

*European and Developing Countries  
Clinical Trials Programme on  
Poverty-related Diseases*



**EUROPEAN  
and DEVELOPING COUNTRIES  
CLINICAL TRIALS PROGRAMME  
ON POVERTY-RELATED DISEASES**

**EDCTP**



# EUROPEAN and DEVELOPING COUNTRIES CLINICAL TRIALS PROGRAMME ON POVERTY-RELATED DISEASES



## EDCTP

### Background

The burden of diseases, especially HIV/AIDS, Tuberculosis and Malaria is disproportionately borne by the poorest countries, in particular sub-Saharan Africa, and in these countries, by the poorest people.

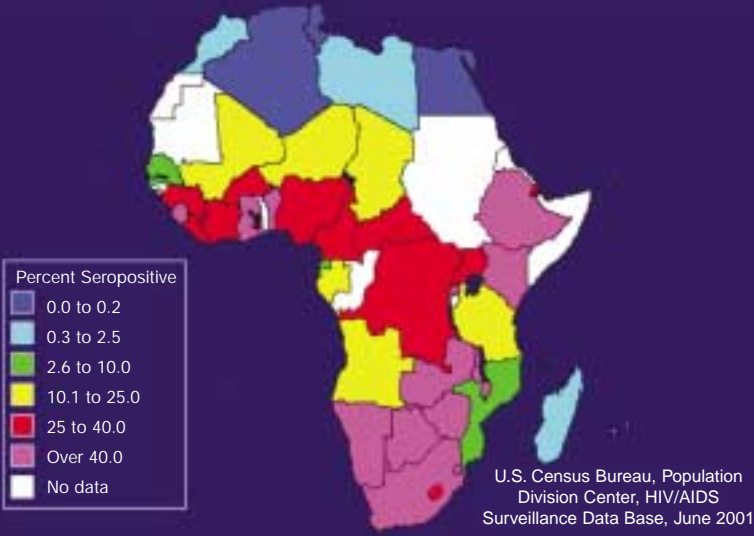
**These poverty related diseases (PRDs) are a cause and consequence of poverty and a drain on the economic, education and health development in many developing countries (DCs).**

The continuing poverty of the DCs means lack of investment in the development of effective prevention and treatment programmes. This situation has been made worse by a general under-investment of public and private funds against infectious diseases, particularly in Africa.

The European Community, together with the WHO, responded to this issue by organising on September 28th, 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."*

### African HIV1 Seroprevalence from High-Risk Urban Populations



The development of the EDCTP is a concrete response to this strategy.

The EDCTP goals are to increase the effectiveness of Europe's investment in clinical trials for interventions against HIV/AIDS, TB and Malaria and to attract more resources into developing these interventions.

In order to achieve this, Europe will use three major tools, networking of national programmes, supporting clinical trials, as well as strengthening

capacities and transferring know-how and technologies in clinical research to the DCs. Furthermore, the EDCTP would add value at European level and help define common strategies between Member and Associated States.

**The EDCTP will be distinguished from many others international initiatives to fight HIV/AIDS, TB and Malaria by its long-term relationship with the DCs, and the proposal to form the EDCTP as a North-South partnership.**

## State of the Art Assessment

**Few investments in development co-operation will give a higher return than those aimed at improving health in those countries.**

The Commission has taken the initiative to establish a broad and coherent European response to the emergency caused in sub-Saharan Africa by the three major communicable diseases (HIV/AIDS, TB and Malaria,) that most affect the poorest populations and undermine their economic and social development. It is recognised that other poverty-related disease PRDs and other geographic regions may be included later.

Clinical interventions against these diseases to be tested through the EDCTP could include:

- Therapy against HIV/AIDS, TB and malaria: simplified combinations therapy of existing drugs; reformulating of existing drugs; development of new drugs
- Development of new drugs and therapeutic strategies against HIV/AIDS related opportunistic infections
- Immune-based interventions against HIV/AIDS, malaria and TB: development of either prophylactic or therapeutic vaccines; development of combinations of vaccines, combination of antiretroviral and immunomodulatory based strategies.
- Microbicides preventing HIV infection and spreading
- Other interventions

## The EDCTP project:

Over 90% of public sector R&D in Europe are conducted at the Member and Associated State level, mainly under national or regional research programmes, but also at Institutions or other organisations.

The proposal for a multi-annual Framework Programme 2002-2006 [COM (2001) 94] of the EC for research, technological development and demonstration activities aims at contributing towards the creation of the European Research Area. The scale of research needed to develop new interventions may be better addressed at a European level.

It is proposed to achieve this goal by the participation of the EU in programmes carried out jointly by participating Member under Article 169 of the EU Treaty of Amsterdam. In that context, the Commission's "Programme for Action: Accelerated action on HIV/AIDS, Malaria and Tuberculosis in the context of poverty reduction" [COM (2001) 96] proposes the creation of a Clinical Trials Programme (EDCTP) to provide the stimulus necessary to accelerate the development of new interventions for use in DCs.

The EDCTP would add value and coherence to EU National R&D programmes and activities aimed at new interventions such as clinical trials of drugs, vaccines and other health interventions for the prevention and control of PRDs in DCs.

**Support for joint implementation of Research Programmes is an effective means for stimulating co-operation between Member States or between several countries within Europe and Africa, and is particularly effective in cost-benefit terms.**

A total of 14 European Member States (Austria, Belgium, Denmark, Finland, France, Germany, Greece, Italy, Ireland, the Netherlands, Portugal, Spain, Sweden and the United Kingdom) plus 1 Associate State (Norway) have conducted preparatory work to identify the operational functions of the EDCTP, and to call for its establishment. The Commission is supporting this first stage of activities with € 1.2 million.

The Research Council of October, 30th, 2001 considered that areas suitable for the use of Article 169 should be linked to Community RTD policy, noting the work under way on the "European Clinical Trials Platform".

## Aims of the EDCTP

- Increase the effectiveness of Europe's investment in clinical trials for interventions against PRDs
- Attract more resources into developing these interventions
- Accelerate candidate products and other interventions through the developmental pipeline (translational research)
- Accelerate the development of capacity and capability in DCs to test the efficacy and effectiveness of interventions against PRDs.

## The operational functions of the EDCTP are:

- Support the networking and pooling of EU national trials activities, including the infrastructures needed in EU to support these trials (notably Phase I trials)
- Support the networking and pooling of DC trials activities.
- Support the development of trials infrastructures in DCs, with a focus on capacity-building and training
- Sponsor clinical trials, by putting together financial packages that attract external sources of co-financing for this purpose, particularly in partnership with the pharmaceutical industry
- Develop a European, rather than national, presence in international initiatives for the PRDs.

## EDCTP Strategic Plan

The final EDCTP strategic plan will be developed by consultation between the stakeholders of the EDCTP.

**The main stakeholders are:**

- **The European participating national programmes and activities**
- **The Developing Countries**
- **The Scientific Community**
- **The Pharmaceutical Industry**
- **NGOs where these are effective ways to engage with communities directly affected by these diseases.**

The basis for developing an EDCTP strategic plan has been developed by a EDCTP committee comprising 5 European and 5 African representatives in consultation with the stakeholders. This plan will form the basis for the operational functions of the EDCTP. This will also guide development of appropriate governance structures and the EDCTP business plan.

## The major outputs from the strategic plan will be:

- Scope of activities of the EDCTP in terms of diseases and geographical focus
- Needs assessment by the Developing Countries
- Agreed priorities in terms of the types of interventions that are to be evaluated with EDCTP support
- A framework for networking of European national programmes and activities
- An understanding of potential partnerships of sponsors (including EDCTP), scientists and clinicians, for clinical trials, particularly in sub-Saharan Africa
- Analysis of the capabilities and capacities of clinical trial centres in sub-Saharan Africa, and if needed elsewhere, and a strategic plan for capacity strengthening and training
- Development of the EDCTP Governance
- Development the EDCTP Business Plan

**The EDCTP will be unable to, and should not, support development of new interventions without a strategic clinical plan. The major priorities are likely to include:**

- A clear understanding of the basis for cooperation with existing or future industry objectives
- A commitment to advance clinical interventions of benefit to sub-Saharan Africa, but also including trials in other clinically relevant geographical areas if required
- Short-term and long-term priorities
- A degree of risk-taking to support new interventions that may not otherwise attract private or public funding



## Policy to network national EU activities

EDCTP will support the networking and pooling of EU national trials activities, including the infrastructures needed in the EU to support these trials (notably Phase I and II trials).

The main goal is to provide added value to national activities and European community programmes by encouragement to reflect the priorities of the EDCTP Strategic Plan in domestic funding policies. It does not explicitly call for direct financial contributions from national programmes or activities to the EDCTP.

The concept of networking can be applied at various levels:

- Intra-national networking: increased co-operation between activities in individual participating states
- Inter-national networking: co-operation between activities of participating member and associated states at the European, Developing Country, and global levels

**Networking will build upon existing or future national activities at various levels of integration.**

These could range from information exchange to development of integrated strategy and financial support of joint projects between participating states. This principle could be extended to networking with already existing European initiatives.

Major outputs of networking are:

- Agreement by national programmes and activities to support the clinical trials framework in terms of internal strategic funding policies
- Identification of duplications or gaps within national/international activities, and, consistent with the framework, an agreed plan to address these
- Added value to national activities by bringing together complementary activities in member and associated states for expedited clinical trials with clear end points for selection of superior clinical interventions for further development
- Identification of new initiatives that cannot be supported at the national level

## Clinical Site assessment in the Developing Countries



A EDCTP associated clinical trials site will be defined as one that has the capability to conduct clinical trials in accordance with ICH - GCP regulations, and that such trials will be accepted by the regulatory authorities for registration and licensure.

In the DCs, sites should be understood to mean a network of clinical and other research structures corresponding to the different skills required for the design, conduct and analysis of clinical trials related to HIV and/or tuberculosis and/or malaria, under GCP/GLP conditions.

A site could be located at one single place. Because of the different skills and facilities needed for some clinical trials, a site could also be developed from the networking of different structures, which complement each other, and allow a more efficient use of resources.

**The principles of fair competition and bidding for being selected for financial support EDCTP is fully endorsed by the EDCTP.**

To become an EDCTP associated site, in addition to fulfilling the criteria for undertaking an EDCTP funded project and succeed in this competition, documented sustainability with political commitment from the Government in the country in question is required.

## Policy for capacity strengthening and training

**EDCTP will support the development of trials infrastructures in DCs with a focus on capacity building and training.**

A major requirement is support to networking between sub-Saharan clinical trials sites and other related institutions and organisations.

These activities are based on four essential criteria:

- Need for assessment by the DCs on the types of clinical interventions that are required, with short and long term timelines for their introduction
- A framework that identifies the pipeline of development of interventions, the probable numbers per year, the state of development (Phase I – IV), and the capabilities and capacities of clinical sites that will be required.
- An assessment of existing clinical trial sites in sub-Saharan Africa (and elsewhere, if justified)
- South-South networking during the undertaking of trials as well as during training and capacity building.

These criteria will be used to develop a strategic plan for capacity strengthening and training of personnel in existing or new (upgraded) clinical trial sites. This strategic plan will be a major responsibility of the DCs in close association with the European Partners.

**Capacity strengthening** refers to the infrastructure that is required to conduct GCP clinical trials, and may include hospital wards, field sites, clinical laboratories and equipment, data management and data filing, repositories for storage of material, and IT support. Development and aid agencies, at the Commission, European, and international levels could participate in more permanent capacity strengthening.

**Training** refers to the clinical skilled personnel that are required for GCP clinical trials. These include principle investigators, physicians, nurses, laboratory staff, data managers, and regulatory experts. Training needs will be closely linked to capacity strengthening in the context of forward planning based on the clinical trials framework. It is essential that EDCTP investments in DCs personnel be linked to sustainable career opportunities within both EDCTP activities and the parent Institutions.

**The final aim is that EDCTP develops a long term sustainable network of GCP clinical trials sites in sub-Saharan Africa, and eventually elsewhere, as needed.**

#### **Policy for EDCTP clinical trials.**

EDCTP will participate in clinical trials, by putting together financial packages that attract external sources of co-financing for this purpose, particularly in partnership with the pharmaceutical industry.

**The EDCTP will act as a 'broker' to assemble funding and other support to advance new interventions through clinical trials.**

Procedures by which the EDCTP will support clinical trials.

- Investigator-driven applications with review by the EDCTP to ensure compliance with the strategic plan
- Pro-active initiation of clinical trials by the EDCTP by soliciting proposals, in line with the strategic plan

The EDCTP decision making process will ensure transparency and accountability by:

- Defining criteria for entry into the EDCTP pipeline, determined by the scientific community in agreement with the EDCTP strategic plan
- Defining clear end points that must be achieved before an intervention can be advanced
- Clear independent review of proposals
- Ethical review and compliance with regulatory requirements

## EDCTP Governance

The structure and governance of EDCTP will reflect four fundamental needs:

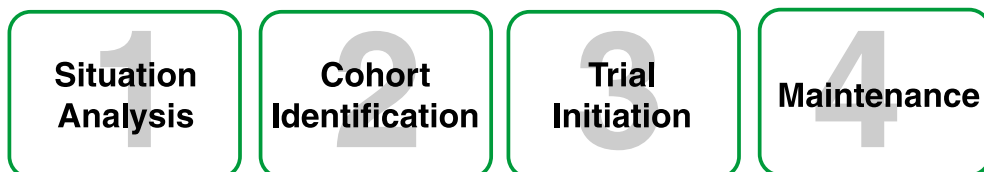
- **Inclusive decision-making:** EDCTP will aim for involvement of relevant European, DC, and other international experts, in major decisions on strategy, scientific/medical priorities, ethics, and major operational policies.
- **A focused Management Team:** EDCTP will need a Director and a small staff supporting the day-to-day operations, based in a central office in a European state. The functions of the central office will include co-ordination of other EDCTP activities dispersed to various European and DC organisations or sites.
- **Accountability:** EDCTP will be accountable at many different levels, reflecting the variety of relationships it has.
- **Flexibility:** EDCTP will develop structures that allow for quick negotiations and decision making in joining together contributions from different sources.

## EDCTP business plan

### Acquisition of financial resources

EDCTP anticipates funding by the European Commission for its stated operations. These will be principally devoted to capacity strengthening of clinical trial sites, and for direct costs of trials as far as they are spent for European and DC participants.

The EDCTP will make a clear accounting of funds derived from different sources and the projects for which they are spent.



## Governing concept for trial support

Preference will be given to trials on interventions which are likely to provide the best sustainable benefits to the local population, considering affordability, lack of industrial interest, and engagement of international intervention programmes.

**EDCTP will encourage an enhanced engagement of industry, SMEs, academic institutions and capital providers.**

**The opportunities provided by EDCTP should substantially lower risk and cost of clinical trials.**

Applicants may apply for EDCTP funds for the conduct of phase I – III trials and phase IV studies according to a four-module system.

- Module 1: Situation analysis
- Module 2: Cohort identification
- Module 3a: Trial initiation phase
- Module 3b: Conduct of clinical trials phase I – III and phase IV studies
- Module 4: Maintenance of existing structures

Applications involve competitive public calls and will be evaluated by a joint DCs/European Peer Review Committee of Advisors supported by the EDCTP Management team.

The principal requirement for funding clinical trials is an existing track record of previous clinical trials as performed according to GCP and GLP. Sites that have fulfilled preparatory modules I and II should meet GCP requirements.

**EDCTP will continuously collect and monitor the availability of new vaccines, drugs, microbicides and other interventions under development and the capacity of trial sites to conduct trials of these interventions.**

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