Combating Aids, malaria and tuberculosis: research partnership Europe/developing countries

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This report outlines the state of progress on the European and Developing Countries Clinical Trials Partnership (the EDCTP Programme) which was established, in 2003, by Decision of the European Parliament and of the Council by 14 Member States (all the then Member States except Finland) and Norway (Switzerland joined the EDCTP in 2005). The objectives were to accelerate the development of new clinical interventions to fight HIV/AIDS, malaria and tuberculosis in the developing countries, particularly in sub-Saharan Africa, and to improve the quality of research in relation to these diseases. Created under the umbrella of the Article 169 of the Treaty, the EDCTP Programme aims at coordinating and jointly implementing activities at Member State level.

EDCTP is managed through a General Assembly where Member States are represented, a Secretariat under the Executive Director, and a High Representative. Advisory bodies include the Partnership Board (the scientific advisory board), the Developing Countries Coordinating Committee, and the European Network of National Programmes.

The Community has made a contribution to the EDCTP through a €200 million financial contribution under the 6th Framework Programme for Research and Technological Development (2002-2006) – FP6. The participating Member States provide 50% co-funding, both in cash and in kind, increasing the total EDCTP budget to €400 million. An additional €200 million funding from third parties is also envisaged.

The EDCTP Programme had an initial implementing phase (from 2003 to 2006) that was slower than initially foreseen. Over that period, budget spending was abnormally low, calls for proposals were cancelled and a 2004 report from the European Court of Auditors (PF-1828 (6046)) revealed several deficiencies. During the same period, the Secretariat was under four different Executive Directors, two of them being ad interim. As a consequence, in 2006 Commissioner Janez Potonik requested a panel of high level experts to prepare an Independent External Review (IER) report on the European and Developing Countries Clinical Trials Partnership, the so called van Velzen report, which was published in July 2007.

This progress report, published as a Commission Staff Working Document, is intended to inform on the achievements and current status of the first five years of the EDCTP Programme, from 2003 to 2008, following the recommendations of the Van Velzen report.

The time that has elapsed since its publication in July 2007 has allowed the implementation of most of its recommendations to the EDCTP Secretariat, Member States and Commission.

Since 2007, the EDCTP Secretariat has **redefined its scientific strategy**, through stakeholders' meetings held on the different diseases and products, increased collaboration with Public-Private Partnerships, renewed calls for proposals and simplified the co-funding.

Participating Member States have created a General Assembly Steering Committee, renewed their commitment to the EDCTP, reinforced African participation in the General Assembly, and are more and more accepting of a single central EDCTP evaluation.

The Commission is joining efforts of its relevant services in relation to EDCTP, working on a **strategic research policy for Africa including EDCTP**, and setting pre-conditions for future Article 169 initiatives, such as the necessity to ensure the pre-existence of national programmes and commitment to funding.

On the **operational side**, from September 2003 to May 2008, the EDCTP Programme has launched 33 calls and financed about 145 projects. Among these, 32 are clinical trials; 55 are training (MSc, PhDs and post doctoral) awards; 11 are supporting network activities; 14 are capacity building in ethics; 16 are Senior Fellowships; one project on strengthening the regulatory framework in Africa through collaboration with WHO; and one for the establishment and maintenance of a clinical trials registry. The projects are based in 26 different countries in sub-Saharan Africa, involving 123 institutions, and practically all participating Member States.

In particular, in 2007, the EDCTP launched 11 new calls for a total of €180 million (including €90 million of co-funding expected from Member States). In May 2008, and as partial outcome of these calls, the EDCTP General Assembly approved the financing of 8 new projects on malaria treatment, malaria vaccine, malaria in pregnancy, and tuberculosis vaccine; 8 new projects on capacity building for African ethical committees; 3 trans-disease regional networks of excellence (East, Central and West Africa), and 6 senior fellowships, for a total of about €87 million, including 50% co-funding from MS. The remaining calls are under evaluation.

As a result of all these calls, EDCTP has committed from 2003 to December 2007 €76.2 million (from EC, MS and third party funding) in grants, including a call co-funded by the Bill and Melinda Gates Foundation on HIV vaccines. In 2008, the EDCTP expects to increase this figure to over € 279 million.

However, since most projects are 3-year contracts, and some of them are just starting, the total EDCTP expenditure on research grants has been so far of €15.7 million. Out of the total commitment, 63% is going to African researchers. In 2007, 88% of the EDCTP budget was devoted to grants.

Member States' co-funding has increased from less than €1 million in 2005, to €6 million in 2006, and up to €21 million in 2007. Data from January to April 2008 already show €67 million committed or pledged from Member States.

Third party contributions contributed or committed from different foundations, product development public private partnerships and industries accounts so far for €34.1 million.

In the almost five years since its creation, the EDCTP has achieved **several important landmarks**:

- enhanced coordination of research activities and demonstrable capacity building;
- African researchers have an equal opportunity to their northern colleagues to develop proposals and become Principal Investigators;
- the EDCTP is urging African countries to establish national research budgets and to further contribute to the establishment of an African Fund for Health Research;
- EDCTP funding gives African researchers more ownership, provides better fora for discussion and knowledge exchange;
- capacities and sites developed are fully owned by the institutions and countries, avoiding scientific colonization;
- grantees have developed new research sites by accessing funding from other sources;

EDCTP funding is instrumental in the approval of some major health policy changes, such as the development of HIV treatment for children.