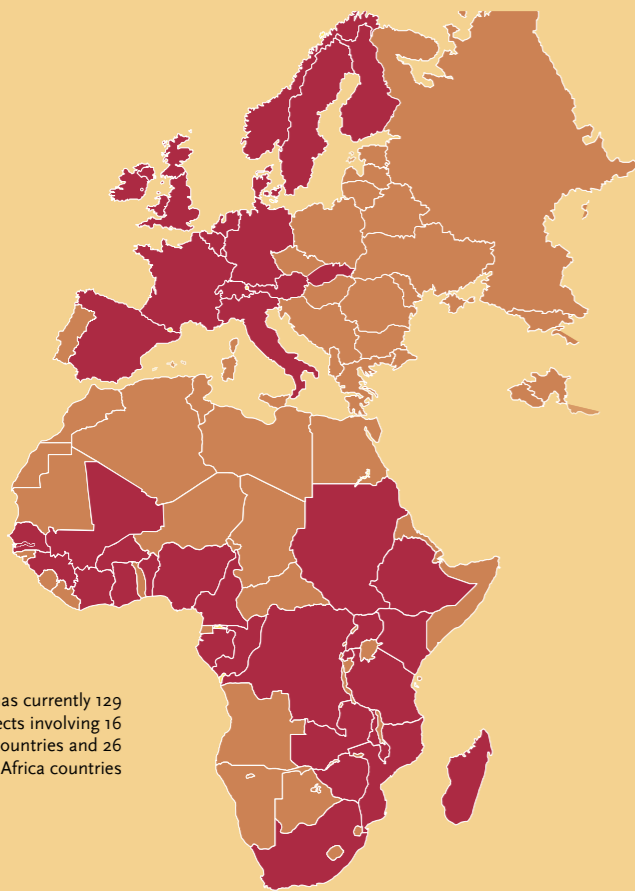




# EDCTP: Big strides towards a true Partnership

Established in 2003 as a European response to the global health crisis caused by the three main poverty-related diseases (PRDs) namely HIV/AIDS, tuberculosis and malaria, the European and Developing Countries Clinical Trials Partnership (EDCTP) is proving to be a promising partnership model. The Partnership joins European national research programmes on poverty-related diseases, and in collaboration with African counterparts, develops new clinical tools against HIV/AIDS, malaria and tuberculosis.

Currently EDCTP is a partnership between 14 European Union member states plus Norway and Switzerland with 47 sub-Saharan African countries. EDCTP is succeeding in transcending traditional research based on colonial affiliations and in breaking down barriers that have impeded broader south-south and north-south cooperation.



EDCTP has currently 129 funded projects involving 16 European countries and 26 sub-Saharan Africa countries

The context of the EDCTP programme is the dramatic health situation in many developing countries, especially sub-Saharan Africa, and the concerted action of the European Union to fight the three main poverty-related diseases. By combating these diseases, EDCTP jointly targets the goal to fight against poverty as well as the three Millennium Development Goals on health.

EDCTP aims to accelerate the development of new or improved drugs, vaccines and microbicides against HIV/AIDS, malaria and tuberculosis, with a focus on phase II and III clinical trials in sub-Saharan Africa. To achieve this, EDCTP offers integrated grants that focus on clinical trials (which are the principal function of EDCTP) as the core integrated with networking and capacity development.

## Way of working

EDCTP funded activities are based on the following components:

- Networking between and coordination of European national research and development programmes with their partners in the south
- Supporting relevant clinical trials
- Networking and coordination of African national programmes
- Strengthening the African capacity in this field

In the funding environment, EDCTP seeks to shape a common research strategy involving EU Member States, and to explore further streamlining through involving Public Private Partnerships (PPPs), Product Development Partnerships (PDPs), industry and other funding bodies. Also, synergy is sought between Research activities and Development Aid activities.

The EDCTP principle of requiring at least two European member states and two African countries to collaborate in projects and the encouragement of third-party participation has been very much instrumental in the formation of various consortia. The formation or support of these research consortia is very cost-effective and fosters strong synergies.

## Sharing science

Establishing genuine partnerships is a hallmark of EDCTP and one of its most significant achievements. The EDCTP model, in which capacity development and networking are integrated, facilitates rational utilisation of created capacity and minimises redundancy and duplication. This approach enhances transfer of technology and proliferation of new collaborations and has been acknowledged by many as a powerful and exemplary approach and copied by others.<sup>1,2,3</sup> Furthermore, the pairing of well-established centres with less endowed ones is proving very effective and has been extended to four Networks of Excellence for conducting clinical trials.

These networks, divided into Central, Eastern, Southern and Western African regions based on regional economic blocks, comprise institutions of varying and complementary capacities that work in synergy to conduct clinical trials, training, south-south mentorship and capacity development in the continent. It is realised that for the networks to be effective and sustainable they must not only work closely with each other, but also with already existing networks. Moreover, there is a strong need for garnering the support and commitment of African leadership and funding. This calls for the various global initiatives to work closely together and with the African governments and regional bodies to ensure effective, synergistic programmes and to ensure sustainability.

<sup>1</sup> Josefina Coloma, Eva Harris. From Construction Workers to Architects: Developing Scientific Research capacity in Low-Income Countries. PLoS Biology. Vol. 7 (7) pp 1-4 e1000156 July 2009.  
<sup>2</sup> Editorial. Strengthening research capacity in Africa. Lancet. Vol. 374 pp 1, 4 July 2009.  
<sup>3</sup> Whitworth, et al. Strengthening capacity for health research in Africa. Lancet. Vol. 372 pp 1590-1593, 1 November 2008.

Notable among the various other consortia that work with EDCTP support include The Malaria in Pregnancy (MiP) Consortium and the Pan-African Consortium for the Evaluation of Antituberculosis Antibiotics (PanACEA). The MiP Consortium conducts clinical trials for improving the management of malaria during pregnancy in terms of evaluation safety and efficacy of drugs for prevention and treatment. The PanACEA is a consortium that was created by EDCTP to conduct a series of cooperative trials that together seek to shorten and simplify the treatment of drug-sensitive tuberculosis. This consortium, which brings together many stakeholders besides EDCTP, includes researchers and funders from public and private institutions such as the Bill and Melinda Gates Foundation, Global TB Alliance, pharmaceutical companies and academic institutions from Africa, Europe and USA.

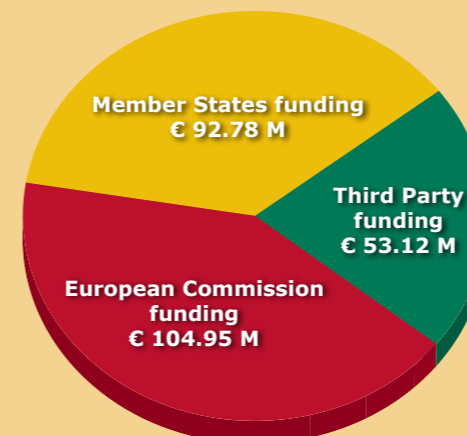


EDCTP is working closely in many projects with other like-minded organisation including the TB Global Alliance, AERAS Global Tuberculosis Vaccine Foundation, Medicines for Malaria Venture, European Vaccines Initiative, Microbicide Development Programme and International Partnership for Microbicides among others.

## African Empowerment

Ensuring that research effectively addresses the needs and priorities of the developing countries by encouraging African ownership and leadership is critical. EDCTP partnership structures which are the Partnership Board (PB) responsible for developing the strategy, and the Developing Countries Coordinating Committee (DCCC) responsible for identifying the needs and gaps, have African representation. EDCTP has made capacity building and African participation mandatory in all its clinical trial activities. It supports the establishment and strengthening of National Ethics Committees (NEC) and Institutional Review Boards (IRB). In collaboration with the World Health Organisation, EDCTP supports strengthening capacity of African national regulatory framework including the African Vaccine Regulatory Forum (AVAREF) activities. EDCTP has been responsible for supporting the establishment of the Pan-African Clinical Trials Registry (PACTR) run by South African Cochrane Centre, the only African registry with WHO primary clinical trial registry status. PACTR is responsible for the registration of all clinical trials in Africa to mitigate the under registration of trials in the region.

By the end of 2009 EDCTP had funded 129 projects worth around 250 million Euros which involve 136 institutions from 26 sub-Saharan countries, 76 institutions from 16 European countries and 40 other partners – non-profit organisations and private sector partner. Of all EDCTP-funded projects, 68 % are led by African project coordinators.



Value of EDCTP funded projects from 2003 to 31 December 2009

Among the positive outcomes of EDCTP funded trials is the CHAPAS trial in Zambia that has contributed to the FDA approval and WHO prequalification of Triomune Baby/ Junior, a fixed-drug combination formulation for the treatment of HIV in children. This has made it possible for the drug to be available under programmes such as US President's Emergency for HIV/AIDS Relief (PEPFAR) and Clinton HIV/AIDS Initiative (CHAI).

## Long-term commitment

The response of EDCTP to the burden of HIV/AIDS, tuberculosis and malaria is simple and pragmatic: the existing national European and African health research programmes have to be strengthened and integrated. Furthermore, the overall environment for carrying out clinical trial activities in Africa has to be improved and African scientific leadership in the conduct of these trials promoted.

The fight against poverty-related diseases is a long-term endeavour requiring equally long-term commitment and investment. The current remit of EDCTP is to support mainly phase II and phase III clinical trials of the three PRDs, and capacity development in Africa. Although this should remain the main focus, there is a need to broaden its base to include related activities that would add value to the programme. Therefore, EDCTP intends to expand its scope to include phase I clinical trials in Africa and phase IV post registration studies, as well as research into health services that will include exploring how best to deliver new products through health systems.

## European & Developing Countries Clinical Trials Partnership

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