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To:	Delegations
No. prev. doc.:	16535/2013 RECH 553 SAN 458 SOC 961 CODEC 2646
No. Cion doc.:	12369/13 RECH 356 SAN 271 SOC 596
Subject:	Proposal for a 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 jointly undertaken by several Member States

Following the vote in European Parliament's ITRE committee on 23 January 2014 and in view of the RECH Working Party on 27 January 2014, delegations will find attached a 4-column document on the proposal for a 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 jointly undertaken by several Member States.

In the column related to the position of the Council (doc.16535/13), the changes to the Commission proposal are indicated in **bold underlined** for additions and in ~~strikethrough~~ for deletions.

In the column related to the position of the ITRE Committee, the changes to the Commission proposal are indicated in ***bold italics*** for additions and in ~~strikethrough~~ for deletions.

Proposal for a 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 jointly undertaken by several Member States

RECITALS

COMMISSION PROPOSAL (doc. 12369/13)	COUNCIL GENERAL APPROACH (adopted on 03/12/13)	ITRE VOTE 23/01/14 PROVISIONAL	COMPROMISE TEXT	Line N°
Whereas:	<i>[no change]</i>	<i>[no change]</i>		1
(1) In its Communication Europe 2020 A Strategy for smart, sustainable and inclusive growth ¹ , the Commission underscores 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 Council have endorsed this strategy.	<i>[no change]</i>	<i>[no change]</i>		2

¹ COM(2010)2020 final of 3.3.2010.

(2) Horizon 2020 — The Framework Programme for Research and Innovation (2014-2020) established by Regulation (EU) No .../2013 of the European Parliament and of the Council of ... 2013² (hereinafter “Horizon 2020 Framework Programme”) 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. ² OJ... [Horizon 2020 Framework Programme].	[no change]	AM 1 (2) Horizon 2020 — The Framework Programme for Research and Innovation (2014-2020) established by Regulation (EU) No .../2013 of the European Parliament and of the Council of ... 2013² (hereinafter “Horizon 2020 Framework Programme”) aims at achieving a greater impact on research and innovation by contributing to the strengthening of developing closer synergies, increasing coordination and avoiding unnecessary duplication with international, national and regional research programmes. Public-public partnerships, including through Union participation in programmes undertaken by several Member States in accordance with Article 185 of the Treaty, should achieve those aims, meet the conditions specified in that Regulation, in particular in Articles 26 and be in full compliance with the General Principles, in particular the conditions relating to the communication and dissemination of information and open access. ² OJ... [Horizon 2020 Framework Programme].	3
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(3) By 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 States³, the Community decided to make a financial contribution to the European and Developing Countries Clinical Trials Partnership (hereinafter "EDCTP1") matching that of the participating states but not exceeding EUR 200 million, 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 of 27 June 2002⁴. _____ 3 OJ L 169 of 8.7.2003, p. 1-5. 4 OJ L 232 of 29.8.2002, p. 1-33.	[no change]	[no change]	4
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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 of 18 December 2006 ⁵ .	<i>[no change]</i>	<i>[no change]</i>		5
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⁵ OJ L 412 of 30.12.2006, p. 1-43.

(4) In 2009, independent experts adopted the report of the interim evaluation of EDCTP1⁶. The opinion of the expert panel was that EDCTP1 provided a unique platform for a genuine dialogue with African scientists and 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 this report, there are fundamental issues to be taken into consideration for a second European and Developing Countries Clinical Trials Partnership Programme (hereinafter "EDCTP2 Programme"): the current scope of EDCTP1 needs to be changed and extended; the integration of European national programmes should be further improved; collaboration with other major public and private funders, including the pharmaceutical industry, needs to be strengthened and extended; synergies with European external policy actions should be developed, in particular with Union development assistance; co-funding rules should be clarified and simplified; monitoring tools need to be strengthened. ⁶ Van Velzen et al., Independent External Evaluation Report, December 2009.	<i>[no change]</i>	CA1 (4) In 2009, independent experts adopted the report of the interim evaluation of EDCTP1⁶. The opinion of the expert panel was that EDCTP1 provided a unique platform for a genuine dialogue with African scientists and 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 this report, there are fundamental issues to be taken into consideration for a second European and Developing Countries Clinical Trials Partnership Programme (hereinafter "EDCTP2 Programme"): - the current scope of EDCTP1 needs to be changed and extended; ⁶ Van Velzen et al., Independent External Evaluation Report, December 2009.	6
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		- the <i>capabilities in developing countries for 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 regularity environment, the coordination, collaboration and where appropriate</i> integration of European national programmes should be further improved; - collaboration with other major public and private funders <i>partners</i>, including the pharmaceutical industry, <i>and public-private partnerships such as the PDPs (Product Development Partnerships), civil society, non-governmental organisations and foundations</i>, needs to be strengthened and extended; - <i>there should be clear and transparent rules of governance;</i> - synergies with European external policy actions should be developed, in particular <i>specifically</i> with Union development assistance; - co-funding rules should be clarified and simplified; - monitoring tools need to be strengthened.		6.1
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(5) According to Council Decision ... /2013/EU of ... 2013 establishing the Specific Programme implementing the Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020)⁷ further support may be provided to the EDCTP2 Programme. ⁷ OJ L ... [Horizon 2020 Specific Programme].	[no change]	AM 36 (5) According to Regulation (EU) N° .../2013 of the European Parliament and of the Council of ... 2013 establishing Horizon 2020^{6a} and Council Decision ... /2013/EU of ... 2013 establishing the Specific Programme implementing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020)⁷ further support may be provided to the EDCTP2 Programme. ^{6a.} OJ L ... [Horizon 2020]. ^{7.} OJ L ... [Horizon 2020 Specific Programme].	7	7
		AM 2 DEVE (AM 37) (5a) <i>The Union is a major funder of research into poverty-related diseases. The Commission and Member States contribute nearly one quarter (22%) of relevant global investment by governments. The Union is also a major player in global health. For example, the Commission and Member States provide about half the financing for the Global Fund To Fight AIDS, Tuberculosis and Malaria.</i>	7.1	7.1

(6) EDCTP1 had major achievements and has so far developed eight improved medical treatments, in particular for new-borns, children or pregnant/lactating 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.	<i>[no change]</i>	<i>[no change]</i>		8
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(7) 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 and affordable medical treatments 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. Moreover, European research activities and programmes are still often fragmented and thus either subcritical in scale or overlapping, whereas research capacity and investment in developing countries are inadequate.	<i>[no change]</i>	AM 3 DEVE (7) 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, <i>suitable, accessible</i> and affordable medical treatments and <i>tailored to developing countries' specific circumstances</i> 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. <i>It should be pointed out that only 10% of global research funding is allocated for the diseases which account for 90% of the world's pathologies.</i> Moreover, European research activities and programmes are still often fragmented and thus either subcritical in scale or overlapping, whereas research capacity and investment in developing countries are inadequate.	9
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			AM 38 <i>(7a) Supporting the fight against poverty-related diseases would also help to safeguard Europe's citizens from these diseases as increasing global mobility (including tourism), migratory movements and shifts in geographic distribution of these diseases mean that Europe may be facing new or returning challenges from these diseases.</i>	9.1
(8) The European Parliament adopted a resolution on 15 June 2010 on progress towards achieving the Millennium Development Goals (hereinafter "MDG") ahead of the UN high-level meeting in September 2010 in which it 'asks 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'.	[no change]		[no change]	10
(9) The Union is committed to the 2012 Rio+20 conference conclusions on developing and achieving internationally agreed Sustainable Development Goals (hereinafter "SDG"), following and including the MDG.	[no change]		[no change]	11

(10) 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.	[no change]	[no change]	12
(11) The Commission presented a communication on 31 March 2010 on the Union's role in global health ⁸ which calls for a more coordinated approach among Member States and across relevant policies to identify and jointly address global priorities for health research. 8 COM(2010)128 final.	[no change]	AM 4 DEVE (11) The Commission presented a communication on 31 March 2010 on the Union's role in global health⁸ which calls for a more coordinated approach among Member States and across relevant policies to identify and jointly address global priorities for health research. <i>In that communication, the Commission also restates 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.</i> 8 COM(2010)128 final.	13

		AM 5 DEVE + AM 40 <i>(11a) in 2010, in its "Council Conclusions on the EU's role in global health", the Council called on the EU 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 costs of R&D and the prices of medicines should be explored, including the opportunities for technology transfer to developing countries.</i>		13.1
(12) The Commission presented a communication on 21 September 2011 on partnering in research and innovation ⁹ which puts partnerships across institutional, national and continental borders at the centre of the Union's research policy. ⁹ COM(2011) 572 final.	<i>[no change]</i>	<i>[no change]</i>		14

		<u>AM 6 DEVE</u> <i>(12a) In its communication of 27 February 2013 entitled "A decent life for all: ending poverty and giving the world a sustainable future "^{11a}, the Commission reaffirmed its commitment to doing its utmost to help achieve the MDG by 2015 and pointed out that EU-funded research under EDTCP1 had contributed to achievement of the MDG.</i> <u>11a (COM(2013) 0092).</u> <u>AM41 + AM 7 DEVE</u> (13) In line with the objectives of Horizon 2020 Framework Programme, any Member State and any country associated to the Horizon 2020 Framework Programme should be entitled to participate in the EDCTP2 Programme. <i>It must be ensured, that projects receiving money from the Horizon 2020 Framework Programme are not in breach of international human rights law.</i>	14.1
(13) In line with the objectives of Horizon 2020 Framework Programme, any Member State and any country associated to the Horizon 2020 Framework Programme should be entitled to participate in the EDCTP2 Programme.	<i>[no change]</i>		15

		<u>AM 42</u> <i>(13a) With a view to the overall aim of Horizon 2020 of achieving greater simplification and harmonisation of the European research and innovation funding landscape Public/Public Partnerships should establish simple governance models and avoid different sets of rules from Horizon 2020.</i>		15.1
		<u>AM 43 + 55</u> <i>(13b) Barriers preventing the participation of newcomers to the programme should be identified and addressed. In this context the participation of SMEs, universities and research centres should be promoted.</i>		15.2

(14) The participating states intend to contribute to the implementation of EDCP2 Programme during the period covered by the EDCP2 Programme (2014 – 2024).	[no change]	CA 2 (14) The participating states intend to contribute to the implementation of EDCP2 Programme during the period covered by the EDCP2 Programme (2014 – 2024). <i>In order to take into account the duration of the Horizon 2020 Framework Programme for Research and Innovation, calls for proposals that require an EU contribution under this Programme should be launched by 31 December 2020.</i>	16
(15) A ceiling should be established for the Union's participation in EDCP2 for the duration of Horizon 2020 Framework Programme. Within that ceiling, the Union contribution should be equal to the initial contributions committed by the participating states in order to achieve a high leverage effect and ensure a stronger integration of participating states' programmes. That ceiling should also provide for matching the contributions from any other Member State or country associated to Horizon 2020 Framework Programme joining the EDCP2 Programme during the Horizon 2020 Framework Programme.	[no change]	AM 46 (15) A ceiling should be established for the Union's participation in EDCP2 for the duration of Horizon 2020 Framework Programme. Within that ceiling, the Union contribution should be equal to the initial contributions committed by the participating states of the states referred to in Article 1 of this Decision in order to achieve a high leverage effect and ensure a stronger integration of participating those states' programmes. That ceiling should also provide for matching the contributions from any other Member State or country associated to Horizon 2020 Framework Programme joining the EDCP2 Programme during the Horizon 2020 Framework Programme.	17

(16) The Union's financial contribution should be subject to formal commitments from the participating states to implement the EDCTP2 Programme and their fulfilment.	<i>[no change]</i>	AM 49 (16) The Union's financial contribution should be subject to formal commitments from the participating states to contribute to implement the EDCTP2 Programme and their fulfilment. <i>In particular, clinical trials should only get Union's financial contribution where they are performed in accordance with the declaration of Helsinki and where the same standards for data transparency apply as in Regulation [2012/0192].</i> AM 50 (16a) <i>It is essential that informed consent for clinical trials conducted in developing countries is always obtained in a way that is truly informed and truly voluntary.</i>	18	18
			18.1	

(17) The joint implementation of the EDCTP2 Programme requires an implementation structure. The participating states have agreed on the implementation structure for EDCTP2 and set up the EDCTP2-Implementation Structure (hereinafter “EDCTP2-IS”). The EDCTP2-IS should be the recipient of the Union’s financial contribution and should ensure efficient implementation of the EDCTP2 Programme.	[no change]	[no change]	[no change]	19
(18) 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 set out in Regulation (EU, Euratom) No 966/2012 of the European Parliament and the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union¹⁰ and Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012¹¹. ¹⁰ OJ L 298 of 26.10.2012, p. 1-96. ¹¹ OJ L 362 of 31.12.2012, p. 1-111.	[no change]	[no change]		20

(19) 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 EDCIP2 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 EDCIP2 Programme. Those rights should be provided for in the delegation agreement to be concluded between the Union and the EDCIP2-IS.	<i>[no change]</i>	<i>[no change]</i>	21
(20) In order to efficiently implement the EDCIP2 Programme, financial support should be provided by the EDCIP2-IS mainly in the form of grants to participants in actions selected at the level of the EDCIP2-IS. The selection of these actions should be made following open and competitive calls for proposals under the responsibility of the EDCIP2-IS.	<i>[no change]</i>	<i>[no change]</i>	22

(21) Participation in indirect actions under the EDC TP2 Programme is subject to Regulation (EU) No .../2013 of the European Parliament and of the Council of ... 2013 laying down the rules for the participation and dissemination in Horizon 2020 Framework Programme for Research and Innovation (2014-2020)¹². However, due to specific operating needs of the EDC TP2 Programme it is necessary to provide for derogations from that Regulation in accordance with Article 1(3) of that Regulation. ¹² OJ [H2020 RfP].	[no change]	[no change]	[no change]	23
(22) Derogations from Articles 8(1)(b), 9(1)(c) and 11 of Regulation (EU) No .../2013 are necessary in order to require participation and allow funding of African entities, and allow cooperation through joint calls between the EDC TP2 Programme and any other legal entity.	[no change]	[no change]	[no change]	24

(23) Audits of recipients of Union funds provided in accordance with this Decision should ensure a reduction of administrative burden, in compliance with the Horizon 2020 Framework Programme.	<i>[no change]</i>	<i>[no change]</i>	<i>[no change]</i>	25
(24) The Union's financial interests should be protected through 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.	<i>[no change]</i>	<i>[no change]</i>	<i>[no change]</i>	26
(25) The Commission should conduct interim evaluations, assessing in particular the quality and efficiency of EDCTP2, progress towards the objectives set and a final evaluation and prepare reports on those evaluations.	<i>[no change]</i>	<i>[no change]</i>	<i>[no change]</i>	27
(26) Upon request from the Commission, 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.	<i>[no change]</i>	<i>[no change]</i>	<i>[no change]</i>	28

(27) 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 EU legislation and local ethics requirements of the countries where the research activities are to be conducted.	[no change]	[no change]	29	
		AM 9 DEVE <i>(27a) It is also important that the activities conducted under the EDCTP2 Programme should meet developing countries' needs and match the Union's global health commitments and that those activities should be consistent with the Union's development policy actions, as provided for by Article 208 of the Treaty on the Functioning of the European Union.</i>	29.1	

(28) 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 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 that purpose.	[no change]	CA 3 SinceThe 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, appropriate and affordable medical interventions for poverty-related and neglected diseases; which are tailored to the specific needs and circumstances of the developing countries and 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, they can 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 that purpose.	30
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	<u>(28a) It is appropriate to ensure a smooth transition without interruption between the EDC TP1 and the EDC TP2 Programme, as well as to align the duration of the EDC TP2 Programme with the Council Regulation laying down the multiannual financial framework for the years 2014-2020¹⁵. Therefore, the EDC TP2 Programme should apply as from 1 January 2014.</u> <u>15 OJ ... [MFF]</u>			31
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		AM 4 <i>(28a) The participant guarantee fund set up under Regulation N° 1906/2006/EC of the European Parliament and of the Council of 18 December 2006 laying down the rules for the participation of undertakings, research centres and universities in actions under the Seventh Framework Programme and for the dissemination of research results (2007-2013) and managed by the Commissio has proved to be an important safeguard mechanism which mitigates the risks associated with the amounts due and not reimbursed by defaulting participants. However the new participant guarantee fund established under Regulation (EU) N°... [Rules for the participation and dissemination in Horizon 2020] may not be legally appropriate to EDCTP2, and the Commission should therefore come forward with proposals to ensure that the fund, or a similar fund, is available to cover all funding bodies related to EDCTP2.</i>		31.1
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		AM 54 <i>(28a) The results of clinical trials and other research activities carried out under the EDCP2 programme should be disseminated as soon as possible by appropriate means and in compliance with Regulation (EU) N° ... [Rules for the participation and dissemination in Horizon 2020], and in particular open access shall apply with regard to the dissemination through research publications.</i>		31.2
HAVE ADOPTED THIS DECISION:	<i>[no change]</i>	<i>[no change]</i>		32

COMMISSION PROPOSAL (doc. 12369/13)	COUNCIL GENERAL APPROACH (adopted on 03/12/13)	ITRE VOTE 23/01/14 PROVISIONAL	COMPROMISE TEXT	Line N°
<i>Article 1</i> <i>Participation in the second European and Developing Countries Clinical Trials Partnership Programme</i> 1. The Union shall participate in the second European and Developing Countries Clinical Trials Partnership Programme (hereinafter 'the EDC TP2 Programme'), jointly undertaken by Belgium, Denmark, Greece, Ireland, Italy, Luxembourg, the Netherlands, Austria, Portugal, Kingdom as well as Switzerland and Norway (hereinafter "participating states") in accordance with the conditions set out in this Decision.	<i>Article 1</i> <i>Participation in the second European and Developing Countries Clinical Trials Partnership Programme</i> 1. The Union shall participate in the second European and Developing Countries Clinical Trials Partnership Programme (hereinafter 'the EDC TP2 Programme'), jointly undertaken by Belgium, Denmark, Germany, Ireland, Greece, Spain, France, Italy, Luxembourg, the Netherlands, Austria, Portugal, <u>Finland</u>, Sweden, and the United Kingdom as well as Switzerland and Norway (hereinafter "participating states") in accordance with the conditions set out in this Decision.	<i>Article 1</i> <i>Participation in the second European and Developing Countries Clinical Trials Partnership Programme</i>		33
		<i>[no change]</i>		34

2. Any other Member State and any other country associated to the Horizon 2020 – The Framework Programme for Research and Innovation (2014 – 2020) established by Regulation (EU) No .../2013... (hereinafter “Horizon 2020 Framework Programme“) may participate in the EDCTP2 Programme provided it fulfils the criterion set out in Article 3(1)(e) of this Decision. Those Member States and countries associated to the Horizon 2020 Framework Programme that fulfil the condition set out in Article 3(1)(e) shall be regarded as ‘participating states’ for the purposes of this Decision.	[no change]	[no change]		35
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COMMISSION PROPOSAL (doc. 12369/13)	COUNCIL GENERAL APPROACH (adopted on 03/12/13)	ITRE VOTE 23/01/14 PROVISIONAL	COMPROMISE TEXT	Line N°
<i>Article 2</i> <i>Union's financial contribution</i>	<i>Article 2</i> <i>Union's financial contribution</i>	<u>CA4</u> <i>Article 2</i> <i>Union's financial contribution</i>		36
1. The maximum Union financial contribution, including EFTA appropriations, to the EDCTP2 Programme shall be EUR 683 million, as follows:	1. The maximum Union financial contribution, including EFTA appropriations, to the EDCTP2 Programme shall be EUR <u>648</u> million, as follows:	1. The maximum Union financial contribution, including EFTA appropriations, to the EDCTP2 Programme shall be EUR 683 648,85 million, as follows : <i>matching the contributions of the participating states covered in Article 1.</i>		37
(a) EUR 594 million to equal the contributions of participating states listed in article 1.1;	(a) EUR 594 564 million to equal the contributions of participating states listed in article 1.1;	(a) EUR 594 million to equal the contributions of participating states listed in article 1.1;		38
(b) EUR 89 million to equal the contributions of any other Member State or any other country associated to Horizon 2020 Framework Programme participating in the EDCTP2 Programme in accordance with Article 1.2.	(b) EUR 89 84 million to equal the contributions of any other Member State or any other country associated to Horizon 2020 Framework Programme participating in the EDCTP2 Programme in accordance with Article 1.2.	(b) EUR 89 million to equal the contributions of any other Member State or any other country associated to Horizon 2020 Framework Programme participating in the EDCTP2 Programme in accordance with Article 1.2.		39

2. The 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 Framework Programme, established by Decision .../2013/EU in accordance with Article 58(1)(c)(vi) and Articles 60 and 61 of Regulation (EU, Euratom) No 966/2012.	<i>[no change]</i>	2. The 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 Framework Programme, established by Decision .../2013/EU and in particular from the appropriations under the specific objective "Health, demographic change and wellbeing" in accordance with Article 58(1)(c)(vi) and Articles 60 and 61 of Regulation (EU, Euratom) No 966/2012.	40
3. Up to 6% of the Union's financial contribution may be used by the implementing structure of EDCTP2 (hereinafter "EDCTP2-IS") to cover its administrative costs.	<i>[no change]</i>	<i>[no change]</i>	41

COMMISSION PROPOSAL (doc. 12369/13)	COUNCIL GENERAL APPROACH (adopted on 03/12/13)	ITRE VOTE 23/01/14 PROVISIONAL	COMPROMISE TEXT	Line N°
<i>Article 3</i> <i>Conditions for the Union's financial contribution</i>	<i>Article 3</i> <i>Conditions for the Union's financial contribution</i>	<i>Article 3</i> <i>Conditions for the Union's financial contribution</i>		42
1. The Union's financial contribution shall be conditional upon the following:	[no change]	[no change]		43
(a) the demonstration by the participating states that the EDC/TP2 Programme is set up in accordance with Annexes I, II and III to this Decision;	[no change]	[no change]		44
		AM 68 <i>(a a) the demonstration by the Participating States that EDC/TP2 is set up in accordance with the objectives and research priorities of the health research challenge laid down in Regulation (EU) N°.../2013 of the European Parliament and of the Council of ... 2013 establishing Horizon 2020 and Council Decision .../2013/EU of ... 2013 establishing the Specific Programme implementing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020);</i>		44.1

		<u>AM 69</u> <i>(a b) the demonstration by the Participating States that EDC'TP2 is set up in accordance with the general principles governing the Horizon 2020 Framework;</i>		44.2
		<u>AM 70</u> <i>(a c) the demonstration by the Participating States that EDC'TP2 is set up in accordance with the conditions laid down in Article 20 of Regulation (EU) N° .../2013 of the European Parliament and of the Council of ... 2013 establishing Horizon 2020;</i> <i>[no change]</i>		44.3
(b) the designation by the participating states or organisations designated by the participating states of the EDC'TP2-IS, an entity with legal personality as the structure responsible for implementing the EDC'TP2 Programme and for receiving, allocating and monitoring the participating states' contribution, as well as the Union's financial contribution;	<i>[no change]</i>			45

(c) the demonstration by the EDC'TP2-IS of its capacity to implement the EDC'TP2 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;	[no change]	[no change]	46
(d) the establishment of a governance model for the EDC'TP2 Programme in accordance with Annex III;	[no change]	[no change]	47
(e) the commitment by each participating state to contribute to the financing of the EDC'TP2 Programme.	[no change]	AM 71 (e) the commitment by each participating state to contribute in cash and in kind to the financing of the EDC'TP2 Programme.	48
2. During the implementation of the EDC'TP2 Programme, the Union financial contribution shall be conditional upon the following:	[no change]	[no change]	49
(a) the implementation by the EDC'TP2-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 ... referred to in Article 6;	[no change]	[no change]	50

(b) the maintenance of an appropriate and efficient governance model for the EDCTP2 Programme in accordance with Annex III to this Decision;	<i>[no change]</i>	<i>[no change]</i>	<i>[no change]</i>	51
(c) the compliance by the EDCTP2-IS with the reporting requirements set out in Article 60(5) of Regulation (EU, Euratom) No 966/2012;	<i>[no change]</i>	<i>[no change]</i>	<i>[no change]</i>	52
(d) the fulfilment of the commitments referred to in point (e) paragraph 1.	<i>[no change]</i>	<i>[no change]</i>	<i>[no change]</i>	53

COMMISSION PROPOSAL (doc. 12369/13)	COUNCIL GENERAL APPROACH (adopted on 03/12/13)	ITRE VOTE 23/01/14 PROVISIONAL	COMPROMISE TEXT	Line N°
Article 4 <i>Activities of the EDCTP2 Programme</i>	Article 4 <i>Activities of the EDCTP2 Programme</i>	Article 4 <i>Activities of the EDCTP2 Programme</i>		54
1. The activities of the EDCTP2 Programme shall meet the objectives described in Annex I to this Decision and comply with Annex II.	[no change]	[no change]		55
Activities may include national programme activities of participating states and new activities, including calls for proposals managed by the EDCTP2-IS.	[no change]	AM 74 Activities may include activities undertaken by public or private not-for-profit research organisations included in the national programme activities of participating states and new activities, including calls for proposals managed by the EDCTP2-IS.		56

Activities shall be included in the work plan of the EDCTP2 Programme adopted annually by the EDCTP2-IS following the positive outcome of their external peer review based on Article 14(1) of Regulation (EU) No ... [Rules for the participation and dissemination in Horizon 2020], and with regard to their contribution to the objectives of the EDCTP2 Programme.	Activities shall be included in the work plan of the EDCTP2 Programme adopted annually by the EDCTP2-IS following the positive outcome of their external evaluation by international peer review based on Article 14(1) of Regulation (EU) No ... [Rules for the participation and dissemination in Horizon 2020], and <u>with regard to their contribution</u> to the objectives of the EDCTP2 Programme.	<u>AM 8</u> Activities shall be included in the work plan of the EDCTP2 Programme adopted annually by the EDCTP2-IS following the positive outcome of their external evaluation by international peer review based on Article 14(1) of Regulation (EU) No ... [Rules for the participation and dissemination in Horizon 2020], and <u>with regard to their contribution</u> to the objectives of the EDCTP2 Programme.	57
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2. The work plan shall detail the budgeted value of each activity and provide for the allocation of the funding managed by the EDCTP2-IS, including the Union contribution.	<i>[no change]</i>	<i>[no change]</i>	<i>[no change]</i>	58
The work plan shall differentiate between the activities funded or co-funded by the Union and those funded by participating states or other revenues.	<i>[no change]</i>	<i>[no change]</i>	<i>[no change]</i>	59
3. The EDCTP2-IS shall implement the annual work plan referred to in paragraph 1.	<i>[no change]</i>	<i>[no change]</i>	<i>[no change]</i>	60
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.	<i>[no change]</i>	<i>[no change]</i>	<i>[no change]</i>	61

4. Activities included in the 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 ... [Rules for the participation and dissemination in Horizon 2020], in particular 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 these activities.	<i>[no change]</i>	<i>[no change]</i>	62
Any activity funded by EDCTP2-IS in accordance with the work plan or following calls for proposals managed by the EDCTP2-IS, shall be considered as an indirect action under the meaning of Regulation (EU) No ... [Rules for the participation and dissemination in Horizon 2020] and be implemented in accordance with Article 6.	<i>[no change]</i>	<i>[no change]</i>	63

5. Any communication or publication related to activities of the EDCTP2 Programme, 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".	5. Any communication or publication related to in the area of activities of the EDCTP2 Programme, and performed in close collaboration with EDCTP-2 , 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" .	<i>[no change]</i>	64
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COMMISSION PROPOSAL (doc. 12369/13)	COUNCIL GENERAL APPROACH (adopted on 03/12/13)	ITRE VOTE 23/01/14 PROVISIONAL	COMPROMISE TEXT	Line N°
<i>Article 5</i> <i>Contributions from participating states</i>	<i>Article 5</i> <i>Contributions from participating states</i>	<i>Article 5</i> <i>Contributions from participating states</i>		65
1. Contributions from the participating states shall consist of the following:	[no change]	[no change]		66
(a) financial contributions to the EDC TP2-IS;	[no change]	[no change]		67
(b) in kind contributions consisting of the costs incurred by the participating states in implementing activities included in the work plan referred to in Article 4(1) or in relation to the administrative budget of the EDC TP2-IS.	[no change]	<u>AM 78</u> (b) in kind contributions consisting of the costs incurred by the participating states in implementing activities included upfront in the work plan referred to in Article 4(1) or in relation to the administrative budget of the EDC TP2-IS.		68
2. For the purpose of evaluating the contributions referred to in point (b) of paragraph 1, the costs shall be determined according to the usual accounting practices and accounting standards of the participating state concerned and to the applicable International Accounting Standards /International Financial Reporting Standards.	[no change]	[no change]		69

COMMISSION PROPOSAL (doc. 12369/13)	COUNCIL GENERAL APPROACH (adopted on 03/12/13)	ITRE VOTE 23/01/14 PROVISIONAL	COMPROMISE TEXT	Line N°
Article 6 <i>Rules for participation and dissemination</i>	Article 6 <i>Rules for participation and dissemination</i>	Article 6 <i>Rules for participation and dissemination</i>		70
1. Regulation (EU) No ... [Rules for the participation and dissemination in Horizon 2020] shall apply to indirect actions selected and funded by EDCTP-IS in accordance with the work plan referred to in Article 4(1) or following calls for proposals managed by EDCTP2-IS. In accordance with that Regulation, the EDCTP2-IS shall be considered a funding body and shall provide financial support to indirect actions in accordance with Annex II to this Decision.	[no change]	<u>AM 79</u> 1. Regulation (EU) No ... [Rules for the participation and dissemination in Horizon 2020] shall apply to indirect actions selected and funded by EDCTP-IS in accordance with the work plan referred to in Article 4(1) or following calls for proposals managed by EDCTP2-IS. In accordance with that Regulation, the EDCTP2-IS shall be considered a funding body and shall provide financial support to indirect actions in accordance with Annex II to this Decision.		71

2. By derogation from Article 8(1)(b) of Regulation (EU) No ... [Rules for the participation and dissemination in Horizon 2020], 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 EDC'P2 work plan referred to in Article 4(1) of this Decision.	<i>[no change]</i>	<i>[no change]</i>	72
3. By derogation from Article 9(1)(c) of Regulation (EU) No ... [Rules for the participation and dissemination in Horizon 2020], any legal entity established in a sub-Saharan country listed in the EDC'P2 work plan referred to in Article 4(1) of this Decision shall be eligible for funding.	<i>[no change]</i>	<i>[no change]</i>	73

4. Where such an activity is included in the workplan, EDC2TP2-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 and product development organisations, in accordance with the rules developed based on Article 11 of Regulation (EU) No ... [Rules for the participation and dissemination in Horizon 2020].	<i>[no change]</i>	AM 9 4. Where such an activity is included in the workplan, EDC2TP2-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 and product development organisations , in accordance with the rules developed based on Article 11 of Regulation (EU) No ... [Rules for the participation and dissemination in Horizon 2020].	74
		AM 10 4a. The participant guarantee fund established under Regulation (EU) N° ... [Rules for the participation and dissemination in Horizon 2020] may not be legally appropriate to EDC2TP2, and the Commission shall therefore come forward with proposals to ensure that the fund, or a similar fund, is available to cover all funding bodies related to EDC2TP2.	74.1

COMMISSION PROPOSAL (doc. 12369/13)	COUNCIL GENERAL APPROACH (adopted on 03/12/13)	ITRE VOTE 23/01/14 PROVISIONAL	COMPROMISE TEXT	Line N°
<i>Article 7</i> <i>Agreement between the Union and the</i> <i>EDCTP-IS</i>	<i>Article 7</i> <i>Agreement between the Union and the</i> <i>EDCTP-IS</i>	<i>Article 7</i> <i>Agreement between the Union and</i> <i>the EDCTP-IS</i>		75
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.	<i>[no change]</i>	<i>[no change]</i>		76
2. The delegation agreement referred to in paragraph 1 shall be concluded in accordance with Articles 58(3), 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:	<i>[no change]</i>	<i>[no change]</i>		77

(a) the requirements for the EDCTP2-IS contribution regarding the performance indicators set out in Annex II to Decision (EU) No ... [the Specific Programme implementing the Horizon 2020 Framework Programme];	<i>[no change]</i>	<i>[no change]</i>	78
(b) the requirements for the EDCTP2-IS contribution in relation to the monitoring referred to in Annex III to Decision (EU) No ... [the Specific Programme implementing the Horizon 2020 Framework Programme];	<i>[no change]</i>	<i>[no change]</i>	79
(c) the specific performance indicators related to the functioning of the EDCTP2-IS;	<i>[no change]</i>	<i>[no change]</i>	80
(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;	<i>[no change]</i>	<i>[no change]</i>	81
(e) the arrangements regarding the provision of data necessary to ensure that the Commission is able to meet its dissemination and reporting obligations;	<i>[no change]</i>	<i>[no change]</i>	82

(f) the modalities for approval or rejection by the Commission of the draft annual work plan of the EDCTP2 Programme referred to in Article 4(1), before it is adopted by the EDCTP2-IS.	<i>[no change]</i>	<i>[no change]</i>		83
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COMMISSION PROPOSAL (doc. 12369/13)	COUNCIL GENERAL APPROACH (adopted on 03/12/13)	ITRE VOTE 23/01/14 PROVISIONAL	COMPROMISE TEXT	Line N°
<i>Article 8</i> <i>Termination, reduction or suspension of the Union's financial contribution</i>	<i>Article 8</i> <i>Termination, reduction or suspension of the Union's financial contribution</i>	<i>Article 8</i> <i>Termination, reduction or suspension of the Union's financial contribution</i>		84
If the EDCTP2 Programme is not implemented or is implemented inadequately, partially or late, the Commission may terminate, proportionally reduce or suspend the Union's financial contribution in line with the actual implementation of the EDCTP2 Programme.	<i>[no change]</i>	<i>[no change]</i>		85
If the participating states do not contribute, contribute partially or late to the financing of the EDCTP2 Programme, the Commission may terminate, proportionally 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.	<i>[no change]</i>	<i>[no change]</i>		86

COMMISSION PROPOSAL (doc. 12369/13)	COUNCIL GENERAL APPROACH (adopted on 03/12/13)	ITRE VOTE 23/01/14 PROVISIONAL	COMPROMISE TEXT	Line N°
<i>Article 9 Ex-post audits</i> 1. Ex-post audits of expenditure on indirect actions shall be carried out by EDCTP2-IS in accordance with Article 23 of Regulation (EU) No ... [the Horizon 2020 Framework Programme].	<i>Article 9 Ex-post audits</i> 1. Ex-post audits of expenditure on indirect actions shall be carried out by EDCTP2-IS in accordance with Article [23] of Regulation (EU) No ... [the Horizon 2020 Framework Programme].	<i>Article 9 Ex-post audits</i> [no change]		87
2. The Commission may decide to carry out the audits referred to in paragraph 1 itself.	2. The Commission may decide to carry out the audits referred to in paragraph 1 itself. <u>The Commission shall only do so in duly justified cases and in consultation with the relevant Participating States.</u>			88
		<u>AM 11</u> 2. <i>Without prejudice to the independence or the role of the Court of Auditors of the European Union, the Commission may, in duly reasoned cases and in consultation with the participating states, decide to carry out the audits referred to in paragraph 1 itself.</i>		89

COMMISSION PROPOSAL (doc. 12369/13)	COUNCIL GENERAL APPROACH (adopted on 03/12/13)	ITRE VOTE 23/01/14 PROVISIONAL	COMPROMISE TEXT	Line N°
<i>Article 10</i> <i>Protection of the financial interests of the Union</i>	<i>Article 10</i> <i>Protection of the financial interests of the Union</i>	<i>Article 10</i> <i>Protection of the financial interests of the Union</i>		90
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.	<i>[no change]</i>	<i>[no change]</i>		91
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.	<i>[no change]</i>	<i>[no change]</i>		92

3. The European Anti-fraud Office (OLAF) may carry out investigations, including on-the-spot checks and inspections, in accordance with Council Regulation (Euratom, EC) No 2185/96¹³ and Regulation (EC) No 1073/1999 of the European Parliament and of the Council¹⁴ 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 an agreement or decision or a contract funded in accordance with this Decision. 13. OJ L 292, 15.11.1996, p. 2-5. 14. OJ L 136, 31.5.1999, p. 1-7.	3. The European Anti-fraud Office (OLAF) may carry out investigations, including on-the-spot checks and inspections, in accordance with Council Regulation (Euratom, EC) No 2185/96¹⁷ <u>the provisions and procedures laid down in Regulation (EC EU, Euratom) No 4073/1999 883/2013</u> of the European Parliament and of the Council¹⁸ <u>and Council Regulation (Euratom, EC) No 2185/96</u>¹⁹ 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 an agreement or decision or a contract funded in accordance with this Decision. 17. OJ L 292, 15.11.1996, p. 2-5. 18. <u>OJ L 248, 18.9.2013, p. 1.</u> 19. OJ L 136, 31.5.1999 292, <u>15.11.1996, p. 1-7 2-5.</u>	[no change]	93
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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, according to their competences.	<i>[no change]</i>	<i>[no change]</i>	<i>[no change]</i>	94
5. In implementing the EDCTP2 Programme, the participating states shall take the legislative, regulatory, administrative and other measures necessary for protecting 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.	<i>[no change]</i>	<i>[no change]</i>	<i>[no change]</i>	95

COMMISSION PROPOSAL (doc. 12369/13)	COUNCIL GENERAL APPROACH (adopted on 03/12/13)	ITRE VOTE 23/01/14 PROVISIONAL	COMPROMISE TEXT	Line N°
<i>Article 11</i> <i>Communication of information</i>	<i>Article 11</i> <i>Communication of information</i>	<i>Article 11</i> <i>Communication of information</i>		96
1. On request, the EDCTP2-IS shall send any information necessary for preparation of the reports referred to in Article 12 to the Commission.	<i>[no change]</i>	<i>[no change]</i>		97
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.	<i>[no change]</i>	<i>[no change]</i>		98
3. The Commission shall include the information referred to in paragraph 2 in the reports referred to in Article 12.	<i>[no change]</i>	<i>[no change]</i>		99
		AM 12 <i>3a. All calls and opportunities to participate shall be widely advertised, including on the Commission's Horizon 2020 website which shall include a chapter dedicated to EDCTP2.</i>		99.1

COMMISSION PROPOSAL (doc. 12369/13)	COUNCIL GENERAL APPROACH (adopted on 03/12/13)	ITRE VOTE 23/01/14 PROVISIONAL	COMPROMISE TEXT	Line N°
Article 12 <i>Evaluation</i>	Article 12 <i>Evaluation</i>	Article 12 <i>Evaluation</i>		100
1. By 31 December 2017 the Commission shall conduct 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 30 June 2018.	[no change]	CA 5 1. By 31 December 2017 30 June 2017 the Commission shall conduct an independent interim evaluation of the EDCTP2 Programme. The Commission shall prepare a report on that independent 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 30 June 2018 31 December 2017. The result of the independent interim evaluation of EDCTP2 shall be taken into account in the interim evaluation of Horizon 2020 In order to respond to unforeseen situations or to new developments and needs the Commission may, following the interim evaluation of Horizon 2020 as referred to in Article 32(3) of the Regulation (EU) N° 1291/2013 review, within the annual budgetary procedure, the budget of EDCTP2.		101

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 includes the results of that evaluation. The Commission shall send that report to the European Parliament and the Council.	<i>[no change]</i>	<i>[no change]</i>		102
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 the Council.	<i>[no change]</i>	<i>[no change]</i>		103

Art. 13

COMMISSION PROPOSAL (doc. 12369/13)	COUNCIL GENERAL APPROACH (adopted on 03/12/13)	ITRE VOTE 23/01/14 PROVISIONAL	COMPROMISE TEXT	Line N°
Article 13 <i>Entry into force</i> This Decision shall enter into force on the twentieth day following that of its publication in the <i>Official Journal of the European Union</i> .	Article 13 <i>Entry into force</i> This Decision shall enter into force on the twentieth day following that of its publication in the <i>Official Journal of the European Union</i> .	Article 13 <i>Entry into force</i>		104
		[no change]		105
	<u>It shall apply from 1 January 2014.</u>			106

COMMISSION PROPOSAL (doc. 12369/13)	COUNCIL GENERAL APPROACH (adopted on 03/12/13)	ITRE VOTE 23/01/14 PROVISIONAL	COMPROMISE TEXT	Line N°
Article 14 Addressees	Article 14 Addressees	Article 14 Addressees		107
This Decision is addressed to the Member States.	[no change]	[no change]		108
Done at Brussels	[no change]	[no change]		109
				110

OBJECTIVES OF THE EDC TP2 PROGRAMME

COMMISSION PROPOSAL (doc. 12369/13)	COUNCIL GENERAL APPROACH (adopted on 03/12/13)	ITRE VOTE 23/01/14 PROVISIONAL	COMPROMISE TEXT	Line N°
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 and affordable medical interventions for poverty-related diseases, in partnership with sub-Saharan Africa.	<i>[no change]</i>	CA 6 <i>[no change]</i>		111
	<i>[no change]</i>	<i>[no change]</i>		112
	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 and affordable medical interventions ²⁰ for poverty-related diseases, in partnership with sub-Saharan Africa. 20 <u>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.</u>	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 , appropriate and affordable medical interventions for poverty-related diseases, in partnership with sub-Saharan Africa.		113

(2) Specific Objectives	[no change]	[no change]		114
In order to contribute to the general objective, EDC/TP2 shall achieve the following specific objectives:	[no change]	[no change]		115
(a) an increased number of new or improved medical interventions for HIV/AIDS, tuberculosis, malaria and other poverty-related diseases, and by the end of the programme to have delivered at least one new medical intervention; to have issued at least 30 guidelines for improved or extended use of existing medical interventions; and to have progressed the clinical development of at least 20 candidate medical interventions;	(a) an increased number of new or improved medical interventions for HIV/AIDS, tuberculosis, malaria and other poverty-related diseases, and by the end of the programme to have delivered at least one new medical intervention; to have issued at least 30 guidelines for improved or extended use of existing medical interventions; and to have progressed the clinical development of at least 20 candidate medical interventions;	(a) an increased number of new or improved medical interventions for HIV/AIDS, tuberculosis, malaria and other poverty-related and neglected diseases, and by the end of the programme to have delivered at least one new medical intervention; to have issued at least 30 [xx/new] guidelines for improved or extended use of existing medical interventions; and to have progressed the clinical development of at least 20 [xx] candidate medical interventions;		116

(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);	<i>[no change]</i>	<i>[no change]</i>		117
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(c) better coordination, alignment and integration of relevant national programmes to increase the cost-effectiveness of European public investments;	<i>[no change]</i>	(c) better coordination, alignment and, <i>where appropriate</i> , integration of relevant national programmes to increase the cost-effectiveness of European public investments; <i>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 and neglected diseases.</i>	118
(d) extended international cooperation with other public and private funders;	<i>[no change]</i>	(d) extended international cooperation with other public and private funders <i>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;</i>	119

(e) an increased impact due to effective cooperation with relevant European Union initiatives, including its development assistance.	[no change]	(e) an increased impact due to effective cooperation better coordination, alignment and, where appropriate, integration with relevant European Union initiatives, including in particular its development assistance and other key initiatives to enhance research and development for poverty-related diseases, product development partnerships and other government-led programmes in order to better take advantage of synergies, create a more complete innovation chain from clinical trials to treatment delivery and increase the effectiveness of European public investments. In this context, synergies between EDCTP2 and the European Development Fund are essential.	120
		<u>AM 95</u> (e a) contribution to the exploration of open innovation models for needs driven research, and available and affordable outcomes in alignment with other EU commitments in health R&D.	120.1

(3) Operational Objectives	<i>[no change]</i>	(3) Operational Indicators and Objectives	121
In order to reach the specific objectives set out in point 2, the following operational objectives, including indicative targets, shall be met by the end of the EDCTP2 programme in 2024:	<i>[no change]</i>	In order to reach the specific objectives set out in point 2, the following operational objectives, including indicative targets, indicators shall be met by the end monitored during the course of the EDCTP2 programme in 2024 .	122
(a) Support clinical trials on new or improved medical interventions for poverty-related diseases through partnerships between European and developing countries, in particular sub-Saharan Africa:	<i>[no change]</i>	(a) Support clinical trials on new or improved medical interventions for poverty-related and neglected diseases through partnerships between European and developing countries, in particular sub-Saharan Africa:	123
Target: increase the number of supported clinical trials to at least 150 compared to 88 under EDCTP1.	<i>[no change]</i>	Target Indicator : increase the number of supported clinical trials, to at least 150 compared to 88 under EDCTP1, compared to 88 under EDCTP1, that lead to new products, processes, methodologies, diagnostics, treatments or preventions.	124

Target: sustain or increase the proportion of clinical trials funded by the EDCP2-IS with African leadership to at least 50 %.	[no change]	Target Indicator : sustain or increase the proportion of clinical trials funded by the EDCP2-IS with African leadership to at least 50 %.	125
Target: Increase the number of peer-reviewed scientific articles published to at least 1000.	[no change]	Target Indicator : <i>Aim to increase the number of peer-reviewed scientific articles published to at least 1000 three times that of EDCP1.</i>	126
(b) Support research capacity-building activities in sub-Saharan Africa enabling clinical trials to be conducted and helping to reduce the brain drain:	[no change]	[no change]	127
Target: sustain or increase the number of sub-Saharan African countries supported by the EDCP2 to at least 30.	[no change]	Target Indicator : <i>aim to sustain or increase the number participation of sub-Saharan African countries supported by in the EDCP2 to at least 30.</i>	128
Target: increase the number of fellowships to sub-Saharan African researchers and MSc/PhD students to at least 600 compared to 400 under EDCP1, with at least 90 % of them continuing their research career in sub-Saharan Africa for at least one year after their fellowship.	[no change]	Target Indicator : increase the number of fellowships to sub-Saharan African researchers and MSc/PhD students to at least 600 compared to from 400 under EDCP1, with at least 90 % of strongly encouraging and supporting them to continuing continue their research career in sub-Saharan Africa for at least one year after following their fellowship.	129

Target: increase the number of capacity-building activities supported for conducting clinical trials in sub-Saharan Africa to at least 150 compared to 74 under EDCTP1.	<i>[no change]</i>	Target Indicator : increase the number of capacity-building activities supported for conducting clinical trials in sub-Saharan Africa to at least 150 compared to from 74 under EDCTP1.	130
(c) Develop a common research agenda, criteria for priority setting and common evaluation:	<i>[no change]</i>	(c) Develop a common 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, for example national programmes may contribute in kind whereas EDCTP may not.	131
Target: at least 50 % of the public investment by participating European states are integrated, aligned or coordinated through the EDCTP2 Programme.	<i>[no change]</i>	<i>[no change]</i>	132
(d) Ensure efficiency of the implementation of the EDCTP2 Programme:	<i>[no change]</i>	<i>[no change]</i>	133
Target: administrative costs are below 5 % of the EDCTP2-IS budget.	<i>[no change]</i>	<i>[no change]</i>	134

(e) Establish cooperation and launch joint actions with other public and private funders.	<i>[no change]</i>	(e) Establish cooperation and launch joint actions with other public and private funders partners, in order to increase their financial contribution to EDCTP.	135
Target: increase the contributions received from developing countries to at least EUR 30 million compared to EUR 14 million under EDCTP1.	<i>[no change]</i>	Target: increase the contributions received from developing countries to at least EUR 30 million compared to EUR 14 million under EDCTP1.	136
Target: obtain additional contributions, either public or private, of at least EUR 71 million compared to EUR 71 million under EDCTP1.	<i>[no change]</i>	Target: obtain additional contributions, either public or private, of at least EUR 500 million compared to EUR 71 million under EDCTP1.	137

(f) Establish cooperation and launch joint actions with Union, national and international development assistance initiatives in order to ensure complementarity and increase the impact of the results of EDCTP-funded activities.	<i>[no change]</i>	(f) Establish cooperation and launch joint actions with Union, national and international development assistance initiatives in order to ensure complementarity and increase the impact of the results of EDCTP2-funded activities. <i>In particular and where appropriate, coordinate EDCTP2-funded activities with initiatives resulting from the WHO Consultative Expert Working Group (CEWG) process on financing and coordination of R&D.</i>	138
		(fa) <i>Raise the profile of actions carried out under the EDCTP2 Programme at European and global level, in particular in developing countries, by making use of political dialogue for a such as the ACP-EU Joint Parliamentary Assembly or EU-Africa Summits.</i>	138.1

ACTIVITIES AND IMPLEMENTATION OF THE EDCTP2 PROGRAMME

COMMISSION PROPOSAL (doc. 12369/13)	COUNCIL GENERAL APPROACH (adopted on 03/12/13)	ITRE VOTE 23/01/14 PROVISIONAL	COMPROMISE TEXT	Line N°
(1) Activities The EDCTP2 Programme shall include the following activities:	<i>[no change]</i>	CA 7 <i>[no change]</i>		139
(a) promoting networking, coordination, alignment, cooperation and integration of national research programmes and activities on poverty-related infectious diseases at scientific, management and financial level;	<i>[no change]</i>	<i>[no change]</i>		140
	<i>[no change]</i>	(a) promoting networking, coordination, alignment, collaboration , cooperation and integration of national research programmes and activities on poverty-related infectious and neglected diseases at scientific, management and financial level; (CA 7+AM 110)		141
(b) supporting clinical trial research and related activities on poverty-related diseases, in particular HIV/AIDS, malaria, tuberculosis and neglected infectious diseases;	(b) supporting clinical trial research and related activities on poverty-related diseases, in particular HIV/AIDS, malaria, tuberculosis and neglected infectious diseases that are poverty-related ;	(b) supporting clinical trial research and related activities on poverty-related diseases, in particular HIV/AIDS, malaria, tuberculosis and other poverty related and neglected infectious diseases ; Special attention should be devoted to neglected diseases that are already affecting Sub-Saharan Africa and Europe.		142

(c) fostering capacity development for clinical trials and related research in developing countries through grants for: career development of junior/senior fellows, promoting mobility, staff exchange grants, research training networks, strengthening ethics and regulatory bodies, mentoring and partnerships at individual or institutional level;	<i>[no change]</i>	(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/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;	143
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(d) establishing cooperation and launching joint actions with other public and private funders;	<i>[no change]</i>	(d) establishing cooperation and launching joint actions with other public and private funders, including industry and product development partnerships, aiming at reinforcing national health systems and facilitating transfers of results to the population concerned;	144
(e) assuring awareness, endorsement and acknowledgment of the EDCTP2 Programme and its activities through advocacy and communication.	<i>[no change]</i>	(e) assuring awareness, endorsement and acknowledgment of the EDCTP2 Programme and its activities through advocacy and communication, not only at European Union level and in developing countries, but also at global level.	145
(2) Programme definition and implementation	<i>[no change]</i>	<i>[no change]</i>	146
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 and adopted by the General Assembly of the EDCTP2-IS following international peer-review and subject to the prior approval by the Commission.	<i>[no change]</i>	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.	147

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.	[no change]	The annual work plan shall identify topics and activities to be implemented, <i>in coordination, where appropriate, with national programmes, including activities initiated by participating states and</i> 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. <i>EDCTP2 should seek scientific coordination and, where relevant, exchange of information with relevant public or private initiatives including those under Horizon 2020 such as the Innovative Medicines Initiative and the Strategic Panel for Health.</i>	148
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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.	<i>[no change]</i>	<i>[no change]</i>	149
The multiannual strategic work plan shall set a common strategic research agenda which shall be prepared and updated on an annual basis.	<i>[no change]</i>	<i>[no change]</i>	150
EDCTP2-IS shall monitor the implementation of the activities included in the workplan, including indirect actions selected through calls for proposals it manages. It shall allocate and manage funding to these in accordance with this Decision and the effective implementation of activities selected and identified in the previous workplans.	<i>[no change]</i>	<i>[no change]</i>	151

(3) Deliverables expected from the implementation of the EDCTP2 Programme	<i>[no change]</i>	<i>[no change]</i>	152
An annual report shall be provided by 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 EDCTP-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	<i>[no change]</i>	An annual report shall be provided by 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 EDCTP-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 <i>and measures taken to ensure access to emerging products for populations in developing countries.</i>	153

With regards to calls managed by EDCTP-IS, the annual report shall moreover include information on the number of projects submitted and selected for funding, the detailed use of the Union financial contribution, the distribution of national and other contributions, the types of participants, country statistics, brokerage events and dissemination activities.	With regards to calls managed by EDCTP-IS, the annual report shall moreover include information on the number of projects submitted and selected for funding, the detailed use of the Union financial contribution, the distribution of national and other contributions, the types of participants, country statistics, brokerage events and dissemination activities, and measures taken to ensure access to emerging products.	154
With regards to calls managed by EDCTP-IS, the annual report shall moreover include information on the number of projects submitted and selected for funding, the detailed use of the Union financial contribution, the distribution of national and other contributions <u>including specification on the type of in kind contributions</u> , the types of participants, country statistics, brokerage events and dissemination activities.	[no change]	155
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.	[no change]	156

GOVERNANCE OF THE EDCTP2 PROGRAMME

COMMISSION PROPOSAL (doc. 12369/13)	COUNCIL GENERAL APPROACH (adopted on 03/12/13)	ITRE VOTE 23/01/14 PROVISIONAL	COMPROMISE TEXT	Line N°
The organisational structure of the EDCTP2 Programme shall comprise the following:	<i>[no change]</i>	CA 8 <i>[no change]</i>		157
(1) The EDCTP2-IS shall be governed by a general assembly (hereinafter "GA"), in which all participating states are represented.	<i>[no change]</i>	<i>[no change]</i>		158
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.	<i>[no change]</i>	<i>[no change]</i>		159
The GA shall decide by consensus. Failing consensus, the GA shall take its decisions by a majority of at least 75% of the votes	<i>[no change]</i>	<i>[no change]</i>		160
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.	<i>[no change]</i>	<i>[no change]</i>		161

(2) The GA shall appoint a management board that shall supervise the secretariat of the EDCTP2-IS (hereinafter "SEC") established by the GA as the executive body of the EDCTP2 Programme.	(2) The GA shall appoint a management board that shall supervise the secretariat of the EDCTP2-IS (hereinafter "SEC") established by the GA as the executive body of the EDCTP2 Programme. <u>The Board of Association shall consist of such number of Board Members as the GA may determine, but not less than five.</u>	[no change]	162
SEC shall have the following tasks:	[no change]	SEC shall have at least the following tasks:	163
(a) represent the EDCTP2-IS;	[no change]	(a) represent the EDCTP2-IS execute the annual work plan;	164
(b) provide support to the GA;	[no change]	[no change]	165
(c) implement the EDCTP2 Programme and manage those of its activities entrusted to EDCTP2-IS by the annual work plan;	[no change]	(c) implement the EDCTP2 Programme and manage those of its activities entrusted to EDCTP2-IS by the annual work plan;	166
(d) monitor and report on the implementation of the EDCTP2 Programme;	[no change]	[no change]	167
(e) 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;	[no change]	[no change]	168
(f) increase the visibility of the EDCTP2 Programme through advocacy and communication;	[no change]	[no change]	169

(g) liaise with the Commission in accordance with the delegation agreement referred to in Article 7.	<i>[no change]</i>	<i>[no change]</i>	170
3. A Scientific Advisory Committee (hereinafter 'SAC') shall advise the GA on the strategic priorities of the EDCTP2 Programme.	<i>[no change]</i>	3. A Scientific Strategic Advisory Committee (hereinafter 'SAC') shall advise the GA on the provide strategic priorities of the EDCTP2 Programme and scientific advice to the GA, the Board and the SEC.	171
The SAC shall be appointed by the GA and consist of European and African independent experts competent in areas relevant to the EDCTP2 Programme.	<i>[no change]</i>	AM 136 The SAC shall be appointed by the GA and consist of European and African independent experts competent in areas relevant to the EDCTP2 Programme. Its composition shall seek to achieve gender equality in accordance with Article 15 of the Regulation (EU) N° .../2013 of the European Parliament and of the Council of ... 2013 establishing Horizon 2020.	172
The SAC shall have the following tasks:	<i>[no change]</i>	<i>[no change]</i>	173
(a) advise the GA on priorities and strategic needs regarding clinical trials in Africa	<i>[no change]</i>	<i>[no change]</i>	174

(b) review and 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	<i>[no change]</i>	(b) review and 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 <i>[no change]</i>	175
(c) review the scientific and technical aspects of the implementation of the EDCTP2 Programme and deliver an opinion on its annual report	<i>[no change]</i>		176
		<i>(ca) advise, where appropriate, on target product profiles in order to guide investment decisions according to agreed priorities.</i> <i>[no change]</i>	176.1
In exercising its tasks, the SAC shall monitor and promote high standards of ethical conduct of clinical trials and engage with vaccine regulatory authorities.	<i>[no change]</i>		177

The SAC may recommend to the GA the setting up of scientific subcommittees, task forces and working groups.	<i>[no change]</i>	<i>[no change]</i>	178
The GA shall establish the number of SAC members, their voting rights and the modalities of their appointment in accordance with Article 37 of Regulation (EU) No ... [Rules for the participation and dissemination in Horizon 2020]. The GA may set up specialised working groups under the SAC with additional independent experts for specific tasks.	<i>[no change]</i>	<i>[no change]</i>	179
