals set out in the Paris Agreement, and the European Green Deal), and to contribute to tackling global challenges and meeting the

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 $^{^{23}\} https://eur-lex.europa.eu/legal-content/\underline{EN/TXT/HTML/?uri=CELEX:12016E/PRO/02\&from=EN/2016E/PRO/02\&from=EN/2016E/PRO/02&from=EN/2016E/FRO/02&from=EN/2016E/FRO/02&from=EN/2016E/FRO/02&from=EN/2016E/FRO/02&from=EN/2016E/FRO/02&from=EN/2016E/FRO/02&from=EN/2016E/FRO/02&from=EN/2016E/FRO/02&from=EN/2016E/FRO/02&from=EN/2016E/FRO/02&from=EN/2016E/FRO/02&from=EN/2016E/FRO/02&from=EN/2016E/FRO/02&From=EN/2016E/FRO/02&FRO/0$

Sustainable Development Goals (SDGs).

(a) Are there significant/appreciable transnational/cross-border aspects to the problems being tackled? Have these been quantified?

The thematic areas covered by the candidate partnerships feature a series of challenges in terms of cross-border/transnational aspects, need to pool resources, need for a critical mass to meet intended policy objectives, need to coordinate different types of actors (e.g. academia, industry, national and regional authorities) across different sectors of the economy and society, which cannot be tackled to the same degree by Member States alone. This is particularly true for the research and innovation (R&I) dimension of the proposed initiative: the importance of a multi-centre and interdisciplinary approach, cross-country data collection and research, and the need to develop and share new knowledge in a timely and coordinated manner to avoid duplication of efforts are key to achieve high quality results and impact. The Interim Evaluation of Horizon 2020 and the impact assessment of Horizon Europe provide extensive qualitative and quantitative evidence on the above points. In addition, Sections 1 and 2 of the individual impact assessments on the candidate partnerships include more detail on the necessity to act at EU-level in specific thematic areas. Finally, it is worth noting that not all Member States have the same capacity or R&I intensity to act on these challenges. As the desired policy objectives can be fully achieved only if the intended benefits are widespread across the Member States, this requires action at the EU-level.

(b) Would national action or the absence of the EU level action conflict with core objectives of the Treaty²⁴ or significantly damage the interests of other Member States?

As per Article 4(3) TFEU, national action does not conflict with core objectives of the Treaty in the area of R&I. The absence of EU level action in this area would however prevent the achievement of core objectives of the Treaty. Indeed, national action alone cannot achieve the scale, speed and scope of support to R&I needed for the EU to meet its long-term Treaty objectives on e.g. competitiveness, to deliver on the EU's strategic policy priorities, and to contribute to tackling global challenges and meet the Sustainable Development Goals (SDGs).

(c) To what extent do Member States have the ability or possibility to enact appropriate measures?

As foreseen by Article 4(3) TFEU, this proposal does not hamper Member States' ability to enact appropriate measures in the field of R&I. However, the scale and complexity of the policy objectives pursued by the present initiative cannot be fully addressed by acting at national level alone.

(d) How does the problem and its causes (e.g. negative externalities, spill-over effects)

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²⁴ https://europa.eu/european-union/about-eu/eu-in-brief en

vary across the national, regional and local levels of the EU?

As described in the horizontal part of the impact assessment accompanying the present proposal, several problems (e.g. on competitiveness, global challenges, demographic change) and their underlying causes affect the EU as a whole rather than individual Member States. Where important differences between Member States are present, these are described in Sections 1 and 2 of the individual impact assessments.

(e) Is the problem widespread across the EU or limited to a few Member States?

The problem of coordinating R&I efforts in the thematic areas covered by the candidate partnerships affects all Member States, albeit to different degrees. However, from a general EU perspective, available evidence shows that the EU as a whole needs to step up efforts and investments in thematic areas that are crucial to tackle present and future policy challenges on several fronts, e.g. ageing population, global technological trends, and climate change to name a few. The way these problems affect the EU and its Member States is described in the horizontal part of the impact assessment and in Sections 1 and 2 of the individual impact assessments.

(f) Are Member States overstretched in achieving the objectives of the planned measure?

As indicated in the horizontal part of the impact assessment and in Sections 1 and 2 of the individual assessments, the sheer scale, speed and scope of the needed support to R&I would overstretch national resources, without guaranteeing the achievement of the intended objectives. Acting at EU-level would achieve greater impact in a more effective and efficient manner.

(g) How do the views/preferred courses of action of national, regional and local authorities differ across the EU?

No specific differences between the views of national, regional and local authorities emerged from the stakeholder consultation.

2.4 Based on the answer to the questions below, can the objectives of the proposed action be better achieved at Union level by reason of scale or effects of that action (EU added value)?

EU funded R&I activities, including those covered by the present proposal, produce demonstrable benefits compared to the corresponding national and regional initiatives, due to the scale, speed and scope achievable by acting at the EU level. In addition, the proposed initiatives should be seen as complementary and reinforcing national and sub-national initiatives in the same area.

(a) Are there clear benefits from EU level action?

Quantitative and qualitative evidence of the benefits of EU level action are available in the interim evaluation of Horizon 2020 and in the impact assessment of Horizon Europe, among others. An analysis of the emerging challenges in each thematic areas, of the EU's competitive positioning, as well as feedback gathered from different types of stakeholders for the present impact assessment indicate that EU level action remains appropriate also for the present proposal. In addition, the benefits of acting at EU-level have been illustrated by the success and the impact achieved by the predecessors to the proposed initiative.

(b) Are there economies of scale? Can the objectives be met more efficiently at EU level (larger benefits per unit cost)? Will the functioning of the internal market be improved?

EU funded R&I activities, including those covered by the present proposal, produce demonstrable benefits compared to the corresponding national and regional initiatives, due to the scale, speed and scope achievable by acting at the EU level. This is the case both in terms of effectiveness in achieving intended policy objectives, but also in terms of efficiency. Positive impact is also visible in terms of competitiveness: recent data on EU funded R&I activities indicate that EU-funded teams grow 11.8% faster and are around 40% more likely to be granted patents or produce patents applications than non-EU funded teams. Efficiency gains are also visible in terms of dissemination of results to users beyond national borders, including SMEs and citizens. EU funded R&I is more effective in leveraging private investment. Finally, there are clear additionality benefits (i.e. EU R&I funding does not displace or replace national funding), as the EU focuses on projects that are unlikely to be funded at national or regional level. Overall, this is beneficial to the functioning of the internal market in several respects, including human capital reinforcement through mobility and training, the removal of barriers to cross-border activity for economic players including SMEs, easier access to finance and to relevant knowledge and research, and increased competition in the area of R&I.

(c) What are the benefits in replacing different national policies and rules with a more homogenous policy approach?

A homogeneous policy approach in the various thematic areas covered by the present proposal would reduce fragmentation and increase efficiency and effectiveness in meeting the intended policy objectives. Indeed fragmentation, persisting barriers in the internal market and differences in the resources available to Member States are some of the key problems that stand in the way of fully achieving the intended policy objectives and reaching the required critical mass to obtain tangible results. Specific detail on how these issues differ in each thematic area are illustrated in Sections 1 and 2 of the individual impact assessments, so as to reflect the specificities of each case.

(d) Do the benefits of EU-level action outweigh the loss of competence of the Member States and the local and regional authorities (beyond the costs and benefits of acting at

national, regional and local levels)?

The proposed initiative does not lead to a loss of competence of the Member States. In fact, the proposed initiative should be seen as complementary and reinforcing national and subnational initiatives in the same area. Previous quantitative and qualitative assessments of Horizon Europe and Horizon 2020 have shown that the proposed EU-level action do not displace national ones and tend to concentrate on initiatives that would not have been funded by the Member States themselves, or would not have reached the same scale and ambition without EU-level intervention, due to their complexity and trans-national nature.

(e) Will there be improved legal clarity for those having to implement the legislation?

Yes. The proposed initiatives will be implemented in line with the Horizon Europe single set of rules for participation; this will ensure increased clarity and legal certainty for end beneficiaries, other stakeholders and programme administrators. It will also reduce the administrative burden for beneficiaries, and for the Commission services. In addition, the accessibility and attractiveness of the broader Horizon Europe programme, in particular for applicants with limited resources, would be sustained.

3. Proportionality: How the EU should act

3.1 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the proportionality of the proposal and a statement allowing appraisal of the compliance of the proposal with the principle of proportionality?

The principle of proportionality underpins the entire analysis of the candidate partnerships. Specifically, the analysis included in the accompanying impact assessment is structured along the following logic: 1. Justification of the use of a partnership approach in a given area (including considerations on additionality, directionality, link with strategic priorities) instead of other forms of intervention available under Horizon Europe; 2. If the partnership approach is deemed appropriate, proportionality considerations guide the assessment of which type of partnership intervention (collaborative calls, co-programmed, co-funded or institutionalised partnership) is most effective in achieving the objectives. This will also be reflected in the explanatory memorandum.

3.2 Based on the answers to the questions below and information available from any impact assessment, the explanatory memorandum or other sources, is the proposed action an appropriate way to achieve the intended objectives?

The proposed initiative only focuses on areas where there is a demonstrable advantage in acting at the EU-level due to the scale, speed and scope of the efforts needed for the EU to meet its long-term Treaty objectives and deliver on its strategic policy priorities and commitments. In addition, the present proposal leaves full freedom to the Member States to

pursue their own actions in the policy areas concerned. This will also be reflected in the explanatory memorandum.

(a) Is the initiative limited to those aspects that Member States cannot achieve satisfactorily on their own, and where the Union can do better?

The proposed initiative only focuses on areas where there is a demonstrable advantage in acting at the EU-level due to the scale, speed and scope of the efforts needed for the EU to meet its long-term Treaty objectives and deliver on its strategic policy priorities and commitments.

(b) Is the form of Union action (choice of instrument) justified, as simple as possible, and coherent with the satisfactory achievement of, and ensuring compliance with the objectives pursued (e.g. choice between regulation, (framework) directive, recommendation, or alternative regulatory methods such as co-legislation, etc.)?

For each of the candidate partnerships, the analysis carried out in the accompanying impact assessment has explored several options for implementation. A comparative assessment of the merits of each option also included an analysis of the simplicity of the intervention, its proportionality and effectiveness in achieving the intended objectives. This is reflected in the fact that a tailored approach has been suggested for each candidate partnership, ranging from looser forms of cooperation to more institutionalised ones, depending on the intended policy objectives, specific challenges, and desired outcome identified in each case.

(c) Does the Union action leave as much scope for national decision as possible while achieving satisfactorily the objectives set? (e.g. is it possible to limit the European action to minimum standards or use a less stringent policy instrument or approach?)

The proposed approach leaves full freedom to the Member States to pursue their own actions in the policy areas covered by the present proposal.

(d) Does the initiative create financial or administrative cost for the Union, national governments, regional or local authorities, economic operators or citizens? Are these costs commensurate with the objective to be achieved?

The proposed initiatives do create financial and administrative costs for the Union, national governments and, depending on the chosen mode of implementation, for regional and local authorities. In addition, economic operators and other stakeholders potentially involved in the candidate partnerships will also incur some costs linked to implementation. The financial cost of the proposed initiative is covered under the Horizon Europe programme. Its exact amount is still subject to political decision. As regards the candidate partnerships and the different modes of implementation (co-programmed, co-funded, institutionalised), the relevant costs and benefits are assessed in the individual impact assessments covering each candidate partnership. The additional administrative costs of implementation via partnerships are

limited, when compared to the administrative costs of implementation through traditional calls. As indicated by comparable experience with previous initiatives and in feedback provided by a variety of stakeholders, these costs are expected to be fully justified by the benefits expected from the proposed initiative. Where available, additional details on costs are provided in Annex 3 of the impact assessment.

(e) While respecting the Union law, have special circumstances applying in individual Member States been taken into account?

Where relevant, differences between Member States in capacity and stage of advancement of R&I in specific thematic areas have been taken into account in the individual impact assessments.

Annex 6 Additional background information

1. BACKGROUND INFORMATION FOR ALL INITIATIVES

1.1. Selection criteria of European Partnerships

Partnerships based on Article 185 and 187 TFEU shall be implemented only where other parts of the Horizon Europe programme, including other forms of European Partnerships would not achieve the objectives or would not generate the necessary expected impacts, and if justified by a long-term perspective and high degree of integration. At the core of this impact assessment is therefore the need to demonstrate that the impacts generated through a Partnership approach go beyond what could be achieved with traditional calls under the Framework Programme – the Baseline Option. Secondly, it needs to assess if using the Institutionalised form of a Partnership is justified for addressing the priority.

The necessity test for a European Partnership (as set out in the Horizon Europe regulation) has two levels:

- 1. The justification for implementing a priority with a European Partnership to address Horizon Europe and EU priorities. This is linked to demonstrating that a European Partnership can produce added value beyond what can be achieved through other Framework Programme modalities, notably traditional calls in the work programmes (Option 0 Baseline).
- 2. The justification for the use of the form of Institutionalised Partnership: Once it has been demonstrated that a partnerships approach is justified, co-programmed and/or co-funded forms are considered for addressing the priorities as they are administratively lighter, more agile and easier to set-up (Options 1 and/or 2). As Institutionalised Partnerships require setting up a legal framework and the creation of a dedicated implementation structure, they have to justify higher set-up efforts by demonstrating that it will deliver the expected impacts in a more effective and efficient way, and that a long-term perspective and high degree of integration is required (Option 3).

The outcomes of the 'necessity test' is presented together with the preferred option.

Figure 5 Horizon Europe selection criteria for the European Partnerships

Common selection criteria & principles	Specifications
1. More effective (Union added value) clear impacts for the EU and its citizens	Delivering on global challenges and research and innovation objectives
	Securing EU competitiveness
	Securing sustainability
	Contributing to the strengthening of the European Research and Innovation Area
	Where relevant, contributing to international commitments

Common selection criteria & principles	Specifications					
2. Coherence and	Within the EU research and innovation landscape					
synergies	Coordination and complementarity with Union, local, regional, national and, where relevant, international initiatives or other partnerships and missions					
3. Transparency and openness	Identification of priorities and objectives in terms of expected results and impacts					
	Involvement of partners and stakeholders from across the entire value chain, from different sectors, backgrounds and disciplines, including international ones when relevant and not interfering with European competitiveness					
	Clear modalities for promoting participation of smes and for disseminating and exploiting results, notably by smes, including through intermediary organisations					
4. Additionality	Common strategic vision of the purpose of the European Partnership					
and directionality	Approaches to ensure flexibility of implementation and to adjust to changing policy, societal and/or market needs, or scientific advances, to increase policy coherence between regional, national and EU level					
	Demonstration of expected qualitative and significant quantitative leverage effects, including a method for the measurement of key performance indicators					
	Exit-strategy and measures for phasing-out from the Programme					
5. Long-term commitment of all the	A minimum share of public and/or private investments					
involved parties	In the case of institutionalised European Partnerships, established in accordance with article 185 or 187 TFEU, the financial and/or in-kind, contributions from partners other than the Union, will at least be equal to 50% and may reach up to 75% of the aggregated European Partnership budgetary commitments					
1.0						

1.2. Overview of potential functions for a common back office among Joint Undertakings

Functions	Current situation	Option of joint back- office	Comments
Organising calls for grant and proposal evaluations	Each JU organises this independently.	A central organisation of evaluation, logistics, contracting evaluators, managing the data of the evaluation results Central database of potential evaluators with domain expertise in thematic areas of partnerships	The evaluations would still need to be supervised by the Scientific staff of the individual Joint Undertakings (consensus meetings of expert evaluators etc)
Human Resources related matters	Each JU has own HR policy and resources Quite some resources spent on recruitment in some JUs	More generic resources and expertise for HR matters More consistency in HR	Ensuring consistency with EC HR policies is already in place

Financial management	Some HR facilities are procured from external contractors Some JUs have a Service Level Agreement with COM for HR Each JU conducts own financial contract management; differences between JUs Each JU is audited separately. Auditing at project level more frequent than in other Horizon 2020 parts and outsourced by JUs thus differences ECA: too many audits on JUs	policy Shared HR investment for specialised expertise (IP and legal) Financial management by one core team of financial staff Would reduce the number of interfaces for audits and simplifies the auditing of the all JUs Harmonisation of project auditing	Simplifies the harmonisation of financial management across JUs in line with Horizon Europe
Communication (internal and external)	Each JU has a separate communication strategies, teams and resources	A common back-office can support activities such as event organisation, dissemination of results, setting up website communication Can help create a more visible Partnership brand	A considerable share of communication activity is partnership specific (addressing particular target groups, synthesising project results) however there are generic communication activities that can be shared Needs to avoid duplication of efforts
Data management on calls, project portfolios, information on project results	Most JUs but not all use e- Corda for project data Overall IT integration of JUs still difficult	Harmonised data management Reduction of IT systems and support that is procured	This will need to happen regardless of the common back office but will likely be more smooth if managed centrally

2. BACKGROUND INFORMATION FOR THIS SPECIFIC INITIATIVE

2.1. General information on the hydrogen sector

2.1.1. Hydrogen Roadmap.

The scope of hydrogen applications is expanding from its present focus on transport, fuel cells and electrolysers, and to include the energy sector (power, heating and gas), industry and new transport applications (maritime, aviation, rail, heavy transport).

The objectives of the proposed Clean Hydrogen Partnership are to address hydrogen production (1), hydrogen distribution (2) and storage (3) in order to supply hydrogen (at scale) to the different sectors (4 to 7) and help them to decarbonise.

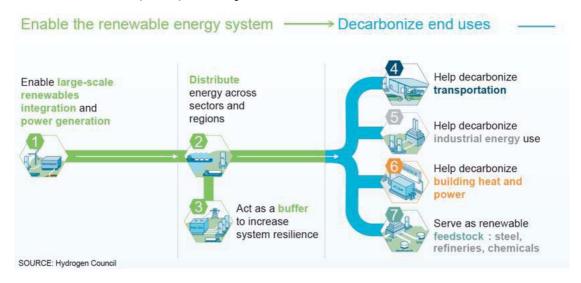
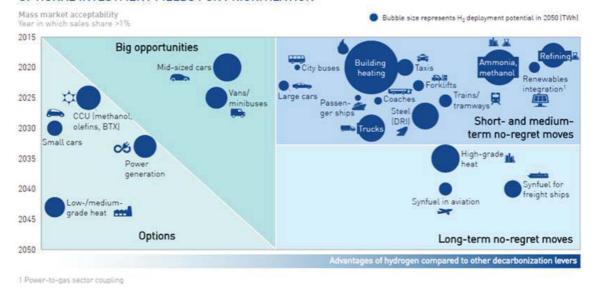


EXHIBIT 28: HYDROGEN OFFERS A NUMBER OF NO-REGRET MOVES, BIG OPPORTUNITIES, AND OPTIONAL INVESTMENT FIELDS FOR PRIORITIZATION



The Figure above highlights the enabling role of hydrogen and the important role it could potentially play in the decarbonisation of a large number of sectors.

2.1.2. Deployment of Hydrogen

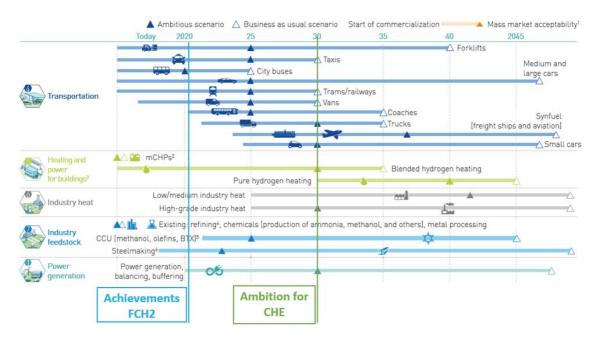
IPHE, the intergovernmental partnership for hydrogen and fuel cells in the economy comprises 20 member countries representing 2/3 of the world's GDP and investing nearly \$1 billion annually in hydrogen and fuel cells. IPHE collects every 6 months information provided by Government officials (Country Reports) on hydrogen deployment.

Today worldwide, there are >14,000 fuel cell electric vehicles (FCEVs), >300 hydrogen refueling stations (HRSs), >1/3 million stationary fuel cells in operation, and 600 MW of electrolyser's installed capacity¹.

Figures for Europe: 1730 FCEVs; 78 fuel cell buses, 15 garbage trucks; 185 HRSs deployed for road transport, 34 Water Electrolysers (PEM, Alkaline, SOEC) 34 deployed within the cutrrent FCH 2 JU (incl. 24 at HRSs, 4 at Telecom, 2 for grid autonomy and 4 for grid services) - 9 more planned, excl. HRSs (2 for H₂ storage, 1 for refinery, 4 Power to Gas applications, 2 for other industrial purposes).

Regarding the production of hydrogen, it is important to note that today hydrogen represents 1% of the energy mix and only 1% of this 1% corresponds to green hydrogen (produced from renewable energy sources). It is clear that the EU has to push for the production of clean hydrogen at scale. This activity will be supported under hydrogen production in the proposed clean hydrogen partnership. There will be no deployment of hydrogen and fuel cell applications without developing the hydrogen supply chain.

In conclusion, despite the potential of hydrogen to contribute to the decarbonisation of many different sectors, one has to acknowledge that the deployment of hydrogen and fuel cells is only marginal today. To accelerate the commercial readiness of hydrogen technologies, the proposed Partnership is building on the work of FCH 2 JU which made the start of commercialisation of a first series of applications possible. It will aim at bringing a second series of applications to commercial level as outlined in the figure below.



It is also expected that the proposed Clean Hydrogen Partnership will improve through research and innovation the cost-effectiveness, reliability and quality of clean hydrogen applications developed in the EU and therefore accelerate and boost the market entry of these innovative competitive clean hydrogen solutions to support the decarbonisation of the EU economy

2.1.3. Specific objectives and targets

In order to have a good understanding of the hydrogen and fuel cells sector, it is worth looking at the KPIs listed in the Multi-Annual Work Plan of FCH 2 JU. One can see that a large number of KPIs are on track (in green in the table below) but that for a few applications technology developments are behind schedule. The case of PEM electrolysers is of concern with current capital costs far from reaching the targets. This fact could delay large scale deployment of this technology with a direct consequence on clean hydrogen production.

It is also clear from this analysis that achieving the 2030 targets will be very challenging. However, there are reasons to remain optimistic if one looks for example at the capital costs of fuel cell buses. Continuous support from a series of FCH JU projects has allowed a drastic reduction of the costs of fuel cell buses, 400% in 15 years. A similar evolution could be expected for other hydrogen and fuel cell technologies.

KPIs FCH 2 JU Programme 2014-2020²

Transport – Demo (MAWP - SoA/Targets)									
Application	KPI	unit	SoA 2012	SoA 2017	FCH 2 JU Projects Results Average values 2018	2020	2024	2030	
Light Duty Vehicles (LDV)	Fuel cell system durability	h	2,500	4,000	5,000	5,000	6,000	7,000	
	Fuel cell system cost	EUR/k W	500	100	Work in progress	60	50	40	
Storage tanks	CAPEX - Storage tank	EUR/kg H2	3,000	1,000	875	500	400	300	
Bus	Bus price	thousan d EUR	1300	650	≈550. Latest figures from JIVE report	625 (150 units)	600 (250 units)	500 (300 units)	
HRS	CAPEX for the HRS	Thousan d EUR/ (kg/day)	7,5	7	2,978.53 (HRS bus)	4-2,1	3-1,6	2,4-1,3	
Energy – Demo Stationary Applications (MAWP - SoA/Targets)									
Application	KPI	unit	SoA 2012	SoA 2017	FCH 2 JU Projects Results Average values 2018	2020	2024	2030	

mCHPs					16,000 (range 6,000-			
	CAPEX	EUR/kW	16000	13000	23,000)	10000	5500	3500
	Lifetime	years of appliance operation	10	12	12.25	13	14	15
	Durability	h	25,000	40,000	55,450	50,000	60,000	80,000
	Electrical Efficiency	% LHV	30-60	33-60	47.4 (between 37 and 60%)	35-60	37-63	39-65
Medium Scale applications	CAPEX	EUR/kW	6,000 - 10,000	5,000 - 8,500	Work in progress for commercial applications	4.500 - 7.500	3.500 - 6.500	1,500 - 4,000
Large Scale Applications	Electrical efficiency	% LHV	45	45	48.3	45	45	50
	Lifetime	years of plant operation	2-20	6-20	15	8-20	8-20	15-20
	Availability	% of the plant	97	97	95	97	97	98
	Electrical efficiency	% LHV	40-45	41-55	50	42-60	42-62	50-65
Er	ergy – H2 Pi	oduction,	Storage	& Distribu	tion (MAWP - S	oA/Tarą	gets)	
Application	KPI	unit	SoA 2012	SoA 2017	FCH 2 JU Projects Results Average values 2018	2020	2024	2030
	Electricity consumption @ nominal capacity	kWh/kg	60	58	58	55	52	50
		€/(kg/d)	8,000	2,900	≈ 8000	2,000	1,500	1,000
227	Capital cost	(€/kW)	(~3,000)	(1,200)	EUR/(kg/d)	(900)	(700)	(500)
PEM electrolysers	O&M cost	€/(kg/d)/yr	160	58	No data	41	30	21
	Electricity consumption @ nominal capacity	kWh/kg	57	-	59 (minimum value 46) @System Level	50	49	48
	Capital cost	€/(kg/d) (€/kW)	8,000 (~3,000)	1,600 (750)	Work in Progress	1,250 (600)	1,000 (480)	800 (400)
Alkaline Electrolysers	O&M cost	€/(kg/d)/yr	160	32	No data	26	20	16
	Electricity consumption	kWh/kg	na	41	2020 Target achieved	40	39	37
	Availability	%	na	na	≈66% Targets have not been achieved (79 @ Stack level)	95%	98%	99%
Solid Oxide Electrolysers	Capital cost	€/(kg/d)	na	12,000	11,000 1,500 at mass production	4,500	2,400	1,500

	O&M cost	€/(kg/d)/yr	na	600	No data	225	120	75
	Capacity	kg	400	850	No data	1000	1000	1000
Compressed gas tube trailers	Capital cost	€/kg	550	400	No data	350	350	350
Large scale H2 storage	€/kg	1.2	1.1	1.0	No data		0.8	0.6

 $^{^{1}}$ There is no data available on installed electrolyser's capacity. The overall figure sums up the figures reported in the press.



Year of bus order & relevant project

Source:https://www.fch.europa.eu/sites/default/files/Strategies_%20for_joint_procurement_of_FCbuses_final_report.pdf

² The complete list of KPIs is available at:

 $https://www.fch.europa.eu/sites/default/files/MAWP\%20final\%20version_endorsed\%20GB\%2015062018\%20\%28ID\%203712421\%29.pdf$

^{*} FCHJU MAWP is the Fuel Cells and Hydrogen Joint Undertaking's Multi-Annual Work Plan, the document that sets out the work plan and strategic targets for the second phase of the FCH JU's programme of research and innovation.

^{**} See http://hydrogenvalley.dk/white-paper/.