COUNCIL OF THE EUROPEAN UNION

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NOTE

From:	Permanent Representatives Committee (Part I)
To:	Council
No. prev. doc.:	15988/13 RECH 520 SAN 438 SOC 920 CODEC 2590
No. Cion doc.:	12369/13 RECH 356 SAN 271 SOC 596
Subject:	Proposals by the Commission to establish public-public partnerships with Member States under Article 185 TFEU for joint implementation of national research programmes 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 - General approach

I. INTRODUCTION

1. On 10 July 2013, the Commission submitted to the European Parliament and to the Council its 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 ("EDCTP2") jointly undertaken by several Member States.

2. The general objective of the EDCTP2 programme is to 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. EDCTP2 is the successor to the current EDCTP programme under FP7.

3. The European Parliament's Committee on Industry, Research and Energy (ITRE) appointed Ms. Vicky FORD (ECR) as the Rapporteur on this proposal. ITRE Committee is expected to vote on its amendments to the Commission proposal on 9 January 2014.

4. The opinion of the European Economic and Social Committee is still pending.

II. WORK WITHIN THE COUNCIL

1. Following the work since September 2013 within the Research Working Party, resulting to some amendments to the initial proposal, the Permanent Representatives Committee on 22 November 2013 reached an agreement in principle on the Presidency compromise text included in annex to this note. In comparison with the previous document (15988/13), the new text is indicated in **bold** and deletions in ~~strikethrough~~.

2. It should be noted that the Commission has entered a general reservation on the whole text, pending the opinion of the European Parliament. Furthermore, DK has a parliamentary scrutiny reservation on the whole text.

III. CONCLUSION

In the light of the above, the Council is invited to consider the compromise proposal presented by the Presidency (in Annex) with a view to reaching a General Approach at the Council (Competitiveness) meeting on 2-3 December 2013.

ANNEX

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.

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 Articles 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 ,

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) In its Communication Europe 2020 A Strategy for smart, sustainable and inclusive growth , 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.

(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 … 2013 (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.

(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 States , 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 2002 . 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 .

(4) 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 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.

(5) According to Council Decision … /2013/EU of … 2013 establishing the Specific Programme implementing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020) further support may be provided to the EDCTP2 Programme.

(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.

(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.

(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’.

(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.

(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.

(11) The Commission presented a communication on 31 March 2010 on the Union’s role in global health[1] which calls for a more coordinated approach among Member States and across relevant policies to identify and jointly address shared global priorities for health research.

(12) The Commission presented a communication on 21 September 2011 on partnering in research and innovation[2] which puts partnerships across institutional, national and continental borders at the centre of the Union’s research policy.

(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.

(14) The participating states intend to contribute to the implementation of EDCTP2 Programme during the period covered by the EDCTP2 Programme (2014 – 2024).

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1 COM(2010)128 final.

2 COM(2011) 572 final.

(15) A ceiling should be established for the Union's participation in EDCTP2 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 EDCTP2 Programme during the Horizon 2020 Framework Programme.

(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.

(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.

(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 Union[3] and Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012[4].

(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 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.

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[3] OJ L 298 of 26.10.2012, p. 1-96.

[4] OJ L 362 of 31.12.2012, p. 1-111.

(20) In order to efficiently implement the EDCTP2 Programme, 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 these actions should be made following open and competitive calls for proposals under the responsibility of the EDCTP2-IS.

(21) Participation in indirect actions under the EDCTP2 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)[5]. However, due to 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.

(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 EDCTP2 Programme and any other legal entity.

(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.

(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.

(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.

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[5] OJ [H2020 RfP].

(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.

(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.

(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.

(28a) It is appropriate to ensure a smooth transition without interruption between the EDCTP1 and the EDCTP2 Programme, as well as to align the duration of the EDCTP2 Programme with the Council Regulation laying down the multiannual financial framework for the years 2014-2020[6]. Therefore, the EDCTP2 Programme should apply as from 1 January 2014.

HAVE ADOPTED THIS DECISION:

[6] OJ … [MFF]

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 (hereinafter 'the EDCTP2 Programme'), jointly undertaken by ~~Belgium,~~ Denmark, Germany, Ireland, Greece, Spain, France, Italy, Luxembourg, the Netherlands, Austria, Portugal, **Finland,** Sweden, and the United Kingdom as well as Switzerland and Norway (hereinafter "participating states") in accordance with the conditions set out in this Decision.

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.

Article 2

Union's financial contribution

1. The maximum Union financial contribution, including EFTA appropriations, to the EDCTP2 Programme shall be ~~[~~EUR ~~600~~ **648** million~~]~~[7], as follows:

   (a) ~~[~~EUR ~~XXX~~ **564** million~~]~~ to equal the contributions of participating states listed in article 1.1;

   (b) ~~[~~EUR ~~XXX~~ **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.

[7] ~~Once the overall figure of Union's financial contribution is agreed, figures under Article 2.1(a) and 2.1(b) will be adjusted accordingly.~~

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.

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.

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 to this Decision;

   (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;

   (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 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 … referred to in Article 6;

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

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

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

Article 4

Activities of the EDCTP2 Programme

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

Activities may include national programme activities of participating states 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 following the positive outcome of their external evaluation by international peer review and with regard to the objectives of the EDCTP2 Programme.

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.

   The 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 annual work plan referred to in paragraph 1.

   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 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.

   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.

5. Any communication or publication in the area of 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 in the work plan referred to in Article 4(1) 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 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.

Article 6

Rules for participation and dissemination

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.

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 EDCTP2 work plan referred to in Article 4(1) of this Decision.

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 EDCTP2 work plan referred to in Article 4(1) of this Decision shall be eligible for funding.

4. Where such an activity is included in the workplan, 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 11 of Regulation (EU) No … [Rules for the participation and dissemination in Horizon 2020].

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 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:

   (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];

   (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];

   (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 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.

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, proportionally 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, 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.

Article 9

Ex-post audits

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].

2. The Commission may decide to carry out the audits referred to in paragraph 1 itself. The Commission shall only do so in duly justified cases and in consultation with the relevant Participating States.

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 Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council[8] and Council Regulation (Euratom, EC) No 2185/96[9] 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.

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.

[8] OJ L 248, 18.9.2013, p.1.
[9] OJ L 292, 15.11.1996, p. 2-5.

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.

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 in the reports referred to in Article 12.

Article 12

Evaluation

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.

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.

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.

Article 13

Entry into force

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

It shall apply from 1 January 2014.

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 TO THE ANNEX

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 and affordable medical interventions[10] 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, 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;

[10] 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 integration of relevant national programmes to increase the cost-effectiveness of European public investments;

d) extended international cooperation with other public and private funders;

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

3) Operational Objectives

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:

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:

Target: increase the number of supported clinical trials to at least 150 compared to 88 under EDCTP1.

Target: sustain or increase the proportion of clinical trials funded by the EDCTP2-IS with African leadership to at least 50%.

Target: Increase the number of peer-reviewed scientific articles published to at least 1000.

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

Target: sustain or increase the number of sub-Saharan African countries supported by the EDCTP2 to at least 30.

Target: increase the number of fellowships to sub-Saharan African researchers and MSc/PhD students to at least 600 compared to 400 under EDCTP1, with at least 90 % of them continuing their research career in sub-Sahara Africa for at least one year after their fellowship.

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.

c) Develop a common research agenda, criteria for priority setting and common evaluation:

Target: at least 50 % of the public investment by participating European 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 million compared to EUR 14 million under EDCTP1.

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

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.

ANNEX II TO THE ANNEX

ACTIVITIES AND IMPLEMENTATION OF THE EDCTP2 PROGRAMME

1) Activities

The EDCTP2 Programme shall include the following activities:

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;

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;

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;

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.

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 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.

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 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.

3) Deliverables expected from the implementation of the EDCTP2 Programme

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.

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 including specification on the type of in kind contributions, the types of participants, country statistics, brokerage events and dissemination activities.

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 TO THE ANNEX

GOVERNANCE OF THE EDCTP2 PROGRAMME

The organisational structure of the EDCTP2 Programme shall comprise the following:

1) The EDCTP2-IS shall be governed by a general assembly (hereinafter "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 (hereinafter "SEC") established by the GA as the executive body of the EDCTP2 Programme. **The Board of the Association shall consist of such number of Board Members as the GA may determine, but not less than five.**

   SEC shall have the following tasks:

   a) represent the EDCTP2-IS;

   b) provide support to the GA;

   c) implement the EDCTP2 Programme and manage those of its activities entrusted to EDCTP2-IS by the annual work plan

   d) monitor and report on the implementation of the EDCTP2 Programme;

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;

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

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

3) A Scientific Advisory Committee (hereinafter '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.

The SAC shall have the following tasks:

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

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

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 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.