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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

(Text with EEA relevance)

{SWD(2013) 253 final}
{SWD(2013) 254 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

The European and Developing Countries Clinical Trials Partnership (EDCTP) was established in 2003 in response to the global health crisis caused by the three main poverty-related diseases — HIV/AIDS, malaria and tuberculosis — and to the EU's commitment to achieving the United Nation's Millennium Development Goals by 2015. The first EDCTP programme (EDCTP1, 2003-2012) is now beyond its active funding period.

Despite the results and impact of EDCTP so far, the health and socio-economic burden of poverty-related diseases persists and hinders the sustainable development of developing countries, in particular in sub-Saharan Africa. More than one billion people, including 400 million children, are suffering from one or more poverty-related diseases, including neglected infectious diseases such as sleeping sickness and worm infections. HIV/AIDS alone kills an estimated 2 million people, while malaria and tuberculosis together kill an estimated 2.2 million people annually. In addition to creating unnecessary suffering and premature deaths these diseases undermine productivity and increase insecurity and infirmity, thus perpetuating the cycle of poverty. Sub-Saharan Africa is disproportionately affected by such diseases, with approximately 90% of all malaria-related deaths occurring in Africa. This region also accounts for over two thirds of all people living with HIV and for nearly three quarters of AIDS-related deaths.

While general improvements in nutrition, sanitation and health infrastructure are important, the effective long-term control of poverty-related diseases also requires the development of new or improved medical interventions (products, treatments and vaccines). While there is a general lack of such medical products, many of the existing drugs and vaccines currently used date back to the early 20th century and, moreover, are no longer effective due to the emergence of drug resistance in these diseases. Most of the new drugs and vaccines under development, however, are stuck at the stage of early clinical development. This is mainly due to the significant costs involved in the clinical development and testing needed in humans to prove the effectiveness and safety of new or improved medical interventions. These costs are linked to three key problem drivers: (i) insufficient investment by the private sector due to a lack of return on investment (market failures), (ii) weak clinical research capacity in sub-Saharan African countries, and (iii) fragmented public support.

Following the recommendations from the independent interim evaluation of EDCTP1 and the conclusions from the Member States' meeting in September 2010, the Belgian EU Council Presidency proposed to the Competitiveness Council on 26 November 2010 the launch of a second EDCTP joint programme (EDCTP2) with at least ten years duration. To that end, the EDCTP1 participating states published a Strategic Business Plan 2014-2024 for EDCTP2.

On these grounds, the Commission puts forward a proposal for a Decision on the participation of the EU in a second European and Developing Countries Clinical Trials Partnership Programme (EDCTP2) based on Article 185 of the Treaty on the Functioning of the EU, which makes provision for the EU to participate in research and development programmes undertaken by several Member States.

Aim of EDCTP2

The general objective of EDCTP2 is to improve the EU''s capacity to invest more efficiently in the research and development of new or improved medical interventions against poverty-related diseases for the benefit of and in partnership with developing countries, in particular sub-Saharan African countries.

More specifically, EDCTP2 aims to achieve the following specific objectives:

- 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, such as a new drug or a new vaccine against TB or any other poverty-related disease; 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.
- Strengthened cooperation with sub-Saharan African countries, in particular on building their capacity for conducting clinical trials in full compliance with fundamental ethical principles and relevant national, Union and international legislation, including the EU's Charter of Fundamental Rights, the European Convention on Human Rights and its Supplementary Protocols, the 2008 version of the World Medical Association's Declaration of Helsinki and the standards on good clinical practice of the International Conference on Harmonisation.
- Better coordination, alignment and integration of relevant national programmes to increase the cost-effectiveness of European public investments.
- Extended international cooperation with other public and private funders.
- An increased impact due to effective cooperation with relevant EU initiatives, including EU development assistance.

EDCTP2 has been conceived to complement the actions implemented under the European Development Funds and the Development Cooperation Instruments, and to respond to the Union's commitment to the 2012 Rio+20 conference conclusions on developing and achieving internationally agreed Sustainable Development Goals, following and including the Millennium Development Goals.

2. RESULTS OF CONSULTATIONS WITH THE INTERESTED PARTIES AND IMPACT ASSESSMENTS

The preparation of the proposal has taken full account of the responses received to an extensive stakeholder consultation, including a public consultation. Views were expressed by European and African policy makers as well as stakeholders from industry, academia and civil society. The proposal also relies on the external interim evaluations of the EDCTP1 programme and the in-depth impact assessment of the prospective EDCTP2 programme. These consultations, evaluations and assessments of the EDCTP consistently call for it to be continued but with the next programme lasting 10 years and covering a scope that extends to other poverty-related diseases (beyond HIV/AIDS, tuberculosis and malaria) and to all phases of clinical development. The geographical focus should continue to be on sub-Saharan Africa, which is disproportionally affected by poverty-related diseases and with which the Union has established a strategic partnership.

3. LEGAL ELEMENTS OF THE PROPOSAL

3.1 Legal basis

The proposal for the EDCTP2 Programme is based on Article 185 of the Treaty on the Functioning of the EU, which allows the Union, in implementing the multiannual framework programme, to make provision, for participation in research and development programmes

undertaken by several Member States, in agreement with the Member States concerned, including participation in the structures created for the execution of those programmes.

3.2 Subsidiarity principle

The fundamental basis of the EDCTP initiative is the joint programme being based on and composed of national programmes and activities of the participating Member States and Associated Countries, with the support and participation of the Union.

It improves cost-effectiveness of Europe's investment in clinical research programmes by providing a common platform that can better exploit research results for the development of new or improved medical interventions against HIV/AIDS, malaria, tuberculosis and other poverty-related diseases for the benefit of the developing countries, in particular in sub-Saharan Africa. The expected impact at the European level will be greater than the sum of the impacts of national programmes and activities. It will allow the required critical mass to be achieved, both in human and financial terms, by bringing together available complementary expertise and resources to accelerate the development of new or improved medical interventions that are urgently needed to reduce the devastating impact of poverty-related diseases in developing countries. Furthermore, at the global level it contributes to a unified voice to represent European research efforts in the fight against these diseases in developing countries. Finally, it promotes a long-term structuring effect on European and developing countries' research policies and systems alike, and helps to integrate the EU's research and development policies and systems in a coherent context.

The Commission's proposal for Horizon 2020 makes provision for the Union's continued participation in a second EDCTP programme under Article 185 of the Treaty, which is the appropriate instrument for the Union to support the EDCTP since it allows for both the coordination of national research programmes and the participation of the Union in the joint programme.

3.3 Proportionality principle

The proposal does not go beyond what is necessary to achieve its objectives. Union participation in the EDCTP2 Programme will take place within the limits of the competence provided by the Treaty and will only facilitate and support, including financially, the fulfilment of the EDCTP2 objectives by the participating states. They will have to collaborate and work towards reaching better coordination, alignment and integration of relevant national programmes or activities and ultimately developing more and better medical interventions against HIV/AIDS, tuberculosis, malaria, as well as other poverty related diseases.

4. BUDGETARY IMPLICATION

The Legislative Financial Statement presented with this decision sets out the indicative budgetary implications. The Union contribution shall be up to EUR 683 million[1] including EFTA contribution. The envelope is in current prices. The Union contribution shall be made from the 'Health, demographic change and wellbeing' challenge, DG Research & Innovation envelope, as part of the implementation of Horizon 2020 – The Framework Programme for Research and Innovation. The maximum amount of Union contribution for administrative costs is up to EUR 41 million.

[1] The amount is indicative and will depend on the final amount for the DG Research & Innovation under the above-mentioned challenge.

During the course of the action, the Union may consider matching additional commitments from Participating Member States or countries associated to Horizon 2020 Framework Programme.

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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[2],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) In its Communication Europe 2020 A Strategy for smart, sustainable and inclusive growth[3], 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[4] (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[5], 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

2 OJ C …[ESC opinion].
3 COM(2010)2020 final of 3.3.2010.
4 OJ... [Horizon 2020 Framework Programme].
5 OJ L 169 of 8.7.2003, p. 1-5.

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[6]. 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[7].

(4) In 2009, independent experts adopted the report of the interim evaluation of EDCTP1[8]. 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)[9] 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

6 OJ L 232 of 29.8.2002, p. 1-33.
7 OJ L 412 of 30.12.2006, p. 1-43.
8 Van Velzen et al., Independent External Evaluation Report, December 2009.
9 OJ L … [Horizon 2020 Specific Programme].

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[10] 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[11] 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).

(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[12] and Commission Delegated

[10] COM(2010)128 final.
[11] COM(2011) 572 final.
[12] OJ L 298 of 26.10.2012, p. 1-96.

Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012[13].

(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.

(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)[14]. 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.

(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

[13] OJ L 362 of 31.12.2012, p. 1-111.
[14] OJ [H2020 RfP].

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.

HAVE ADOPTED THIS DECISION:

Article 1

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

1. The Union shall participate in the second European and Developing Countries Clinical Trials Partnership Programme (hereinafter 'the EDCTP2 Programme'), jointly undertaken by Belgium, Denmark, Germany, Ireland, Greece, Spain, France, Italy, Luxembourg, the Netherlands, Austria, Portugal, 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 683 million, as follows:

   (a) EUR 594 million to equal the contributions of participating states listed in article 1.1;

   (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.

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 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.

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 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".

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.

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 Council Regulation (Euratom, EC) No 2185/96 [15] and Regulation (EC) No 1073/1999 of the European Parliament and of the Council[16] 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.

[15] OJ L 292, 15.11.1996, p. 2-5.
[16] OJ L 136, 31.5.1999, p. 1–7.

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.

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 twentieth day following that of its publication in the *Official Journal of the European Union.*

Article 14

Addressees

This Decision is addressed to the Member States.

Done at Brussels,

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

ANNEX I
OBJECTIVES OF THE EDCTP2 PROGRAMME

EDCTP2 shall contribute to the following objectives:

(1) General Objective

EDCTP2 shall contribute to the reduction of the social and economic burden of poverty-related diseases in developing countries, in particular in sub-Saharan Africa, by accelerating the clinical development of effective, safe and affordable medical interventions 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;

(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
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;

(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, 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
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.

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.

LEGISLATIVE FINANCIAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

1.2. Policy area(s) concerned in the ABM/ABB structure

1.3. Nature of the proposal/initiative

1.4. Objectives

1.5. Grounds for the proposal/initiative

1.6. Duration and financial impact

1.7. Management mode(s) envisaged

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

2.2. Management and control system

2.3. Measures to prevent fraud and irregularities

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

3.2. Estimated impact on expenditure

3.2.1. Summary of estimated impact on expenditure

3.2.2. Estimated impact on operational appropriations

3.2.3. Estimated impact on appropriations of an administrative nature

3.2.4. Compatibility with the current multiannual financial framework

3.2.5. Third-party contributions

3.3. Estimated impact on revenue

LEGISLATIVE FINANCIAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

Decision of the European Parliament and of the Council on the participation of the European Union in a second European and Developing Countries Clinical Trials Partnership Programme (EDCTP2) jointly undertaken by several Member States

1.2. Policy area(s) concerned in the ABM/ABB structure[17]

Title 08 Research and Innovation, Horizon 2020 Framework Programme

1.3. Nature of the proposal/initiative

☐ The proposal/initiative relates to **a new action**

☐ The proposal/initiative relates to **a new action following a pilot project/preparatory action**[18]

☐ The proposal/initiative relates to **the extension of an existing action**

☒ The proposal/initiative relates to **an action redirected towards a new action**

1.4. Objectives

1.4.1. The Commission's multiannual strategic objective(s) targeted by the proposal/initiative

EDCTP2 will contribute to the Europe 2020 strategy and the completion of the European Research Area, including the target of 3% of the EU's GDP to be invested in R&D, by developing a real partnership with developing countries to help eradicate poverty, promote growth and contribute to the Millennium Development Goals.

1.4.2. Specific objective(s) and ABM/ABB activity(ies) concerned

EDCTP2 implementation: EDCTP2 will contribute to reducing the social and economic burden of poverty-related diseases (PRDs) in developing countries, in particular in sub-Saharan Africa, by accelerating the clinical development of effective, safe and affordable medical interventions for PRDs in partnership with sub-Saharan Africa.

ABM/ABB activity concerned: 08.02 Cooperation — Health

[17] ABM: Activity-Based Management — ABB: Activity-Based Budgeting.

[18] As referred to in Article 49(6)(a) or (b) of the Financial Regulation.

1.4.3. Expected result(s) and impact

Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.

1) More of new or improved medical interventions for HIV/AIDS, tuberculosis, malaria and other poverty-related diseases for the benefit of developing countries, and by the end of the programme to have delivered at least 1 new medical intervention; to have issued at least 20 guidelines for improved or extended use of existing medical interventions; and to have progressed the clinical development of at least 10 candidate medical intervention.

2) Strengthened cooperation with sub-Saharan African countries, in particular on building their capacity for conducting clinical trials.

3) Better coordination, alignment and integration of relevant national programmes to increase the cost-effectiveness of European public investment.

4) Extended international cooperation with other public and private funders.

5) An increased impact due to effective cooperation with other Union initiatives, including EU development assistance.

1.4.4. Indicators of results and impact

Specify the indicators for monitoring implementation of the proposal/initiative.

- Number of clinical trial results integrated in guidelines or recommendations for improved clinical practice or submitted to regulators.

- Proportion of public investments of participating European states that are integrated, aligned or coordinated through the EDCTP joint programme.

- Number of African countries involved in EDCTP-funded projects.

- Share of EDCTP-funded clinical trials with African leadership.

- Number of medical interventions proceeding to further development (through additional trials or next phase).

- Number of joint peer-reviewed scientific articles.

- Number of African researchers supported by EDCTP fellowships staying on in Africa at least one year after the end of their training.

- Number of clinical trials supported.

- Number of capacity-building activities supported for conducting clinical trials in sub-Saharan Africa.

- Number of fellowships to African researchers and MSc/PhD students.

- Time-to-grant and Time-to-pay.

- Volume and proportion of co-funding from the Union and the PSs, including funds raised by the PSs and the EDCTP from other public and private third parties.

- Administrative costs.

1.5. Grounds for the proposal/initiative

1.5.1. Requirement(s) to be met in the short or long term

Despite the promising results of EDCTP1 and other international initiatives, there is still a lack of effective medical interventions for PRDs. The socio-economic burden of these diseases remains a limiting factor for the sustainable development of developing countries, in particular in sub-Saharan Africa. While a general improvement in factors such as nutrition, sanitation and infrastructure is certainly important, the development of new and better medical interventions is essential for an effective containment and long-term control of PRDs.

The persistent lack of effective medical interventions for PRDs is affected by five key drivers that require Union intervention through EDCTP2: insufficient investment; weak clinical research capacity in sub-Saharan African countries; fragmented public support; the limited scope of the EDCTP1 programme; and insufficient links to other EU initiatives. First and foremost, the medical interventions needed for PRDs will not be developed by the private sector alone owing to limited financial incentives (market failure). Second, clinical trials are of such scale and complexity that no single country can provide the necessary resources. The EU-level approach on which EDCTP is built makes it possible to achieve the necessary critical mass of resources, with Union funding complementing participating states' contributions to EDCTP2.

For more information, please read the impact assessment report of EDCTP2 accompanying this legislative proposal.

1.5.2. Added value of EU involvement

Public intervention at EU level is necessary to bring together compartmentalised national research programmes, help design common research and funding strategies across national borders and achieve the critical mass of actors and investment needed for undertaking resource-intensive clinical trials of new medical interventions for poverty-related diseases in developing countries. In doing so, the impact of European activities and effectiveness of public investment in this field is maximised. In light of budgetary restrictions and from a purely economic perspective, it makes more sense than ever to invest collectively in order to maximise the cost-effectiveness and impact. Public intervention is in line with the overall provisions of the EU Treaty, related EU policies and, in particular, contributes to delivering on the Union's commitments to promote aid effectiveness, inclusive growth and progress towards achieving the Millennium Development Goals.

1.5.3. Lessons learned from similar experiences in the past

Up until now, EDCTP has funded 241 projects involving 185 African and 70 European research institutions. This includes 88 clinical trials which were all subject to ethical clearance from the competent national ethics board(s) in the country or countries in which the trial(s) were due to take place before any funding was granted by EDCTP. Most of the clinical trials supported by EDCTP were launched after 2007 and are still on-going. Nevertheless, they have already generated more than 350 scientific publications in peer-reviewed journals, while the results of eight clinical trials so far have been integrated in guidelines for improved clinical practice.

Despite these achievements, a number of issues were raised in the 2009 interim evaluation report and the public consultation. These following issues are fundamental to the design and subsequent implementation of EDCTP2:

- the current scope of EDCTP 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 EU development assistance;

- co-funding rules should be clarified and simplified;

- monitoring tools need to be strengthened.

For more information, please read the impact assessment report of EDCTP2 accompanying this legislative proposal.

1.5.4. Compatibility and possible synergy with other appropriate instruments

EDCTP was conceived to complement the actions implemented under the European Development Fund (EDF) and the Development Cooperation Instrument (DCI) to ensure the development and delivery of medical interventions to those in need. So far, interaction with these European programmes for development assistance has been limited, but the opportunity remains to better exploit synergies and achieve greater impact of Union actions in research and development assistance. The remit of EDCTP is restricted to support clinical trials and corresponding capacity-building. However, in resource-poor settings like sub-Saharan Africa, such activities do not exist in isolation, and would achieve a far greater impact if they were integrated in and coordinated with national healthcare systems and programmes.

For more information, please read the impact assessment report of EDCTP2 accompanying this legislative proposal.

1.6. Duration and financial impact

☒ Proposal/initiative of **limited duration**

– ☒ Proposal/initiative in effect from 1/1/2014 to 31/12/2024

– ☒ Financial impact from 2014 to 2020 for commitment appropriations and from 2014 to 2024 for payment appropriations

☐ Proposal/initiative of **unlimited duration**

– Implementation with a start-up period from YYYY to YYYY,

– followed by full-scale operation.

1.7. Management mode(s) envisaged[19]

☐ **Centralised direct management** by the Commission

☒ **Centralised indirect management** with the delegation of implementation tasks to:

– ☐ executive agencies

[19] Details of management modes and references to the Financial Regulation may be found on the BudgWeb site: http://www.cc.cec/budg/man/budgmanag/budgmanag_en.html.

– ☐ bodies set up by the Communities[20]

– ☒ national public-sector bodies/bodies with public-service mission

– ☐ persons entrusted with the implementation of specific actions pursuant to Title V of the Treaty on European Union and identified in the relevant basic act within the meaning of Article 49 of the Financial Regulation

☐ **Shared management** with the Member States

☐ **Decentralised management** with third countries

☐ **Joint management** with international organisations ***(to be specified)***

If more than one management mode is indicated, please provide details in the 'Comments' section.

Comments

EDCTP2 shall be implemented through the EDCTP legal entity as the implementation structure (EDCTP2-IS). The current EDCTP legal entity was established by the 15 European founding countries as a European Economic Interest Group (EEIG) in the Netherlands. A new EDCTP legal entity will be established before the launch of the EDCTP2 Programme, based on organisational principles detailed in Annex III.

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

Specify frequency and conditions.

Implementation of EDCTP2 will be monitored through annual reports covering a single year N, which will be provided by the EDCTP-IS in year N+1. These annual reports will give a detailed overview of EDCTP2 activities in year N in comparison to the multiannual strategic work plan (covering year N to year N+2) and the annual work plan of year N. They will also provide detailed information on the performance and progress towards meeting EDCTP2 objectives and targets. These annual reports will also include updated figures on the indicators listed in section 1.4.4.

An interim evaluation will be carried out with the assistance of independent external experts after three years of operation but not later than 31 December 2017.

Before the end of EDCTP2 but not later than 31 December 2023, the Commission will conduct another interim evaluation with the assistance of independent external experts.

A final independent ex-post evaluation after EDCTP2 has ended but not later than 31 December 2026 will be conducted by an independent expert panel set up by the Commission and tasked with reviewing the performance and quality of EDCTP2 implementation and funded activities.

2.2. Management and control system

2.2.1. Risk(s) identified

1) The main risk concerns the capacity of participating states to effectively integrate their national programmes and activities, and thus deliver their contribution to the programme.

[20] As referred to in Article 185 of the Financial Regulation.

2) A second risk concerns effective protection against fraud and possible financial losses, especially due to weak governance and financial capacity in some of the developing countries and the corresponding beneficiaries of EDCTP2 grants.

3) A third risk concerns the capacity of the implementation structure to manage the Unions budget contribution and monitor the national activities contributing to the programme.

4) A fourth risk relates to the high costs, long duration, ethical clearance and regulatory control required for clinical trials in humans, which can result in clinical trials lasting longer than initially planned and/or being more costly. This is often linked to delays in ethical clearance and/or to clinical findings that require modification of clinical trials design.

2.2.2. Control method(s) envisaged

The Union's financial interests will 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, penalties.

Article 8 states that if EDCTP2 is not implemented or is implemented inadequately, partially or late, or if the Participating States do not contribute, contribute partially or late to the financing of EDCTP2, the Commission may reduce, withhold or terminate the European Union financial contribution.

Articles 9 and 10 set out the EDCTP-IS' duty to guarantee a level of protection of the financial interests of the Union and makes provision for access to information and premises to control, evaluate and carry out audits on EDCTP2 implementation.

2.2.3. Costs and benefits of controls and probable non-compliance rate

Article 9 provides for ex-post audits of expenditure on indirect actions to be carried out in accordance with the Horizon 2020 Framework Programme. To ensure consistency, the Commission may decide to carry out the audits referred to in herein.

2.3. Measures to prevent fraud and irregularities

Specify existing or envisaged prevention and protection measures.

Article 10 sets out that the EDCTP-IS has to grant access to information and premises necessary for the Commission to control, evaluate and carry out audits on EDCTP2 implementation or for OLAF to carry out investigations.

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

- Existing budget lines

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Heading la - Competitiveness for growth and jobs	Diff./non-diff. (21)	from EFTA countries 22	from candidate countries[23]	from third countries	within the meaning of Article 18(1)(aa) of the Financial Regulation
	Administrative Expenditures 08.01.05.03 Other management expenditure for Research	NDA	YES	YES	YES	YES
	Operational Expenditures *Societal challenges* 08.02.03.01 Improving lifelong health and wellbeing	DA	YES	YES	YES	YES

- New budget lines requested

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Heading la - Competitiveness for growth and jobs	Diff./non-diff.	from EFTA countries	from candidate countries	from third countries	within the meaning of Article 18(1)(aa) of the Financial Regulation
	Administrative Expenditures 08.01.05.03 Other management expenditure for Research	NDA	YES	YES	YES	YES
	Operational Expenditures *Societal challenges* 08.02.03.01 Improving lifelong health and wellbeing	DA	YES	YES	YES	YES

21 Diff. = Differentiated appropriations / Non-Diff. = Non-differentiated appropriations.

22 EFTA: European Free Trade Association. .

23 Candidate countries and, where applicable, potential candidate countries from the Western Balkans.

3.2. Estimated impact on expenditure

3.2.1. Summary of estimated impact on expenditure

EUR million (to three decimal places)

Heading of multiannual financial framework:	1A	Heading la - Competitiveness for growth and jobs

DG: RTD			Year **2014**	Year **2015**	Year **2016**	Year **2017**	Year **2018**	Year **2019**	Year **2020**	**Years 2021-2024**	**TOTAL**
• Operational appropriations											
08.02.03.01	Commitments	(1)	25,000	55,000	80,000	110,000	110,000	110,000	193,000	0,000	683,000
	Payments	(2)	4,000	20,000	50,000	110,000	110,000	130,000	130,000	129,000	683,000
• Appropriations of an administrative nature financed from the envelope of specific programmes[24]											
08.01.05.03		(3)	0,297	0,303	0,309	0,315	0,321	0,328	0,334	0,000	2,207
TOTAL appropriations under HEADING 1A of the multiannual financial framework	Commitments	=4+6	**25,297**	**55,303**	**80,309**	**110,315**	**110,321**	**110,328**	**193,334**	**0,000**	**685,207**
	Payments	=5+6	**4,297**	**20,303**	**50,309**	**110,315**	**110,321**	**130,328**	**130,334**	**129,000**	**685,207**

[24] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

Heading of multiannual financial framework	**1A**	Heading la - Competitiveness for growth and jobs 'Administrative expenditure'

EUR million (to three decimal places)

		Year **2014**	Year **2015**	Year **2016**	Year **2017**	Year **2018**	Year **2019**	Year **2020**	**Years 2021-2024**	**TOTAL**
DG: RTD										
• Human resources		0,297	0,303	0,309	0,315	0,321	0,328	0,334	0,000	2,207
• Other administrative expenditure		0,000	0,000	0,000	0,000	0,000	0,000	0,000	0,000	0,000
TOTAL DG RTD		0,297	0,303	0,309	0,315	0,321	0,328	0,334	0,000	2,207

TOTAL appropriations for HEADING 1A of the multiannual financial framework	(Total commitments = Total payments)	0,297	0,303	0,309	0,315	0,321	0,328	0,334	0,000	2,207

EUR million (to three decimal places)

		Year **2014**	Year **2015**	Year **2016**	Year **2017**	Year **2018**	Year **2019**	Year **2020**	**Years 2021-2024**	**TOTAL**
TOTAL appropriations under HEADINGS 1 to 5 of the multiannual financial framework	Commitments	**25,297**	**55,303**	**80,309**	**110,315**	**110,321**	**110,328**	**193,334**	**0,000**	**685,207**
	Payments	**4,297**	**20,303**	**50,309**	**110,315**	**110,321**	**130,328**	**130,334**	**129,000**	**685,207**

3.2.2. Estimated impact on operational appropriations

– ☐ The proposal/initiative does not require the use of operational appropriations

– ☒ The proposal/initiative requires the use of operational appropriations, as explained below:

Commitment appropriations in EUR million (to three decimal places)

Indicate objectives and outputs * ⇩			Year **2014**		Year **2015**		Year **2016**		Year **2017**		Year **2018**		Year **2019**		Year **2020**		**TOTAL**	
	OUTPUTS																	
	Type[25]	Average cost **	Number	Cost	Number	Cost	Number	Cost	Number	Cost	Number	Cost	Number	Cost	Number	Cost	Total Number	Total Cost
SPECIFIC OBJECTIVE No 1			EDCTP2 implementation															
- Output	**R&D activity**	**1,442**	**87**	**126,060**	**104**	**149,826**	**116**	**166,798**	**135**	**194,999**	**131**	**188,759**	**129**	**186,695**	**198**	**284,923**	**900**	**1.298,060**
- Output																		
Subtotal for specific objective No 1																		
TOTAL COST			**87**	**126,060**	**104**	**149,826**	**116**	**166,798**	**135**	**194,999**	**131**	**188,759**	**129**	**186,695**	**198**	**284,923**	**900**	**1.298,060**

* Provided that the PS contribution is increased by at least 15% through new Participating Countries joining EDCTP2 as provided in Article 2.1, such that the total value of the EDCTP2 programme is at least EUR1.366,379 million, including up to 5% (EUR 68,319 million) for administrative costs, with an EU contribution of EUR 683,000 million (out of which 6% equal to EUR 41 million for administrative costs).

** An average cost per R&D activity was calculated on the basis of the operational targets for the minimum number of specific R&D activities to be supported by the EDCTP2 programme and estimated average costs per specific R&D activity: 150 clinical trials (€7,254 million); 600 fellowships (€0,200 million); 150 capacity strengthening activities (€0,600 million)

[25] Outputs are products and services to be supplied (e.g.: number of student exchanges financed, number of km of roads built, etc.).

3.2.3. Estimated impact on appropriations of an administrative nature

3.2.3.1. **Summary**

– ☐ The proposal/initiative does not require the use of appropriations of an administrative nature

– ☒ The proposal/initiative requires the use of appropriations of an administrative nature, as explained below:

EUR million (to three decimal places)

	Year **2014**	Year **2015**	Year **2016**	Year **2017**	Year **2018**	Year **2019**	Year **2020**	**TOTAL**
HEADING 5A of the multiannual financial framework								
Outside HEADING 5A of the multiannual financial framework								
Human resources	0,297	0,303	0,309	0,315	0,321	0,328	0,334	**2,207**
Other expenditure of an administrative nature								
Subtotal outside HEADING 5A of the multiannual financial framework	0,297	0,303	0,309	0,315	0,321	0,328	0,334	**2,207**
TOTAL	0,297	0,303	0,309	0,315	0,321	0,328	0,334	**2,207**

The administrative appropriations required will be met by the appropriations of the DG which are already assigned to management of the action and/or which have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

3.2.3.2. Estimated requirements of human resources

– ☐ The proposal/initiative does not require the use of human resources.

– ☒ The proposal/initiative requires the use of human resources, as explained below:[26]

Estimate to be expressed in full time equivalent units

		Year 2014	Year 2015	Year 2016	Year 2017	Year 2018	Year 2019	Year 2020
• Establishment plan posts (officials and temporary agents)								
08 01 01 01 (Headquarters and Commission's Representation Offices)								
08 01 01 02 (Delegations)								
08 01 05 01 (Indirect research)		2	2	2	2	2	2	2
10 01 05 01 (Direct research)								
• External personnel (in Full Time Equivalent unit: FTE)[27]								
XX 01 02 01 (CA, INT, SNE from the 'global envelope')								
XX 01 02 02 (CA, INT, JED, LA and SNE in the delegations)								
XX 01 04 **yy**[28]	- at headquarters							
	- in delegations							
08 01 05 02 (CA, SNE, INT — Indirect research)		0.5	0.5	0.5	0.5	0.5	0.5	0.5
10 01 05 02 (CA, SNE, INT — Direct research)								
Other budget lines (specify)								
TOTAL		**2.5**	**2.5**	**2.5**	**2.5**	**2.5**	**2.5**	**2.5**

XX is the policy area or budget title concerned.

The human resources required will be met by staff from the DG who are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

Description of tasks to be carried out:

Officials and temporary staff	Participation in EDCTP General Assembly: 2 two-day meetings/year (Director, Head of Unit). Participation in EDCTP Scientific Advisory Committee: 2 two-day meetings/year (Head of Unit, project officer). Participation in stakeholder consultation and information events: 8 events per year (Head of Unit, project officer). Negotiation, preparation and payment of delegation agreement with the EDCTP-IS (project officer, financial officer, administrative assistant). Monitoring of EDCTP2, assistance to interim/final evaluations (project officer). Financial and legal auditing of EDCTP2 (financial officer).
External staff	Monitoring of EDCTP2, assistance to interim/final evaluations (contract agent)

[26] Staff needed after 2020 for follow-up of EDCTP2 implementation will be determined at a later stage.

[27] CA= Contract Agent; LA = Local Agent; SNE = Seconded National Expert; INT = agency staff ('Intérimaire'); JED= 'Jeune Expert en Délégation' (Young Experts in Delegations).

[28] Sub-ceiling for external staff covered by operational appropriations (former 'BA' lines).

3.2.4. Compatibility with the current multiannual financial framework

– ☒ Proposal/initiative is compatible with the current multiannual financial framework.

– ☐ Proposal/initiative will entail reprogramming of the relevant heading in the multiannual financial framework.

Explain what reprogramming is required, specifying the budget lines concerned and the corresponding amounts.

– ☐ Proposal/initiative requires application of the flexibility instrument or revision of the multiannual financial framework[29].

Explain what is required, specifying the headings and budget lines concerned and the corresponding amounts.

3.2.5. Third-party contributions

– The proposal/initiative does not provide for co-financing by third parties.

– ☒The proposal/initiative provides for the co-financing estimated below:

Appropriations in EUR million (to three decimal places)

	2014	2015	2016	2017	2018	2019	2020	Total
Commitments of EDCTP2 Participating States* as listed in Article 1	106,833	102,216	77,616	77,616	71,116	68.966	90,016	594,379
Commitments of any other Member State or any other country associated to Horizon 2020 joining the EDCTP2 Programme in accordance with Article 2	0,000	0,000	17,800	17,800	17,800	17,800	17,800	89,000
TOTAL appropriations co-financed	**106,833**	**102,216**	**95,416**	**95,416**	**88,916**	**86,766**	**107,816**	**683,379**

* EDCTP2 Participating States' (PS) commitments as endorsed by the EDCTP General Assembly of PS representatives and communicated to the Commission in June 2013. Accordingly, an updated EDCTP2 Strategic Business Plan will be published by EDCTP: http://www.edctp.org/Towards_EDCTP2.799.0.html

Co-Financing details:

The Participating States' contributions shall be at least equal to the EU contribution. The EU contribution shall in any case not exceed EUR 683,000 million.

Up to 5% of the total value of the EDCTP2 programme will be for administrative costs of the EDCTP2-IS, up to a maximum of EUR 68,319 million. The maximum EU contribution to these administrative costs will be up to 6% of the EU contribution to EDCTP2, thus not exceeding EUR 41,000 million.

[29] See points 19 and 24 of the Interinstitutional Agreement.