The European & Developing countries Clinical Trials Partnership (EDCTP) is a Public- Public Partnership between Europe and sub-Saharan Africa and was established in 2003 by the Decision No 1290/2003/EC of the European Parliament and of the Council of the European Union under article 185 of the Treaty on the Functioning of the European Union (TFEU). This article enables the European Union (EU) to participate and co-fund research programme jointly undertaken by EU Member States. The EDCTP programme is now entering its second phase.

**AN INNOVATIVE PARTNERSHIP IN R&D FOR POVERTY-RELATED AND NEGLECTED DISEASES (PRNDs)**

The European & Developing countries Clinical Trials Partnership (EDCTP) is a Public-Public Partnership between Europe and sub-Saharan Africa and was established in 2003 by the Decision No 1290/2003/EC of the European Parliament and of the Council of the European Union under article 185 of the Treaty on the Functioning of the European Union (TFEU). This article enables the European Union (EU) to participate and co-fund research programme jointly undertaken by EU Member States. The EDCTP programme is now entering its second phase.

**EDCTP SUPPORTS THROUGH COLLABORATIVE RESEARCH THE CLINICAL DEVELOPMENT**

**of effective, safe, accessible, suitable and affordable drugs, vaccines, microbiicides and diagnostics against HIV and AIDS, malaria, tuberculosis and neglected diseases prevalent in sub-Saharan Africa.**

By pooling resources, EDCTP reduces fragmentation and duplication and increases coordination of national research programmes. Concretely, EDCTP contributes to boosting the development of new or improved health technologies by:

- **Supporting multicentre and multinational projects that combine clinical trials, capacity-building and networking activities.** EDCTP2 will keep its priority focus on phase II and phase III clinical trials that are often too expensive to be supported by one single agency. Additionally, EDCTP2 will support phase I and phase IV clinical trials. Importantly, EDCTP activities including clinical trials are carried out in full compliance with European legislations and internationally recognised ethical principles.

- **Strengthening scientific capacity for clinical trials and clinical research in endemic countries.** These capacity development activities also include ethics and regulatory components.

- **Promoting collaboration with industry, like-minded organisations, product development partners, research funders and development cooperation agencies.**

**SCOPE OF EDCTP**

**Discovery & Pre-clinical research**

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**Pre-clinical studies**

**Post-registration studies**

**Policy, Practice**

**First in humans**

**Registration**

1. Charter of Fundamental Rights of the European Union, the European Convention Human Rights and Its Supplementary Protocols, the World Medication Association’s Declaration of Helsinki of 2008, the standards of good clinical practice adopted by the International Conference on Harmonisation of Technical Requirement for Registration of Pharmaceuticals for Human Use, and local ethics requirements of the countries where the research activities are to be conducted.
In preparation for EDCTP2, on April 10 2014, EDCTP became an Association under Dutch law. The EDCTP Association is the dedicated implementation structure for EDCTP2. This new governance structure enhances co-ownership of the programme by European and African Participating States. In particular, this new structure allows African States to become full members of EDCTP and consequently to participate in EDCTP’s General Assembly. To date, the EDCTP-Association has admitted 23 full members including 14 European Participating States and 9 African Participating States and one aspirant member.

The EDCTP-Association comprises the following governing bodies:
- The General Assembly (GA)
- The Board
- The Executive Secretariat (SEC).

In addition, the EDCTP-Association has an independent advisory body, which is the Strategic Advisory Committee (SAC).

These four statutory bodies, which are governed by the internal regulations, are outlined in the figure on the left.

**GOVERNANCE**

**LEGAL SETUP OF THE EDCTP**

**IMPLEMENTING STRUCTURE**

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2. EDCTP’s full members are: Austria, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, the United Kingdom, Cameroon, Republic of Congo, Mozambique, Senegal, South Africa, Tanzania, Uganda and Zambia. Switzerland is an aspirant country.

3. Decision No566/2014/EU of the European Union and of the Council on the participation of the Union in a second European and Developing countries Clinical Trials Partnership Programme (EDCTP2) jointly undertaken by several Member States.

4. This requirement is in compliance with Article 1 (3) of the EU Regulation No 1290/2013 of the European Parliament and of the Council of the European Union of December 11th 2013 laying down the rules for participation and dissemination in Horizon 2020—the Framework Programme for Research and Innovation (2014-2020). EDCTP2 legislation also enshrines derogation to Article 9(1)(b), Article 10(1)(c) and, Article 12 of the above mentioned regulation in order to allow participation and funding of African entities, and allow cooperation through joint calls between EDCTP2 programme and any other legal entities.
The European Union provides a cash contribution, which amounts to a maximum ceiling of 683 million euros for 2014-2023. This contribution comes out of the specific objective Health, Demographic Change and Wellbeing of the Societal Challenges pillar of Horizon 2020, the EU’s Framework Programme for Research and Innovation.

For the overall period, European Participating States will at least match the European Union’s contribution. Participating States’ contribution can exceed the European Union’s contribution as during EDCTP1 programme. All Participating States’ annual commitments are indicated up-front in the EDCTP’s annual work plan. These contributions can be in-kind and cash.

Third parties, like industry or Product Development Partnerships, have also the possibility to contribute to EDCTP. For this second programme, EDCTP will endeavour to raise 500 million euros in contributions from third parties.

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EDCTP’s Funding Schemes

Participating States’ Initiated Activities (PSIA) are independently funded by Participating States. These activities are counted as in-kind contribution and are included up-front in the annual work plan. For these activities, EDCTP works as a platform of integration. Provided that two or more Participating States launch a joint activity call, EDCTP can potentially provide top-up funding for this call through the so-called PSIA co-fund mechanism. This mechanism acts as an incentive for further integration between Participating States.

Integrated activities are selected, administered and funded by the EDCTP. The European Union’s contribution is primarily allocated to integrated activities. Through these activities, EDCTP mainly supports clinical trials, which also include project management, networking and capacity development components. As EDCTP supports collaborative research, project proposals must involve at least three legal independent entities established in two different European participating States and one sub-Saharan African State.

Within the limit of this requirement, EDCTP funding scheme is equally open to collaborative clinical activities from public and private sectors, profit and not-for-profit organisations. EDCTP will also support research capacities development projects from individual researchers or teams. Implementation follows the rules of participation of Horizon 2020.

Joint activities are activities between one or more third parties, EDCTP and Participating States. These joint activities are mainly reserved for complex research opportunities of strategic importance in the scope of EDCTP2 that require a coordinated response from the field to maximise their impact. A joint activity may for instance be an open call launched jointly by EDCTP and other legal entities or EDCTP could launch a call for proposals for co-funding of joint activities.

Third parties (pharmaceutical industry, product development partnership, charities, etc)
MONITORING AND EVALUATION

The implementation of the EDCTP2 programme will be monitored and evaluated against clear objective and indicators set into the Decision (No 556/2014/EU) of the European Parliament and of the Council of the European Union. By the end of the second programme, EDCTP is to deliver at least one new medical intervention, to issue approximately 30 guidelines for improved or extended use of existing medical interventions, and to make progress on the clinical development of approximately 20 candidate medical interventions.

On a day-to-day basis, the implementation of the EDCTP2 programme is monitored using key performance indicators, such as the number of supported clinical trials that lead to new products, processes, methodologies, diagnostics, treatments or preventive vaccines. Another example of key performance indicators is the proportion of clinical trials funded by EDCTP with African leadership. The effectiveness of EDCTP’s governance structure is also closely monitored through similar indicators.

EDCTP 2 MID-TERM REVIEW BY 2017

By June 30th 2017, the European Commission will carry out an interim evaluation of the EDCTP2 programme with the assistance of independent experts. This interim evaluation report will be sent to the European Parliament and the Council of the European Union. The European Parliament will have the opportunity to react to this interim evaluation report by for instance formulating recommendations for the second half of the EDCTP2 programme. EDCTP2 interim evaluation report will inform the Horizon 2020 interim evaluation report.

KEY DEFINITION

Poverty related and neglected diseases (PRNDs), namely HIV and AIDS, malaria, tuberculosis and 17 neglected tropical diseases listed by the World Health Organization, are infectious diseases that disproportionately affect the world’s poorest and most vulnerable population. Adequate, affordable and quality health products to prevent, diagnose and treat neglected infectious diseases are however crucially lacking. The private sector does not have enough incentives to develop urgently needed products. EDCTP’s scope encompasses all PRNDs prevalent in sub-Saharan Africa that means that Chagas disease, which is prevalent in Latin America, is not addressed within the EDCTP framework.