



## The power of sharing science

*The impact of EU-funded research can  
be increased significantly if forces are joined*

The European and Developing Countries Clinical Trials Partnership (EDCTP) was created in 2003 as a European response to the global health crisis caused by the three main poverty-related diseases (PRDs) of HIV/AIDS, tuberculosis and malaria. Currently EDCTP is a partnership between 14 European Union member states plus Norway and Switzerland with 47 sub-Saharan African countries. The Partnership aims to create sustainable and genuine research collaboration between European and African 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 namely HIV/AIDS, tuberculosis and malaria. By combating these diseases, EDCTP jointly targets the goal to fight against poverty as well as the three Millennium Development Goals on health that include reduction in childhood and maternal mortality rates.

The aim of the programme is to accelerate the development of new or improved drugs, vaccines and microbicides against HIV/AIDS, malaria and tuberculosis through promoting the integration of national programmes of EDCTP European Member States and development of a genuine partnership with African counterparts.



# EDCTP for integration of research funds

EDCTP was formed by a European Parliament and European Council decision as a response to the increasing need to pool funding and activities in the battle against the three PRDs. It combined political will and defined health priorities of both the developing and the developed world. EDCTP is cofunded by the European Commission and European Member States under Article 169 of the EU Treaty to promote a more integrated approach to health research among European countries.

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, EDCTP aims to improve the overall environment for carrying out clinical trial activities in Africa and promote African scientific leadership in the conduct of these trials, and it has implemented a robust funding strategy to meet this aim: a strategy to do more and to do it better.

## *The response of EDCTP to the burden of HIV/AIDS,*

### **Fighting poverty by accelerating the development of tools against HIV/AIDS, tuberculosis and malaria**

EDCTP provides a platform for the conduct of clinical trials and the development of the required capacity in developing countries. Clinical trials form an essential step to assess the safety and efficacy of drugs, vaccines and microbicides. Trials for safety and efficacy of investigational products occur at a later stage in the development of these products, when they are tested in humans. They are expensive and require high standards of regulations and ethics within the countries concerned. Clinical trials can be a bottleneck where there is not enough financial support or capacity on the ground. There are some signs of progress thanks to increased funding and efforts from a number of sources, but continuous and long-term investments are needed to prevent refuelling these epidemics. EDCTP aims to bridge these gaps.

Currently EDCTP funds primarily phase II and III clinical trials (research in human beings) on HIV/AIDS, tuberculosis and malaria in sub-Saharan Africa. EDCTP maintains its focus on supporting clinical trials as its core activity within a strategic integrated approach to capacity development and networking thus creating an enabling environment for conducting these trials. The mandate of EDCTP is however expected to broaden in the near future to cover all four phases of clinical trials as well as aspects of health systems research. By funding research on the safety and efficacy of drugs, vaccines, microbicides and diagnostics, EDCTP accelerates the development of tools to fight the diseases and reduce poverty.

## Creating a true European-African Partnership

The EU member states and their partners in developing countries have substantial research activities on HIV/AIDS, tuberculosis and malaria. The impact of EU-funded research and capacity development in sub-Saharan Africa can be increased significantly if forces are joined. Donors, funders and policy makers seek efficient allocation of funds and efforts. EDCTP's mandate is 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.

EDCTP is emerging as model example of a genuine north-south partnership. From its conceptualisation to implementation, there has been consultation and participation of all relevant stakeholders from both the north and south. As part of its main objective EDCTP ensures that the clinical trials and research it funds are effectively addressing the needs and

### *tuberculosis and malaria is simple and pragmatic*

priorities of developing countries by encouraging African commitment, ownership and leadership. The EDCTP partnership structure which comprise the Partnership Board responsible for developing strategy and overseeing of the scientific integrity has equal representation from north and south whereas the Developing Countries Coordinating Committee (DCCC) responsible for identifying the African needs and priorities is entirely African. EDCTP has made capacity building and African participation mandatory in all its clinical trial 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. Furthermore, EDCTP is succeeding in transcending traditional research activities based on colonial affiliations and in breaking down barriers that have impeded south-south cooperation.

EDCTP emphasises developing capacity for clinical trials in Africa to fight HIV/AIDS, tuberculosis and malaria, and ensuring adherence to internationally recognised scientific, ethics and regulatory standards. Strengthening of the ethics and regulatory environment within Africa is an essential part of EDCTP's activities. EDCTP supports the establishment and strengthening of National Ethics Committees (NEC) and Institutional Review Boards (IRB). In collaboration with the World Health Organisation, EDCTP supports capacity strengthening of African national regulatory framework including the African Vaccine

*Most activities take place in African countries,  
and rely on the local study sites, institutions,  
expertise and human resources*

Regulatory Forum (AVAREF) activities. EDCTP has been responsible for supporting the establishment of the Pan-African Clinical Trials Registry (PACTR), 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.

### **A promising model**

The EDCTP model, in which capacity development is embedded within the core business of clinical trials and integrated in both south-south and north-south networking to enhance transfer of technology and proliferation of the developed capacity, has been acknowledged by many as a powerful and exemplary approach and copied by others. Furthermore, fostering of collaboration between well-established centres with less endowed ones is proving very effective and has been extended to four regional *Networks of Excellence*.

Establishing genuine partnerships is a hallmark of EDCTP and one of its most significant achievements. Notable among the various consortia that work this way with EDCTP support are: 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, 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 (MMV), Microbicide Development Programme (MDP), International Partnership for Microbicides (IPM), TuBerculosis Vaccine Initiative (TBVI), International AIDS Vaccine Initiative (IAVI), Foundation for Innovative New Diagnostics (FIND), and EVI: European Vaccine Initiative.



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## Future Outlook

The fight against poverty-related diseases is a long-term project 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.

Forming partnerships means sharing responsibility. EDCTP has emerged as a model of a true partnership. While important progress has been made, the poverty related diseases still kill millions of people each year. Investing in EDCTP activities will lead to improvements in health and save lives of people in sub-Saharan Africa, and enhance Europe's role as an important player in the global arena, where European-African partnership defines joint priorities, avoiding duplication and creating a win-win situation for all parties involved.