



The European & Developing Countries Clinical Trials Partnership (EDCTP)

The EDCTP initiative has become a true success story and is an excellent example of a mutually beneficial EU-Africa partnership, helping to tackle the global challenge of poverty-related infectious diseases and make progress towards the Millennium Development Goals. To date, 16 European countries¹ take part in this voluntary programme. They team up with institutions and researchers from sub-Saharan Africa to coordinate their national research programmes, carry out joint projects, and share resources and results.

A genuine partnership

EDCTP has succeeded in establishing a genuine partnership with its African partners who retain a high degree of ownership and leadership. They coordinate more than half of the clinical trials carried out and have been awarded three quarters of EDCTP funding. So far, the initiative has supported 57 clinical trials and it has helped train hundreds of African researchers and medical doctors through its fellowship programme and other training schemes.

More effective investments

EDCTP is also a role model for structuring the European Research Area through joint programming between European countries, which is financially supported by the EU (€400 million in total). Set up under Article 185 of the EU's Lisbon Treaty - a first! - to create synergies, share resources and increase cost-effectiveness, it has created a win-win situation for those involved by linking up individual countries' health research efforts.

Moving further

EDCTP-1 has provided a first important step towards the creation of a common European platform for clinical trials against poverty related diseases. The challenge lies now in getting even more countries, industries funders and donors involved. Indeed, preparations to continue and expand the partnership have already started. The current 16 European EDCTP partner countries¹ plus Latvia have already expressed their interest in supporting an EDCTP-2 programme, while expecting again co-funding from the EU (through Horizon 2020, the next EU Research and Innovation programme 2014-2020).

EDCTP aims to receive pledges of € 500 million each from the EU, the European partner countries, and third parties (such as pharmaceutical companies, foundations, charities, NGOs, and other countries), i.e. 1.5 billion in total for 2014-2024.

The European Commission, together with the EDCTP partner countries, is currently developing a detailed roadmap for the preparation of EDCTP-2.

¹ Austria, Belgium, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Mandate

The EDCTP's core objective is to accelerate the development of new clinical interventions to fight HIV/AIDS, malaria and tuberculosis in developing countries, particularly in sub-Saharan Africa, and to improve generally the quality of research in relation to these diseases.

Organisation

The EDCTP Secretariat is legally established in the Netherlands (Headquarter in The Hague, Liaison Office in Cape Town) and involves 16 European countries as founding members. EDCTP's scientific governance and strategy-making involves political representation from the African Union, the WHO Regional Committee for Africa, and the African Regional Economic Communities, as well as scientific experts from Africa.

Major Achievements

Under the umbrella of EDCTP, the 16 European partner countries established the strategic and operational capacities to manage a joint programme of actions, including agreed common rules for selecting and funding clinical research activities in sub-Saharan Africa.

57 clinical trials have been launched under EDCTP, including multi-site clinical trials involving patients and trials sites in several African countries, and involving more than 100,000 patients so far, with a special focus on infants, children/adolescents, and/or pregnant/lactating women: 27 trials on HIV/AIDS (€ 118 million); 18 on tuberculosis (€110 million); 12 on malaria (€76 million). Most clinical trials are ongoing. However, some first positive results have been achieved:

- The US Food and Drug Administration (FDA) has approved an anti-retroviral formulation for HIV infected children in Africa, which was tested in an EDCTP project.
- The 'Kesho Bora Study' demonstrated a 43% reduction in HIV infections in infants and more than 50% reduction of mother to child transmission during breastfeeding. These findings were influential for the new WHO guidelines on prevention of mother-to-child transmission of HIV, which were released in July 2010.
- PRO2000 is an example of a completed clinical trial for a HIV microbicide which demonstrated that although safe, PRO2000 vaginal gel was not efficacious against vaginal HIV-1 transmission and further development was discontinued.

Significant EDCTP funding is also targeted towards capacity strengthening and competence development. It aims to foster sound ethical and conducive regulatory environment for clinical research in Africa as it is an indispensable pre-condition for carrying out clinical trials meeting international standards. Up to now, EDCTP has supported 75 ethics and regulatory capacity building activities, including the Vaccine Regulators Forum (AVAREF) as well as for National Ethics Committees (NECs) in countries with almost non-existent capacity, such as Benin, Gabon, Mozambique and Rwanda. EDCTP fostered also the establishment of four regional clinical research networks of excellence in each of the four sub-Saharan regions and provided over 150 training awards to African scientists. Last-but-not-least, the Pan-African Clinical Trials Registry (PACTR) was established as an African initiative funded by EDCTP (officially recognised as WHO Primary Registry) <http://www.pactr.org/>

EDCTP in Figures

- Launched in 2003
- 16 European and 29 sub-Saharan African countries currently cooperating
- €400 million in EU funding, including €200 million from the 16 European partner countries
- €80 million in co-funding from third parties, such as pharmaceutical companies, foundations, charities, NGOs
- 195 projects worth around €350 million, including 57 clinical trials on-going or carried out
- 156 African and 42 European institutions being funded
- 62% of projects led by African researchers, 70% of funding going to African institutions