

The EDCTP pillars:

Knowledge

- generated by conducting high quality clinical trials
- disseminated to be widely available and freely accessible
- designed to inform policy decision

Sustainability

- capacity: transfer empowerment to the development world by increasing generally the quality of research and building leadership in health research
- ownership: full involvement and contribution of stakeholders in establishing priorities and conducting research
- partnership: optimise synergies between research programmes of stakeholders and partner organisations

The EDCTP aims to contribute towards reducing the burden of the main poverty-related diseases and transferring empowerment to the developing world whilst synergising European research programmes.



building

better

health

for a future

together

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EDCTP – European & Developing Countries Clinical Trials Partnership



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The vicious circle of illness and poverty

Disease in the developing world is killing people as never before. Combined, HIV/AIDS, tuberculosis and malaria kill some 6 million people each year. They affect heavily the health and wealth of households, communities and societies. This is first and foremost a crisis in developing countries, but it also creates a global problem for the entire world.

This need not to be the case. The now-developed world experienced similar problems in years gone by. Sanitation and inventions such as vaccines and antibiotics changed that. Liberated from disease, the economies of the North grew and the standard of living improved.

But where are the technologies against HIV/AIDS, malaria and tuberculosis which would allow developing countries to grow the same way? Recent years have witnessed an increased awareness of these diseases, mirrored by a diverse array of new initiatives. However, scientific advances have yet to translate into tangible health benefits for the poor.

Lack of adequate research capacities play a central role in sustaining the vicious cycle of illness and poverty. Developing countries at large lack the ability to research their health priorities and develop the necessary drugs and vaccines.

The essential research is amazingly simple: making better use of the interventions we have; conducting more R&D for vaccines, microbicides and better drugs. However, this is not happening, or at least not to the extent that it is needed.

The European and Developing Countries Clinical Trials Partnership (EDCTP) calls for a united and coordinated response of developed and developing countries towards reducing the health and economic burden of diseases such as HIV/AIDS, tuberculosis and malaria.

EDCTP: Origin and goals

The EDCTP was formed by the European Parliament and Council decision as a response to the combined political will and health priorities of both the developing and developed world.

The EDCTP aims to contribute to the development of new and affordable therapeutics and prophylactics for HIV/AIDS, tuberculosis and malaria. Initially, it will focus on the countries most severely afflicted, primarily Sub-Saharan Africa.

The EDCTP comprises 14 EU Member States plus Norway and is funded by the European Commission under the previously unexercised Article 169 of the Treaty of the European Union to promote a more integrated approach to health research amongst European countries.



A platform for clinical trials and capacities



The EDCTP is poised to provide a platform for the conduct of large-scale clinical trials and the development of the required capacities in developing countries. Furthermore, it aims at improving synergies of, and collaboration amongst, national and international research programmes.

The EDCTP is jointly owned by participating programmes and creates a framework to synchronise efforts and pool resources. It is readily apparent that there are multiple opportunities for partnership between public, private for- and not-for-profit organisations to develop both products and capacities.

Essentially, the EDCTP does not discover products nor develop them to registration. Rather it participates in studying interventions, which can be used in humans to support registration and policies, whilst promoting wide dissemination and use of results. Clinical trials are an essential step to assess the viability and

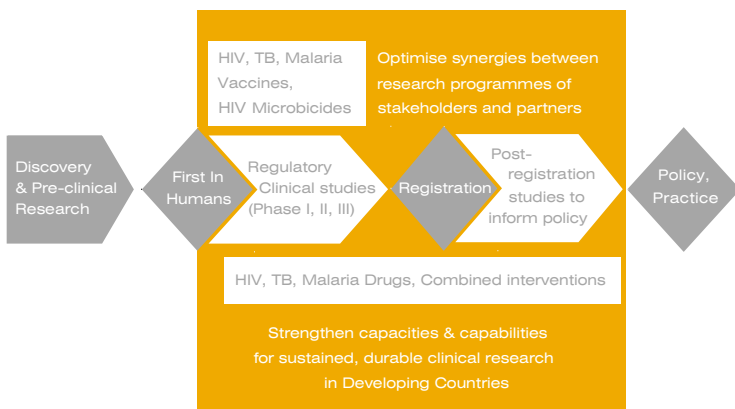
suitability of a product, be it a drug or a vaccine. Trials occur late in development, when products are ready to be tested for their safety and efficacy in human beings. They are expensive and require high standards of regulations and ethics within the countries concerned. Clinical trials can be a bottleneck where there is not enough financial support or capacities. The EDCTP aims to bridge these gaps. Training personnel and upgrading institutions is a crucial element of the EDCTP mandate and activities, thus enabling the concerned countries to conduct clinical trials independently in the future.

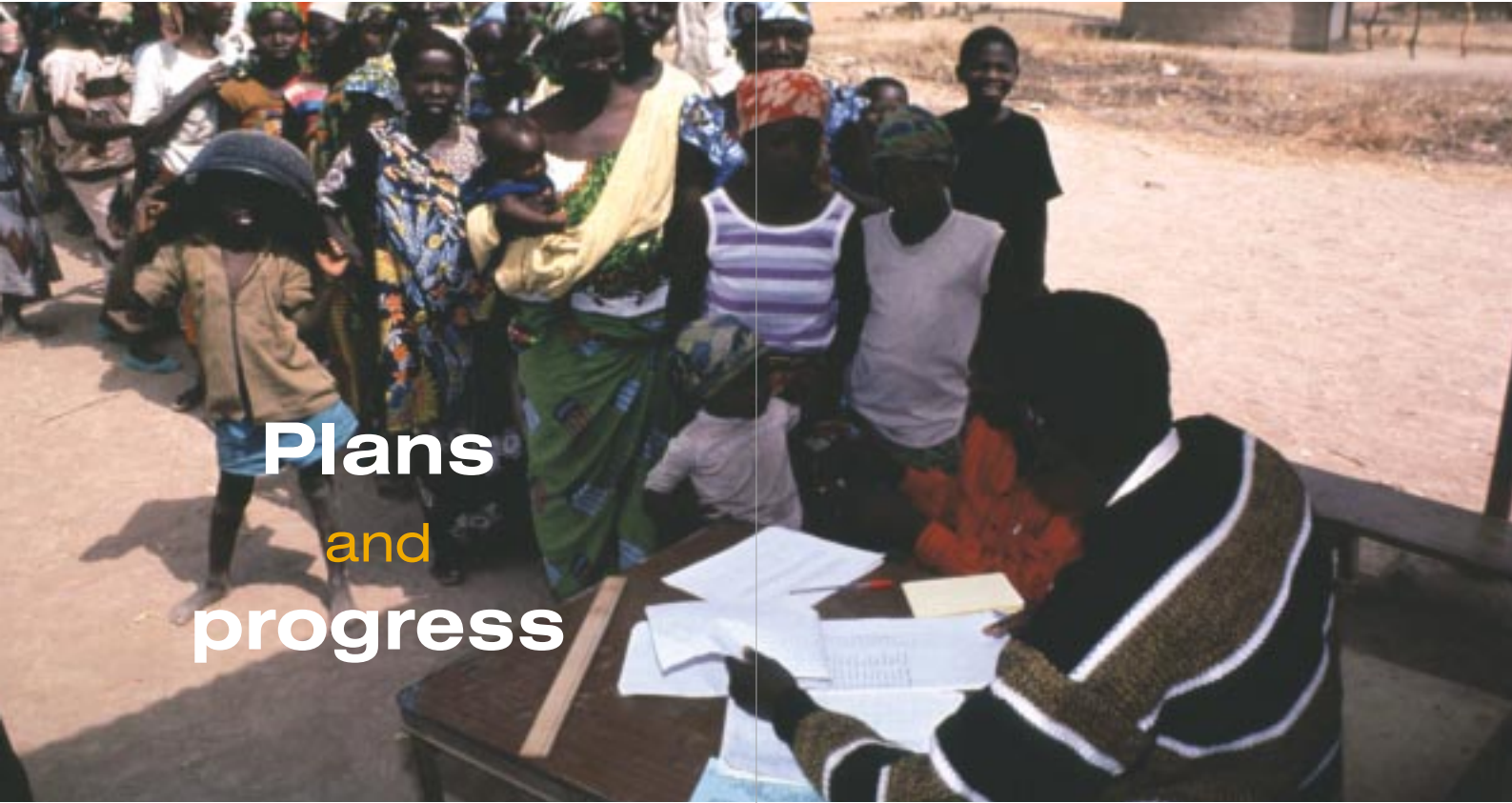
Ultimately, the developing countries will benefit not only from new and more adapted drugs and vaccines, but also from the technologies, expertise and knowledge which investigators and institutions have acquired.

Obviously, adequate funding is critical. Today, there is more money available than ever to fight these diseases, but that is still inadequate and uncoordinated. Action against diseases of poverty is a collective responsibility; donors must scale up funding, organisations must ensure optimal use of funds, and activities need to be better coordinated.

At present, the EDCTP operates on a European Commission contribution of € 200 million distributed over 5 years, matched by current level of funds invested collectively in poverty-related diseases by the EDCTP member states through their national programmes. The EDCTP is about partnership, pursuing a common platform to optimise synergies and maximise efficiencies across European country programmes. The EDCTP is also forming strategic alliances with like-minded organisations in the public and private sector towards achieving common goals.

EDCTP scope and remit





Plans and progress

The problems posed by these diseases require immediate action. The initial objective of the EDCTP in its first semester of operations in 2004 has been to start delivering without delay. Plans of action and mechanisms have been put in place.

We have immediately circulated 2 rounds of calls for the conduct of drug and vaccine trials, assigned a number of senior fellowship grants and approved the establishment of a clinical trial registry. Recently also 9 projects for funding have been selected. They involve collectively 14 African and 8 European countries and provide an excellent basis for networking institutions, studying interventions and building capacities. More calls for proposals are to be expected.

Current status of main EDCTP activities

Interventions	Short and medium-term priorities	Grants	Senior Fellows
Drug trials on HIV/AIDS	Simplified treatment, including once-daily regimens	1	1
	Reduce mother-to-child transmission	Projected	1
Drug trials on Tuberculosis	Validated surrogate markers of activity to shorten trials and time to registration	2	1
	Simplified & improved treatment, including shortening duration and management of TB/HIV	2	1
Drug trials on Malaria	Clinical evaluation of artemisinin-containing regimens for uncomplicated malaria in Africa	3	2
	Clinical evaluation of artemisinin-containing regimens for severe malaria in Africa	1	0
	Malaria in pregnancy	Preparatory phase	
Vaccine trials on HIV/AIDS, Tuberculosis, Malaria	Capacities in Africa to conduct GCP quality trials on preventative vaccines	Selection of projects underway	
Microbicide trials on HIV/AIDS	Capacities in Africa to conduct GCP quality trials	Selection of projects underway	
Clinical trial registry	International registry for randomised clinical trials in HIV/AIDS, tuberculosis and malaria	1	
Trial conduct	Strengthen the ethical review process in Africa	Preparatory phase	
	Strengthen capacities in Africa to conduct GCP quality trials	As part of funded projects	

The EDCTP aims at funding partnerships that will advance the development of relevant health interventions. Projects must have the potential to advance scientific knowledge, transfer relevant capacities, increase capabilities and inform health policy in resource-poor settings, and to deliver interventions for disease control in developing countries.

Organisation of the EDCTP

The **EDCTP-EEIG** is the legal entity and the operative arm of the EDCTP, which provides the legal, financial and operational structures needed to receive, dispense and account for funds, and implement actions. It has two organs:

- the EEIG Assembly, the final decision-making authority in which all participating European states are officially represented;
- the Secretariat, the organisation's day-to-day management body.

The **Partnership** structures provide the EDCTP with guidance, scientific and regional expertise. They comprise

- the Partnership Board, the strategic advisory committee with equal representation of European and African scientists;
- the Partnership Forum, to represent Africa (the Developing Countries Coordinating Committee) and Europe (the European Network of National Programmes).

The EDCTP has established offices in The Hague, the Netherlands hosted by the Netherlands Organisation for Scientific Research and in Cape Town, South Africa hosted by the South Africa Medical Research Council.