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EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT

Accompanying the document

Proposal for a

DECISION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the participation by the European Union in a second European and Developing Countries Clinical Trials Partnership programme (EDCTP2) undertaken by several Member States

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Disclaimer: This executive summary commits only the Commission's services involved in the preparation and does not prejudge the final form of any decision to be taken by the Commission.

This Executive Summary outlines the main findings of the Impact Assessment (IA) report accompanying the Commission's proposal for a decision on the continued participation of the European Union (EU) in a second European and Developing Countries Clinical Trials Partnership programme (EDCTP2), as requested by the participating European states and recommended in the independent evaluation of the first EDCTP programme (EDCTP1). It falls under Article 185 of the *Treaty on the Functioning of the EU*, which is the basis for the EU to participate in the joint implementation of national programmes for research and development. The proposal is put forward in the context of the Multiannual Financial Framework *MFF 2014-20* as part of the implementation of the EU Framework Programme for Research and Innovation, *Horizon 2020*. The budget allocation for EDCTP2 is subject to the outcome of the EU's decision on the *MFF 2014-20* and *Horizon 2020*.

1. OBJECTIVES

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 active funding period for the first EDCTP programme (EDCTP1) is now over. Despite the achievements of the EDCTP so far, the socio-economic burden of poverty-related diseases persists and hinders the sustainable development of developing countries, particularly in sub-Saharan Africa.

1.1. Effective medical interventions for poverty-related diseases are lacking

Poverty-related diseases have huge negative impacts on health, society and the economy. They particularly affect the world's poorest and most marginalised communities. More than 1 billion people, including 400 million children, are suffering from one or more of the three major poverty-related diseases — HIV/AIDS, malaria and tuberculosis — or from neglected infectious diseases, such as Buruli ulcer, trachoma, lymphatic filariasis and sleeping sickness. Malaria and tuberculosis alone kill an estimated 2.1 million people annually. 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 in 2010. This region also accounted for over two thirds (68%) of all people living with HIV and for nearly three quarters (72%) of AIDS-related deaths in 2008.

General improvements of nutrition, sanitation and health infrastructures are important, but long-term control requires the development of new or improved medical interventions. Medical interventions of these diseases are either lacking or no longer effective. Most of the new medical interventions — drugs, vaccines, microbicides — under development are stuck at the stage of early clinical development.

1.2. These problems persist, mainly due to insufficient investment, weak local capacity and fragmented public support

The lack of effective medical interventions is due to five key drivers: (i) insufficient investment (market failures), (ii) weak clinical research capacity in sub-Saharan African countries, (iii) fragmented public support, (iv) limited scope of the first EDCTP programme, and (v) insufficient links to other EU initiatives.

– Firstly, medical interventions are not developed due to insufficient investment from both the private and public sector. This is linked to market failures: the research required is risky and expensive, especially late-stage clinical trials in humans. Moreover, research costs cannot be fully recovered because neither the people

affected by these diseases nor the health system in developing countries can afford to pay the full market price to secure the return on private investment.

– Secondly, most developing countries, in particular in sub-Saharan Africa, lack the basic infrastructure, human resources and know-how to tackle these problems on their own and conduct clinical trials in compliance with international standards of good clinical practice.

– Thirdly, EU Member States acting through uncoordinated national research policies, programmes and projects compromise the critical mass and effectiveness of European public action. This is exacerbated by the fact that aid budgets (which account for about 60% of research funding for poverty-related diseases) are shrinking as a result of the European economic and financial crisis.

– Fourthly, the limited scope of the first EDCTP programme made it difficult to tackle poverty-related diseases in a comprehensive manner. It prevented support for other poverty-related diseases such as neglected infectious diseases. Extending its scope would also allow the EDCTP programme to support all stages of clinical development.

– Fifthly, stepping up cooperation between EDCTP and EU development assistance could unlock significant synergies, and promote introduction of newly available medical interventions that are more effective and safe, and their delivery.

1.3. EDCTP1 has made substantial achievements

EDCTP1 has produced a number of important results:

– It has funded 55 clinical trials projects, involving 88 individual clinical trials, with so far 8 of which have resulted in recommendations for improved patient treatment;

– A new anti-retroviral formulation for HIV-infected children in Africa, which was tested in an EDCTP project, was approved by the US Food and Drug Administration (FDA);

– National regulatory authorities and ethics review capacities have been strengthened in many African countries;

– The Pan-African Clinical Trials Registry (PACTR) was created with the support of EDCTP1 and is now officially recognised as a WHO Primary Registry;

– EDCTP1 has helped to structure the research landscape in Africa by creating African Networks of Excellence for clinical trials.

EDCTP is also an excellent example of a principle that we advocate in Europe: to open our research programmes to worldwide collaboration. The EDCTP is spectacularly good at this, with projects that involve institutions from Europe and Africa, with 75% of funding going to African institutions and with 73% of projects led by African researchers. In addition to boosting clinical development and capacity in sub-Saharan Africa, the programme has succeeded in triggering structural changes in terms of better coordination of the participating European states' national programmes. The level of integrating national programmes in EDCTP has now reached around 30% of overall national research investment in clinical trials for medical interventions against the three big poverty-related diseases.

1.4. The lessons learned from EDCTP1 have fed into the design of EDCTP2

Despite its achievements, implementation of EDCTP also revealed a number of shortcomings:

i) The current scope of EDCTP is too limited to provide a comprehensive response to poverty-related diseases: more diseases and all stages of clinical development should be included.

ii) The potential for coordinating and integrating European national programmes in the scope of EDCTP has not yet been fully exploited: aligned and concerted activities among participating European states are now being implemented (so-called Participating States Initiated Activities) and procedures are being simplified.

iii) The monitoring and evaluation of specific targets need to be stepped up: systematic performance and impact indicators have therefore been developed upfront for EDCTP2;

iv) Stable working relations with major research funders and with pharmaceutical industry have not been established yet: strategic discussions with other funders, such as the Bill and Melinda Gates Foundation and pharmaceutical industry, are ongoing.

v) Coordination with EU external policy and development assistance has not been developed sufficiently: to tackle this, work is ongoing to coordinate with other EU initiatives of relevance to EDCTP.

1.5. The initiative would have a significant impact on people and stakeholders

Tackling the problem and its drivers would have a high positive impact on health, well-being and the economic development of millions of people living in sub-Saharan Africa, in particular on children and women in the region who are disproportionately affected by these diseases. Supporting the fight against poverty-related diseases would also help to safeguard Europe's citizens from these diseases as increasing global mobility (including tourism) and migratory movements mean that Europe will be facing new or returning challenges from infectious diseases. Global warming may amplify these risks in Europe as it may lead to a higher prevalence and shift in geographic distribution of these diseases. European and African researchers would also benefit from better coordinated and structured research programmes and activities on poverty-related diseases at European and international level.

1.6. Public intervention at EU level is fully justified

The market failures and resulting investment gap outlined above provide strong justification for public intervention. 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 investments that is needed to tackle major global health challenges, which couldn't be tackled by single countries alone. It would also increase the cost-effectiveness and impact of European activities and investments in this field.

EU intervention is in line with the *Treaty on the Functioning of the EU* and related EU policies. It contributes to delivering on the EU's commitments to promote aid effectiveness, inclusive growth and progress towards the achievement of the Millennium Development Goals.

The aim of this initiative is to better align EU and national research programmes on poverty-related diseases. It is embedded into the Treaty's objectives to strengthen the EU's scientific and technology bases (Article 179.1 TFEU), and to create a European research area based on cooperation between researchers across borders (Article 179.2 TFEU), such as through the EU's participation in research and development programmes undertaken by several Member States (Article 185 TFEU). It also contributes to the EU's new and extended competences brought in by the *Lisbon Treaty on the EU* (TEU) on pursuing common actions in the field of international relations and cooperation (Article 21 TEU) and thus to a Global Europe.

2. OBJECTIVES

2.1. General objectives

In line with the *Europe 2020* strategy, the *Innovation Union* flagship initiative, *Horizon 2020*, the EU-Africa strategic partnership and the EU's commitment to the 2012 Rio+20 conference conclusions on the development and achievement of internationally agreed Sustainable Development Goals, including the Millennium Development Goals, the general objective of this initiative is **to contribute to the reduction of the social and economic burden of poverty-related diseases in developing countries, particularly in sub-Saharan Africa, by accelerating the clinical development of effective, safe and affordable medical interventions for poverty-related diseases.**

2.2. Specific objectives

In order to meet the above general objective, the specific objectives of the EDCTP2 programme are to result in:

- **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 product, 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 drugs; and to have progressed the clinical development of at least 20 candidate products.

- **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 Charter of Fundamental Rights of the European Union, the European Convention on Human Rights and its Supplementary Protocols, the 2008 version of the World Medical Association's Declaration of Helsinki and the ICH standards on good clinical practice.

- **Enhanced coordination, alignment and integration of relevant national programmes** and thus increased cost-effectiveness of European public investments.

- **Extended international cooperation and increased leverage of investments** from other public and private funders.

- **An increased impact of the partnership due to effective cooperation with relevant EU initiatives**, such as EU development assistance.

3. POLICY OPTIONS

The impact assessment considered a number of options and sub-options with different legal bases, scope, duration, budget and EU contribution.

Under **Option 1** ('no EU action'), there would be no EDCTP2, and no provision in EU policies, programmes or funded actions to support EDCTP objectives, either in terms of clinical trials or to integrate Member States' national research programmes to combat poverty-related diseases. European support for clinical trials and related capacity-building would be based solely on Member States' national programmes.

Under **Option 2** ('programme-based'), there would be no EDCTP2 but provision would be made in EU policies, programmes or funded actions to support EDCTP objectives. Support for clinical trials and related capacity-building would thus rely on Member States' national programmes and EU programmes.

Under **Option 3** ('business-as-usual' — baseline scenario), EDCTP1 would essentially be extended as it is: same thematic focus, same funding strategy and activities, same budget and duration, i.e. € 500 million over five years.

Under **Option 4** ('extended scope'), EDCTP1 would be extended with the same geographical focus (sub-Saharan Africa) but with an extended duration and thematic scope consisting of (i) doubling the lifetime of the programme to 10 years, (ii) addressing other poverty-related diseases (in addition to the big three diseases HIV/AIDS, malaria and tuberculosis), and (iii) supporting all stages of clinical development.

Regarding the overall budget and the EU's contribution, three sub-scenarios were considered: Under **sub-option 4A**, the total budget of EDCTP2 would be € 0.85 billion with an EU contribution of up to € 350 million to match the participating European states' contribution of at least € 500 million. Under **sub-option 4B**, the total budget of EDCTP2 would be € 1 billion with an EU contribution of up to € 500 million to match the participating European states' contribution of at least € 500 million. Under **sub-option 4C**, the total budget would be € 2 billion with an EU contribution of up to € 1 billion to match the participating European states ' contribution of at least € 1 billion.

4. ASSESSMENT OF IMPACTS AND COMPARISON OF OPTIONS

The impacts of each of the policy options were compared in terms of their effectiveness, efficiency and consistency in reaching the general and specific objectives.

Option 4C, which would maintain EDCTP's geographical scope but extend its duration, thematic scope and budget, is **the preferred option**.

Option **4C** would be the most effective, efficient and consistent option. It requires the largest EU budget, but it has the potential to transform EDCTP into a major global player in product development for global health. It would have sufficient financial volume to provide leadership in developing new effective and safe medical interventions against the three major and other poverty-related and neglected diseases, for instance in developing a tuberculosis vaccine. This option would transform EDCTP from a pure collaborative research programme between Europe and sub-Saharan Africa into a programme that would contribute to the long-term sustainable development of sub-Saharan Africa.

This option would also:

– allow EDCTP to launch expensive late-stage trials, which cost € 50-400 million;

– increase the leverage effect of EU public spending on poverty-related diseases;

– maintain the EU's leadership in poverty-related diseases research and innovation.

5. MONITORING AND EVALUATION

It is important to devise a monitoring and evaluation system at programme and project level to make sound assessments of whether EDCTP2 is on track and successfully achieving its objectives. The evaluation framework should be composed of the following:

– updates on EDCTP2 indicators published annually;

– annual reports on the implementation, performance and progress of EDCTP2 towards meeting its objectives and targets;

– an independent mid-term evaluation on the performance and quality of the EDCTP2 implementation and funded activities carried out no later than 31 December 2017, and at the end of the EDCTP2 programme, no later than 31 December 2023; and

– a final independent ex-post evaluation conducted no later than 31 December 2026.

The Commission will ensure that all action taken in the context of EDCTP2 respects the Charter of Fundamental Rights of the EU and is in line with international standards on good clinical practice.