

# **PUBLIC CONSULTATION REGARDING A FUTURE PROPOSAL FOR A NEW EUROPEAN AND DEVELOPING COUNTRIES CLINICAL TRIALS PARTNERSHIP (EDCTP)**

## **CONSULTATION DOCUMENT**

### **BACKGROUND**

Although HIV/AIDS, malaria and tuberculosis are three treatable and preventable diseases, they have a devastating impact on the world's poorest countries. The health impact of these three diseases is undeniable, but their social and economic impacts are also significant. Investments in the fight against these three poverty-related diseases would lead to very significant improvements in people's health and lives.<sup>1</sup>

The European Commission has financed research on HIV/AIDS, malaria, and tuberculosis for many years. The projects supported until year 2002 involved mainly basic and preclinical research, and early clinical trials.

The prioritisation of these three main poverty-related diseases during the Fifth Framework Programme (1998-2002)<sup>2</sup> led to the development of vaccines and candidate drug which were tested in Europe and Africa up to the early clinical trial stage. Further development into advanced clinical trial stage needing large scale clinical trials (phases II and III) under the Sixth Framework Programme (2002-2006)<sup>3</sup> in Africa proved very difficult. Neither the EU nor the African scientific community had the capacity to prepare for and perform large scale clinical trials in Africa.

At that time, Member States were undertaking individual research and development programmes or activities to address HIV/AIDS, malaria and tuberculosis without sufficient co-ordination at European level to allow for a coherent approach to a fully effective research programme. Moreover, the enabling environment to conduct clinical trials in Africa in accordance with good clinical and laboratory practice, sound ethical review and competent regulatory oversight, was limited.

The European and Developing Countries Clinical Trials Partnership (EDCTP)<sup>4</sup> was established in September 2003 by 15 European countries<sup>5</sup> with the aim to develop capacity building for clinical trials and new clinical interventions to address the needs of sub-Saharan Africa in the fields of HIV/AIDS, malaria and tuberculosis.

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<sup>1</sup> BMC Public Health: <http://www.biomedcentral.com/content/pdf/1471-2458-9-249.pdf>

<sup>2</sup> Decision No 1513/2002/EC of the European Parliament and of the Council of 27 June 2002

<sup>3</sup> Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006

<sup>4</sup> Decision No 1209/2003/EC of the European Parliament and of the Council of 16 June 2003 on Community participation in a research and development programme aimed at developing new clinical interventions to combat HIV/AIDS, malaria and tuberculosis through a long-term partnership between Europe and developing countries, undertaken by several Member States. OJCE N° L 169/1 of 8.7.2003

<sup>5</sup> Austria, Belgium, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, and the United Kingdom, plus Norway

Created in terms of Article 169 of the Treaty,<sup>6</sup> the EDCTP aims at better integrating existing research from different European Member States in the field of poverty-related diseases.

## **EDCTP: THE OBJECTIVES**

The EDCTP programme was created to address three main strategic objectives:<sup>7</sup>

1) Development of new interventions and products. The fight against HIV/AIDS, malaria and tuberculosis needs both prophylactic (vaccine and microbicides) and therapeutic (drugs) tools to prevent infection and control disease progression.

2) Sustainable capacity-building in Africa. Public health and research activities in Africa should be sustainable so local populations can better control the pandemic. The coordination of development aid and research policies with African countries should aim at a better implementation of these separate policies into a long term strategy against the three diseases.

3) Coordination of European Member States' research policies. Although the research activities of some EU Member States in Africa have been remarkable, these could profit from a better collaboration and coordination. The coordination of European national research programmes and policies on poverty-related diseases in Africa in terms of Article 185 of the Treaty has increased and will increase the efficacy of European interventions against these diseases.

The EDCTP is mainly funded through a €200 million grant under the Sixth Framework Programme. The grant agreement requires an equivalent amount of co-funding from Member States, increasing the total EDCTP budget to €400 million. Member States contribute to this co-funding budget both in cash and in kind. Additional funding from third parties (foundations, public-private partnerships, industry and other stakeholders) is envisaged for later clinical phases, especially in the case of industry which could become involved in the EDCTP activities when a product moves closer to marketing authorisation.

## **EDCTP GOVERNANCE**

The legal form chosen for implementing the EDCTP programme and managing funding is the European Economic Interest Group (EEIG).

The EEIG consists of:

- The General Assembly, the ultimate and exclusive decision-making body, in which all participating European Member States are represented. It acts collectively and the full members are jointly and severally liable for the actions of the EEIG. The principal responsibility of the Assembly is to ensure that all necessary activities are undertaken to achieve the statutory objectives of EDCTP and that its resources are properly and efficiently managed. It

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<sup>6</sup> Since re-numbered as Article 185 of the Treaty on the Functioning of the European Union.

<sup>7</sup> EDCTP website at <http://www.edctp.org/>

determines the EDCTP's general strategies, annual action plans (including calls for proposals), and the annual budgets and accounts.

- The Secretariat, the executive body which assures the day-to-day management.

Partnership structures external to the EEIG include:

- The Partnership Board (PB), an independent expert panel that develops the strategic planning of the 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 to coordinate and joint national activities and funding.

The Partnership structures and the European Commission hold permanent seats as observers in the EEIG Assembly.

## **EDCTP: THE CONTEXT**

The EDCTP Programme is the first of its kind, having been created in terms of article 169 of the treaty. As such, it encountered difficulties in its initial operational work since new structures had to be created and new procedures devised. In addition, the coordination of European National Research Programmes, the original EDCTP goal and the subject matter of the Article 169, is an ambitious task.

During this initial period of the EDCTP, the coordination of national programmes, has been a difficult task for two main reasons. First, some participating Member States lacked a national programme on HIV/AIDS, malaria and tuberculosis, so this had to be created. In the second place, participating Member States with ongoing activities in the field had to achieve an internal coordination that required re-adjusting their national activities.

The EDCTP was launched for an initial period of 5 years. In July 2007, after the publication of the independent mid-term external review (the Van Velzen report),<sup>8</sup> the grant agreement was extended until 2010, without additional budget being required. The external review provided recommendations on how EDCTP could better integrate Member State national programmes and increase clinical trial and capacity building activities through a stronger partnership with Africa.<sup>9</sup>

The European Commission submitted on October 2008 a communication<sup>10</sup> to the European Parliament and to Council on the progress made by EDCTP.<sup>11</sup>

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<sup>8</sup> Independent External Review Report: European and Developing Countries Clinical Trials Partnership (July 2007); also known as the Van Velzen Report; see [http://ec.europa.eu/research/health/povertydiseases/doc/final\\_ier\\_report\\_12july2007\\_en.pdf](http://ec.europa.eu/research/health/povertydiseases/doc/final_ier_report_12july2007_en.pdf)

<sup>9</sup> [ftp://ftp.cordis.europa.eu/pub/fp7/docs/van\\_velzen\\_final\\_ier\\_report\\_12july2007\\_en.pdf](ftp://ftp.cordis.europa.eu/pub/fp7/docs/van_velzen_final_ier_report_12july2007_en.pdf)

<sup>10</sup> COM(2008)688 of 30.10.2008

<sup>11</sup> SEC(2008)2723 of 30.10.2008

In 2009, a second independent external review of the EDCTP programme was conducted. The report made a number of recommendations to the EDCTP secretariat, the Member States and the European Commission.

## **OBJECTIVES OF THIS CONSULTATION**

The initial funding phase of the 2003-2009 EDCTP programme will expire in 2010. The purpose of this consultation is to invite the views and opinions of EDCTP stakeholders, experts active in the fields and the public at large on the need for and nature of a new EDCTP initiative. It will be used as input for a possible new EDCTP initiative by the European Commission.

The statements and questions proposed are informed by the outcome and recommendations of previous evaluations of EDCTP. We will report on the outcome of the consultation, taking all contributions into account.