



A strategy

# The Power of

to do more

# Sharing Science

and better



E D C T P

European Union - Department for International Development

**‘There is an increasing need to pool funding and activities in the battle against the three PRDs’**



## Funding environment

The European & Developing Countries Clinical Trials Partnership (EDCTP) was created as a European response to the global health crisis caused by the three main poverty-related diseases of HIV/AIDS, malaria and tuberculosis. These diseases kill over 7 million people each year. Sub-Saharan Africa is the world's worst-affected region where besides ravaging lives, they impede development and cause poverty. EDCTP is a partnership of European and sub-Saharan countries, which aims to reduce poverty by fighting HIV/AIDS, malaria and tuberculosis. EDCTP has implemented a robust funding strategy upto 2010 to meet this aim: a strategy to do more and better.

### **The burden of HIV/AIDS, tuberculosis and malaria in sub-Saharan Africa**

The heavy burden of HIV/AIDS, tuberculosis and malaria, seriously impedes economic development and causes unnecessary death and suffering in developing countries. Sub-Saharan Africa is the world's worst affected region. Approximately 40 million people worldwide are infected with HIV, seventy percent of whom are living in sub-Saharan Africa. Over 1.5 million people are infected with TB in this region each year. In recent years this number has been rising rapidly, largely due to high prevalence of HIV. 90% of malaria deaths occur in sub-Saharan Africa. It is therefore not a matter of *if* we should fight these three poverty-related diseases (PRDs), but of *how* this can be done most effectively.

### **Political awareness and increasing available funds**

Only 10% of global health research funds are devoted to addressing health problems in the regions where 90% of the world population live. To date investments in research have been modest. There is a need to set research priorities, strengthen research capacity and address funding issues. The three main poverty-related diseases of HIV/AIDS, tuberculosis and malaria offer a vast terrain to African researchers in areas varying from prevention and treatment to public health measures.



In the past decade, global political awareness has increased sharply, and efforts to reduce the burden of HIV/AIDS, tuberculosis and malaria have been intensified. In September 2000, 189 countries signed the Millennium Declaration. This declaration was translated into eight Millennium Development Goals to be met by 2015 to improve the general circumstances of those living in poverty. One of them is the goal to combat HIV/AIDS, malaria and other diseases, which states that by 2015 we must:

- Halt and begin to reverse the spread of HIV/AIDS
- Achieve universal access to treatment for HIV/AIDS for all those who need it
- Halt and begin to reverse the incidence of malaria and other major diseases (source: United Nations Statistics Division).

In Africa, similar raising of awareness and action took place. On 25 April 2000, the Summit of African leaders from 44 malaria-endemic countries took place in Abuja, Nigeria. To stress the burden of malaria on the continent, the leaders signed the historic Abuja Declaration, committing governments to an intensive effort to halve the burden of malaria in Africa by 2010 and setting interim targets for the year 2005. Furthermore, a special summit in May 2006, the African Union adopted far-reaching decisions to fight HIV/AIDS, tuberculosis and malaria (ATM). The summit adopted the Abuja Call for accelerated action towards universal access to ATM services in Africa, and a resolution to achieve this by 2010.

#### **Global and European funding of research into the three PRDs**

There is an increasing need to pool funding and activities in the battle against the three PRDs. The most visible pooling initiative is the Global Fund to fight AIDS, malaria and tuberculosis (GFAMT), which generates and channels funding, mainly to purchase drugs and commodities for national governments. Nearly a hundred other global initiatives, often in the form of public-private partnerships (PPP) focus on the three diseases.

The European Community, together with the World Health Organization (WHO), responded to this issue by organising on 28 September 2000 a High Level Round Table on PRDs with key players in health and development and political leaders from Africa. Emphasis was placed on the critical need for an international response.

Dr Gro Harlem Brundtland, Director-General of WHO, declared:

*“We must invest in the future – for new drugs, new vaccines and new diagnostic tools. Our challenge is to create the incentives – and the right kind of economic environment – that will give priority to the diseases that create and perpetuate poverty. Research and development is a critical part of the strategy.”*

#### **EDCTP for integration of European research funds**

The European- and Developing Countries Clinical Trials Partnership (EDCTP) was formed by the European Parliament and European Council decision as a response to this strategy. It combined political will and defined health priorities of both developing and developed world. EDCTP is a partnership of 14 participating European Union (EU) Member States plus Norway and Switzerland with sub-Saharan African countries. It is funded by the European Commission 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 programs 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 leadership in the conduct of these trials.

‘The partnership ensures synergy and optimal use of resources, and creates a win-win situation for all parties involved’



## Mission and core activities

### Mission

Essentially, EDCTP provides a platform for the conduct of clinical trials and the development of the required capacity in developing countries. Clinical trials are an essential step to assess the viability and suitability of drugs, vaccines and microbicides. Trials occur late in the development of these products, when they are 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. EDCTP aims to bridge these gaps.

**EDCTP aims to accelerate the development of new or improved drugs, vaccines, microbicides and diagnostics against HIV/AIDS, malaria and tuberculosis, with a focus on phase II and III clinical trials in sub-Saharan Africa.**

At the basis of this is partnership. All EDCTP-funded projects are undertaken in partnership with sub-Saharan countries. The partnership helps EU Member States to integrate and coordinate their own national research and development programmes and form partnerships with their African counterparts. The partnership ensures synergy and optimal use of resources, and creates a win-win situation for all parties involved.

### Vision

EDCTP aims to complement the European Member States' national programmes to carry out essential research and competence building programmes, and to gain from the diverse and complementary aspects covered by these programmes. This may include activities such as exchanging information, mutual opening of programmes, different forms of joint activities such as joint calls for proposals and evaluations, training schemes and campaigns to disseminate results.

**European research into HIV/AIDS, tuberculosis and malaria may operate as joint programmes with pooling of resources, thus maximising the benefit of their research.**



Developing a joint programme for research into the three PRDs requires a committed political process by both European Member States and African countries. This requires political will at the national, institutional and project levels. EDCTP should be viewed as an instrument to enhance collaborative efforts of European and developing countries and thus to maximise efficacy to develop new interventions. In this regard, EDCTP addresses issues of research politics that may have a wider implication and are about the ongoing development of a European Research Area.

### Scope

Primarily, EDCTP funds phase II and III clinical trials on HIV/AIDS, tuberculosis and malaria in sub-Saharan Africa. To create an enabling environment for carrying out these trials, EDCTP also enhances research capacity in Africa, creates synergies across research programmes, acts as a broker for more research into product development, and encourages transnational research that informs policy. It also ensures an enabling environment for conducting these trials by strengthening capacities in ethics review and regulatory affairs.

EDCTP does not discover products nor develop them to registration. EDCTP involvement starts after approval for first-in-human studies has been granted to a product. Nevertheless, EDCTP will keep abreast of new developments in the late discovery or pre-clinical stages and will continuously interact with scientists, developers and the broader scientific environment to formulate strategic plans around promising candidates. Therefore, EDCTP is not a tools developer, but a partner and a platform for clinical trials to ensure complete clinical development and transfer of its technologies to sub-Saharan Africa.

### Mandate and budget

EDCTP is jointly owned by participating EU national programmes and those of developing countries, and creates a framework to synchronise and pool resources. The budget of EDCTP is € 400 million for 2003-2010. By applying Article 169 the national commitment of each Member State is used to mobilise their publicly funded organisational and institutional activities within the scope of EDCTP programme into a joint programme under EDCTP. Additionally, the

Member States are expected to cofund both in kind and with new money to top up the contribution of the European Commission (EC) to € 400 M by 2010. EDCTP is also forming strategic alliances with like-minded organisations in the public and private sector towards achieving common goals.

### Ethics and regulatory affairs

The products and outcomes of EDCTP have the African populations and research communities in mind as the major beneficiaries. In addition, most activities take place in African countries, and rely on the local study sites, institutions, expertise and human resources. Large clinical trials following international quality and ethical standards require extensive and costly infrastructural and organisational set-ups in developing countries. Thus, coordination and strengthening of the ethics and regulatory environment within Africa is an essential part of EDCTP's activities.

All EDCTP funded projects must comply with internationally accepted standards. EDCTP requires that all studies that are funded by EDCTP are performed in accordance with the standards and codes of conduct accepted by the International Conference on Harmonisation (ICH) guidelines and that they comply with the local ethical requirements of the countries where the studies will be conducted.

### Core activities

To achieve its objectives EDCTP has the following seven main activities:

- Networking and coordination of European national programmes
- Networking and coordination of African programmes
- Supporting relevant clinical trials
- Strengthening the African capacity in conducting clinical trials
- Advocacy and fundraising
- Management
- Information management.

Specific strategies and action plans have been developed for each of these seven activity areas.

**'The aim is to deliver more and faster'**



## **Funding Strategy 2007-2010**

EDCTP's strategy for 2007-2010 focuses on accelerating the roll-out of grants to step up the pace of supporting clinical trials as well as that of capacity development and networking. The aim is to deliver more and faster. Therefore while in the previous years the focus has been on setting up of delivery instruments and African ownership and leadership, the emphasis now is on the actual delivery. This approach will include implementing a close follow-up and monitoring of approved projects to ensure quick negotiation and signing of contracts. To facilitate this, a database and tracking system that includes automatic alerts, count-downs and target milestones for contract negotiation have been developed.

### **Integrated calls**

Researchers in sub-Saharan Africa are faced with the need for multi-centre protocols, a demanding regulatory environment and universal ethical standards. With the right resources and training, sub-Saharan countries have the opportunity to take leadership and create a sustainable environment for conducting high-quality clinical research.

To achieve this, EDCTP offers integrated grants that focus on clinical trials (which is the principal function of EDCTP) as the core and use networking and capacity development to create an enabling and sustainable environment for the conduct of clinical trials in Africa. EDCTP-funded activities are therefore based on the following components:

- Networking and coordination of European national research and development programmes in partnership with sub-Saharan programmes
- Supporting relevant clinical trials
- Creating and strengthening a research enabling environment.

EDCTP believes that capacity development gives African researchers the opportunity to 'learn by doing', to utilise the developed capacity and to ensure a successful outcome and capacity retention. Networking through north-south and south-south mentorship will create the critical mass that is required for sustainability.

Fund allocation (in € 1,000)									
	Clinical trials	North-North networking	South-South networking	Career dev. Fellowships	PhD Fellowships	Infrastructure development	Short term training	Baseline studies	Total
HIV treatment	4,500	500	300	100	75	329	611	229	6,643
HIV vaccines	5,023	500	300	100	75	329	611	229	7,166
HIV microbicides	4,000	500	300	100	75	329	611	229	6,143
TB treatment	10,000	1,000	600	200	150	658	1,222	458	14,287
TB vaccines	7,749	500	300	200	150	658	1,222	458	11,236
Malaria treatment	7,000	500	300	100	75	329	611	229	9,143
Malaria in pregnancy	7,000	500	300	100	75	329	611	229	9,143
Malaria vaccines	12,262	500	300	100	75	329	611	229	14,405
Ethics and regulatory									4,387
Senior Fellowships									3,600
Networks of Excellence									10,000
Funds for intergated projects are expected to be matched by equal amounts of Member State and third party funding									

## Themes

EDCTP's integrated calls are linked to themes, which are explored by EDCTP and its stakeholders before launching the calls. Thematic stakeholder meetings, which are based on disease and intervention methods, are used to identify which products should be supported, to identify gaps and requirements for conducting the required clinical trials, and to agree on the mode of formulating grant proposals. The proposals can result in open calls or brokering.

Themes for EDCTP calls for proposals or brokering are:

- HIV treatment
- HIV vaccines
- HIV microbicides
- Tuberculosis treatment
- Tuberculosis vaccines
- Malaria treatment
- Malaria in pregnancy
- Malaria vaccines
- Ethics review and regulatory framework
- Senior Fellowships
- Networks of Excellence.

## Joint programme activities

EDCTP recognises the need and importance of networking in ensuring successful and sustainable outcomes. Networking is therefore one of the main pillars and is used to achieve integration and coordination of European national programmes, strong north-south partnerships, transfer of technology, synergy and sustainability of the Partnership. To this end, EDCTP aims to identify and strengthen Joint Programme Activities (JPAs): existing and/or ongoing research activities within the scope of the EDCTP programme of two or more EU Member States working independently on the same area with one or more African institutions.

## Category A: funding existing Member State collaboration

The first category of Joint Programme Activities comprises already existing collaborations between EDCTP Member States in which there is joint funding of research projects. Such projects may or may not be receiving third-party funding. In this case EDCTP records the level of funding from each Member State (including funds from other national agencies e.g. development and health ministry funding) and third parties (if any), and EDCTP or its Member States may identify or suggest opportunities for enhancement through additional funding. The purpose of EDCTP funding in this case is to contribute to expanding (more sites, larger cohort, additional Member States involved) or extending (e.g. phase I to phase II or phase II to phase III) the project.

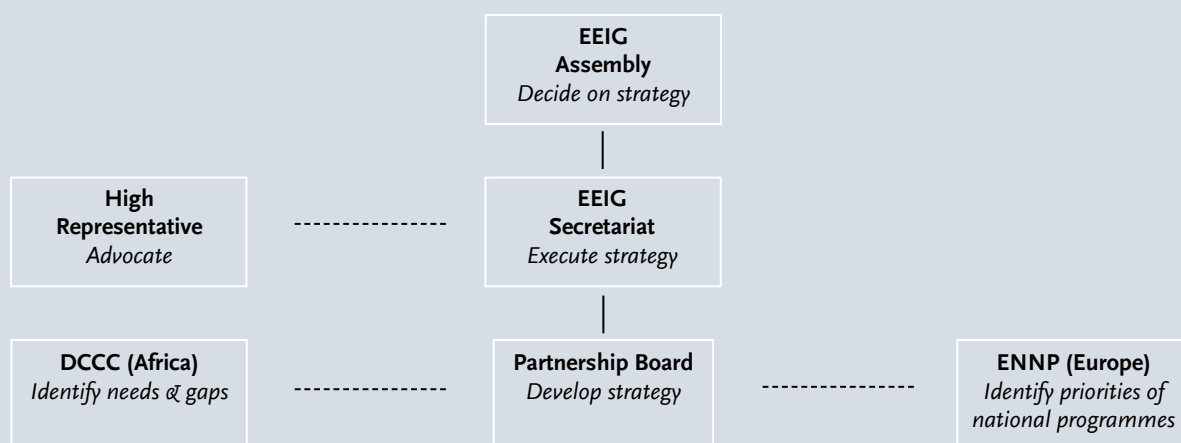
## Category B: joining existing Member State research projects

The second category is formed by the already ongoing activities where two or more EDCTP Member States are funding similar research projects and/or work with the same African institution (or institutions) but with limited or no collaboration or coordination of activities or funding. In this case EDCTP will identify levels of funding by each Member State (including funds from other national public sources e.g. development and health ministry funding), identify or suggest current and future opportunities for collaboration and identify or suggest opportunities for enhancement of activities through further funding from Member States, EDCTP and third parties. The purpose of EDCTP funding in this category is to enhance the activities or projects through coordination/networking initiatives and to develop a valid Joint Programme Activity.

## Category C: launching joint calls for proposals

The third category includes current or future plans by two or more Member States to open calls and/or fund research on EDCTP themes where there may be scope for cooperation or collaboration in order to reduce overlaps and duplication. The purpose of this type of funding is to add value to projects and to enhance Joint Programmes.

## GOVERNANCE



## Governance

### Governance structure

The legal, operational and financial structure of EDCTP is provided by the European Economic Interest Group (EDCTP-EEIG) through its two organs, namely the EEIG Assembly and the Secretariat. The EEIG Assembly, headed by its Chair, is the final decision-making authority in which all participating European Member States are represented. The Secretariat, headed by the Executive Director, is responsible for the day-to-day running of the organisation.

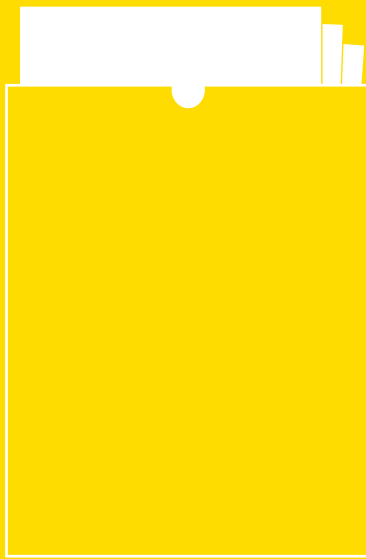
The EEIG Assembly is assisted by the Partnership structure, which is the strategic and planning arm comprising of the scientific and regional expertise necessary for effective steering of the EDCTP programme and its funding both in Europe and in sub-Saharan Africa. Constituents of the Partnership include:

- The Partnership Board (PB), a scientifically independent expert panel that develops the strategic planning of EDCTP
- The Developing Countries Coordinating Committee (DCCC), which consists of representative African scientists and ensures the input and commitment of African countries and researchers
- The European Network of National Programmes (ENNP), which consists of representatives of the European national programmes and develops proposals for joint national activities and funding.

The Partnership structures and the European Commission hold permanent seats in the EEIG Assembly. The role and operations of each body are determined in the EEIG statutes and the Internal Regulations.



## Fact sheets



European & Developing Countries  
Clinical Trials Partnership

**EDCTP – Europe Office**

P.O. Box 93015  
2509 AA The Hague  
The Netherlands  
Phone: +31 70 344 0880/0897  
Fax: +31 70 344 0899

**EDCTP – Africa Office**

PO Box 19070  
Tygerberg 7505  
South Africa  
Phone: +27 21 938 0819  
Fax: +27 21 938 0569

E-mail: [info@edctp.org](mailto:info@edctp.org)  
Web: [www.edctp.org](http://www.edctp.org)



EUROPEAN  
COMMISSION

Supported by the EU DG Research