

**Analysis of the impact of a new EDCTP**

**Report of the Independent Expert Panel  
contributing to the Impact Assessment report  
on the new EDCTP**

**Brussels, August 28, 2010**

## TABLE OF CONTENTS

<b>Acronyms</b> .....	3
<b>Glossary</b> .....	5
<b>Executive Summary</b> .....	8
<b>1. Introduction</b> .....	9
<b>2. Terms of reference</b> .....	11
<b>3. Methodology</b> .....	12
<b>4. Background</b> .....	14
4.1 EDCTP’s performance so far.....	14
4.2 The options for EDCTP’s future .....	18
<b>5. Problem definition by EU</b> .....	19
<b>6. Discussion of EU’s problem statement</b> .....	21
6.1 Burden of disease .....	21
6.2 The lack of capacity for clinical R&D in Africa.....	23
6.3 A fragmented European landscape in R&D for Poverty-Related Diseases.....	23
<b>7. Analysis of Impact</b> .....	25
7.1 Political Impact .....	25
7.2 Financial Impact.....	27
7.3 Socio-economic Impact.....	29
7.4 Ecological impact.....	31
<b>8. Comparing the options</b> .....	32
<b>9. Monitoring and Evaluation</b> .....	33
<b>10. Discussion and recommendations</b> .....	35
List of Attachments.....	40

## **ACRONYMS**

AIDS	Acquired Immuno-Deficiency Syndrome
AO	EDCTP Africa Office
ARV	Antiretroviral Treatment
AU	African Union
CT	Clinical Trials
DC	Developing Country
DCCC	Developing Countries Coordinating Committee
EAC	East African Community
EC	European Commission
ECCAS	Economic Community of Central-African States
ECOWAS	Economic Community of West African States
EDCTP	European and Developing Countries Clinical Trials Partnership
EEIG	European Economic Interest Group
EU	European Union
EP	European Parliament
DALY	Disability Adjusted Life Year
DC	Developing Country
FDA	Food and Drug Administration
FP7	Seventh Framework program for Research and Technological Development
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund)
GCLP	Good Clinical Laboratory Practice
GCP	Good Clinical Practice
HIV	human immunodeficiency virus
IASG	Impact Assessment Steering Group
IEE	Independent External Expert evaluation
IGAD	Intergovernmental Authority on Development
IRB	Institutional Review Board
IPR	Intellectual Property Rights

MDG	Millennium Development Goals
MEP	Member of the European Parliament
MS	Member State of the EU
MRC	Medical Research Council
MTCT	Mother to Child Transmission
NEPAD	New Partnership for Africa's Development
NID	Neglected Infectious Disease
NIH	National Institute of Health (USA)
NN	North-North Networking
NP	National Programme
PB	Partnership Board
PDP	Product-Development Partnerships
PRD	Poverty-Related Disease
PPP	Public Private Partnership
R&D	Research and Development
RCT	Randomised Clinical Trials
SADC	Southern African Development Community
SSA	sub-Saharan Africa
TB	Tuberculosis
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
WHO	World Health Organisation
WHO/AFRO	WHO Regional Office for Africa

## GLOSSARY

**AIDS** - stands for 'Acquired immunodeficiency syndrome' and is a definition based on signs, symptoms, infections and cancers associated with the deficiency of the immune system that stems from infection with HIV.

**Antiretroviral** – a drug that is active against a retrovirus; in the context of the HIV/AIDS, any medication that is designed to inhibit the process by which HIV replicates.

**ART** – stands for an antiretroviral therapy that in a standard coverage consists of the use of at least three antiretroviral (ARV) drugs to maximally suppress the HIV virus and stop the progression of the HIV disease. Given huge reductions have been seen in rates of death and suffering when use is made of a potent ARV regiment, ART is now considered an integral part of the comprehensive response to HIV prevention, care and support.

**ARV** – stands for antiretroviral drugs that are medications for the treatment of infection by retroviruses, primarily HIV.

**Capacity building** - an approach to build skills and competence to deal with any future problems that arise. In the field of research refers to infrastructure as well as human resource development. The latter can include training of scientists at post-graduate (M.Sc./MPH), doctoral (pH.D.) as well as post-doctoral level

**Clinical research** - health research relating to individual patients and the development and evaluation of treatments for diseases.

**Clinical trial** - a research activity designed to test a drug or treatment in humans and so establish its efficacy and safety and to identify groups of patients who can be expected to benefit from such a drug or treatment. See also Phase-1, Phase-2, Phase-3, phase-4 trial

**Co-infection** - in the context of HIV/AIDS, the term used to describe the circumstance in which a person is concurrently infected with HIV and another infectious agents such as tuberculosis or hepatitis.

**Communicable disease** - an illness caused by a specific infectious agent or its toxic products that arises through transmission of that agent or its product from an infected person, animal or other reservoir to a susceptible host.

**Epidemiology** - a study of the distribution and determinants of health-related states or events (such as likely routes of transmission of disease and trends in epidemics) in specified populations and the application of knowledge to deal with health problems.

**East African Community (EAC)**- EAC is the regional intergovernmental organisation of the Republics of Kenya, Uganda, the United Republic of Tanzania, Republic of Rwanda and Republic of Burundi with its headquarters in Arusha, Tanzania.

**Economic Community of Central-African States (ECCAS)**- ECCAS is an Economic Community of the African Union for promotion of regional economic co-operation in Central Africa

**Economic Community of West African States (ECOWAS)**- ECOWAS is a regional group of fifteen West –African countries, founded in 1975. Its mission is to promote economic integration in all fields of economic activity, particularly industry, transport, telecommunications, energy, agriculture, natural resources, commerce, monetary and financial questions, social and cultural matters.

**European Developing Countries Clinical Trial Partnership (EDCTP)** - A partnership created by the EU in 2003 to support drug development for malaria, HIV/AIDS and TB in Developing Countries. The partnership involves today 14 European Union member states, Norway, Switzerland and several sub-Saharan African states. Switzerland joined the partnership in 2006. EDCTP is implemented by a dedicated European Economic Interest Group (EEIG) and is managed from a European (The Hague) and an African (Cape Town) office. Funded by EC from 2003 to 2007, first no cost-extension granted to 2010, second no-cost extension granted to 2015.

**European Economic Interest Group (EEIG)** – A structure created in terms of Council Regulation (EEC) No 2137/85 of 25 July 1985 on the European Economic Interest Grouping which permits cooperation across the EU between natural and legal persons. The EDCTP is implemented through such a dedicated structure with offices in Europe (The Hague) and Africa (Cape Town).

**HIV** – stands for human immunodeficiency virus that is a lentivirus (a member of the retrovirus family) that causes *acquired immunodeficiency syndrome* (AIDS), a condition in humans in which the immune system begins to fail, leading to life-threatening opportunistic infections. Infection with HIV occurs by the transfer of blood, semen, vaginal fluid, pre-ejaculate, or breast milk. Within these bodily fluids, HIV is present as both free virus particles and virus within infected immune cells. The four major routes of transmission are unsafe sex, contaminated needles, breast milk and transmission from an infected mother to her baby at birth (vertical transmission).

**Intergovernmental Authority on Development (IGAD)** – IGAD groups seven countries in the Horn of Africa - Djibouti, Ethiopia, Kenya, Somalia, Sudan and Uganda – and is an intergovernmental body for development and drought control in the East-African region.

**Neglected Infectious Diseases (NIDs)**-NIDs are a group of tropical diseases caused by protozoal, bacterial, viral and helminth (worm) infections, which share the fact that they are poverty-related. Taken together they affect over one billion people in the world, mainly in the poorest regions in the South. Protozoan infections include African Trypanosomiasis (i.e. sleeping sickness), Leishmaniasis/Kala-azar and Chagas disease, all three fatal diseases if not treated. The bacterial infections also lead to serious conditions, ranging from the mycobacteria family (causing leprosy and Buruli ulcer) to Chlamydia (causing trachoma) and gastrointestinal bacteria such as enterotoxigenic E. coli (ETEC) and Shigella (both causing infantile diarrhoea). Parasitic worms can be classified as either nematodes, cestodes or trematodes. Lymphatic filariasis (elephantiasis), which is one of the most devastating NIDs, is caused by nematode worms. Nematodes include also the soil-transmitted (or gastrointestinal) helminths, causing ascariasis, trichuriasis and hookworm infection. The Cestodes include tapeworms of the Taenia and Echinococcus families, whereas Schistosomiasis is caused by worms of the trematode family.

**Phase-1 trial** - In clinical drug development, Phase-1 means the first stage of testing of a new drug in human subjects. Usually, a small (20-100) group of healthy volunteers will be selected. The study assesses the safety, tolerability, and pharmacological properties of a drug (known as pharmacokinetics and pharmacodynamics). These trials are often conducted in an inpatient clinic, where the subject can be observed by full-time staff.

**Phase-2 trial** - Once the initial safety of the study drug has been confirmed in Phase I trials, Phase II trials are performed on larger groups of patients (20-300) and are designed to assess how well the drug works.

**Phase-3 trial** – Phase-3 studies are randomized controlled trials on large patient groups (300–3,000 or more) and aim to provide a definitive answer to the question how effective a drug is.

**Phase-4 trial** - also known as **Post-Marketing Studies**. Phase-4 trials involve the safety surveillance (pharmacovigilance) of a drug after it receives permission to be marketed. The aim is to detect any rare or long-term adverse effects over a much larger patient population and longer time period than was possible during the Phase 1-3 clinical trials.

**Poverty-related Diseases (PRDs)** include the three main scourges HIV/AIDS, malaria and tuberculosis, Anti-microbial Drug Resistance (AMDR), Emerging Epidemics (EE) and Neglected Infectious Diseases (NID).

**Prevalence** - a measurement of all individuals affected by a disease at a particular moment in time, whereas **incidence** is a measurement of the number of new cases (i.e. individuals who contract a disease) during a particular period of time.

**Southern African Development Community (SADC)** SADC is an inter-governmental organisation with a mission to promote sustainable and equitable economic growth and socio-economic development in the Southern African region. Currently SADC has a membership of 15 Member States, namely; Angola, Botswana, Democratic Republic of Congo (DRC), Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, South Africa, Swaziland, United Republic of Tanzania, Zambia and Zimbabwe.

**LIST OF FIGURES**

Figure 1: EDCTP projects currently based in 29 different sub-Saharan countries ..... 3

Figure 2: Funds committed or spent by EDCTP against time.....15

Figure 3: Clinical Trials Approved from 2004-December 2009..... 3

Figure 4: Capacity building activities (as of December 31, 2009) ..... 3

## EXECUTIVE SUMMARY

An expert panel was convened in July-August 2010 to contribute to the ex ante impact assessment of a renewal of the EDCTP grant (henceforth called EDCTP2), commenting on the 4 options for the future identified by the EC:

1. No EU action,
2. Programme –based option,
3. the ‘Business as usual’ option , i.e. a continuation of the EDCTP with identical scope, and
4. the ‘Expanded Scope Option’ giving EDCTP 2 an extended mandate to i) other geographical regions than Africa, to ii) other diseases (NIDs) and/or iii) to Phase-1 and Phase-4 clinical trials.

The panel reviewed the problem definition as formulated by the European Commission (EC) and examined the political, financial, economic and social impacts of the four proposed paths forward. Sources used were: EDCTP-related documents, a literature review and interviews with key-informants (EC staff, Dr. P. Moçumbi (High Representative of the EDCTP), Prof.Dr.C. Mgone (Executive Director of the EDCTP) and staff of the EDCTP African Office in Cape Town.

Since inception in 2003, there have been numerous accomplishments. The 142 projects funded (~€269 million from the EC and EU Member States) by EDCTP involve 136 institutions from 29 sub-Saharan countries, 42 institutions from 16 European countries and 51 other partners from non-profit organizations and private sector groups. These (almost all still ongoing) projects include 44 clinical trials: 20 on HIV/AIDS, 14 on tuberculosis and 10 on malaria. The infrastructure and training of individuals to conduct these trials is a substantial accomplishment. There were over 100 peer-reviewed publications related to EDCTP-funded research.

The panel endorses the problem definition as formulated by EC in terms of i) burden of disease, ii) lack of capacity for clinical research and development in Africa and EU iii) fragmented R&D landscape. Given the accomplishments so far, the panel is of the view that to maximize the political and socio-economic impact of EDCTP2, it should get an expanded mandate (as foreseen under Option 4, Expanded Scope). Expansion to phase 1 and 4 trials is justified. Geographic expansion seems not relevant at this stage. The countries involved should primarily be the sub-Saharan countries but EDCTP2 should be encouraged to engage in alliances with other regions. EDCTP2 should be allowed to work on other NIDs as needed by the participating African countries.

In addition, the expert panel recommends that any EDCTP2 program should, from the start, outline clear objectives with measurable outcomes both in clinical research as well as in capacity strengthening. It also recommends that the governance structures of EDCTP be modified to include the EC as voting members and eventually to grant full voting rights to the African partners. Monetary funding from the collaborating sub-Saharan African nations would enhance sustainability and lead to true partnership.



## 1. INTRODUCTION

In response to the need for better treatment of malaria, HIV/AIDS, and Tuberculosis (TB) in the African continent, the EU created in 2003 the European and Developing Countries Clinical Trials Partnership (EDCTP), a partnership of 14 European Union (EU) member states, Norway and the sub-Saharan African states. The strategic objectives of the EU intervention were to: (1) develop new interventions and products against Poverty Related Diseases (PRDs); (2) build sustainable clinical research capacity in Africa; (3) coordinate EU Member States' research policies.

EDCTP supports activities in seven domains related to drug development: North-North/North-South networking, South-South (intra sub-Saharan) networking, support to clinical trials, support to research capacity building, advocacy and fund raising, management and information management. Since its inception, and as per March 2010, the EDCTP Programme has funded 142 projects for a total value of ~ €269 M. These projects involve 136 research institutions from 29 sub-Saharan countries and 42 institutions from 14 European countries; and 51 other partners from non-profit organizations and private sector groups. The ongoing projects include 44 clinical trials, 20 in HIV/AIDS, 14 in TB, 10 in malaria. Capacity strengthening included the funding of 29 Senior Fellows, 5 Career Development Fellows, 26 regulators and 101 PhD/MSc scholarships for African scientists (Source: EDCTP/update 2010).

The EDCTP program was created by a co-decision of the European Parliament and the Council in June 2003 (Decision No 1209/2003/EC) for an initial period of 5 years with a €200 million contribution from the European Commission (EC), and expected matching funds from European Member States (MS) via their National Programmes and third parties (pharmaceutical industry and Public-Private Partnerships). The program was established under Article 169 of the EC treaty that allowed participation of the European Community in EU member states' national research and development programmes, at the time an innovative funding mechanism that was put to test for the first time in the Sixth Framework programme. Switzerland joined the partnership in 2006. A first no-cost extension of the EDCTP program was granted for the years 2008-2010, a second no-cost extension has been granted for the period 2010-2015.

The EDCTP program was subjected to a mid-term review in 2007 (IER/12 July 2007) and to an Independent External Expert evaluation (IEE/EDCTP Report) in December 2009. The 2009 IEE report acknowledged the achievements made by EDCTP over the period 2007-2009 but identified a lack of integration of National Programmes as a major issue. Nonetheless, since the start of EDCTP in 2003 and up until December 2009, Member States have contributed a total of € 76 M as cash contributions to EDCTP signed projects (Source: EDCTP annual report 2009). At the time of this report this figure had risen to ~ €100 M cash co-funding (C.Mgone, personal communication). Additionally, there are direct cash contributions to projects and in-kind contributions. Member States also provide eligible cofunding for national programme activities within the scope of EDCTP, but not funded by EDCTP. At the end of the 2009 reporting period, the eligible cofunding by Member States had reached €463, well above the € 200 M target. Nonetheless the 25% "co-funding" arrangement required by EDCTP for any research application constitutes a major hurdle for researchers to participate in the program, probably because many Member States still face difficulties to contribute with cash to the program, and at most can contribute in-kind. The 2009 IEE report also cited a lack of industry participation and the need for better coordination between EU's research and development Directorates as major weaknesses. Finally, the evaluators recommended EU to renew the grant to EDCTP.

The Commission proposes 4 possible options for the future EDCTP: 1. No EU action, 2. Programme-based option, 3. the 'Business as usual' option, i.e. a continuation of the EDCTP with identical scope, and 4; the 'Expanded Scope Option' with an EDCTP with an extended mandate to i) geographical regions other than Africa, to ii) other diseases (NIDs) and iii) to Phase 1 and Phase 4 trials. As part of the process of grant renewal, the European Commission initiated an Impact Assessment process, including 1) a public consultation to consult stakeholders on these 4 future options, 2) an independent expert panel to contribute to the Impact Assessment Report and 3) a Member States' consensus workshop organised with the Belgian Presidency in September 2010. The public consultation was issued in the form of a web-based questionnaire open for comment from 8 April-22 June 2010. (A detailed review of this consultation will be included in the Impact Assessment Report that will be published by the EU Commission at the end of 2010). A majority of respondents supported an expanded scope for a future EDCTP with expansion to clinical trials Phase I-IV (79%), to other infectious diseases (65%) and to other geographical areas (57%). About 80% of respondents replied that the EDCTP should reduce its operational complexity by creating a single fund. An overwhelming majority of respondents (91%) agreed that EDCTP should better define its cofunding arrangements at the start of the programme. Fifty-four percent (54%) of respondents recommended revision of the legal structure to incorporate voting rights for African government representatives as a high priority.

To contribute to the required Impact Assessment Report, a panel of 3 independent experts was appointed end of June 2010 to examine the political, economic, social and environmental impact of these four options. This document is the report of the expert panel.

Brussels, August 28, 2010.

A.Christianson, J.White, M.Boelaert (rapporteur).

## 2. TERMS OF REFERENCE

A panel of three independent experts was appointed on June 28, 2010 and was asked to report by September 1, 2010. The panel's terms of reference are the following:

- (1) *Identify the needs that need to be met in the short-, medium- and long-term in the field of EU's support to help alleviate the burden of poverty-related infectious diseases in developing countries.*

*Provided that account to be taken of the needs that can be met without putting excessive strain on capacities or resources.*

- (2) *Consider the added value of Union involvement for each of the policy options identified in the roadmap which foresee EU action.*

*Provided that account shall be taken especially of the application of the principles of subsidiarity and proportionality<sup>1</sup>.*

- (3) *Consider any political, financial, economic, social and environmental impact and results, actors, administrative burden and enforcement costs<sup>2</sup> that can be anticipated for each of the policy options identified in the roadmap, both in the EU as well as in developing countries.*

- (4) *Consider the internal coherence of the proposed policy option with other relevant instruments.*

- (5) *Estimate the volume of appropriations, human resources and other administrative expenditure to be allocated with due regard for the cost-effectiveness principle<sup>3</sup>.*

- (6) *Propose indicators and evaluation arrangements that can be use in economic, social and environmental impact measurement of the preferred policy option should it be implemented.*

- (7) *Set out arrangements for monitoring, reporting and evaluation, taking due account of the respective responsibilities of all levels of government that will be involved in the implementation of the preferred policy option.*

*As a decision establishing a new EDCTP would be a legislative measure occasioning budgetary expenditure, this impact assessment is to also to meet the requirements for an ex ante listed in Article 21 of the Commission's Implementing Rules of the Financial Regulation. Most of these requirements have been included in the panel's terms of reference with the rest being contributed to by the Commission in the final version of the impact assessment.*

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<sup>1</sup> Article 5 of the Treaty on the European Union and Protocol (No 2) on the Application of the Principles of Subsidiarity and Proportionality.

<sup>2</sup> In the context of the FP, "enforcement costs" are those costs incurred by the European Commission to manage the FP in contrast to "administrative burden" which are costs incurred by those subjected to EU legislation and, in particular reference to the FP, costs incurred by participants programme.

<sup>3</sup> "The principle of effectiveness is concerned with attaining the specific objectives set and achieving the intended results" – Article 27(2) of the Financial Regulation.

*In drawing up its impact assessment report the panel will take into account previous interim and ex-post evaluations of the first EDCTP listed in section 5 as well as the operations of the EDCTP-EEIG.*

### **3. METHODOLOGY**

#### **3.1 Panel**

The 3 independent experts appointed to conduct this ex ante impact assessment are:

**A.Christianson, M.D., Ph.D.:** Arnold Christianson is currently Professor and Head of the Division of Human Genetics, National Health Laboratory Service and University of the Witwatersrand, Johannesburg. Born in South Africa, he was brought up in Zambia and Zimbabwe where he qualified in medicine. He trained in paediatrics at the Red Cross Children’s Hospital, University of Cape Town. After a short period in private practice he trained in neuro-developmental paediatrics at the University of the Witwatersrand before moving into the field of medical genetics. His research interests are the global epidemiology of congenital disorders and the development of appropriate services for the care and prevention of congenital disorders in middle- and low-income nations. He is an expert advisor to the Human Genetics Programme of the WHO, was an invited participant on the EU’s EuroGentest programme and a participant in CAPABILITY, an extension of EuroGentest researching the transfer of medical genetic knowledge and technology to developing nations.

**C. Jo White, M.D.** Dr. White has 23 years of clinical and product development experience in the pharmaceutical industry. Her experience has been focused in vaccine development, primarily in the areas of infectious diseases. Over the past 23 years she has co-authored over 10 INDs, designed and conducted over 50 Phase 1-4 clinical trials, filed 6 BLA/MAAs, one NDA and has licensed 4 different vaccines: Certiva® (DTaP vaccine), VARIVAX® (live, attenuated varicella vaccine), VAQTA® (hepatitis A vaccine), and Neisvax-C® (conjugated meningococcal C vaccine) in both the United States and Europe. She also made significant contributions to the clinical development programs for RotaTeq® (rotavirus vaccine), FluMist® (live, attenuated influenza vaccine), GARDASIL® (human papilloma vaccine), and ZOSTAVAX® (varicella vaccine for prevention/amelioration of herpes zoster). She has had senior management positions at Merck, Aviron (now MedImmune/AstraZeneca), North American Vaccine (now Baxter), Wyeth (now Pfizer), and VGX Pharmaceuticals (now Inovio Biomedical). Dr. White received her M.D. with honors (member of AOA) from Baylor College of Medicine, completed an internship and residency in Internal Medicine at North Carolina Baptist Hospital (Bowman Gray School of Medicine) and a fellowship in Infectious Diseases at the National Institutes of Health (NIH). She is board certified in both Internal Medicine and Infectious Diseases.

**M.Boelaert, M.D.,Ph.D.** is a Professor of Epidemiology in the Department of Public Health of the Institute of Tropical Medicine (ITM), Antwerp, Belgium. Her research concentrates on control of tropical infectious diseases, mainly leishmaniasis and sleeping sickness. She is the coordinator of the EU/FP6 KALANET and the FP7/NIDIAG projects, and participated in several other EU-funded projects. She is director of the MPH in Disease Control at ITM and lectures epidemiology and biostatistics in various courses of ITM. She coordinates two programs for capacity strengthening with partners in the south: the Institut National de Recherche Biomédicale in Kinshasa, Democratic Republic of Congo, and the BP Koirala Institute of Health Sciences in Nepal. She chairs the “Neglected Diseases” research group at ITM as well as the steering committee of ITM’s Clinical Trial Unit.

### 3.2 Desk review

Documents received during the impact assessment were put on a dedicated internal Website (CIRCA/Expert group working on the analysis of the impact of a new EDCTP). This included a formal literature review carried out on the themes. A list of EDCTP related documents reviewed by the panel- as well as the code for referencing in this document - can be found in **Attachment 1**.

### 3.3 Meetings

Table 1 lists the meetings held by the expert panel between June 28, 2010 and September 1, 2010.

**Table 1 List of meetings held by the expert panel**

	Date	Place	Participants	Topic
1	July 8, 2010	European Commission, Brussels, Belgium	AC, JW, MB with <b>R. Dhragia-Akli, A. Nieto, F.Mamo, G. Quaglio, S.Mathewson, A.Belaey</b>	Briefing
2	July 13, 2010	Teleconference	AC, JW, MB	Planning
3	July 13, 2010	Meeting	JW with Dr. Pablo Tebas, HIV expert with the AIDS Clinical Trial Group	Clinical research
4	July 15, 2010	Teleconference	AC, JW, MB	Planning
5	July 27, 2010	Teleconference	AC, JW,MB with <b>Dr. C. Mgone</b>	General
6	July 30, 2010	Teleconference	AC, JW, MB	Planning
7	August 11, 2010	African Office of EDCTP in Cape Town, RSA	AC with <b>Drs M Makanga, Dr P Moçumbi and Dr T Nyirenda</b>	African perspective on EDCTP
8	August 18-19, 2010	European Commission, Brussels, Belgium	AC, JW, MB with EU commission IA team	Preliminary report

AC: Arnold Christianson, JW: Jo White, MB: Marleen Boelaert

## 4. BACKGROUND

### 4.1 EDCTP'S PERFORMANCE SO FAR

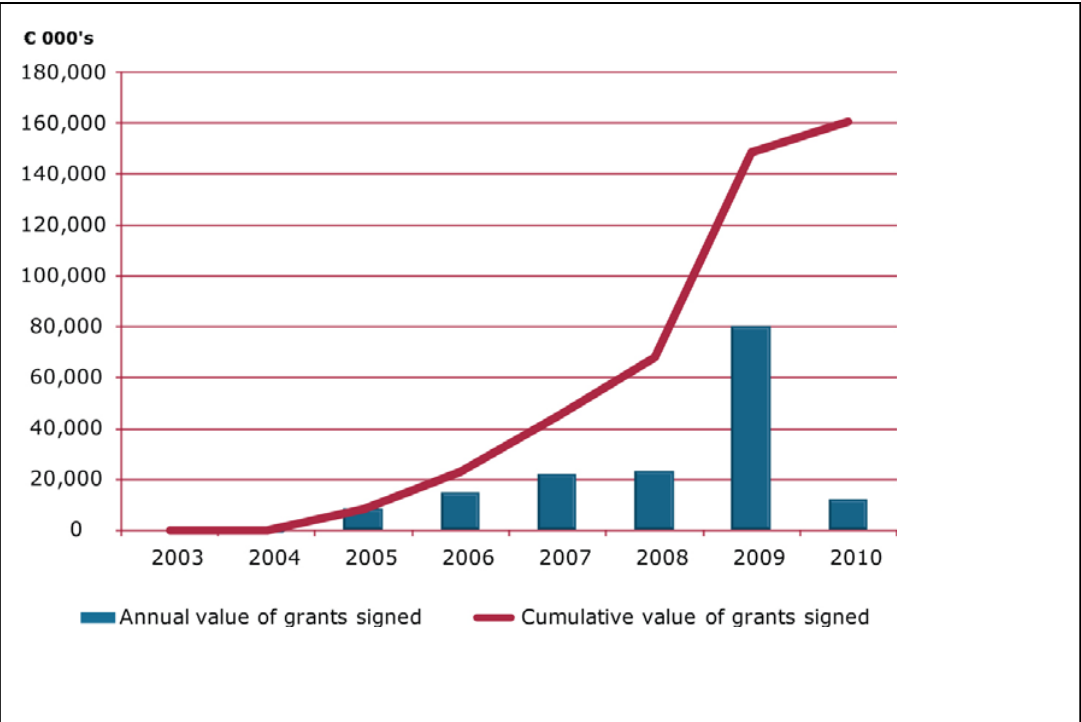
Over the past 4 years EDTCP has made significant achievements in initiating clinical trials, building African-led research teams and obtaining co-funding for ongoing projects (Zumla et al. 2010)(Gryseels et al 2009). Between 2003 and 2009 there were 108 peer-reviewed scientific papers published on studies that were totally or partially sponsored by EDCTP. As it takes several years to complete clinical development of a new drug, there are not yet many EDCTP-funded new products in the field today. EDCTP's CHAPAS trial in Zambia has contributed to the FDA approval and WHO prequalification of Triomune Baby/Junior products for HIV in children. The drug is now available under programmes such as US President's Emergency Fund for HIV/AIDS Relief (PEPFAR) and Clinton HIV/AIDS Initiative (CHAI). Results are expected soon from the 0.5% PRO 2000 microbicide and the I.V. Artesunate trials. All the other projects are still 'in progress'. **Attachment 2** (*"List of African countries with EDCTP-funded projects"*) provides a list of beneficiary African institutions, location and type of grant and coordinator. A graphic map of the countries in Africa involved with the EDTCP is provided in Figure 1 below.



Figure 1: EDCTP projects currently based in 29 different sub-Saharan countries

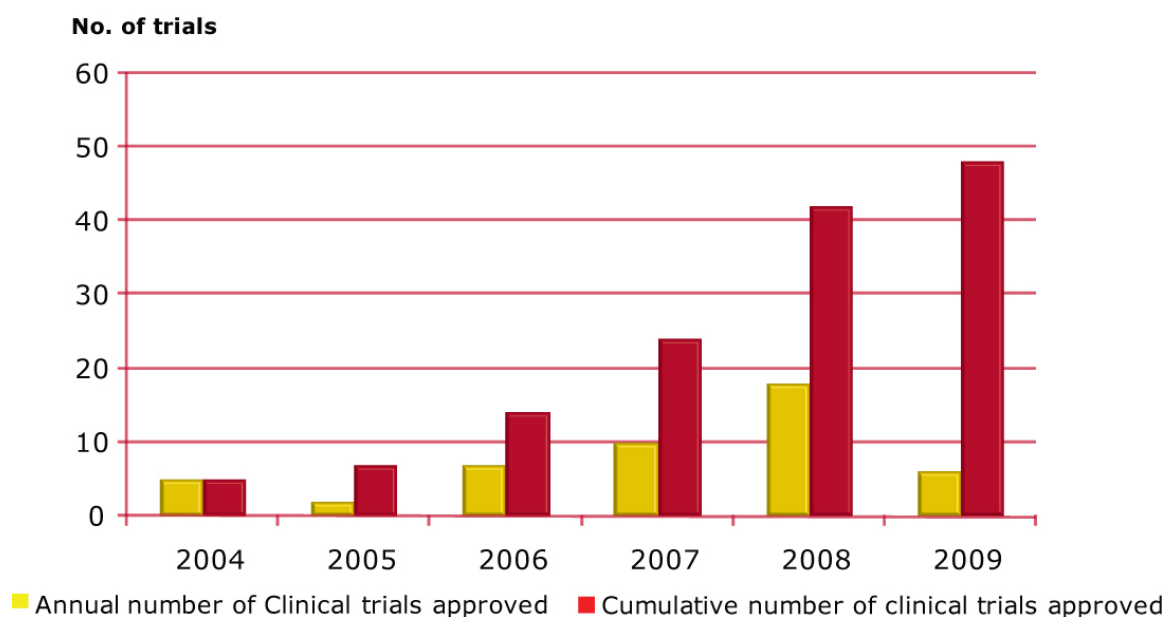
The projects funded (~ €269 million) by EDCTP up to March 2010 and listed in Attachment 2 involve 136 institutions from 29 sub-Saharan countries, 42 institutions from 16 European countries and 51 other partners from non-profit organizations and private sector groups. The ongoing projects include 44 clinical trials: 20 on HIV/AIDS, 14 on tuberculosis and 10 on malaria. The infrastructure and training of individuals to conduct these trials is a substantial accomplishment. More details of these studies can be found in **Attachment 3** (“Update on the EDCTP programme: 2003-2010”).

It appears that substantial efforts have been made to increase the number of EDCTP grants signed, clinical trials approved and capacity building activities as expressed on Figures 2, 3 and 4, respectively, and as illustrated below.



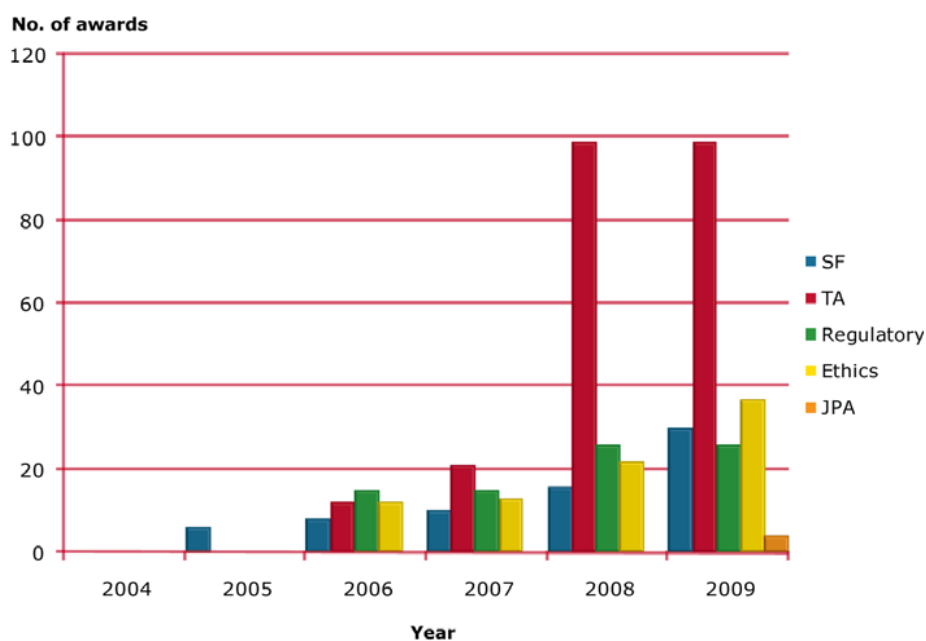
**Figure 2 Funds committed or spent by EDCTP\* against time**

\* Figures only include EDCTP or MS funding through EDCTP, excluding MS and Third party funding. Figures until April 2010. Source EDCTP/KPI 2010



**Figure 3: Clinical Trials Approved from 2004-December 2009**

*Source:* EDCTP/KPI 2010



**Figure 4 Capacity building activities (Cumulative data up to December 31, 2009)**

**Legend:** SF: Senior Fellowships Projects; TA: Training Awards, including Masters, PhD scholarships and Career Development Fellowships; Regulatory: Number of national regulatory authorities (NRA's) included in EDCTP-WHO collaboration capacity strengthening activities; Ethics: number of projects for strengthening ethics framework activities and mapping; JPA: Joint programme activities projects. Projects that have the key objective to integrate European Member State activities in sub-Saharan Africa on the three PRDs.

*Source:* EDCTP/KPI 2010



Seventy percent of the Principal Investigators (PI)s funded by EDCTP are African scientists. The EDCTP Senior Fellowship grant scheme has served as a re-entry grant and has effectively brought back 6 scientists from the African Diaspora (3 from UK, 3 from USA) (See M.Makanga, personal communication, **Attachment 4**). The Senior Fellowship grant scheme has also enabled fellows to start up research projects in two post-war countries (Ivory Coast, Liberia). Additionally, the Senior Fellowship grant scheme has facilitated 4 African scientists to run projects in better endowed African institutions and countries with a hope of them developing capacity in their African countries of origin (See **Attachment 4**).

Finally, the achievements of EDCTP should not only be looked at quantitatively in terms of number of clinical trials and number of platforms for clinical research that were developed, but also qualitatively in terms of the pioneering approach taken to develop the partnership. The African scientists are appreciative that they have had the space to develop this innovative approach and are pleased with the progress made to date on this dimension (See SCIH/EDCTP 2009 and IEE/EDCTP 2009).

Amongst the issues raised by previous independent evaluations, a major concern was that the third strategic objective of EDCTP, networking and co-ordinating the national research policies of the EU member states, did not seem to be progressing well by comparison with EDCTP's achievements in Africa. The EDCTP secretariat has recently undertaken an internal assessment and developed a specific action plan to address this issue (See EDCTP/JPA:B 2009 p 37).

Other deficiencies in the African clinical R&D landscape which had not yet been adequately addressed by the EDCTP set-up according to external evaluators include 1) insufficient laboratory facilities and/or rapid field diagnostic testing, 2) cultural stigma on the recruitment of individuals for clinical studies, 3) lack of standing local IRBs to provide ethical review, and 4) inexperienced health regulatory authorities with limited expertise on labelling and distributing new products for correct use. (Source: IEE/EDCTP 2009)

## **4.2 The options for EDCTP's future**

The European Commission has identified four different scenarios (called 'options' below) with regard to EDCTP's future. The 4 options are described below (Source: Roadmap):

### **Option 1- baseline: No EU action**

Under this option the EU would no longer fund any activity in the field of clinical trials for HIV/AIDS, TB and malaria in African countries nor pursue theof integration of EU Member States' research programmes. After the end of the current funding phase, no successor programme to the current EDCTP will be funded by EU, nor will any provision be made in EU research policies or funding schemes to support EDCTP objectives.

### **Option 2- Program-based option**

EU would no longer fund a partnership as EDCTP but would continue to fund clinical drug development for PRDs under its regular framework programs (FP7 and its successors). Provision could still be made in EU research policies and funding to support clinical trials in HIV/AIDS, TB, and malaria in Africa but not the integration of EU Member States' research programmes.

### **Option 3- Business as usual**

A new EU decision establishes a successor programme to the current EDCTP under the same terms as the original (Article 185 (ex-169) of the Treaty on the Functioning of the EU). EU would renew the grant to the EDTCP for a second term of 5 (or more) years. The mandate and scope of operations of EDCTP would be similar to the current one. Current EDCTP objectives on clinical trials and the integration of Member State research programmes are maintained. The successor takes account of the recommendations provided in the 2007 and 2009 evaluation reports.

### **Option 4- Expanded scope**

As in Option 3, a new EU decision establishes a successor programme to the EDCTP under similar terms. The successor takes account of the recommendations provided in the 2007 and 2009 evaluation reports. The scope of the programme is expanded to include some or all of the following (i) other diseases, ii) other phases of clinical trials, iii) other geographical areas.

## **5. PROBLEM DEFINITION BY EU**

The EC's 'Roadmap to EDTCP2' defines the problem to be addressed in the following way.

### ***“1) Burden of disease;***

*The high prevalence and severe effects of HIV/AIDS, tuberculosis and malaria in Developing Countries are such that they not only drain the resources available to public health services (already limited in these countries) but also negatively affect economic growth and human and social development. Trends in population movements and the increase in the occurrence of drug-resistant pathogens in certain parts of Europe increase the risk of more generalised epidemics.*

*Currently there are over 33 million people infected and living with HIV. In 2007 only 3 million people had access to anti-retroviral therapy. Each year there are more than 250 million new infections and 1 million deaths due to malaria, and tuberculosis remains one of the most devastating infectious diseases with more than 9 million cases annually and with more than 1.7 million fatalities. The worrying trends of PRDs in several eastern European countries and in developing countries calls for an intensified action in order to avoid more generalized epidemics.*

### ***2) Inability of individual EU Member States and DCs to carry out clinical trials adequately;***

*The human and financial resources required to perform clinical trials are such that they can no longer be provided either by individual national programmes or by DCs. Although public investment has already encouraged some private investment, pharmaceutical companies remain reluctant to invest without a guaranteed market where economies of scale exist to offset their costs. Specifically phase III trials are very expensive and no single member state can afford to invest independently.*

### ***3) Fragmented research and persistent knowledge gaps;***

*It is imperative to coordinate research and technological development to avoid duplication of activities, fragmentation of research policies and lack of coherence*

*with other EU policies (e.g. Development policies). Good definition of roles for stakeholders and clearly defined consultation mechanisms are needed to confront the persistent "knowledge gaps" relating to development and implementation of novel technologies and treatments for these diseases.*

***EU action is justified on grounds of subsidiarity***

*The current EDCTP has demonstrated that the financial and human resources required to have significant effects in this field are of such scale that results cannot be achieved sufficiently by the Member States acting on their own but are best met at Union level. This justifies Union action .*

*The Commission intends to consult widely through a structured external consultation, and will therefore invite the views of local and regional actors alongside other relevant stakeholders as is required in the proper application of the principle of subsidiarity .”*

***Source: Roadmap, Final version 17/03/2010***

## 6. DISCUSSION OF EU'S PROBLEM STATEMENT

Essentially the givens as presented above by the European Commission are correct. We present some additional data, arguments and references that may be useful for the Impact Assessment Report.

### 6.1. Burden of disease

#### HIV/AIDS

In 2008, the number of people living with HIV worldwide was estimated at 33.4 million [31.1 million–35.8 million] and there were 2.0 million [1.7 million–2.4 million] AIDS-related deaths (*Source: AIDS epidemic update 2009, UNAIDS<sup>4</sup>*). Africa bears the highest burden with 67.1% of all HIV-infections and 72% of the world's AIDS-related deaths. In some countries in southern-Africa (e.g. Botswana, Swaziland) a quarter of the population is affected. The HIV/AIDS epidemic continues to have an enormous impact on families, communities and economies in the African region (Zaba, Whiteside, & Boerma 2004). In Swaziland, e.g., life expectancy fell by half between 1990 and 2007, to 37 years. In 2008, more than 14.1 million [11.5 million–17.1 million] children in sub-Saharan Africa were estimated to have lost one or both parents to AIDS. (*Source: AIDS epidemic update 2009, UNAIDS<sup>4</sup>*)

There is no cure or preventive vaccine for HIV infections available. Antiretroviral Therapy (ART), introduced in the mid-1990s, has had a profound effect on the course of HIV infection. The unprecedented scale-up of ART in developing countries over the past decade has allowed individuals to live longer and enjoy a better quality of life. An estimated four million HIV-positive people now benefit from ART but another six million still do not have access to it. Even for patients on ART, the psycho-social burden of HIV infection remains significant.

In the face of 2.7 million new infections annually worldwide there is an urgent need for a vaccine or a definitive cure for HIV/AIDS. Also, the evolving drug resistance and ensuing need for second-line ART regimens makes continued R&D investment necessary.

#### Malaria

Malaria continues to be a major public health problem in sub-Saharan Africa. In 2008, the worldwide malaria burden was estimated at 243 million cases [190 million -311 million] and 863,000 deaths [708,000-1,003,000]. The African region accounted for 85% of the worldwide malaria cases and 89% of the deaths. Young children and pregnant women are the most vulnerable groups, especially in areas of stable transmission: in sub-Saharan Africa, 20% of all deaths in children <5 years of age are related to malaria. Malaria in pregnancy is a major cause of maternal anaemia and about one fifth of the cases of low birth weight are due to

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<sup>4</sup> AIDS Epidemic Update 2009, UNAIDS. Accessed on August 16 2010 on [http://data.unaids.org/pub/Report/2009/jc1700\\_epi\\_update\\_2009\\_en.pdf](http://data.unaids.org/pub/Report/2009/jc1700_epi_update_2009_en.pdf)

maternal malaria. Malaria exerts an enormous economic toll, and the estimated cost to Africa alone is more than \$12 billion per year in lost GDP<sup>5</sup>. The World Health Organization estimates that a poor family in Africa can spend 25% of its income on malaria prevention and treatment (WHO 2003).

Treatment of malaria requires continuous research and development efforts to generate new anti-malaria drugs, as expanded use of drugs triggers the development of resistance. Research is also needed to reveal the mechanisms of such resistance development, and how these can be circumvented.

### **Tuberculosis**

The World Health Organization (WHO) declared tuberculosis (TB) a global public health emergency in 1993. In 2008 there were an estimated 9.4 million TB cases and 1.8 million deaths<sup>6</sup>. TB is one of the world's leading mortality in adults as well as children, causing nearly 5000 deaths a day. 1.4 million TB cases occurred in HIV-positive persons and the disease is a leading killer of people with HIV. People who are HIV-positive and infected with TB are 20 to 40 times more likely to develop active TB than people not infected with HIV living in the same country.

There is an urgent need for better and more effective treatment as current regimens are long and cumbersome, adverse effects are common and they are ineffective in the growing number of multidrug-resistant cases (Schluger et al. 2007). To improve TB treatment in the near future, clinical trials should be carried out to examine alternative regimens using existing drugs (dosage changes, frequency of dosing, etc.) and the modest but growing pipeline of new compounds.

### **Neglected infectious diseases (NIDs)**

Globally an estimated 1.2 billion people are affected by one or more NIDs. They include a range of poverty-related chronic disabling and/or fatal infections, such as Buruli ulcer, cysticercosis, Guinea worm, endemic treponematoses, human African trypanosomiasis (HAT), leishmaniasis, leprosy, lymphatic filariasis, onchocerciasis, schistosomiasis, soil-transmitted helminthiasis, trachoma, food-borne trematodiasis but also more acute infections such as brucellosis, enteric fever, cholera, dengue and rabies (Holveck et al. 2007). NIDs cause an estimated 500,000 deaths each year and inflict severe physical disabilities. This group of diseases thrives among impoverished populations of developing countries and is very important in Africa (WHO & Carter Center 2008). By reducing economic productivity, NIDs hinder development and effect the quality of life at all levels (Conteh, Engels, & Molyneux 2010). Treatment options for NIDs are generally few (Robays et al. 2008) (Chappuis et al. 2007). The problem is exacerbated by a critical lack of appropriate diagnostic tools to guide treatment (Pang & Peeling 2007).

NIDs currently receive less than 5% of the global investment for tropical diseases research. Despite their high burden, NIDs do not rank high on the international political agenda. Most of the global investment for tropical diseases research goes to the so-called "big three"

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<sup>5</sup> Source: Malaria in Africa by Roll Back Malaria see

[http://rbm.who.int/cmc\\_upload/0/000/015/370/RBMInfosheet\\_3.htm](http://rbm.who.int/cmc_upload/0/000/015/370/RBMInfosheet_3.htm)

<sup>6</sup> Source: [http://www.who.int/tb/publications/global\\_report/2009/update/en/](http://www.who.int/tb/publications/global_report/2009/update/en/)

diseases (54% to HIV/AIDS, 12.6% to TB and 12.4% to malaria), while very little goes to kinetoplastid (Chagas disease, trypanosomiasis, and leishmaniasis) diseases (2.5%), helminths (2.1%) or typhoid fever (0.5%) (Moran et al. 2009).

## **6.2. The lack of capacity for clinical R&D in Africa**

There is a large consensus that there is no real enabling environment for clinical research in Africa. The legislative framework has not kept pace with recent evolvments in ethical conduct of clinical trials, material exchange and intellectual property rights (Whitworth et al. 2008). Regulatory authorities tend to take nationalistic approaches without having the resources to conduct thorough independent assessments of the evidence. Human Resources are inadequate, especially in the field of data management, project management and leadership for clinical research and there is a general lack of infrastructure.

Many of the problems of undertaking medical research in Africa, particularly with obtaining funding in the present competitive and, at times, adversarial system, are described by Zumla et al. EDCTP has been pioneering a new, enlightened and innovate approach to 'mutual' partnership in medical research between Europe and Africa, an approach that the Africans' hope will eventually lead to true partnership and could have future relevance between industrialised and developing nations in this and other fields.

The Africa Office of EDTCP noted that one of their major challenges was the heterogeneity of the countries and the institutions they work with. There are middle- and low-income nations with different levels of development of health services and different languages. Institutions range from the very basic to quite sophisticated with differing focuses, capabilities and infrastructure. One of their tasks was to try and get collaboration between countries and institutions so that cross-fertilization could occur and weaker institutions could gain and develop from the experience. One of the advantages of the funding coming through EDCTP was that the inclusion of the weaker institutions could be funded in twinning arrangements with stronger partners in the South. In the mainstream international competitive research funding schemes those weaker institutions would have been otherwise limited in their ability to access funding.

EDCTP's approach has shown success in the short-term. It has enabled African scientists to undertake clinical trials, it has developed capacity (in many different ways), put together functional networks at regional, institutional and personal level, improved ethical and regulatory frameworks in many countries and built confidence for the future in the field. However, from the articles of (Zumla et al. 2010), (Matee et al. 2009) (Ofori-Adjei 2008) there is clearly an understanding that much still needs to be done to consolidate this success and further develop the approach.

## **6.3. A fragmented European landscape in R&D for Poverty-Related Diseases**

The original co-decision (2003) clearly pointed to the fragmented landscape in EU with regard to clinical R&D for PRDs. *“Member States are undertaking individual research and development programmes or activities aimed at developing new clinical interventions to combat the global problem of HIV/AIDS, malaria and tuberculosis. These programmes or activities, the required funds for which have been granted, form part of long-term partnerships with developing countries. At present, the research and development*

*programmes or activities undertaken individually at national level are not sufficiently coordinated at European level and do not allow a coherent approach at European level for an effective research and technological development programme to combat HIV/AIDS, malaria and tuberculosis in the developing countries or make it possible to find optimal treatments suited to conditions in the developing countries.”*

Prior to 2005, EU Member States (MS) funded clinical trials on PRDs from their own National Research Programmes, often in partnership with historical collaborators in Sub-Saharan Africa but rarely in collaboration with other EU MS. EDCTP was therefore launched as a pilot experiment to test mechanisms to bring EU MS research programs closer together (see Reply by J.Potocnik to EP question E-3778/2005). Today EDCTP involves on average 3 participating EU MS and 3 African countries per project. Seventy-two percent of all current clinical trials with joint funding by 3 or more EU MS are EDCTP-initiatives. The proportion of EU MS funds that are channelled directly through the EDCTP is steadily increasing (~31%). The Netherlands, UK, Sweden, Germany, Spain, France and Switzerland have made special funding arrangements to provide support to EDCTP. About 36 percent (96/268) of the total €268 M funds allocated to EDCTP projects up to March 2010 was provided by EU MS (*Source: EDCTP/2010 update*). However, there are EU MS that clearly do not (yet) participate in the program. Moreover, European scientists perceive the 25% co-funding requirement by MS on any single EDCTP-application as a major stumbling block.

Therefore though EDCTP definitely has had some impact on the integration of the EU MS programs, as traditional post-colonial ties for R&D funding are breaking up, and north-north, north-south and south-south networks are enlarging, there is still a long way to go. The situation is not rendered easier by the multiplication of PPP and PDPs in recent times.



## 7. ANALYSIS OF IMPACT

The analysis of impact of EDCTP is described below in terms of political, financial, socio-economic and ecological. These dimensions are off course interrelated.

### 7.1. Political Impact

The EDCTP was established by the European Parliament and the Council of the EU (Decision No 1209/2003/EC) to address, in collaboration with developing countries (DCs), particularly sub-Saharan Africa, challenges in research and development (R&D) on PRDs particularly HIV/AIDS, malaria and tuberculosis (TB). Congruent with the aims of this decision, EDCTP has shown success in meeting some of its aims, notably with its work with clinical trials and building sustainable public health and research capacity in Africa (Whitworth et al. 2008; Zumla et al. 2010).

The current management of EDCTP has, in line with principles espoused in the Lisbon Declaration, the EU-Africa summit (December 2007), the Africa-EU Partnership document and the Strategic European Framework for International Framework for Science and Technology, put significant effort into making EDCTP a genuine EU and Africa partnership. At present they term this a ‘mutual’ partnership approach, ‘mutual’ in the sense that ‘true’ partnership in which African and European member states will sit as equal members on the General Assembly is the ultimate objective. The approach is considered innovative and more equitable than past relationships between African and industrialised nation funding organisations in the fields of medical research and development. It has been considered successful to date, particularly from an African perspective, and has been noted and attracted favourable attention in international fora (Gryseels et al. 2009; Whitworth et al. 2008; Zumla et al. 2010) and from other organisations. E.g. the Wellcome Trust<sup>7</sup> and DIFID/MRC (UK) have adopted a similar approach regarding networks of excellence, capacity building and south-south/north-south networking (Source: C.Mgone personal communication).

EDCTP has undertaken considerable advocacy to gain acceptance for its current European-African ‘mutual’ partnership approach. In Africa this advocacy has been from the highest level at the African Union through regional organisations (ECOWAS, EAC, ECCAS, IGAD & SADC) to national governments. The recent inclusion of 4 African representatives on the EDCTP’s General Assembly, including a member from the African Union, is a significant success for EDCTP’s advocacy in Africa and evidence of genuine African confidence in its approach to European-African partnership. Therefore, any decision regarding the future of EDCTP will have political consequences for future African –European Union collaboration in the fields of medical research and development, and possibly beyond.

In Europe itself, the EDCTP approach is now recognized as an innovative and key instrument of the EU’s PRD programme (*Source: Several Communications from the Commission to the European parliament COM (2001) 96 final; COM (2005) 179 final; COM/2008/688 and several parliamentary questions E-0098/2010, E-3120/2010, E-6176/2009, E-4765/2009, E-*

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<sup>7</sup> <http://www.wellcome.ac.uk/Funding/International/Global-health-research/WTX055734.htm>

1049/2008, E-0934/2008, P-3405/2005, E-2473/05, E-1518/2005, E-0347/2004 ) , and as one of the ways how EU contributes to reaching the MDGs (E-4649/2010). The approach to build genuine partnerships is congruent with the Paris Declaration on Aid effectiveness, and is quite innovative in the collaborative research landscape (See a.o. PhD thesis G.Priebe 2010)<sup>8</sup>. Moreover, the EU effort to integrate its national programmes in the fight against PRDs is appreciated on the international scene. EDCTP has e.g. been specifically mentioned in this respect in the final text on the 'Fight against infectious diseases' issued by the 2006 G8 Summit in St Petersburg<sup>9</sup> .

Therefore, the political consequences of the policy options available for the future of EDCTP can be considered as follows:

**Options 1 and 2** effectively mean that EDCTP is closed down and many of the gains achieved on the programme in Africa will be damaged or lost. Currently there is a clear buy-in from the African colleagues, and the political damage would be great if EDCTP is discontinued. The current mutual understanding, trust and confidence between the European and African 'partners' of EDCTP would be broken and these options would be viewed by Africans as a European vote of no confidence in the organisations' largely African management and its current approach to 'mutual' partnership and vision for achieving true partnership in the future.

In the short to medium term this would adversely influence future European-African research and development collaboration in the field of PRDs and perhaps this would extend further into other fields of science and technology research and development. Obviously the political implications for the African and European Unions, if this occurred, would also be serious.

Option 2, while maintaining a similar budget under the Main Framework Agreement, foregoes the unique mechanism EDCTP offers for the African partners to give concrete strategic input on the calls for proposals and workplan. Under the current FP7, African countries are not directly consulted on the annual workplans. Moreover, the institutional arrangements of EDCTP allow African countries with weaker track records in scientific research to get on board. In this respect the South-South networks that impose twining of a 'stronger' and 'weaker' African partner are unique.

By comparison **option 3**, allowing EDCTP to continue in its present form, would be considered more acceptable from an African perspective. However, from discussions with EDCTP senior management and the 'Recommendations from the EDCTP-EEIG for a second EDCTP Programme' report it could be viewed as a vote of limited confidence in EDCTP, particularly to its approach to the partnership issue. Within the organization this option would curb the future planned development from the "mutual" to the "true" partnership approach and the expansion of EDCTP's footprint in Africa. Although not as serious as the political damage from **options 1 & 2** it is possible that this option could limit further African political commitment to EDCTP. Furthermore, it might be anticipated that key staff members might lose confidence and seek employment in other organizations that are adopting a partnership approach.

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<sup>8</sup> <http://www.malariaworld.org/blog/e-interview-dr-gunilla-priebe-should-more-malaria-research-be-based-africa>

<sup>9</sup> <http://en.g8russia.ru/docs/10.html>

**Option 4** offers positive prospects from both an African and European perspective. It recognizes that, despite challenges, EDCTP has made significant progress towards its goals – not only the undertaking of the research but also with respect to capacity development, establishing networks and striving towards the establishment of a mutual partnership for this between the EU and Africa. To the Africans the issue of partnership is very important (Ofori-Adjei 2008; Zumla & Costello 2002). Taking **option 4** would be a vote of confidence from their European partners that would enable them to continue working towards true partnership. This would signal a major change in the nature of the relationship between Africa and Europe in the fields of science and technology that is consistent with policy developments between the two regions (Lisbon Declaration - EU Africa Summit, Lisbon 2007; the Africa-EU Strategic Partnership-A Joint Africa-EU Strategy). Option 4 leaves in fact more space to the African partners to decide on what the local priorities in poverty-related diseases are, something mentioned by Ofori and Gyapong as a limiting factor of the current EDCTP (Ofori-Adjei & Gyapong 2008).

The kudos for the EU and the member states if the EDCTP approach is accepted and developed further should not be underestimated. The approach will probably be taken and adapted in other fields of science and technology. Moreover, capacity building has now come to be acceptable and desirable among many funding organisations. It might encourage more MSs to join and those already involved to increase their contribution. It could also lead to African nations' financially contributing to EDCTP as part of the progression to achieving true partnership.

Another political advantage of accepting options 3 and 4 is that these options will allow EDCTP to continue forging collaborations and networks, north-south and south-south, between individuals, institutions and countries that cross past 'colonial' lines of affiliation. Whilst difficult with past funding arrangements between Africa and industrialised nations this is encouraged and is being achieved through EDCTP.

## **7.2. Financial Impact**

For **options 1 and 2** the financial impacts both for Africa are similar. The implications are consequent on the removal of funding for future research and for the support of structures that have been put in place including the regional networks and networks of excellence. It is unlikely that replacement funding from other sources will be acquired to support the EDCTP as it is presently structured, including the Framework Programmes (**option 2**).

For the EU the direct costs would initially decrease with **option 1**, as compared to the current situation. They might subsequently increase over time as stakeholders pressurize the EU to resume funding of clinical trials through other funding mechanisms. With option 2 there is no change in the costs for the EU as the monies presently spent on EDCTP would be absorbed back into the Framework Programme. They may, however, not be spent on clinical trials research for HIV/AIDS, malaria and TB. The contribution of the member states will be re-disbursed at the discretion of each state.

The financial implications for the EU and member states are clear if **Option 3** is chosen. This option implies a continuation of current financial commitments (€ 400 Million) over the

period designated to the next EDCTP programme. From an African financial perspective the status quo is maintained.

**Option 4** implies that an expanded scope of work will be offered by EDCTP. A budget necessary to meet the requirements of such a programme is then necessary. This will have to be partly acquired through increased contributions of the EU and member states. For Africa the benefits of increased funding are obvious. More research, further development of infrastructure, increased networking and the development of national regulatory and ethical capacities. If the scope of the mandate also includes limited translation of the positive research results into health care this would hopefully also induce the process towards improved health care.

It is understood that African governments fund health research poorly, sometimes not even including this in their budgetary arrangements. Between 70 and 90% of health research funding in Africa is by external donors. Through advocacy, EDCTP has achieved African acceptance of their approach to 'mutual' partnership. Through **option 4** the envisaged goal of 'true' partnership becomes possible, inducing African partners to give more importance to their role in R&D and its funding. This will require more explicit political commitment from Africa, as Africa's financial contributions should help meet the increased budgetary needs of **option 4**.

For both **Option 3 and 4** the impact and leverage of EDCTP would be greatly enhanced if a significant financial contribution from the private sector, i.e. industry as well as not-for-profit Product Development Partnerships (PDP), was secured. Several evaluations in the past have pointed to private sector involvement as one of the major challenges for EDCTP. Though anecdotal reports point to industry being only lukewarm because of the high transaction costs and limited funds available under EDCTP, at the same time industry makes a global appeal for public subsidy to clinical development of drugs for poverty-related diseases (Herrling 2009). So there is definitely common ground and mutual interests to cover. Though EDCTP has recently developed a pro-active policy in this regard, it needs to ensure this policy is translated successfully. An opportunity to work with pharmaceutical partners could be collaboration with the US –sponsored International AIDS Clinical Trial Group (IACTG) in South Africa and participation of EDCTP-sites in Phase III-IV testing of a tenofovir- based vaginal gel to prevent spread of HIV-1 and HSV-2 to women from infected partners (Karim et al. 2010). This treatment was recently reported in clinical trials to significantly decrease the transmission of HIV and genital HIV-1 and -2. Enlarging EDCTP under Option 4, would allow EDCTP to engage in alliances with PDPs developing drugs for Africa's NIDs and create synergies with the capacity strengthening platforms they develop (Hailu et al. 2005).

In conclusion, the expert panel notices that considerable amount of money and effort has been expended to date to ensure EDCTP's achievements. If EDCTP is extended to EDCTP2, with either **option 3 or 4** then a similar amount of money, and in the case of **option 4**, more money will be required, primarily from the EU and Member states. This money will be being directed through one funding agency, EDCTP2. It will therefore have the responsibility of ensuring that to the greatest extent possible, the expectations of the EU and Member States are realised. To realize the ambitions of **Option 4**, it will be of paramount importance to diversify the financial support, including support from African nations as well as the private sector.

### 7.3. Socio-economic Impact

**Option 1**, leading to total discontinuation of EU's funding of clinical research in HIV/AIDS, TB and malaria could have serious socio-economic repercussions involving multiple stakeholders in the EU engaged in research, service provision, training and support activities, public health aspects and more. **Option 2** may have the same consequences- though to a lesser extent. As explained above, an abolition of EDCTP in the current context of economic crisis may send a negative signal to Member States and the private sector and potentially lead to reduction of the resources available for addressing HIV/AIDS, TB and malaria. The discontinuation of EU's commitment would not necessarily be compensated by bilateral or multilateral cooperation without EU funding. In addition, it may lead the pharmaceutical sector to reduce its investment in preclinical research in AIDS, TB and malaria. Therefore the withdrawal of EU funding (Option 1) or its integration in mainstream EU/Framework Program funding (Option 2) would most likely mean that institutions and individuals who have been or could be funded through EDCTP would have to find other funding for their research. Because of the competitiveness of the current international research funding mechanisms, which competitiveness could be considered as not having served Africa well in the past, many of these institutions and particularly individuals may not find funding to continue their work. A secondary implication of this is that individuals, including those trained through EDCTP efforts, will have to find work elsewhere. For many, particularly the senior and well-qualified individuals and those of the African Diaspora that returned this will probably mean leaving Africa. Africa cannot afford any such losses given its limited human resources in the field (Eastwood et al. 2005).

**Option 3 and 4** have a high potential for socio-economic impact on the PRDs and on the R&D clinical trial capacity in Africa, as can be deduced from an analysis of current achievements of EDCTP (see Section 2). As EU commissioner K.De Gucht recently put it in his reply to a question by MEP ME Koppa, "*The European and Developing Countries Clinical Trials Partnership (EDCTP) is the European response to the need for developing new or improved drugs, vaccines, and microbicides for HIV/AIDS, Tuberculosis and Malaria*" (E-3120/2010). It is today not yet possible to evaluate the direct impact of EDCTP on the health of the African populations, but the newly FDA approved pediatric formulation of Triomune for HIV in children gives a good example of the tangible difference EDCTP can make for clinical care. Pediatric formulations or ART are one of the most immediate R&D needs<sup>10</sup>. Even if in the circumstances EDCTP's economic and social impact cannot yet be fully appreciated as several more projects are still underway, it is obvious that - if successfully completed- a positive impact on health and health research capacities is to be expected. Regarding the latter, EDCTP's capacity strengthening program included so far the funding of 29 Senior Fellows, 5 Career Development Fellows, 26 regulators and 101 PhD/MSc scholarships for African scientists. In addition 257 African researchers are involved in EDCTP supported projects as investigators receiving their core salaries from their hosting institutions or African governments. The IEE 2009 report mentions that 2 scientists -1 from Mali, 1 from SA – were able to stay in their respective countries thanks to EDCTP funding instead of seeking a career in a high-income country (Source: IEE report p 36). An update by the EDCTP secretariat puts this number at six (See **Attachment 4** , personal communication by M.Makanga). Creating career opportunities for African scientists would also be one of the major outcomes expected of EDCTP2. Nonetheless higher numbers are needed to create a significant impact and fill the current gaps in research capacity in the African states. Only in this way can a critical mass of expertise be created to enable countries to develop their clinical

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<sup>10</sup> <http://www.ifpma.org/index.php?id=2327>

trials capacity. Finally, the EC is fully aware of the impact EDCTP can have on strengthening the quality of clinical trials in sub-Saharan Africa. In at least 4 replies to questions in the European Parliament, EDCTP was mentioned as the mechanism through which EU fosters respect of the ethical framework for clinical research in developing countries (See EP questions and replies E-5940/2009, E-2703/2009, E-4953/2009, E-1167/2008).

The 2009 IEE evaluation team conducted a qualitative impact assessment based on document review and interviews with key informants (IEE/EDCTP 2009). There was a consensus among informants that strengthening research capacities in low-income countries was one of the most effective ways of advancing health and development in these countries. *‘However, this needs not only commitment from funders but also political commitment and budget lines from African governments’*. Below, we list the areas identified by the respondents to the IEE survey as elements of potentially positive social impact of EDCTP:

- Access to treatment and health monitoring for vulnerable and high risk groups such as newborns and infants, pregnant and lactating women and disadvantaged patients coming from poor communities or minority groups during the inclusion in EDCTP funded clinical trials.
- Health education and behavioural empowerment in decision making of citizens in sub-Saharan Africa relating to personal preventive health practices, coping skills and to the health of (future) children; as such EDCTP could have a future impact on healthy child development.
- Improving institutional development of health services and capacity strengthening for health research by improving laboratory research capacity and IT-facilities, collection of epidemiological and social science baseline data, harmonization and strengthening of regulatory processes and operational standards for clinical trials.
- Improving the level of education and training of health professionals and researchers via fellowships and training activities thus improving job opportunities

Respondents to the public consultation felt that EDCTP should have a high level impact on promoting collaboration between research and development funding institutions (86%), promoting academic research (81%) and facilitating the introduction and dissemination of new products, technologies and production methods (80%). Sixty-eight percent of respondents answered that a new EDCTP initiative should have a high level of impact on reducing the cost of clinical trials and 48% of respondents felt that EDCTP should have a high level of impact on both promoting industrial research and facilitating job creation. Respondents to the public consultation felt that it should have a high level impact on ensuring access to the products of research findings (87%) and improving health care benefits and equal treatments (87%). They also felt it should have a high level of impact on improving public understanding of clinical trials (74%), promoting cultural exchange through research (72%) and improving public awareness of ethics (72%).

A potential negative impact of fostering clinical research in resource-constrained settings is that patients may choose to join the trials because of the availability of drugs and the perception of receiving better care. After the trials completion many become disgruntled if, those drugs are no longer available from the health care system. Hence the importance for EDCTP to monitor the continued availability of successfully developed products, which is a major ethical requirement. Partnerships with programs supported by DG Development may be of interest to increase access to drugs.

In conclusion, the panel considers **Option 3 & 4** offer considerable advantages for socio-economic impact over **option 1 &2** given that brain drain, i.e. the emigration of health professionals and scientists, has a particular negative effect in sub-Saharan Africa, the region that faces the greatest shortage of human resources for health.

#### **7.4. Ecological impact**

The African Office staff of EDCTP noted that when they started there was little or no consideration of ecological issues when the research applications were entered. EDCTP now has an ecological policy (see EDCTP website) which it requires individuals to consider in grant applications and EDCTP funded institutions to apply. An extra budget can be set aside within a project grant to address environmental issues. This will continue under **options 3 & 4**, not under **options 1 &2**.

Realising that many African states and institutions have limited or no discernable ecological policies or programmes, the EDCTP should be commended for developing its own ecological policy. An issue raised previously but not emphasised in the EDCTP ecological policy is the matter of biosafety and medical waste disposal. EDCTP should highlight this matter in its ecological policy and make every effort to ensure its sustained application.

## 8. COMPARING THE OPTIONS

Table 2: Comparison of options

	OPTION 1	OPTION 2	OPTION 3	OPTION 4
	No EU involvement	Program-based	Business as usual	Expanded Scope
ADVANTAGES	Net financial gain	More control by EU on resource allocation	Strategic participation of African partners	Strategic participation of African partners
DISADVANTAGES	Political damage  Loss of investment in EDCTP	Political damage  Loss of investment in EDCTP	No budget increase	Budget increase required, corresponding to expanded scope. A possible scenario could have an indicative funding of up to 2 x original budget, to approx. € M 750 million instead of € 400 for a comparable project duration



## 9. MONITORING AND EVALUATION

Previous evaluations have pointed to the lack of ex-ante identified indicators for outcome and impact assessment of EDCTP. EDCTP currently uses a set of key performance indicators that allow tracking of its output in terms of number of clinical trials, time to contract etc. These tend to be rather managerial in nature and as said by the external evaluators (IEE 2009), “*they are a good start,..but too broad and unspecific for EDCTP2*”. The IEE 2009 report suggests a number of more specific key performance indicators.

It is indeed not easy to assess the successes and failures of EDCTP in the present data collection format, and/or due to the multiplicity of formats. Any continuation of EDCTP should under the guidance of a single ‘Scientific Advisory Board’ (see below) develop a strategic set of priorities and goals. Accomplishments should be tracked against this set of explicit goals. This will allow more transparent observation of where progress has been made and where more attention/training/investment should be focussed.

Therefore, any future EDCTP option should work with a set of relevant and measurable indicators that will allow the prospective monitoring and evaluation of EDCTPs **outcomes and impact** on its stated objectives in each of the three domains, i) capacity building in Africa, ii) development of new interventions against poverty-related diseases and iii) scientific and financial integration of the MS national programmes. Below we list a number of indicators that can be used to i) monitor ongoing operations and ii) evaluate outcomes/impact on a periodic basis:

### A. For monitoring

#### A.1 Clinical Trials Activity

- Number of subjects in each approved study
- Time tracking for each trial, with
  - Estimated study start dates
  - Estimated date for last subject enrolled
  - Estimated date for Clinical Study Report
  - Estimated date for submission for publication
- Cost tracking: travel budget, telephone and videoconferences costs, allowable overhead costs for institutions performing clinical trials
- Costs per subject enrolled for each clinical trial

#### A.2 Capacity strengthening:

Number of needs assessment for capacity building conducted

Number of persons trained and at what level [administrative, project planning, study nurse, Primary Investigators (PI), laboratory technologist]

Name the standardized training programs that the EDCTP has adopted, e.g. data management, database formation, Good Clinical Practices, HIV prevention, malaria prevention

#### B. For evaluation

More specific indicators for the periodic evaluation of **impact** could focus on:

#### **Social impact**

- Number of studies planned/calendar year in HIV, TB and malaria
- Treatments that move to the next phase of clinical trials
- Scientific impact
  - Number of publications for each PI
  - Number of publication with African scientist as first author
  - Meetings attended and presentations given by EDCTP members each year
- The number of successfully developed products registered in African countries
- The number of successfully developed products available and in use African countries
- The number of African scientists effectively brought back from the diaspora

#### **Economic impact**

- Job creation: Numbers of each profession paid by EDCTP: administrative, project planning, study nurse, PIs, laboratory technologists and overall yearly loss of personnel

#### **Political impact**

- The proportion of African country financial contributions to the total EDCTP budget- direct and indirect.
- The proportion of co-funding obtained from member states

## 10. DISCUSSION AND RECOMMENDATIONS

This expert panel recommends to the EC that Option 4 (Expanded Scope) be considered as the preferred option. The expansion to phase-1 and 4 trials is justified, as is the expansion to other poverty-related diseases, the NID, as far as they are identified as priorities by African countries. This expansion is consistent with the European Parliament resolution on Major and Neglected Diseases in Developing Countries (2005/2047(INI) that under article 51 ‘...Calls for the activities of the EDCTP to be broadened to include other neglected diseases and other phases of clinical development (Phase I and IV)’.

Geographic expansion of EDCTP seems not relevant at this stage given the huge need and knowledge gap in sub-Saharan countries that needs to be addressed as the highest priority. The beneficiaries of EDCTP-funding should primarily be the sub-Saharan countries but EDCTP should be encouraged to build alliances with similar initiatives in other regions. This will allow African partners to share their successes and remove obstacles for EU member states wishing to support similar R&D infrastructure to combat poverty-related diseases in Latin-America or Asia.

The panel supports expanding EDCTP’s scope to Phase-1 and Phase-4 studies for the following reasons. While the focus should remain on Phase-2 and Phase-3, fully GCP compliant phase-1 units operated in sub-Saharan African countries would allow for early testing of potentially significant compounds designed for HIV, AIDS, malaria and NIDs by the private sector and also bioequivalence studies of generic drugs for these diseases to reduce the cost of treatment. These facilities can also test fixed-drug combination formulations when multiple drugs are needed to treat diseases, i.e. HIV and tuberculosis. Phase-4 studies and pragmatic trials are desperately needed to determine the safety and effectiveness of new therapeutic interventions under real-life conditions in case EDCTP funded research leads to significant results at Phase-3. Such studies may provide insight to what extent these innovations might contribute to reducing the disease burden.

The panel also recommends to the EC to expand the technology, infrastructure and clinical trial expertise to other poverty-related NIDs, as per need and priorities identified by the African partners. The original co-decision (Decision No 1209/2003/EC) mentioned NIDs under Article 12), as follows. “Art 12 ) A similar initiative could be launched at a later stage, including other neglected diseases which particularly affect poor people in the developing countries, provided that the Member States are implementing such programmes and that the Framework Programme has a corresponding research priority.” The 2005 resolution of the European Parliament explicitly asked for a broadening of the EDCTP scope to other NIDs, based on the report on Major and Neglected Diseases in Developing Countries by the Committee on Development (2005/2047(INI)). The panel considers that the infrastructure and human capacity developed by the EDCTP to perform GCP-compliant clinical trials can form a template to support new drug/vaccine for treating other poverty-related neglected infectious diseases that are a priority in Africa.

A time frame for an expanded EDCTP for at least 10 years is advisable; considering the time needed for clinical trials phase 2, 3 and/or 4, capacity building including regulatory framework, to allow growth of African leadership and infrastructure.

The panel strongly advises the development of a new legal entity that would include African representation as full members of the EDCTP partnership with monetary contributions to the EDCTP funds. Monetary funding from the collaborating sub-Saharan African nations would enhance sustainability and lead to true partnership. The current governance structures of EDCTP should be modified to include the EC as voting member and eventually to grant full voting rights to the African partners.

Other items for consideration and discussion are the need for a more simplified and agile governance structure with a single strong Scientific Advisory Committee (SAC) merging (and replacing) the current DCCC and Partnership Board of the EDCTP. Such SAC will be able to both give strategic direction to paths of research and provide objectives and timelines to be met. We refer to the 2009 IER report for more detailed recommendations on the EDCTP2 governance structure (IER/EDCTP 2009 p 9).

Such future Scientific Advisory Committee to EDCTP2 should very clearly identify the strategic priorities that will lead to requests for proposals and monitor milestones of these programs. This will provide more measurable output to review progress of the EDCTP2 and highlight deficiencies. EDCTP2 should from the start outline clear and specific objectives with measurable outcomes both in clinical research as well as in capacity strengthening.

At the moment the African Office in Cape Town has 4 members of staff and undertakes oversight and advocacy for all the African activities. This gives the South African scientists an obvious comparative advantage and participation of French-speaking West African countries might prove relatively harder to secure. Ideas are floated to increase EDCTP's visibility in several African countries. While a cap on management costs is essential, and EDCTP representation in each African country seems superfluous, EDCTP might consider permanent representation/ regional offices in the 4 geographic regions of Africa, west, east, central and south.

Last but not least, if effective "interventions" resulting from the EDCTP project are to be successfully implemented in developing countries, operational research, health system research, advocacy and capacity building on how to implement these in the local context are needed. Additional funding will be necessary in order to strengthen the health services that need to realise the activities. Research is needed to help develop policies and formulate strategies adapted to the resource-poor environment of developing countries and the local social-cultural context. Existing or future health technology for disease control must be adapted and/or implemented in developing countries. But research is also necessary on more general issues such as the organisation of health services in order to provide easy access to the population. While such health system research is direly needed, it is not necessarily EDCTP2 that should manage this type of research funds. Clinical research for development of drugs, vaccines and diagnostic devices requires a specific skill set, and appropriate clinical research platforms that are not identical to those required for health system research. Matching funds should be made available for health systems/implementation research under the mainstream EU FP7/FP8 research funding.

The high cost of innovative drugs has delayed their introduction in the health systems of developing countries in the past (e.g. the cost of anti-retroviral drugs has hampered for many years the possibility to even consider ARV therapy for

HIV/AIDS patients in resource constrained settings, until major price reductions were obtained in 2000). EDCTP should monitor access to the products it has successfully developed and a partnership with Directorate-General (DG) Development seems highly desirable for ensuring effective availability and access to products. *“A new funding policy is needed that ensures future availability of two flexible funding streams: one from DG research and one from DG development”* (IEE/EDCTP 2009).

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## **LIST OF ATTACHMENTS**

- 1. LIST OF EDCTP-RELATED DOCUMENTS REVIEWED**
- 2. LIST OF AFRICAN COUNTRIES WITH EDCTP-FUNDED PROJECTS**
- 3. UPDATE ON THE EDCTP PROGRAMME: 2003-2010**
- 4. PERSONAL COMMUNICATION BY M.MAKANGA ON AFRICAN DIASPORA**
- 5. PAPER BY A. ZUMLA ET AL 2010**
- 6. PAPER OFORI-ADJEI D. & GYAPONG J.A. (2008) A DEVELOPING COUNTRY PERSPECTIVE ON INTERNATIONAL RESEARCH PARTNERSHIPS ON HEALTH. PAPER PRESENTED AT THE NUFFIC CONFERENCE 'KNOWLEDGE ON THE MOVE'**



**ATTACHMENT 1. List of EDCTP-related documents consulted**

(All were obtained through the Commission's services or directly from EDCTP)

<b>Reference code in this document</b>	
	• <b><i>Establishment of EDCTP</i></b>
Decision No 1209/2003/EC	Co-Decision of the European Parliament and of the Council.N°. 1209/2003/EC, 16 June 2003
COM (2008) 688	Communication by the Commission on Progress of EDCTP COM (2008)688, of 30/10/2008
	• <b><i>Activities of EDCTP</i></b>
EDCTP/JPA:A 2007	EDCTP. Joint Programme of the Action Part A Update 2007, 06/12/2007
EDCTP/JPA:B 2009	EDCTP. Joint Programme of the Action Part B Update 2009, 24/11/2009
Annual report EDCTP YEAR	Annual reports by EDCTP 2005 to 2009
EDCTP/update 2010 See <b>Attachment 3</b>	Update on the EDCTP programme: 2003-2010, n/07/2010
See <b>Attachment 2</b>	List of African institutions with EDCTP –funded projects
EDCTP/KPI 2010	EDCTP: Key Performance Indicators (April 2010). Available from <a href="http://www.edctp.org/Performance.572.0.html">http://www.edctp.org/Performance.572.0.html</a>
	• <b><i>Internal and External Assessments of EDCTP</i></b>
IER/EDCTP 2007	Independent External Review Report, 12/07/2007, the ‘Van Velzen report’
SCIH/EDCTP 2009	Internal Assessment of the 2003/2009 EDCTP Programme, SCIH 28/10/2009
IEE/EDCTP 2009	Independent External Evaluation Report, 14/12/2009
	• <b><i>On EDCTP2</i></b>
EDCTP/EEIG 2009	Recommendation by EDCTP-EEIG for a second EDCTP Programme, 2009
Roadmap 2010	Roadmap “European and Developing Countries Clinical Partnership II”, 17 March 2010
EDCTP2/JPA:A 2010	EDCTP. Joint Programme of the Action EDCTP-II Part A, 29/04/2010

**ATTACHMENT 2 List of African institutions with EDCTP-funded projects** (Please double-click on document below to open)

<b>List of African institutions with EDCTP funded projects</b>			
<b>Country</b>	<b>Institution</b>	<b>Location</b>	<b>Type of grant and coordinator</b>
Benin	Ministere de la Sante Publique	Cotonou	- CB.2007.41302 - Ethics/Ministry of Health-Benin-Support project for the establishment and the strengthening of the Benin National Ethic Committee
	Universite d'Abomey-Calavi	Cotonou	- IP.2007.31080.Menendez - Evaluation of alternative antimalarial drugs to sulfadoxine-pyrimethamine for intermittent preventive - CB. 2008.31060/ Issifou- Mal Treatment(2)- Development of Fosmidomycin and Clindamycin, in a Fixed Dose Combination, for the Treatment of Acute Uncomplicated Plasmodium falciparum Malaria
	Ministere de la Sante Publique	Cotonou	- IP.2007.31080.Menendez - Evaluation of alternative antimalarial drugs to sulfadoxine-pyrimethamine for intermittent preventive
	Institut de Recherche pour le Développement (IRD)	Cotonou	- CB. 2008.31060/ Issifou- Mal Treatment(2)- Development of Fosmidomycin and Clindamycin, in a Fixed Dose Combination, for the Treatment of Acute Uncomplicated Plasmodium falciparum Malaria
Botswana	Botswana Harvard AIDS Institute Partnership for HIV Research and Education	Gaborone	- CB.2007.41700. TESA – Trials of Excellence in Southern Africa
	University of Botswana	Gaborone	- CB.2008.41302/Kasule-HRU Botswana-Ethics-Strengthening of the Botswana IRB, and establishment of Health Institutions and Health Districts Ethics Committees
	Ministry of Health	Gaborone	- CB.2008.41302/Kasule-HRU Botswana-Ethics-Strengthening of the Botswana IRB, and establishment of Health Institutions and Health Districts Ethics Committees
Burkina Faso	Centre Muraz	Bobo Dioulasso	- CT malaria/d' Alessandro - Evaluation of 4 artemisinin-based combinations for treating uncomplicated malaria in African children - CT.2006.33020/van der Perre - A phase III double blind placebo/controlled trial of the efficacy and safety of infant perieposure - NW/Temmerman - Strengthening laboratory capacity and nutrition skills in the context of an ICH-GCP clinical trial for the prevention of mother-to-child transmission of HIV*** - NW MSc/Hall - Distance learning Master course in Clinical Trials - CT.2006.33111 Kapiga HIVTA - Capacity development and strengthening in preparation for HIV vaccine trials in Tanzania and Burkina Faso - IP.2007.31080 D'Alessandro IP - Safe and efficacious artemisinin-based combination treatments for African pregnant women with malaria - IP.2007.41700 NOE/M'boup - IP- Capacity building to prepare West African sites for clinical trials on HIV, TB and Malaria
	Institut de Recherche en Sciences de la Sante	Bobo Dioulasso	- IP.2007.31080 D'Alessandro IP - Safe and efficacious artemisinin-based combination treatments for African pregnant women with malaria - IP.2007.31060 Djimde 2007- An integrated approach to clinical trials, capacity building and networking in West

# Update on the EDCTP programme: 2003-2010



July 2010 – The Hague



## ATTACHMENT 4 Personal communication by M.Makanga, EDCTP African Office

----- Original Message -----  
Subject: RE: EDCTP update  
From: "Makanga, Michael" <Makanga@edctp.org>  
Date: Thu, August 19, 2010 12:45  
To: arnoldc@webmail.co.za  
-----

Dear Arnold,

Apparently I missed out one Senior Fellow, Dr Badara Cisse from Senegal who returned from the UK to work in Senegal because of this grant. Attached is a letter of appreciation that I received from him in 2009 expressing this.

Kind regards,

Michael

-----Original Message-----  
From: Makanga, Michael  
Sent: 19 August 2010 11:34 AM  
To: 'arnoldc@webmail.co.za'  
Subject: RE:

Dear Arnold,

Nice to hear from you. The EDCTP Senior Fellowship grant scheme has served as a re-entry grant and has brought back scientists from Diaspora for 5 African scientists:

1. Dr Alexis Nzila, a Congolese scientist originally based in the UK to work in (KEMRI, Kenya),
2. Dr Willem Hanekom, South African formally in the USA now associate Professor of immunology at University of Cape Town, UCT)
3. Dr Keerta Dheda, South African formally in the UK now at UCT, Cape Town
4. Dr Jean Nachega, a Congolese originally in the USA now associate Professor University of Stellenbosch, South Africa
5. Dr Abdoulaye Djimde from Mali was contemplating moving to the USA, now is settled in Mali. He has improved his scientific competitiveness by progressing from Senior Fellowship to being PI of a larger integrated clinical trial project.

The Senior Fellowship grant scheme has also enabled 2 fellows to start up research projects in post war countries:

1. Dr Didier Ekouevi from Ivory Coast successfully completed an HIV peri-natal prophylaxis study and establishing a research team there. He has recently succeeded in getting a larger EU Member States initiated grant
2. Dr Stephen Kennedy from Liberia: Senior Fellowship project entitled "Building research infrastructure and capacity to implement an HIV/STD prevention trial in post conflict Liberia".

Additionally, the Senior Fellowship grant scheme has facilitated African scientists to run projects in better endowed African institutions and countries with a hope of them developing capacity in their African countries of origin (4). This is reflected in these projects where collaborations with institutions in countries of origin are established.

1. Dr Happi Tienta Christian, Cameroonian now running fellowship project at University of Ibadan Nigeria
2. Dr Nicaise Ndembi, Cameroonian now completing fellowship project at the Uganda Virus Research Institute in Entebbe, Uganda
3. Dr Harr Freeya Njai, Gambian now completing fellowship project at the Uganda Virus Research Institute in Entebbe, Uganda
4. Dr Alexis Nzila, a Congolese scientist based in Kenya Medical Research Institute (KEMRI), Kenya
5. Dr Jean Nachega, a Congolese originally in the USA now associate Professor University of Stellenbosch, South Africa.

Kind regards,

Michael

## Trials and tribulations of an African-led research and capacity development programme: the case for EDCTP investments

A. Zumla<sup>1,2,3</sup>, J. Huggett<sup>1,3</sup>, K. Dheda<sup>2,3,4</sup>, C. Green<sup>1,3</sup>, N. Kapata<sup>1,3,5</sup> and P. Mwaba<sup>1,4</sup>

1 University of Zambia – University College London Medical School Research and Training Project, UNZA School of Medicine, Lusaka, Zambia

2 University College London Medical School – University of Cape Town Collaboration, South Africa

3 Department of Infection, Centre for Infectious Diseases and International Health, University College London Medical School, UK

4 Division of Pulmonology, Department of Medicine, University of Cape Town, South Africa

5 National TB/Leprosy Programme Zambia Ministry of Health, Lusaka, Zambia

6 University Teaching Hospital, Lusaka, Zambia

### Summary

We describe the initiation and establishment of The University of Zambia – University College London Medical School (UNZA-UCLMS) Research and Training Project, an entirely African scientist-led, south–north partnership. In its 16 year existence, the project, by successfully obtaining competitive grant funding, has transformed itself into one of Africa's most productive African-led R&D programmes with training and visible research outputs. The project serves as a role model and now networks R&D and training activities with six southern African (10 institutions) and six European countries. This project case study illustrates that deep commitment is essential for success and that the factors which facilitate success in R&D in Africa need to be evaluated. The long-term prospects for sustaining the UNZA-UCLMS Project appear bright and are dependent on several factors: the ability to retain trained African scientists; obtaining continued competitive or donor grant funding support; and serious investment by the African governments involved. The recent 255 million Euros EDCTP investment in sub-Saharan Africa through south–north partnerships is expected to enhance existing African-led R&D programmes. African governments and scientists must rise to the challenge.

**keywords** African scientists, capacity development, European and developing countries clinical trials partnership, funding, research, sub-Saharan Africa, training

### Introduction

Since the 1950s, as African countries became independent from colonial domination, they embarked on developing their own medical schools and training programmes. The fact, that several African institutions had not been able to develop their medical and scientific Research and Development (R&D) programmes to international standards, has been a subject of debate and discussion for decades (Andersson & Marks 1989; Deacon 2000; Clarke 2007). Because of poor economies, African governments were unable to invest adequately in sustaining local R&D. In the early 1990s, several African countries took up the challenge and embarked on developing their own African-led R&D programmes. This viewpoint describes the trials and tribulations of initiation and establishment of The University of Zambia – University College London Medical School Research and Training Project, (UNZA-UCLMS Project) an entirely Zambian-led, successful, south–north, partnership.

### Historical background: formation, evolution and funding of an African-led project

In 1991, a substantive NIH-RO1 grant for R&D and training on HIV/AIDS enabled Herbert Dupont (UT, USA), Chifumbe Chintu and Alimuddin Zumla to set up the University of Texas–University of Zambia R&D Project (UTZAM) at the University Teaching Hospital in Lusaka for R&D and capacity development. After the NIH grant was completed in 1994, further funds for R&D were difficult to obtain. However, this project and its research outputs (Chintu *et al.* 1993a,b; Luo *et al.* 1994; Mathewson *et al.* 1994, 1995; Oshitani *et al.* 1994) formed the foundation for the subsequent joint R&D developed with UCLMS. Chintu and Zumla, both Zambians, took the opportunity to develop a novel, African-led, equitable, collaborative south–north partnership project. Their focus was R&D on health policy relevant research on important adult and paediatric infectious diseases that would result in a good quality, R&D project for Zambia and in

**ATTACHMENT 6 Ofori-Adjei D. & Gyapong J.A. (2008) A developing country perspective on international research partnerships on health. Paper presented at the NUFFIC conference 'Knowledge on the move'**

**A Developing Country Perspective on International Research Partnerships on Health**

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**INTRODUCTION**

A partnership involves two or more parties working to achieve common interests and goals. The concept of partnership is used by many international agencies and African policy makers without a precise definition. There is the tendency to refer to agencies that provide financial and technical support as 'partners'. In reality not all of these agencies are in partnership with the recipient body. Partnerships in international research on health exist in developed as well as developing countries. However, it is the relationship between the have (developed economies) and the have-nots (developing economies) that have always been the subject of discussion. In practice this concept involves a relationship between an industrialised country and a developing country (north-south partnership). However, partnerships also exist between entities in the developing world (usually referred to as south-south partnership). In general there is more of north-south international research partnerships than south-south arrangements. There are other expressions like collaboration<sup>1</sup> and networks that are used sometimes to reflect the meaning of 'partnership'. In its broader sense collaboration and networks may be part of a partnership arrangement.

The principles underlying a partnership have been described in various ways but many take inspiration from the principles in the "Guidelines for Research in partnership with Developing Countries" of the Swiss Commission for Research Partnership with Developing Countries (KFPE). The Globethics.net Board's outlines twelve principles that should underline partnership in health research<sup>2</sup>.

In general these principles include ownership, mutual trust and respect, shared responsibility, clearly defined roles, sustainability, capacity development and utilisation of research findings to inform health decision making and health practice. In no particular partnership arrangement are all these principles manifested.

In this paper, we describe examples of models of international research partnership and discuss some of the problems associated with them. These are only examples and do not in anyway attempt to give an exhaustive account of the numerous arrangements in existence.

**MODELS OF RESEARCH PARTNERSHIPS**

Existing models of research partnership in health depend on the institutional relationships underlying the partnership arrangements. The arrangements in academia may not be the same as that between governments, governments and academic/research institutions and between a 'Funding agencies' and research institutions.

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<sup>1</sup> Collaboration is a structured, recursive process where two or more people work together toward a common goal—typically an intellectual endeavour that is creative in nature - by sharing knowledge, learning and building consensus.

<sup>2</sup> [http://www.globethics.net/globethics\\_research](http://www.globethics.net/globethics_research) (accessed 1st February 2008)