EUROPEAN UNION

THE EUROPEAN PARLIAMENT **THE COUNCIL**

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DECISION
OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
ON THE PARTICIPATION OF THE UNION
IN A SECOND EUROPEAN AND DEVELOPING COUNTRIES
CLINICAL TRIALS PARTNERSHIP PROGRAMME (EDCTP2)
JOINTLY UNDERTAKEN BY SEVERAL MEMBER STATES

DECISION NO .../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

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 185, and the second paragraph of Article 188, thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[1],

Acting in accordance with the ordinary legislative procedure[2],

[1] Opinion of 10 December 2013 (not yet published in the Official Journal).

[2] Position of the European Parliament of 15 April 2014 (not yet published in the Official Journal) and decision of the Council of 6 May 2014.

Whereas:

(1) In its Communication of 3 March 2010 entitled 'Europe 2020 A Strategy for smart, sustainable and inclusive growth' ("the Europe 2020 strategy"), the Commission emphasised the need to develop favourable conditions for investment in knowledge and innovation so as to achieve smart, sustainable and inclusive growth in the Union. The European Parliament and the Council have endorsed that strategy.

(2) Regulation (EU) No 1291/2013 of the European Parliament and of the Council[1] established Horizon 2020 — The Framework Programme for Research and Innovation (2014-2020) ("Horizon 2020"). Horizon 2020 aims at achieving a greater impact on research and innovation by contributing to the strengthening of public-public partnerships, including through Union participation in programmes undertaken by several Member States in accordance with Article 185 of the Treaty on the Functioning of the European Union.

(3) Public-public partnerships should aim to develop closer synergies, increase coordination and avoid unnecessary duplication with Union, international, national and regional research programmes, and should fully respect the Horizon 2020 general principles, in particular those relating to openness and transparency. Moreover, open access to scientific publications should be ensured.

[1] Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) and repealing Decision No 1982/2006/EC (OJ L 347, 20.12.2013, p. 104).

(4) By Decision No 1209/2003/EC of the European Parliament and of the Council[1], the Community decided to make a financial contribution to the European and Developing Countries Clinical Trials Partnership ("EDCTP1") matching that of the Participating States but not exceeding EUR 200 000 000, for the duration of the Sixth Framework Programme of the European Community for research, technological development and demonstration activities, contributing to the creation of the European Research Area and to innovation (2002 to 2006) established by Decision No 1513/2002/EC of the European Parliament and of the Council[2]. EDCTP1 was also supported under the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007 – 2013) established by Decision No 1982/2006/EC of the European Parliament and of the Council[3].

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1 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 (OJ L 169, 8.7.2003, p. 1).

2 Decision No 1513/2002/EC of the European Parliament and of the Council of 27 June 2002 concerning the sixth framework programme of the European Community for research, technological development and demonstration activities, contributing to the creation of the European Research Area and to innovation (2002 to 2006) (OJ L 232, 29.8.2002, p. 1).

3 Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013) (OJ L 412 of 30.12.2006, p. 1).

(5) In 2009, independent experts adopted the report of the interim evaluation of EDCTP1. The opinion of the expert panel was that EDCTP1 provided a unique platform for a genuine dialogue with African scientists, and that it has started to bridge the gap between North and South in building research capacities and in providing learning and working opportunities for young African researchers. Following that report, there are fundamental issues to be taken into consideration for a second European and Developing Countries Clinical Trials Partnership Programme ("EDCTP2 Programme"): the current scope of EDCTP1 needs to be amended and extended; the capabilities in developing countries for the sound conduct and management of clinical trials should, where necessary, be further developed and strengthened, in particular the role and development of ethical review committees and the corresponding regulatory environment, the coordination, collaboration and, where appropriate, integration of European national programmes should be further improved; collaboration with other major public and private partners, including the pharmaceutical industry, and public-private partnerships such as the Product Development Partnerships ("PDPs"), civil society, non-governmental organisations and foundations, need to be strengthened and extended; there should be clear and transparent rules of governance; synergies with European external policy actions should be developed specifically with Union development assistance; co-funding rules should be clarified and simplified; and monitoring tools need to be strengthened.

(6) Pursuant to Council Decision 2013/743/EU[1], further support may be provided to the EDCTP2 Programme.

(7) The Union is a major funder of research into poverty-related diseases and neglected infectious diseases. The Commission and Member States contribute nearly one quarter (22 %) of the relevant global investment made by governments. The Union is also a major player in global health. For example, the Commission and the Member States provide approximately half the financing of the Global Fund To Fight AIDS, Tuberculosis and Malaria.

(8) EDCTP1 produced major achievements, and developed eight improved medical treatments, in particular for newborns, children and pregnant or breastfeeding women suffering from HIV/AIDS or malaria. It has resulted in the launch of the first four African Regional Networks of Excellence promoting South-South cooperation on clinical research, and more than 400 African researchers have been trained. It has also contributed to establishing the Pan-African Clinical Trials Registry and the African Vaccine Regulators Forum.

[1] Council Decision 2013/743/EU of 3 December 2013 establishing the specific programme implementing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) and repealing Decisions 2006/971/EC, 2006/972/EC, 2006/973/EC, 2006/974/EC and 2006/975/EC (OJ L 347, 20.12.2013, p. 965).

(9) Despite the considerable results and achievements of EDCTP1, poverty-related diseases still represent a major obstacle to the sustainable development of developing countries due to their social and economic burden, especially in sub-Saharan Africa. Effective, safe, suitable and affordable medical treatments tailored to the specific circumstances of developing countries still do not exist for most poverty-related diseases, and investment in clinical research remains inadequate as conducting clinical trials is costly and the return on investment is limited due to market failure. It should be underlined that only 10 % of global research funding is allocated to the diseases which account for 90 % of the world's pathologies. Moreover, European research activities and programmes are still often fragmented and are therefore either subcritical in scale or overlapping, whereas research capacity and investment in developing countries are inadequate.

(10) Supporting the fight against poverty-related diseases would also help to safeguard Europe's citizens from those diseases as increasing global mobility (including tourism), migratory movements and shifts in the geographic distribution of those diseases mean that Europe may be facing new or returning challenges in connection with those diseases.

(11) On 15 June 2010, the European Parliament adopted a resolution on progress towards achieving the Millennium Development Goals ("MDG") in advance of the UN high-level meeting in September 2010, in which it asked the Commission, the Member States and developing countries to address MDG 5 (on improving maternal health), MDG 4 (on child mortality) and MDG 6 (on HIV/AIDS, malaria and tuberculosis) in a coherent and holistic way.

(12) The Union is committed to the 2012 Rio+20 conference conclusions on developing and achieving internationally-agreed Sustainable Development Goals ("SDG"), following and including the MDG.

(13) In 2000, the Union launched a high-level policy dialogue with Africa leading to the establishment of an Africa-EU Strategic Partnership, following which a Joint Africa-EU Strategy was adopted in 2007 and a high-level policy dialogue on Science, Technology and Innovation was established in 2011.

(14) On 31 March 2010, the Commission presented a communication on the Union's role in global health, which called for a more coordinated approach among Member States and across relevant policies to identify and jointly address shared global priorities for health research. In that communication, the Commission also restated the need to promote equitable and universal coverage of quality health services, plus effective and fair financing of research that benefits the health of all people.

(15) In the Council Conclusions of 10 May 2010 on the EU role in global health, the Council called on the Union to promote effective and fair financing of research that benefits the health of all and ensures that innovations and interventions lead to affordable and accessible solutions. In particular, models that dissociate the costs of Research and Development ("R&D") from the prices of medicines should be explored, including the opportunities for technology transfer to developing countries.

(16) In its Communication of 21 September 2011 on partnering in research and innovation, the Commission put partnerships across institutional, national and continental borders at the centre of the Union's research policy.

(17) In its Communication of 27 February 2013 entitled "A decent life for all: ending poverty and giving the world a sustainable future", the Commission reaffirmed its commitment to doing its utmost to help achieve the MDG by 2015, and pointed out that EU-funded research under EDCTP1 had contributed to achieving the MDG.

(18) In line with the objectives of Horizon 2020, any Member State and any country associated to Horizon 2020 should be entitled to participate in the EDCTP2 Programme.

(19) Contribution to the exploration of open innovation models for needs-driven research, and available and affordable outcomes in alignment with other Union commitments in health R&D should be considered.

(20) The Participating States intend to contribute to implementing the EDCTP2 Programme during the period covered by it, namely 2014 – 2024. In order to take into account the duration of Horizon 2020, calls for proposals under the EDCTP2 Programme should be launched at the latest by 31 December 2020. In duly justified cases, calls for proposals may be launched by 31 December 2021.

(21) A ceiling should be established for the Union's financial participation in EDCTP2 Programme for the duration of Horizon 2020. Within the limits of that ceiling, the Union contribution should be equal to the contribution of the states referred to in this Decision in order to achieve a high leverage effect and ensure a stronger integration of those states' programmes.

(22) The Union's financial contribution should be subject to formal commitments from the Participating States to contribute to implementing the EDCTP2 Programme and to the fulfilment of those commitments.

(23) The joint implementation of the EDCTP2 Programme requires an implementation structure. The Participating States have agreed on the implementation structure for EDCTP2 Programme and have set up the EDCTP2-Implementation Structure ("EDCTP2-IS"). The EDCTP2-IS should be the recipient of the Union's financial contribution and should ensure the efficient implementation of the EDCTP2 Programme.

(24) EDCTP2 activities should be in line with the objectives and research and innovation priorities of Horizon 2020 and with the general principles and conditions laid down in Article 26 of Regulation (EU) No 1291/2013.

(25) Calls for proposals by EDCTP2-IS should also be published on the single portal for participants, as well as through other Horizon 2020 electronic means of dissemination managed by the Commission.

(26) The Union's financial contribution should be managed in compliance with the principle of sound financial management and in accordance with the relevant rules on indirect management laid down in Regulation (EU, Euratom) No 966/2012 of the European Parliament and the Council[1] and Commission Delegated Regulation (EU) No 1268/2012[2].

[1] Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298 of 26.10.2012, p. 1).

[2] Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 (OJ L 362 of 31.12.2012, p. 1).

(27) In order to protect the Union's financial interests, the Commission should have the right to reduce, suspend or terminate the Union's financial contribution if the EDCTP2 Programme is implemented inadequately, partially or late, or if the Participating States do not contribute, or contribute partially or late, to the financing of the EDCTP2 Programme. Those rights should be provided for in the delegation agreement to be concluded between the Union and the EDCTP2-IS.

(28) In order to implement the EDCTP2 Programme efficiently, financial support should be provided by the EDCTP2-IS mainly in the form of grants to participants in actions selected at the level of the EDCTP2-IS. The selection of those actions should be made following open and competitive calls for proposals under the responsibility of the EDCTP2-IS.

(29) Participation in indirect actions under the EDCTP2 Programme is subject to Regulation (EU) No 1290/2013 of the European Parliament and of the Council[1]. However, due to the specific operating needs of the EDCTP2 Programme, it is necessary to provide for derogations from that Regulation in accordance with Article 1(3) of that Regulation.

(30) Derogations from point (b) of Article 9(1), point (c) of Article 10(1) and Article 12 of Regulation (EU) No 1290/2013 are necessary in order to require participation and allow funding of African entities, and allow cooperation through joint calls between the EDCTP2 Programme and any other legal entity.

[1] Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" and repealing Regulation (EC) No 1906/2006 (OJ L 347, 20.12.2013, p. 81).

(31) For the purpose of simplification, administrative burdens should be reduced for all parties. Double audits and disproportionate documentation and reporting should be avoided. When audits are conducted, the specificities of the national programmes should be taken into account, as appropriate.

(32) Audits of recipients of Union funds provided in accordance with this Decision should ensure a reduction of the administrative burden, in compliance with Horizon 2020.

(33) The Union's financial interests should be protected by means of proportionate measures throughout the expenditure life-cycle, including the prevention, detection and investigation of irregularities, the recovery of funds lost, wrongly paid or incorrectly used and, where appropriate, administrative and financial penalties in accordance with Regulation (EU, Euratom) No 966/2012.

(34) The Commission should conduct interim evaluations, assessing in particular the quality and efficiency of the EDCTP2 Programme, the progress made towards the objectives set and a final evaluation, and should prepare reports on those evaluations.

(35) Upon request from the Commission, the EDCTP2-IS and the Participating States should submit any information the Commission needs to include in the reports on the evaluation of the EDCTP2 Programme.

(36) It is essential that the research activities carried out under the EDCTP2 Programme are in full compliance with the Charter of Fundamental Rights of the European Union, the European Convention on Human Rights and its Supplementary Protocols, ethical principles included in the World Medical Association's Declaration of Helsinki of 2008, the standards of good clinical practice adopted by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, relevant Union legislation and local ethics requirements of the countries where the research activities are to be conducted.

(37) It is essential that informed consent for clinical trials conducted in developing countries should always be obtained in a way that is truly informed and voluntary.

(38) It is also important that the activities conducted under the EDCTP2 Programme should be coherent with the Union's development policy actions. In this context, synergies between EDCTP2 and the European Development Fund should be sought.

(39) Within the objective of cooperation with international development assistance initiatives, EDCTP2 funded activities should take into account the recommendations proposed by the relevant World Health Organisation (WHO) initiatives where appropriate, including the consultative Expert Working Group on Research and Development ("CEWG").

(40) The Scientific Panel for Health was set up by Horizon 2020 as a science-led stakeholder platform, in order to elaborate scientific input, to provide a coherent scientific focused analysis of research and innovation bottlenecks and opportunities related to the Horizon 2020 societal challenge on health, demographic change and well-being, to contribute to the definition of its research and innovation priorities and to encourage Union-wide scientific participation. Through active cooperation with stakeholders, it helps to build capabilities and to foster knowledge-sharing and stronger collaboration across the Union in that field. EDCTP2 should, therefore, collaborate and exchange information with the Scientific Panel for Health, where appropriate.

(41) Since the objectives of this Decision, namely to contribute to the reduction of the social and economic burden of poverty-related diseases in developing countries, and in particular in sub-Saharan Africa, by accelerating the clinical development of effective, safe, accessible, suitable and affordable medical interventions for poverty-related diseases, cannot be sufficiently achieved by the Member States due to the lack of necessary critical mass to be achieved, both in human and financial terms, and can therefore, by reason of the scale of the action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on the European Union. In accordance with the principle of proportionality, as set out in that Article, this Decision does not go beyond what is necessary for those objectives,

HAVE ADOPTED THIS DECISION:

Article 1

Participation in the second European and Developing Countries Clinical Trials Partnership Programme

1. The Union shall participate in the second European and Developing Countries Clinical Trials Partnership Programme (the "EDCTP2 Programme"), jointly undertaken by Austria, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom (the "Participating States") in accordance with the conditions laid down in this Decision.

2. Any Member State other than those listed in paragraph 1 and any other country associated to Horizon 2020 may participate in the EDCTP2 Programme, provided it fulfils the condition set out in point (e) of Article 3(1) of this Decision. If it fulfils the condition set out in point (e) of Article 3(1), it shall be regarded as a Participating State for the purposes of this Decision.

Article 2

Union's financial contribution

1. The Union's financial contribution, including EFTA appropriations, to the EDCTP2 Programme shall be up to EUR 683 000 000 to equal the contributions of Participating States.

2. The Union's financial contribution shall be paid from the appropriations in the general budget of the Union allocated to the relevant parts of the Specific Programme implementing Horizon 2020, established by Decision 2013/743/EU, and in particular from the appropriations under the specific objective "Health, demographic change and wellbeing" in accordance with point (c)(vi) of Article 58(1) and Articles 60 and 61 of Regulation (EU, Euratom) No 966/2012.

3. Up to 6 % of the Union's financial contribution referred to in paragraph 1 may be used by the implementing structure of EDCTP2 (the "EDCTP2-IS") to cover its administrative costs.

Article 3

Conditions for the Union's financial contribution

1. The Union's financial contribution shall be conditional upon the following:

   (a) the demonstration by the Participating States that the EDCTP2 Programme is set up in accordance with Annexes I, II and III;

   (b) the designation by the Participating States or organisations designated by the Participating States of the EDCTP2-IS, an entity with legal personality, as the structure responsible for implementing the EDCTP2 Programme and for receiving, allocating and monitoring the Participating States' contribution, as well as the Union's financial contribution;

(c) the demonstration by the EDCTP2-IS of its capacity to implement the EDCTP2 Programme, including receiving, allocating and monitoring the Union's contribution in the framework of indirect management of the Union budget in accordance with Articles 58, 60 and 61 of Regulation (EU, Euratom) No 966/2012;

(d) the establishment of a governance model for the EDCTP2 Programme in accordance with Annex III; and

(e) the commitment by each Participating State to contribute to the financing of the EDCTP2 Programme.

2. During the implementation of the EDCTP2 Programme, the Union's financial contribution shall be conditional upon the following:

(a) the implementation by the EDCTP2-IS of the objectives set out in Annex I, and activities set out in Annex II, to this Decision, in particular the activities and indirect actions that it funds, in compliance with Regulation (EU) No 1290/2013 as referred to in Article 6 of this Decision;

(b) the maintenance of an appropriate and efficient governance model for the EDCTP2 Programme in accordance with Annex III;

(c) the compliance by the EDCTP2-IS with the reporting requirements set out in Article 60(5) of Regulation (EU, Euratom) No 966/2012; and

(d) the fulfilment of the commitments referred to in point (e) of paragraph 1.

Article 4

Activities of the EDCTP2 Programme

1. The activities of the EDCTP2 Programme shall meet the objectives described in Annex I and shall comply with Annex II.

   Activities may include national programme activities of Participating States, including activities undertaken by public or private not-for-profit research organisations, and new activities, including calls for proposals managed by the EDCTP2-IS.

   Activities shall be included in the work plan of the EDCTP2 Programme adopted annually by the EDCTP2-IS ("the EDCTP2 annual work plan"), following the positive outcome of their external evaluation by international peer review with regard to the objectives of the EDCTP2 Programme.

2. The EDCTP2 annual work plan shall detail the budgeted value of each activity and shall provide for the allocation of the funding managed by the EDCTP2-IS, including the Union's financial contribution.

   The EDCTP2 annual work plan shall differentiate between the activities funded or co-funded by the Union and those funded by Participating States or other revenues.

3. The EDCTP2-IS shall implement the EDCTP2 annual work plan.

The EDCTP2-IS shall monitor and report to the Commission on the implementation of all the activities included therein or selected following calls for proposals managed by the EDCTP2-IS.

4. Activities included in the EDCTP2 annual work plan that are not funded by the EDCTP2-IS shall be implemented in compliance with common principles to be agreed by the Participating States and the Commission, taking into account the principles set out in this Decision, in Title VI of Regulation (EU, Euratom) No 966/2012 and in Regulation (EU) No 1290/2013, in particular the principles of equal treatment, transparency, independent peer review evaluation and selection. The Participating States and the Commission shall also agree on the reporting requirements to the EDCTP2-IS, including with regard to indicators inserted into each of those activities.

Any activity funded by the EDCTP2-IS in accordance with the EDCTP2 annual work plan, or following calls for proposals managed by the EDCTP2-IS, shall be considered to be an indirect action within the meaning of Regulation (EU) No 1290/2013, and shall be implemented in accordance with Article 6 of this Decision.

5. Any communication or publication in the area of the activities of the EDCTP2 Programme, and performed in close collaboration with EDCTP2, whether undertaken by the EDCTP2-IS, a Participating State, or participants to an activity, shall be labelled or co-labelled as "[name of the activity] is part of the EDCTP2 programme supported by the European Union".

Article 5

Contributions from Participating States

1. Contributions from the Participating States shall consist of the following:

   (a) financial contributions to the EDCTP2-IS;

   (b) in-kind contributions consisting of the costs incurred by the Participating States in implementing activities included and clearly identified in the EDCTP2 annual work plan, or in relation to the administrative budget of the EDCTP2-IS.

2. For the purpose of evaluating the contributions referred to in point (b) of paragraph 1, the costs shall be determined in accordance with the usual accounting practices and accounting standards of the Participating State concerned and to the applicable International Accounting Standards / International Financial Reporting Standards.

Article 6

Rules for participation and dissemination

1. Regulation (EU) No 1290/2013 shall apply to indirect actions selected and funded by the EDCTP2-IS on the basis of the EDCTP2 annual work plan or following calls for proposals managed by the EDCTP2-IS. In accordance with that Regulation, the EDCTP2-IS shall be considered to be a funding body and shall provide financial support to indirect actions in accordance with Annex II to this Decision.

2. By way of derogation from point (b) of Article 9(1) of Regulation (EU) No 1290/2013, the minimum number of participants shall be two legal entities established in two different Participating States and a third legal entity in a sub-Saharan African country listed in the EDCTP2 annual work plan.

3. By way of derogation from point (c) of Article 10(1) of Regulation (EU) No 1290/2013, any legal entity established in a sub-Saharan country listed in the EDCTP2 annual work plan shall be eligible for funding.

4. Where such an activity is included in the EDCTP2 annual work plan, the EDCTP2-IS may launch joint calls with third countries or their scientific and technological organisations and agencies, with international organisations or with other third parties, in particular non-governmental organisations, in accordance with the rules developed based on Article 12 of Regulation (EU) No 1290/2013.

Article 7

Agreements between the Union and the EDCTP2-IS

1. Subject to a positive ex-ante assessment of the EDCTP2-IS in accordance with Article 61(1) of Regulation (EU, Euratom) No 966/2012, the Commission, on behalf of the Union, shall conclude a delegation agreement and annual transfer of funds agreements with the EDCTP2-IS.

2. The delegation agreement referred to in paragraph 1 shall be concluded in accordance with Article 58(3) and Articles 60 and 61 of Regulation (EU, Euratom) No 966/2012 and Article 40 of Delegated Regulation (EU) No 1268/2012. It shall also set out, *inter alia*, the following:

(a) the requirements for the EDCTP2-IS contribution regarding the performance indicators set out in Annex II to Decision 2013/743/EU;

(b) the requirements for the EDCTP2-IS contribution in relation to the monitoring referred to in Annex III to Decision 2013/743/EU;

(c) the specific performance indicators related to the functioning of the EDCTP2-IS;

(d) the requirements for the EDCTP2-IS regarding the provision of information on administrative costs and on detailed figures concerning the implementation of the EDCTP2 Programme;

(e) the arrangements regarding the provision of data necessary to ensure that the Commission is able to meet its dissemination and reporting obligations;

(f) the arrangements for the approval or rejection by the Commission of the draft EDCTP2 annual work plan, before it is adopted by the EDCTP2-IS; and

(g) provisions for the publication of calls for proposals by EDCTP2, in particular on the single portal for participants as well as through other Horizon 2020 electronic means of dissemination managed by the Commission.

Article 8

Termination, reduction or suspension of the Union's financial contribution

If the EDCTP2 Programme is not implemented or is implemented inadequately, partially or late, the Commission may terminate, proportionately reduce or suspend the Union's financial contribution in line with the actual implementation of the EDCTP2 Programme.

If the Participating States do not contribute, contribute partially or late to the financing of the EDCTP2 Programme, the Commission may terminate, proportionately reduce or suspend the Union's financial contribution, taking into account the amount of funding allocated by the Participating States to implement the EDCTP2 Programme.

Article 9

Ex-post audits

1. Ex-post audits of expenditure on indirect actions shall be carried out by the EDCTP2-IS in accordance with Article 29 of Regulation (EU) No 1291/2013.

2. The Commission may decide to carry out itself the audits referred to in paragraph 1. In such cases, it shall do so in accordance with the applicable rules, in particular the provisions of Regulations (EU, Euratom) No 966/2012, (EU) No 1290/2013 and (EU) No 1291/2013.

Article 10

Protection of the financial interests of the Union

1. The Commission shall take appropriate measures ensuring that, when actions financed under this Decision are implemented, the financial interests of the Union are protected by the application of preventive measures against fraud, corruption and any other illegal activities, by effective checks and, if irregularities are detected, by the recovery of the amounts wrongly paid and, where appropriate, by effective, proportionate and dissuasive administrative and financial penalties.

2. The EDCTP2-IS shall grant Commission staff and other persons authorised by it, as well as the Court of Auditors, access to its sites and premises and to all the information, including information in electronic format, needed in order to conduct their audits.

3. The European Anti-Fraud Office (OLAF) may carry out investigations, including on-the-spot checks and inspections, in accordance with the provisions and procedures laid down in Council Regulation (Euratom, EC) No 2185/96[1] and Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council[2] with a view to establishing whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the Union in connection with a grant agreement or grant decision or a contract funded in accordance with this Decision.

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[1] Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

[2] Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.9.2013, p.1).

4. Contracts, grant agreements and grant decisions resulting from the implementation of this Decision shall contain provisions expressly empowering the Commission, the EDCTP2-IS, the Court of Auditors and OLAF to conduct such audits and investigations, in accordance with their competences.

5. In implementing the EDCTP2 Programme, the Participating States shall take the legislative, regulatory, administrative and other measures necessary to protect the Union's financial interests, in particular, to ensure full recovery of any amounts due to the Union in accordance with Regulation (EU, Euratom) No 966/2012 and Delegated Regulation (EU) No 1268/2012.

Article 11

Communication of information

1. On request, the EDCTP2-IS shall send any information necessary for preparation of the reports referred to in Article 12 to the Commission.

2. The Participating States shall submit to the Commission, through the EDCTP2-IS, any information that is requested by the European Parliament, the Council or the Court of Auditors concerning the financial management of the EDCTP2 Programme.

3. The Commission shall include the information referred to in paragraph 2 of this Article in the reports referred to in Article 12.

Article 12

Evaluation

1. By 30 June 2017 the Commission shall carry out, with the assistance of independent experts, an interim evaluation of the EDCTP2 Programme. The Commission shall prepare a report on that evaluation which includes conclusions of the evaluation and observations by the Commission. The Commission shall send that report to the European Parliament and to the Council by 31 December 2017. The result of the interim evaluation of EDCTP2 Programme shall be taken into account in the interim evaluation of Horizon 2020.

2. At the end of the Union participation in EDCTP2 but not later than 31 December 2023, the Commission shall conduct another interim evaluation of the EDCTP2 Programme. The Commission shall prepare a report on that evaluation which is to include the results of that evaluation. The Commission shall send that report to the European Parliament and to the Council.

3. The Commission shall conduct a final evaluation of the EDCTP2 Programme by 31 December 2026. The Commission shall send the results of that evaluation to the European Parliament and to the Council.

Article 13

Entry into force

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 14

Addressees

This Decision is addressed to the Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

ANNEX I

OBJECTIVES OF THE EDCTP2 PROGRAMME

EDCTP2 shall contribute to the following objectives:

(1) General Objective

EDCTP2 shall contribute to the reduction of the social and economic burden of poverty-related diseases in developing countries, in particular in sub-Saharan Africa, by accelerating the clinical development of effective, safe, accessible, suitable and affordable medical interventions[1] for poverty-related diseases, in partnership with sub-Saharan Africa.

(2) Specific Objectives

In order to contribute to the general objective, EDCTP2 shall achieve the following specific objectives:

(a) an increased number of new or improved medical interventions for HIV/AIDS, tuberculosis, malaria and other poverty-related diseases, including neglected ones, and by the end of the programme to have delivered at least one new medical intervention; to have issued approximately 30 guidelines for improved or extended use of existing medical interventions; and to have progressed the clinical development of approximately 20 candidate medical interventions;

[1] For the purpose of this decision, "medical interventions" encompass measures whose purpose is to improve or sustain health or alter the course of a disease, in particular prevention and treatment based on medicinal products such as drugs, microbicides or vaccines, including their delivery modality, follow up of treatment and prevention in the affected population as well as medical diagnostics to detect and monitor disease/health evolution.

(b) strengthened cooperation with sub-Saharan African countries, in particular on building their capacity for conducting clinical trials in compliance with fundamental ethical principles and relevant national, Union and international legislation, including the Charter of Fundamental Rights of the European Union, the European Convention on Human Rights and its Supplementary Protocols, the World Medical Association's Declaration of Helsinki of 2008 and the standards on good clinical practice adopted by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH);

(c) better coordination, alignment and, where appropriate, integration of relevant national programmes to increase the cost-effectiveness of European public investments. Moreover, 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;

(d) extended international cooperation with other public and private partners to ensure that the impact of all research is maximised and that synergies can be taken into consideration and achieve leveraging of resources and investments;

(e) an increased impact due to effective cooperation with relevant Union initiatives, including its development assistance.

(3) Operational Indicators and Objectives

In order to reach the specific objectives set out in point 2, the following indicators shall be monitored during the course of the EDCTP2 programme:

(a) Support clinical trials on new or improved medical interventions for poverty-related diseases, including neglected ones, through partnerships between European and developing countries, in particular sub-Saharan Africa:

Indicator: increase the number of supported clinical trials to at least 150, compared to 88 under EDCTP1, that lead to new products, processes, methodologies, diagnostics, treatments or preventions.

Indicator: sustain or increase the proportion of clinical trials funded by the EDCTP2-IS with African leadership.

Indicator: aim to increase the number of peer-reviewed scientific articles published to three times that of EDCTP1.

(b) Support research capacity-building activities in sub-Saharan Africa enabling clinical trials to be conducted and help to reduce the brain drain:

Indicator: aim to sustain or increase the participation of sub-Saharan African countries in the EDCTP2 Programme.

Indicator: increase the number of fellowships to sub-Saharan African researchers and MSc/PhD students from 400 under EDCTP1, strongly encouraging and supporting them to continue their research career in sub-Sahara Africa following their fellowship.

Indicator: increase the number of capacity-building activities supported for conducting clinical trials in sub-Saharan Africa from 74 under EDCTP1.

(c) Develop a research agenda for EDCTP2 based on common criteria for priority setting and common evaluation, whilst recognising that contributions from national programmes and EDCTP may differ.

Target: at least 50 % of the public investment by Participating States are integrated, aligned or coordinated through the EDCTP2 Programme.

(d) Ensure efficiency of the implementation of the EDCTP2 Programme:

Target: administrative costs are below 5 % of the EDCTP2-IS budget.

(e) Establish cooperation and launch joint actions with other public and private funders.

Target: increase the contributions received from developing countries to at least EUR 30 000 000 compared to EUR 14 000 000 under EDCTP1.

Target: obtain additional contributions, either public or private, of at least EUR 500 000 000, compared to EUR 71 000 000 under EDCTP1.

(f) Establish cooperation and launch joint actions with Union, national and international development assistance initiatives, including where appropriate, relevant WHO initiatives, in order to ensure complementarity and increase the impact of the results of EDCTP-funded activities.

ANNEX II

ACTIVITIES AND IMPLEMENTATION OF THE EDCTP2 PROGRAMME

(1) Activities

The EDCTP2 Programme shall include the following activities:

(a) promoting networking, coordination, alignment, collaboration and integration of national research programmes and activities on poverty-related diseases, including neglected ones, at scientific, management and financial level;

(b) supporting clinical trial research and related activities on poverty-related diseases, in particular HIV/AIDS, malaria, tuberculosis and other poverty-related diseases, including neglected ones;

(c) fostering capacity development for clinical trials and related research in developing countries, in particular in Sub-Saharan Africa, through grants for: career development of junior and senior fellows, promoting mobility, staff exchange grants, research training networks, strengthening ethics and regulatory bodies, mentoring and partnerships at individual or institutional or regional level;

(d) establishing cooperation and launching joint actions with other public and private funders;

(e) assuring awareness, endorsement and acknowledgment of the EDCTP2 Programme and its activities through advocacy and communication, not only at Union level and in developing countries, but also at global level.

(2) Programme definition and implementation

The EDCTP2 Programme shall be implemented by the EDCTP2-IS on the basis of an annual work plan and a multiannual strategic work plan prepared by the EDCTP2-IS, in consultation with the relevant stakeholders, and adopted by the General Assembly of the EDCTP2-IS following international peer-review and subject to the prior approval by the Commission.

The annual work plan shall identify topics and activities to be implemented, including calls for proposals to be launched by EDCTP-IS to select and fund indirect actions, as well as the budgets and EDCTP2 funding for those topics and activities. Where appropriate, EDCTP2 may exchange information with other public or private initiatives, including those under Horizon 2020.

The annual work plan shall differentiate between the activities funded or co-funded by the Union and those funded by Participating States or other revenues.

The multiannual strategic work plan shall set a common strategic research agenda which shall be prepared and updated on an annual basis.

EDCTP2-IS shall monitor the implementation of the activities included in the work plan, including indirect actions selected through calls for proposals it manages. It shall allocate and manage funding to those in accordance with this Decision and the effective implementation of activities selected and identified in the previous work plans.

(3) Deliverables expected from the implementation of the EDCTP2 Programme

An annual report shall be provided by the EDCTP2-IS, which shall give a detailed overview of the implementation of the EDCTP2 Programme. That overview shall provide information on each activity selected in accordance with the work plan, including indirect actions selected through calls for proposals managed by the EDCTP2-IS. Such information shall include a description of each activity, including indirect action, its budget, the value of the funding allocated to it if any, and its status.

With regard to calls managed by the EDCTP2-IS, the annual report shall moreover include information on the number of projects submitted and selected for funding, the detailed use of the Union's financial contribution, the distribution of national and other contributions including specification on the type of in kind contributions, the types of participants, country statistics, brokerage events and dissemination activities. The annual report may also include, when appropriate, information on measures taken to facilitate access to products stemming from EDCTP2.

The annual report shall also include information on the progress towards achieving the EDCTP2 Programme objectives set out in Annex I.

In addition, the EDCTP2-IS shall provide any report and information foreseen by this Decision and the agreement concluded with the Union.

ANNEX III

GOVERNANCE OF THE EDCTP2 PROGRAMME

The organisational structure of the EDCTP2 Programme shall be as follows:

(1) The EDCTP2-IS shall be governed by a general assembly ("GA"), in which all Participating States are represented.

The GA's principal responsibility shall be to ensure that all necessary activities are undertaken to achieve the objectives of the EDCTP2 Programme, and that its resources are properly and efficiently managed. It shall adopt the annual work plan.

The GA shall decide by consensus. Failing consensus, the GA shall take its decisions by a majority of at least 75 % of the votes.

The Union, represented by the Commission, shall be invited to all GA meetings as an observer, and shall receive all necessary documents. It may take part in discussions.

(2) The GA shall appoint a Management Board that shall supervise the secretariat of the EDCTP2-IS ("'SEC") established by the GA as the executive body of the EDCTP2 Programme. The Management Board shall consist of such number of Board Members as the GA may determine, but not less than five.

SEC shall have at least the following tasks:

(a) execute the annual work plan;

(b) provide support to the GA;

(c) monitor and report on the implementation of the EDCTP2 Programme;

(d) manage the financial contributions from the Participating States, the Union and any third party, and report on their use to the GA and the Union;

(e) increase the visibility of the EDCTP2 Programme through advocacy and communication;

(f) liaise with the Commission in accordance with the delegation agreement referred to in Article 7.

(3) A Scientific Advisory Committee ("SAC") shall advise the GA on the strategic priorities of the EDCTP2 Programme.

The SAC shall be appointed by the GA and consist of European and African independent experts competent in areas relevant to the EDCTP2 Programme, taking into account gender balance.

The SAC shall have the following tasks:

(a) advise the GA on priorities and strategic needs regarding clinical trials in Africa;

(b) advise the GA on the content, scope and dimension of the EDCTP2 draft annual work plan, including diseases covered and approaches to be adopted, from a scientific and technical standpoint;

(c) review the scientific and technical aspects of the implementation of the EDCTP2 Programme and deliver an opinion on its annual report.

In exercising its tasks, the SAC shall monitor and promote high standards of ethical conduct of clinical trials and engage with vaccine regulatory authorities.

The SAC may recommend to the GA the setting up of scientific subcommittees, task forces and working groups.

The GA shall establish the number of SAC members, their voting rights and the arrangements for their appointment in accordance with Article 40 of Regulation (EU) No 1290/2013. The GA may set up specialised working groups under the SAC with additional independent experts for specific tasks.