INDEPENDENT EXTERNAL EVALUATION REPORT

OF THE EUROPEAN AND DEVELOPING COUNTRIES

CLINICAL TRIALS PARTNERSHIP

(EDCTP PROGRAMME)

14 December 2009

Evaluation conducted by the EDCTP / IEE Panel:

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EXECUTIVE SUMMARY

The European and Developing Countries Clinical Trials Partnership (EDCTP) was established in 2003 by 15 European countries to develop new clinical interventions and adapt existing treatments to address the needs of sub-Saharan Africa in the field of poverty related diseases.

The European Union contributes to EDCTP with a grant of € 200 million under the 6th Framework Programme for European Research. The European countries participating in the EDCTP are expected to provide an equivalent investment before the end of 2010. Additional participation from third parties (donors, industry) is encouraged but remains limited for the time being.

The duration of the grant agreement was first extended from 2008 to 2010, at no extra costs. The IEE Panel strongly supports the case for a second extension at no-costs for another three years. The EDCTP is also seeking fresh funding for a second EDCTP Programme, possibly starting in 2010, from participating countries and from the European Union, under the 7th Framework Programme.

A first independent external review (IER) took place in 2007. In accordance with the funding decision, a second evaluation was due at the end of the first five years of the Programme. At the request of

the Commission this independent external evaluation (IEE) was conducted between June and December 2009 and is the subject of the present report.

The Independent External Evaluation panel analyzed the documentation available, held seven meetings and conducted interviews with representatives from the Commission services, from Permanent Representations and from one pharmaceutical company. In depth discussions took place with the Executive Director, the Chairperson of the General Assembly and members of the various EDCTP bodies as well as organizations in contact with the EDCTP. A special questionnaire was addressed to researchers working with EDCTP. Additional information was gathered during a site visit to the EDCTP Cape Town Office, at the EDCTP Conference in Arusha (October 2009) and through a case study conducted in Burkina Faso.

After the initial difficult start-up phase, the EDCTP decided to focus on product orientated clinical trials, networking and capacity development. Compared to the first four years, the general management has improved, as well as the scientific review processes. Several promising clinical results have been presented in Arusha. The EDCTP has been particularly successful in working with scientists and clinicians in Africa and in providing a unique platform for a genuine dialogue with African scientists.

The present IEE report describes progress made between 2007 and 2009, following the 2007 IER recommendations. It provides new recommendations on how the EDCTP could better integrate Member States' national programmes and increase clinical trial and capacity building activities through a stronger partnership with Africa.

The report addresses possible improvements to the current Programme (“EDCTP1”) as well as conditions for a second Programme (“EDCTP2”) if it were to be funded by the participating countries and by the European Union under the 7th Framework Programme for European Research.

OPINION AND KEY RECOMMENDATIONS FROM THE INDEPENDENT EXTERNAL EVALUATION (IEE) PANEL

At the conclusion of its activities, the independent external evaluation panel adopted unanimously the following opinion and recommendations, together with the full report:

1. The European and Developing Countries Clinical Trials Partnership (EDCTP), established by European countries to address the needs of sub-Saharan Africa in the field of poverty related diseases, brings a new model of international research cooperation, promoting African ownership and Africa/EU networking.

Consultations conducted by the panel show that the EDCTP Programme has been successful in working with scientists and clinicians in Africa. It has provided a unique platform for a genuine dialogue with African scientists and this should be institutionalised in future.

In financial terms, EDCTP is a small player amongst the various research initiatives in the field, but it has started to bridge the gap between North and South in building research capacities and in providing learning and working opportunities for young African researchers.

2. The EDCTP has managed to substantially improve its operations over the last two years, due to the combined efforts of its new Executive Director and the Chairperson of the General Assembly. The governance has improved on several critical aspects such as the functioning of the General Assembly (GA). The panel has examined the content of calls, their design, evaluation and adoption, as well as the way the resulting activities are made visible to the scientific community.

Compared to the difficulties encountered during the previous period (2003 to 2006), the output has dramatically increased since 2007, in terms of product orientated clinical trials, networking (nodes of excellence, fellowships) and capacity development embedded within clinical trials (ethical review, regulations). The number of clinical trials has been multiplied by four, capacity building projects by five, the value of grants and the number of African institutions involved by three.

3. The EDCTP has not yet succeeded in its second major task, namely the integration of national clinical trials programmes. The current "co-funding" arrangements constitute a major source of difficulties and confusion. Only seven Member States had, until April 2008, shown substantial commitments (in cash or in kind) towards the EDCTP. The promised target of 200 million Euros co-funding has to be met before the end of 2010. The other participating countries should demonstrate their commitments, according to size and financing capacities. The present complex co-funding requirements generate multiple evaluations and unnecessary administrative delays and costs. There are still discriminations on the basis of the nationality of researchers in certain countries. African researchers are still wrestling with uncertainties concerning funding and with red tape regarding proposals. It has a discouraging effect on their research efforts.

4. The third task, namely the association with major Product Development Public/Private Partnerships for sharing know-how and avoiding duplication has started too recently to be judged satisfactory. There is no evidence of stable working relations with major research funders in the area, or with the pharmaceutical industry, which is by far the major sponsor of clinical trials around the world. More efforts are needed here from the EDCTP bodies as well as from the Commission acting as a facilitator.

5. Earlier IER Recommendations

Whilst many efforts have been made in the meantime by the EDCTP and the Commission services, several of the IER recommendations published in 2007 have still not been entirely fulfilled. Some recommendations have to be repeated in the present report (see relevant extracts in table below, and more details in Annex 1).

IER / EDCTP 2007 KEY RECOMMENDATIONS NOT ENTIRELY FULFILLED

To the EDCTP:

Define a clear, convincing and realistic EDCTP strategy with a common shared vision, clearly defined contributions from each partner and equitable sharing of results.

Make the General Assembly more political.

Expand association with major Product Development Public/ Private Partnerships for access to know-how and to provide visibility and avoid unnecessary duplication.

Simplify and streamline co-funding, from a virtual to an actual common pot, in order to reduce operational complexity and allow African initiation of EDCTP projects.

To the EDCTP Member States:

Interested Member States should directly finance an EDCTP "common funding pot".

Member States should refrain from imposing national criteria, and accept one integrated scientific and ethical evaluation conducted by EDCTP, utilizing a pool of the best experts.

To the European Commission:

Create a joint DG Research / DG Development platform to engage in a dialogue with EDCTP.

6. Recommendations to EDCTP in case of an extension, at no costs, until 2013.

The IEE Panel strongly supports the principle that the Commission should extend to 2013 the EDCTP grant agreement under the 6th EU Research Framework Programme at no extra costs. The IEE makes several suggestions for improving the functioning of the current Programme (EDCTP1) in Part 3 of the present report. The main recommendations are as follows, especially if EDCTP1 is indeed extended until 2013:

6.1. The Commission should extend the EDCTP Grant agreement at no cost until 2013 and should request that the co-funding rules be made simpler, open and transparent.

6.2. The EDCTP should review the way it handles the proposals in the light of critical remarks brought to the attention of the panel and raised also in the recent self-assessment exercise, and publish revised procedural guidelines on its Website.

6.3. The EDCTP should, as soon as possible, publish on its Website more detailed information, on how it intends to verify compliance with internationally recognized ethical principles.

6.4. The EDCTP should, as soon as possible, publish on its Website its detailed guidelines on Intellectual Property Rights.

6.5. The IEE Strongly supports the intention of the General Assembly to include at least 4 high level political decision-makers from African governments as associate members in the General Assembly; if not appointed by WHO AFRO or regional organizations active in the field, they should come from countries conducting the most research activities of HIV, TB and Malaria.

6.6. By mid 2010, the general Assembly should have adopted a realistic and viable strategy for private sector collaboration; the Executive Director should start to implement a concrete business plan, attractive to the research-based industry, including a clear Intellectual Property Rights policy.

6.7. By mid 2010, the EDCTP should forge strategic alliances with major international funding agencies, given the high costs of phase III clinical trials; in a highly competitive funding environment, the EDCTP should pursue a proactive agenda for operations and translational research, focusing on clinical trials.

6.8. Well before the end of the extended EDCTP1 Programme, the General Assembly should explore, in consultation with the Commission, alternatives to the present EEIG legal structure, in order to give equal voting rights to the African Government Representatives.

7. Recommendations to EDCTP in view of a Second Programme (EDCTP2)

Part 3 of the IEE report focuses on conditions for a possible grant agreement under FP 7 for a second EDCTP Programme under article 169 of the Treaty (EDCTP 2). In preparation for a possible Second Programme, the IEE Panel formulates the following recommendations to the EDCTP:

7.1. The General Assembly should finalize proposals on how each country intends to fund EDCTP2 and each member should consult accordingly with their Minister(s) in charge.

7.2. The EDCTP should engage in a profound outreach activity towards Member States who are not substantially contributing to the Programme and towards EU countries not yet members of the EDCTP.

7.3. For the purposes of EDCTP2, the General Assembly composition and voting rights should be restricted to representatives from countries who have made the necessary financial commitments in cash or in kind, as it is the case in several EU research projects based on Article 169 of the Treaty.

7.4. General Assembly members must be able to operate with a political and financial mandate from their government and be in a position to effectively coordinate EDCTP with relevant national activities.

7.5. General Assembly members and the Commission should actively seek to expand the financial commitments through the use of additional financial resources such as national development funds and EU funds for Africa.

7.6. The General Assembly should continue to review the number of EDCTP Bodies, clarify their respective roles and review the number of meetings in order to reduce costs and improve the efficiency of its communication, especially on the Website, where all corporate minutes should be made public.

7.7. The Chair person of EDCTP General Assembly must have the authority to discuss financial and policy matters with the Commissioner and relevant Ministers.

7.8. The EDCTP General Assembly should adopt, as soon as possible, a coherent Second Programme (EDCTP2) with a clear strategy linked to the EU Health Research and existing national policies on poverty diseases. The EDCTP should continue to focus on clinical trials and operational research for the introduction of new technologies for HIV/AIDS, TB, and Malaria.

7.9. The IEE Panel supports the current efforts and encourages EDCTP to develop more comprehensive indicators for assessing EDCTP's activities. According to the panel, this assessment should include two complementary components:

- ***Monitoring the performance of the Programme,***
- ***Evaluating the impacts on research capacity, with a view to reduce the disease burden of HIV/AIDS, Malaria and Tuberculosis in sub-Saharan Africa.***

7.10. In particular, the EDCTP General Assembly should develop more specific key performance indicators and monitor, on an annual basis, the EDCTP Key performances, including:

- ***Number, quality of implementation and output of clinical trials,***
- ***Number, quality of implementation and output of capacity building projects,***
- ***Number, quality of implementation and output of networking activities,***
- ***Performances of EDCTP Secretariat in The Hague and Cape Town,***
- ***Measuring cost efficiency and effectiveness,***
- ***Number and quality of EDCTP links with other global health initiatives in the field,***
- ***Number and quality of EDCTP links with industry in the field.***

7.11. The EDCTP General Assembly should adopt a transparent information and communication strategy and publish, on an annual basis, performances and outcomes.

8. In preparation for a possible future Second Programme (EDCTP 2) the IEE Panel formulates the following recommendations to the European Commission, before the start of EDCTP2:

8.1. The Commission and the Member States should strive to achieve synergy between Development and FP 7 Research activities, at EU as well as national level.

8.2. The Commission should urgently implement a proactive plan to seriously address the earlier IER recommendations on the use of joint DG Research / DG Development platform to engage a genuine dialogue with EDCTP. Commission (DG DEV) delegations in African countries should promote synergies with EDCTP in terms of capacity building.

8.3. The Commission should define a sound rationale for a central role for EDCTP in the context of the Africa/EU Partnership on research, development and global health, for example through a new specific Communication to Parliament and Council, making reference to the present Report.

8.4. The Commission should prepare guidelines (soft law), based on experience with Article 169:

- ***on the way the "common or virtual pot" should be operated,***
- ***on the use of national funds before the start of EDCTP2,***
- ***on the inclusion of non-national researchers in national co-funding schemes.***

9. Concerning the future Decision for a new Programme (EDCTP 2), the IEE Panel formulates the following recommendations to the European Institutions:

9.1. The Commission should only submit a new proposal for EDCTP2 if there is:

- ***a satisfactory Implementation by EDCTP of the IEE recommendations for EDCTP1,***
- ***an agreement with EDCTP on annual performance criteria for EDCTP2,***
- ***a solid upfront financial commitment by individual participating Member States,***
- ***an agreement between the Commission and each of the concerned Member States on a common financial pot for cash contributions and on rules concerning in kind contribution.***

9.2. The future Council and Parliament decision should strictly define the new co-funding arrangements and should exclude double evaluations and national researchers' exclusivity clauses.

PART I

IEE MANDATE AND ACTIVITIES

- **Introduction**
- **Terms of reference, membership**
- **Questions and methodology**
- **IEE meetings**
- **IEE contacts, visits and Arusha Conference**

INTRODUCTION

The European and Developing Countries Clinical Trials Partnership (EDCTP) was established in 2003. It is presently shared between 17 European countries[1] to address three main strategic objectives:

- Development of new interventions and products against poverty-related diseases: The fight against HIV/AIDS, malaria and tuberculosis needs both prophylactic (vaccine and microbicides) and therapeutic (drugs) tools to prevent infection and control diseases.
- Capacity building: Public health and research activities in Africa that should be sustainable, to protect local populations. The coordination of development aid policy and research policy should aim at a better implementation of these separate policies to form a long term strategy against the three diseases.
- Coordination of European Member States research policies on poverty-related diseases: Research activities of some European Union Member States in Africa could profit from better collaboration and coordination. This coordination of national research programmes should increase the efficacy of European interventions, in line with Article 169 of the Treaty.

The Independent External Review Report[2] of July 2007 (IER 2007) had already underlined the difficulty for the EDCTP Programme to combine integration of national clinical trials programmes and collaboration with scientists and clinicians in Africa. This very long-term ambition can only produce progressive results if all interested partners respect their commitments. The EDCTP remains unique in providing strong support to African scientists and this should be reinforced in future.

The IER findings and recommendations for the period 2003 to 2007 have been discussed and endorsed by all members of the new Independent External Evaluation panel. Answers given by EDCTP and the Commission to the main IER recommendations are briefly described in **Annex 1**. The Independent External Evaluation Panel focused on EDCTP achievements from 2007 to 2009 and on possible future developments.

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[1] *Norway and Switzerland plus 15 EU Member States: Austria, Belgium, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Slovakia, Spain, Sweden and the United Kingdom.*

[2] *See http://www.edctp.org/fileadmin/documents/Final_IER_report.pdf*

The European Commission submitted on 30 October 2008 a communication[3] to the European Parliament and to Council on the progress made by EDCTP, together with a more detailed Commission staff working document[4].

The EDCTP describes its activities on a public Website (www.edctp.org). For the purposes of the present evaluation, the EDCTP has provided specific briefings and access to its internal minutes and to all documents requested by the IEE panel, including a draft internal-assessment report. **Annex 2** gives a summary of facts and figures in relation with EDCTP activities.

In financial terms, EDCTP is a small, though significant, player among the various AIDS, malaria and tuberculosis research initiatives, and operates in a competitive funding environment. The European Union contributes to EDCTP with a grant of € 200 million under the 6th Framework Programme for European Research. The European countries participating in the EDCTP must provide an equivalent investment by 2013. Additional participation from third parties is encouraged but remains limited.

MANDATE AND COMPOSITION OF IEE PANEL

Article 8 of the Decision N° 1209/2003/EC on Community participation in EDCTP[5] requests that an evaluation should be performed by the Commission and presented to the European Parliament and to the Council at the end of a five-year period, the original duration of the programme.

In this context, the European Commission has, in May 2009, mandated six independent experts to conduct an external evaluation of the EDCTP programme, to review its progress and achievements.

The IEE panel was asked by the European Commission, by November 2009, to:

a) Assess the EDCTP Programme performance:

- as an integration of national programmes in the spirit of Article 169 of EU Treaty
- as an operational structure (clinical trials, capacity building and networking);

[3] *COM(2008)688 of 30.10.2008*

[4] *SEC(2008)2723 of 30.10.2008*

[5] *OJCE N° L 169/1 of 8.07.2003*

- as a partnership with African countries.

b) Address the role of EDCTP in the broader international research and development agenda, taking into account the nature and values of the Programme and its comparative advantages.

c) Assess the economic, social and environmental impacts of EDCTP.

d) On the basis of this evaluation, draw possible lessons to be learnt and recommendations for future initiatives on the basis of Article 169.

In May 2009, Commissioner Janez Potočnik appointed a multidisciplinary team of six individuals to conduct the Independent External Evaluation. The panel elected their Chair and Rapporteur during their first meeting, in June 2009. The Chair and Rapporteur had already participated in the previous Independent External Review of 2007. Having discussed and reviewed the IER 2007 Report, the other members of the panel endorsed its findings and recommendations for the period 2003 to 2006. The whole panel decided therefore to focus its attention on EDCTP performances from 2007 to 2009.

The Independent External Evaluation panel appointed in May 2009 comprised:

Wim Van Velzen (Chair): advises Covington & Burling LLP clients on European institutional affairs, legislation and accession issues. He is particularly involved in energy, ICT and R&D policies. Since 1989, he has worked extensively in Central and Eastern Europe, and more recently, in the Balkans and Turkey. He was a Member of the European Parliament from 1994 to 2004, where he became Vice-President of the EPP-ED group. He is currently Chairman of the Rathenau Institute; Chairman of the Committee of Wise Men advising the Dutch government on research; Chairman of the Dutch Roadmap Committee for Research infrastructure; member of the Supervisory Board of the Technical University of Twente.

Randa Kamal: Graduated and received master and PhD degrees in paediatrics from the Faculty of Medicine, Ain-Shams University of Cairo, Egypt. Clinical and research post doctoral fellowship in paediatric pulmonary (1996/1997) from the paediatric department, John Hopkins School of Medicine, John Hopkins University of Baltimore, MD, USA. Currently, a full professor of paediatrics in the Institute of postgraduate children studies, Ain-Shams University of Cairo, she has experience in projects planning and implementation with foreign organizations. Since 2000, she worked as a senior consultant for national programmes planning and implementation in the Egyptian Ministry of Health, children with special needs department, primary health care sector. Since 2002, she held the position of technical director of the national genetic counselling program in the Egyptian Ministry of Health.

Nicolas Meda: MD, PhD, medical epidemiologist, associate professor in public health at University of Ouagadougou (Burkina Faso), and senior health researcher at Centre MURAZ (Bobo-Dioulasso, Burkina Faso), is also the Country Coordinator of French National Agency for AIDS Research (ANRS) in Burkina Faso. At Centre MURAZ (Burkina Faso Ministry of Health Institute of Biomedical Research), he is the Chief of Department of HIV/AIDS and Reproductive Health. Its research areas of interest include Mother-to-Child Transmission of HIV and its prevention, Research ethics, Epidemiological studies, Reproductive Health (safe motherhood) for which he is the national principal investigator for several HIV, maternal and child health international clinical trials and demonstration projects funded by ANRS, European Commission, EDCTP, DFID, Gates Foundation and various other funding agencies. He is the author of more than 100 papers, reviewer in different international journals, consultant for different UN system agencies and member of several scientific review committees and networks.

Irmgard Nippert: Full professor at the Westfaelische Wilhelms-University Muenster Medical School and director of the Women's Health Research Unit. For more than two decades, she has participated in EU funded projects (as co-ordinator or partner). Currently, she coordinates the EU "CAPABILITY" project (capacity building for the transfer of genetic knowledge into practice) and is partner in "EUROGENTEST" (Network of excellence for test development harmonization, validation and standardization of services in human genetics) and in "EUROGENGUIDE" (patient led education and development for genetic testing in research and medicine). In addition, she runs an international project in 4 European countries on cancer risk communication in primary care (InCRisC). She is a member of the ethics committee of her Medical School and has served on the ethics committee of the German Federal Association of Physicians (1998 to 2007). She has acted as an expert for the German Federal Parliament and the Parliament of North-Rhine for more than two decades.

Peter Piot, MD, PhD is Professor of Global Health and Director of the Institute for Global Health at Imperial College, London, UK. He was the founding Executive Director of UNAIDS and Under-secretary of the United Nations from 1995 until 2008, and was an Associate Director of the Global Programme on AIDS of WHO .Under his leadership UNAIDS became the chief advocate for worldwide action against AIDS, also spear heading UN reform by bringing together 10 UN system organizations in the global aids response. Dr. Piot co-discovered the Ebola virus in Zaire in 1976, and led research on HIV/AIDS, women's health, and public health in Africa. He was a professor of microbiology, and of public health at the Institute of Tropical Medicine, Antwerp, the Free University of Brussels, and the University of Nairobi, was a Senior Fellow at the University of Washington, a Scholar in Residence at the Ford Foundation, and a Senior Fellow at the Bill and Melinda Gates Foundation. He holds the chair 2009/2010 "Science against poverty" at the College de France in Paris, and is a visiting professor at the London School of Economics. He is a member of the Institute of Medicine of the US National

Academy of Sciences, and of the Royal Academy of Medicine of his native Belgium, and a fellow of the Royal College of Physicians. He is the President of the King Baudouin Foundation, was knighted as a baron in 1995, and published over 500 scientific articles and 16 books.

Fernand Sauer (Rapporteur): studied Pharmacy at Strasbourg and Law at Paris University. After a few years in France as hospital pharmacist and health inspector, he became the Head of Pharmaceuticals at the European Commission in charge of harmonization of pharmaceutical legislation in Europe and worldwide. He became the first Executive Director of the European Medicines Agency in London (1994-2000). Director for Public Health of the European Commission from 2001 to 2005, he was responsible for the European Public Health Programme, for health measures such as anti-smoking legislation and for the establishment of the European Centre for Diseases Control in Stockholm in 2005 (ECDC). He is a member of the French High Council for Public Health and of the National Academy of Pharmacy.

MAIN QUESTIONS FOR THE IEE PANEL

At the start of its work, the IEE panel decided to conduct its evaluation in exploring some key questions, through meetings, hearings, interviews, a questionnaire and a case study:

- Has the EDCTP Programme, under FP6 delivered at the end of 2009? If not, does it have the potential to deliver by September 2010 or by end of 2013?
- What are the tangible EDCTP results to improve the fight against AIDS, TB and Malaria?

  If so, what are the concrete achievements? If not, what are the main reasons for delays or failure?
- Has the EDCTP Programme improved research collaboration and/or integration between

  North/South, North/North, South/South partners? If not, why not?
- What recommendations can the IEE make for the continuation of the present programme (EDCTP1), assuming that the Commission will accept a no-cost extension until 2013?
- Recommendations for a second financing round of EDCTP under FP7 (EDCTP2) based on the exploration of a number of conditions, such as:
    - Compatibility with FP7 health priorities and RTD neglected diseases research,
    - Complementary to DEV capacity building activities,

- Significant integration of national projects and programmes,
- Sufficient cooperation with Funding organizations and industry R&D,
- Suitable structures to associate African researchers (EEIG?),
- Suitable co-financing planning and implementation,
- Single scientific and financial evaluation of EDCTP projects,
- Recognized scientific excellence,
- Compliance with international regulatory and ethical requirements.

And finally, has the EDCTP Programme provided new lessons and experiences to improve Article 169 initiatives and the European Research Area (ERA)?

IEE METHODOLOGY

The collective work of the IEE team members was based on preliminary desk study of a number of relevant documents, in particular those provided by the Commission and EDCTP, and on the Report from the Independent External Review published in July 2007. The IEE Panel decided to take this previous report as a starting point for its own investigations and to focus on EDCTP activities from 2007 to end of 2009.

The IEE interviewed key players during seven meetings held in Brussels and The Hague between June and November 2009. In addition, each member of the team conducted specific activities and reported back to each of the IEE meetings: interviews in Europe and Africa, visit to the EDCTP office in Cape Town, questionnaire to researchers, case study in Burkina Faso, review of clinical trials, feedback from an EDCTP Conference in Arusha, impact assessment.

A self-administered questionnaire was developed by and analyzed by Randa Kamal to assess researchers' feedback regarding EDCTP projects and their impact, and to solicit their suggestions for improvement. The questionnaire included 41 multiple choice questions. Forms were sent by E-mail to researchers to be filled in 10 days and sent to edctp2009@gmail.com (**see Annex 3).** Additional forms were distributed at the Arusha Forum during a panel discussion with principal investigators. Analysis of the results and conclusions are used in the relevant parts of the report.

The outcomes of the Arusha discussions were analyzed **(see Annex 4).** On the basis of contacts in Cape Town, The Hague, Burkina Faso and Arusha, a paper on EDCTP capacity building was produced and used for the report **(see Annex 5).**

Forty five EDCTP clinical trial proposals were reviewed. The projects were coded and data were collected, tabulated and analyzed A SWOT analysis was performed, and the results and conclusions are used in the relevant parts of this report (**see annexes 6 and 7**).

Burkina Faso was selected for a case study in order to examine the EDCTP real impact in a West-African developing country. This qualitative study was conducted by Nicolas Meda with various ministries, the EU delegation, research institutions, and individual researchers. Findings from this study (see **Annex 8)** are used in Part 2 and 3 of this report.

The Panel greatly appreciated the organizational support provided by Manuel Romaris, Francesco Ronfini, Ana Nieto, Anja Belaey and Gianluca Quaglio from the Health Research Directorate of the Commission: organization of meetings, visits and interviews, support for minutes. In addition, Anja Belaey provided travel assistance for panel members and archiving of documentation for the rapporteur. Relevant documents were put on a dedicated internal Website (CIRCA/EDCTP Independent External Evaluation). The list of source material used by the IER panel is in **Annex 9**.

The panel would also like to thank the Executive Director, Charles MGONE, for the considerable time and efforts he and his team have invested in the timely preparation of briefs and contributions for the IEE work.

IEE MEETINGS

Seven IEE meetings took place between June and November 2009, generally with hearings and internal discussions over a full day.

1st IEE Meeting, 10.06.2009, Commission, Brussels: Presentation and discussion of mandate; discussion of working methods; planning of activities; verification of absence of conflicts of interests; election of Chair and Rapporteur; discussion of findings and recommendations from IER 2007; inventory of initial documentation and setting-up of an internal Website (CIRCA).

2nd IEE Meeting, 10.07.2009, Commission, Brussels: Policy brief by K. Vandenberghe (Cabinet Potočnik); EDCTP legal entity and Treaty alternatives to Article 169 (F. Ronfini, DG RTD F); division of tasks between IEE members, overview of article 169 initiatives (E. Magnien and collaborator, DG RTD

B1); finances (G. Zisimatos and collaborators, DG RTD F6); development policies (J. Garay, DG DEV B3).

3rd IEE meeting, 23.07.2009, EDCTP, Den Haag: Hearings of Charles Mgone and collaborators from EDCTP Secretariat (D. Coles, S. Belcher and W. Salami); Diana Dunstan Chair of General Assembly and Andrew Kitua, DCCC Chairman.

4th IEE meeting: 25.08.2009, Commission, Brussels: Interviews of EDCTP GA members: M. Esveld (NL), B. Gryseels (BE) and S. Jepsen (DK); preparation of events during Arusha Forum; outlines of case study, review of clinical trials and questionnaire.

5th IEE Meeting, 25.09.2009, Commission, Brussels: Interview of Dirk van der Roost, ENNP chairman; preparation of questionnaire for researchers; progress reports on Burkina Faso case study, clinical trials analysis and country visits.

6th IEE Meeting, 30.10.2009, Commission, Brussels: Interview with Gerald Voss, Glaxo Smith Kline; interim conclusions and progress of main IEE activities; interview of R. Draghia, Director for Health Research (DG RTD); questions for L. Riera, Director for development policy (DG DEV); feedback from events and interviews during Arusha Conference.

7th IEE Meeting, 26.11.2009, EDCTP, The Hague: Presentation and discussion of draft IEE report with EDCTP management and representatives from General Assembly; considerations on EDCTP self-evaluation conducted by Swiss Centre for International Health; panel discussion of comments and reactions to the draft report; agreement on steps for finalization of the report and transmission to the Commission and EDCTP by mid 2009.

IEE CONTACTS, VISITS AND ARUSHA CONFERENCE

Irmgard Nippert and Nicolas Meda visited the EDCTP Office in Cape Town on 20 July. They interviewed the High Representative, Pascoal Mocumbi and the Head of Office, Michael Makanga.

Nicolas Meda interviewed Dr Sodomion B. Sirima, Chairman of EDCTP Partnership in Ouagadougou, as well as Pr Patrice Debré (GA and ambassador for AIDS) and Pr J.F Delfraissy (ANRS in France).

Irmgard Nippert interviewed in Berlin Dr Claudia Herok, member of ENNP and DRL representatives (Dr. C. Eggert and Dr D. Boecking from Deutsches Zentrum fuer Luft und Raumfahrt).

Fernand Sauer interviewed Pr JF Girard (ex GA member, IRD, Marseille) and Yves Charpak, previously international director at Institut Pasteur. He contacted the European Medicines Agency in London about recent regulatory development in the EU oversight of foreign clinical trials.

Peter Piot interviewed senior officials, usually the executive head, of the following organizations:

- UK: Medical Research Council, Department for International Development, Wellcome Trust;
- US: Fogarthy Center, National Institutes of Health, Bill and Melinda Gates Foundation;
- FR: Agence Nationale de Recherche sur le Sida;
- Geneva: UNAIDS, the Global Fund to fight Aids, TB, Malaria, Stop TB, Roll Back Malaria.

Wim Van Velzen contacted in November the Permanent Representations to the EU from Sweden, The Netherlands, Poland and Spain.

This year's EDCTP Forum in Arusha, Tanzania, from 12 to 14 October 2009, was attended by Irmgard Nippert and Nicolas Meda. They organized a special IEE panel discussion with researchers and interviewed many participants in the margins of the Conference. Their findings, in particular a SWOT analysis and views from Regional Organizations and young African scientists have been used in Parts 2 and 3 of this report.

In general, the participation of scientists has tripled from the first forum in Roma (Italy) in 2004 to the fifth forum in Arusha (Tanzania): 450 attendees from Africa, Europe and other parts of the world. 26 African countries participated, 15 European countries were represented, as well as Cuba, Peru, Cambodia, China, Indonesia, Nepal, Australia, and the USA. The West African Health Organization (WAHO) and WHO AFRO were also represented.

During the special IEE panel discussion held on 14 October, researchers were asked to outline the strengths, weaknesses, opportunities and threats of EDCTP. Investigators in attendance came from: Belgium, Botswana, Congo, Gabon, Gambia, Germany, Mali, Nigeria, Senegal and Uganda. The EDCTP funded researcher from South Africa was interviewed separately. Other participants included: EDCTP: High Representative Pascoal Mocumbi, GA members from Germany, Austria, Sweden and the United Kingdom, and from DG RTD, R. Draghia and, M. Romaris.

PART 2

EDCTP RESULTS

(2007 TO 2009)

- **Overall progress of EDCTP**
- **EDCTP achievements in terms of clinical trials**
- **EDCTP achievements in terms of capacity building**
- **EDCTP achievements in terms of networking with Africa**
- **Shortcomings in terms of integration of national program**
- **EDCTP in the international research and development agenda**
- **Impacts of EDCTP, especially on Africa, (researchers' opinions)**

OVERALL PROGRESS OF EDCTP

The Independent External Review panel noted in 2007 that the output of EDCTP so far had been very limited and commented on some of the reasons (quick succession of directors, cancellation of calls, long delays, bureaucratic obstacles for project evaluations, and under-spending of budget). The performances during the first three years were not satisfactory in view of the available resources. The EDCTP had not been able to fulfil its promises. The IER noted nevertheless that operations had started to improve in 2006, due to the involvement of stakeholders, and more realistic priority setting. The IER suggested in particular the monthly publication on EDCTP Website of a one-page table with key performance indicators.

This has been implemented and extracts of the latest table on EDCTP Performance Indicators, published on the EDCTP Website in November 2009,[6] are reproduced in Annex 2.

According the published EDCTP performance table, and compared to the previous period (2004 to 2006), the EDCTP output from 2007 to July 2009 has dramatically increased:

- Four times more approved clinical trials;
- Five times more capacity building projects;
- Three times more African institutions involved;
- A three-fold increase in the value of signed grants.

In addition, the Website also indicates a regular decrease of the much criticized time-to-contract: from 19 months in 2004, to 10 in 2006 and 5 months in 2008. The percentage of African project coordinators is decreasing, from 80% in 2005 to 60% at present.

Clearly, the European and Developing Countries Clinical Partnership has managed to improve its operations over the last two years, at least in quantitative terms, in particular due to the combined efforts of its Executive Office and the General Assembly and with an increased support from the Commission services. Since 2007, the EDCTP Programme has been more successful in working with scientists and clinicians in Africa, and this should further be reinforced in future.

From a qualitative point of view, EDCTP has become effective in strengthening clinical research capacity. In the EDCTP model, capacity development is embedded within the core business of clinical

[6] www.edctp.org/Performance.572.0.html

trials. This integration takes place in both South-South and North-South networking activities. The establishment of a clinical trial register, the training and support for ethical committees and regulatory activities are concrete examples of successful initiatives. The pairing of well-established centres with weaker ones is an important feature of the networks of excellence created by EDCTP.

EDCTP ACHIEVEMENTS IN TERMS OF CLINICAL TRIALS

As noted in the EDCTP presentations, it takes several years to complete clinical trials and for their results to be translated into policies for implementation. Outcomes from EDCTP funded projects are just beginning to bear fruit. Nevertheless, EDCTP was able to cite the CHAPAS trial in Zambia that 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 for HIV/AIDS Relief (PEPFAR) and Clinton HIV/AIDS Initiative (CHAI). Promising results are expected from the 0.5% PRO 2000 microbicide and the I.V. Artesunate trials.

Beyond the significant increase in approved clinical trial, the panel was interested in their relevance and scientific quality. For that purpose, forty five EDCTP clinical trial proposals were reviewed by Randa Kamal. The projects were coded and data were collected, tabulated and analyzed and an analysis was performed (for more details, see Annexes 6 and 7), and the main findings are summarized below in terms of strengths, weaknesses, opportunities and threats (SWOT analysis).

Strengths:

There has been a gradual increase in the number of accepted proposals over the last 2 years (60%). More than half have integrated various types of activities including clinical trials, capacity building and networking and a third offer integrated type of services including diagnostic, therapeutic and follow-up services. Concrete efforts are evident in the majority of the projects for African scientific capacity building including technical training, SOPs, internal quality assurance, recruitment strategies, ethics and regulatory procedures. There are 10 projects with exclusive capacity building activities.

Preparedness studies constitute (42.9%) of the AIDS clinical trials projects, including: setting preparation, involvement of new sites, increasing acceptability by the community, community recruitment, promoting and monitoring adherence to participation. Progress has been made in the field of Malaria treatment as half of Malaria clinical trials have reached clinical phase 3 and 20% have reached phase 4.

There is equity in participation of African and Non-African researchers in EDCTP funded projects. Most project coordinators and project leaders or principal investigators are African researchers (55.5%), with good representation of female researchers: 40% in AIDS projects and 25% in TB and Malaria projects. North to South and South to South networking activities are evident in 3/4 of the projects, with up to 11 African and 10 non-African institutions in one given project.

A total of 38 countries (23 African and 15 non-African countries) are participating in EDCTP clinical trials. This is considered a unique achievement in the field of clinical trials in AIDS, Malaria and TB that no other project or funding agency was able to accomplish, and gather in all those countries in collaborative networking activities. The UK is participating in 70% of the clinical trials, with parallel financial contribution.

There is good representation of specific groups in clinical trials. The groups include neonates and infants in (17.8%), children in (24.4%), adolescents in (8.9%), pregnant and lactating women in (15.6%) of the projects.

Weaknesses:

Only a few projects (11%) address the need for community health education and measures for community approach in clinical trials. The community should be engaged at an early stage of any clinical trial.

Only a few projects (15%) started their clinical trial with epidemiological studies to determine either the incidence or prevalence of the disease in the selected community.

Annual progress reports show delays in cohort recruitment after the start of the clinical trials.

None of the projects have included the outcome evaluation measures as final indicators of success or failure in achieving their goals.

Many researchers are participating in 3 or more projects at a time. This might affect the quality of work and minimize the opportunity for other researchers to participate in such projects.

Opportunities:

EDCTP offers good learning opportunities (MSc. and PhD.) and Infrastructure development with innovation and renovation of labs, clinics and other health facilities.

It allows the forming of consortia from specialized group of expertise in the field, working in known academic and research institutions and preparing African partners to take the lead afterwards.

There is a better knowledge of the problems with three main poverty related diseases in African countries and a better understanding of the attitude and behaviour of the affected groups.

There is an involvement of national policy makers and some increase in partnership with the private sector especially in phase 3 clinical trials.

Threats:

Intellectual property rights protection is not considered one of the items to be fulfilled in the project proposal.

The diversity of committees for ethical clearance and the subsequent modifications to protocols could delay the start of the projects. Harmonized and consistent ethics practices in the context of the diversity of ethics committees of participating African countries must be promoted.

Projects are reviewed by independent experts within the scientific review committee. In addition, monitoring and auditing of projects should preferably be done by an external contract organization to avoid bias and to ensure transparency.

Co-funding is a big problem that could hamper the whole process of project acceptance. It is a burden on the researchers who are responsible for securing co-funding before applying for a grant from the EDCTP.

EDCTP ACHIEVEMENTS IN TERMS OF CAPACITY BUILDING

To ensure successful and sustainable outcomes, EDCTP is paying great attention to capacity development and strengthening of an enabling environment for conducting clinical trials in Africa using best practices. The purpose of EDCTP capacity building and strengthening activities is to create and maintain sufficient capacity within Africa to formulate and conduct clinical research, based on the concept of integrated projects.

Each clinical trial funded has to include personnel incentives, infrastructure/laboratories improvement, and initial (MSc, PhD) and continued (short-term) training activities. Additional grants

offer opportunities for senior and career development fellowships. EDCTP also proposes training grants to ethics review committees and to national regulatory agencies and has supported the establishment of a clinical trials registration system in Africa. Finally, networking is part of the critical EDCTP strategies for capacity building in Africa. EDCTP facilitates North-South and also South-South networking.

The establishment of sub-regional networks of excellence in Western, Central, Eastern and Southern parts of Africa is the central component of EDCTP South-South networking strategy. The networking component should facilitate North-South technology transfer and South-South mentorship allowing proliferation of the developed capacity and enhancement of the critical mass of knowledgeable researchers and research institutions.

To date, EDCTP has funded 141 projects worth around 255 million €, involving;

- 126 institutions from 28 sub-Saharan countries,
- 43 European institutions,
- 51 non-profit organizations and private sector partners mainly from the North.

These projects are divided into:

- 45 clinical trials,
- 4 networks of excellence,
- 27 senior and career development fellowships,
- 51 ethics & regulatory framework support,
- 14 training and joint programme activities, particularly the setting up of a registration system for clinical trials conducted in Africa.

Currently, 52 projects are in contract negotiation phase. Each clinical trial funded is supposed to train at least one MSc and one PhD student. The total sum spent on capacity building in the member states during 2003-2008 is 113 233 515 €.

In reviewing EDCTP documents, no partnership analysis tool seems to have been applied at the beginning. No EDCTP document presents the needs assessment exercise for capacity building. All the components of a partnership are used interchangeably in EDCTP's communication. Annex 5 makes

suggestions for a stricter terminology and for a cycle of seven actions to be accomplished for a genuine partnership for the next EDCTP business plan.

The EDCTP concept of capacity building is heavily focused on training. In fact, health research capacity building is a compact of five building blocks including training, logistical support to institutions, motivation of researchers, improving behaviours, and acting on national research systems). If this compact is not satisfied, researchers well trained by EDCTP will inevitably join international organizations and NGOs for good working conditions and better salaries. There is a real need[7] for a capacity development plan and some orientations are suggested in Annex 5 to that effect.

Personnel incentives and logistic (office construction, laboratory equipment, IT equipment & supply, etc.) support are already part of EDCTP capacity building agenda. EDCTP Networks of Excellence help but are not enough to cover all institutional capacity needs in order to better focus on behaviour and systems (accountability, professionalism and integrity). Twinning research institutions can facilitate the transfer of best practices in research governance and management and also in communication for research dissemination. Involving national governments, international partners can help to influence the national research system governance and functioning towards the facilitation of research activities and promotion of researchers' career development.

When acting on national research systems, EDCTP focuses mainly on ethics and regulatory bodies' needs. This, alone, cannot maintain trained researchers in sub-Saharan Africa. EDCTP needs to propose some forms of country grants to help develop in each sub-Saharan country a health research policy framework able to sustain the core functions of a national health research system.

EDCTP ACHIEVEMENTS IN NETWORKING WITH AFRICA

Overall, EDCTP brings a new model of international research cooperation, promoting African ownership and leadership. There was consensus among diverse constituencies consulted by members of the evaluation team that EDCTP has significantly increased inter-African and European-African networking**.** Several new regional networks of centres of excellence were launched under

[7] *As an example the Welcome Trust and Fogarty International currently train 125 PhDs per year.*

EDCTP's aegis, such as the Central Africa Network on Tuberculosis, HIV/AIDS and Malaria, the African Clinical Trial Partnership, Trials of Excellence for Southern Africa.

The inclusion of less experienced African institutions has been an opportunity for targeted capacity building, although we have not been able yet to evaluate its impact. It is unclear whether inter-European networking has been increased to the same degree.

Whereas the regular EDCTP Forum conferences provide a major opportunity for networking, and is attracting a growing number of investigators", there was widespread criticism of conference management with regard to co-ordination: e.g. no information available to facilitate contacts among participants (names, e-mails and addresses), as to whether or not presentations will be available after the conference , poor infrastructure to support poster representations and allow time for viewing and discussions with young presenting researchers (particularly for electronic posters). The costs of the meeting were considered high by Member States representatives and the need for cost containment was stressed.

Others, namely members from the Partnership Board, stressed that without these meetings and EDCTP's networking efforts in Africa, most of the African participants would not meet. Bringing the African partners together in these meetings seems to be the greatest asset of the meeting. Young African researchers stated that the forum offered a huge possibility to present their current work and to search for new partners and new research ideas.

Non-English speaking African countries seem to be under represented among the grantees, and in EDCTP's structures. EDCTP has started networks of excellence to pro-actively target Central Africa.

EDCTP's overall visibility is still limited and communication among the networks must be reinforced.

EDCTP DIFFICULTIES IN INTEGRATING NATIONAL PROGRAMMES

The main EDCTP shortcomings are in the area of integration of national programmes, in the spirit of Article 169 of the Treaty. It is clear that EDCTP was the first Article 169 "experiment" set up under huge political pressure and not always thought through sufficiently in advance. Had the co-funding rules been better explained in advance, the present financing gaps could have been resolved.

Some countries (e.g. Germany, Switzerland, etc.) have projects, but not a national programme related to the three diseases targeted by EDCTP. Other countries namely Belgium, France, the U.K. have one or several national programmes. However, countries like Germany and Switzerland perceive EDCTP's integration efforts as positive because it provides an international platform for their research institutes. On the other hand, Member States with national programmes report integration difficulties because their research institutes act independently and define their own research agenda and priorities.

Merging Member States research programmes into a true European Research Area will take time and needs continuous support (and maybe pressure) from national policy makers and the European Commission in order to achieve better collaboration, information exchange and understanding between participating countries. However, some progress can be seen with some Member States increasingly involved in EDCTP funding. EDCTP funded clinical trials now involve an average three participating European countries per project. More than a third of all funded clinical trials have four or more EU MS participants.

According to the EDCTP briefing to the Independent External Evaluation Panel in July 2009:

- Member States have so far contributed less than 100 million Euros to EDCTP activities;
- Countries have spent 66 million Euros with another Member State (outside EDCTP)
- Countries have spent 204 million Euros within the EDCTP domain of activities
- Countries have funded organizations other than EDCTP for another 226 million Euros.

EDCTP uses as an "integration indicator'' the annual amount of Member States co-funding in proportion to the total of all four categories of spending mentioned above.

The proportion of Member States funding for HIV/AIDS/Malaria and Tuberculosis research activities in Africa that flows through EDCTP is on average only 17%, with a slow, but steady increase.

EDCTP "national programmes integration indicator'':

MS co-fund	2003	2004	2005	2006	2007	2008
integration	0 %	0 %	2.2 %	9.8 %	31.3 %	38.1 %

The integration of Member States national research programmes is progressing too slowly. Overall, Member States national programme integration and financial commitment does not follow a convincing realistic strategy, and a common shared vision. There are no clearly pre-defined contributions to be made each partner. A real synchronization of national research programmes by EDCTP has not yet taken place.

The EDCTP Executive Director provided additional data to the IEE panel in November 2009. The level of cofounding has recently increased and is now estimated at nearly 175 million Euros, if one includes 75 million Euros joint funding by two or more countries for "activities within the scope of EDCTP" (see Annex 2 for more detailed information). He noted that Belgium, Germany and Denmark exclusively conduct clinical trials on the three diseases through EDCTP.

ROLE OF EDCTP IN THE BROADER INTERNATIONAL CONTEXT

Relationship with other global health initiatives

In financial terms, EDCTP is a small, though significant, player among the various AIDS, malaria and tuberculosis research initiatives. It therefore has to operate in a highly competitive funding environment. For example, the collective budget for 2008 of the product development partnerships on the three diseases is estimated at over 200 million US dollars, and the US National Institutes of Health, the Bill and Melinda Gates Foundation, the Wellcome Trust and the UK Medical Research Council together spend several times this amount on development and delivery research in the same areas.

This makes it even more compelling to define EDCTP's strategic niche. It is essential that EDCTP regularly assesses its position and added value in relationship to similar research funding initiatives working in Africa.

Very few EDCTP grants are with Product Development Partnerships (PDP). However, it must also be said that African and European involvement in these PDPs is generally minimal, even if EU member states are major contributors to them. **S**enior officials, usually the executive head, of the following organizations were interviewed: Medical Research Council, Department for International Development, Wellcome Trust, all in the UK; the Fogarthy Center, National Institutes of Health, and the Bill and Melinda Gates Foundation, US; Agence Nationale de Recherche sur le Sida, France; UNAIDS, the Global Fund to fight Aids, TB, Malaria, Stop TB, Roll Back Malaria, all in Geneva, Switzerland. Questions focused on the quality of EDCTP, value added, and synergies.

The UK Medical Research Council was very positive about the EDCTP in general, feeling strongly that EU member states should contribute more to EDCTP's work. The responses by other informants revealed a lack of understanding of the role and activities of EDCTP. The head of the US Fogarthy Center would welcome identifying synergies, particularly on research capacity building.

Examples of international collaboration mentioned by EDCTP

The EDCTP requires at least two European member states and two African countries to collaborate in projects. The encouragement of third-party participation has led to the formation of various consortia, breaking the tradition of research based on colonial affiliations, such as:

- the Malaria in Pregnancy (MiP) Consortium,
- the Pan-African Consortium for the Evaluation of Antituberculosis Antibiotics (PanACEA),
- the Microbicide Development Programme (MDP) on microbicide PRO 2000.

EDCTP gave examples of links with global initiatives, such as for example:

- The African AIDS Vaccines Programme (AAVP),
- The African Network for Drugs and Diagnostic Innovation (ANDI),
- the Southern African Development Community (SADC),
- The African Union (AU), New Partnership for African Development.

EDCTP has participated in important strategy planning meetings, for example:

- Special summit of the African Union on HIV/AIDS, TB and malaria in Abuja, Nigeria, May 2006
- The Algiers African Health Ministers Summit,
- Preparations for the Bamako Ministerial Conference,
- The Global HIV Enterprise Strategy ,
- WHO-TDR stakeholders meeting on neglected diseases of poverty in Berlin.

EDCTP engagement with industry

A working group has been set up in April 2009 on how to develop a "Private Sector Relations" strategy. A preliminary report has been forwarded to the panel. So far, EDCTP has been reluctant to go ahead with 3rd parties and industry involvement as long as it has no clear strategy and some working group members seem reluctant to engage with industry. At Arusha, the presence of industry was minimal and a reach out to industry hardly visible. Representatives from small/medium size enterprises were disappointed by the way EDCTP presented itself to the business community, in terms of mission statement, capacity building in business (no information for interested SMEs on the Website).

Relationship with development activities and policy

There does not seem to be a systematic platform between EDCTP and the development arm of the European Commission. This leads to insufficient leverage of resources and policies as already underlined in the IER 2007 Report.

The dedicated inter-service group on poverty diseases, chaired by DG Development, had very rarely met before 2007. Since then, the group held six meetings but EDCTP was rarely discussed. The EDCTP director, Charles Mgone has apparently never been invited to be heard by the group.

The recommendation of the first external review to engage EU Commission delegations in Africa must also be repeated. Some EU Commission Delegations are still not aware of EDCTP funded projects in their countries. When EDCTP staff conduct site visits (6 to 9 per year), they always brief the local European Commission delegate.

IMPACTS OF EDCTP ON AFRICA (RESEARCHERS' OPINIONS)

The panel noted that DG RTD wishes to conduct an impact assessment exercise for a possible new co-decision on "EDCTP2" and that the retrospective assessment of potential social, economic and environmental impacts of the EDCTP during the period from 2003 till 2008 can become part of this exercise. Members of the panel have underlined the fact that, in the absence of any a-priori formulated measurable indicators for the expected outcome set at the start of the EDCTP programme, the ex-post evaluation is difficult for economic and social impacts. It can only be

"qualitative" (an educated guess) in the absence of indicators that provide baseline data, over a specified time period, against which changes can be measured.

Since 2004 EDCTP has funded 141 projects worth approximately € 255 million. Of these, only 28 projects have been completed (source: EDCTP office), the majority still being conducted. As a consequence, EDCTP's economic and social impacts are not yet very clear and visible.

The qualitative assessment below is based upon the material made available by EDCTP and by the European Commission and upon the interviews conducted by the IEE panel with representatives from the General Assembly, ENNP, PB , the Executive Director and EDCTP staff in The Hague. Personal interviews were conducted with EDCTP representatives in Cape Town, and with principal Investigators and other attendants of the EDCTP Fifth Forum meeting, Arusha 2009.

Overall the quantifiable evidence base available to the IEE panel on economic and social impact was limited. The EDCTP has to conduct a systematic prospective internal evaluation that addresses a priori defined economic and social impact indicators. The Internal Assessment of the 2003-2009 EDCTP Programme conducted by the Swiss Centre for International Health in close collaboration with EDCTP focuses on retrospective performance indicators.

Economic impact

Governmental administrative "burden" is considered to be adequate by General Assembly members. However, EDCTP management could do better if the extra time and efforts it takes for national governments to identify EDCTP officers in charge of specific calls/or topics which need to be dealt with were reduced.

EDCTP programme objectives are addressing R&D objectives as well as developmental-aid objectives. With the implementation of the funding instrument for creating regional Networks of Excellence EDCTP is intensifying its commitment on developmental activities in sub-Saharan Africa. Because EDCTP is involved at the interface of two funding traditions and cultures - research funding and developmental aid funding – Research and Development funding institutions at Member States and Commission level need to improve collaboration and develop innovative two-track funding strategies. A new funding policy is needed that ensures the future availability of two flexible funding streams one from research and the other one from development.

There is a consensus that strengthening research capacities in low-income countries is one of the most effective ways of advancing health and (economic) development in these countries. However,

this needs not only commitment from funders but also political commitment and budget lines from African governments. So far, EDCTP promotes capacity building for health research in 28 sub-Saharan African states via training health professionals, improving facilities/laboratories, promoting international standards (GCP, CGLP, and bioethics) and North-South and South-South networking. As most projects are not yet completed their success remains to be seen – however, if successfully completed – a positive impact on health research capacities in participating countries should be expected. However, more commitment for sustainability of an improved health research infrastructure is needed from African governments.

EDCTP needs a clear strategy on how to deal with intellectual property rights. EDCTP is considering the issue. However, no general policy has been adopted so far.

EDCTP lacks – until now – a strategy on how to cooperate with industry/business. This impacts negatively co-funding opportunities. EDCTP has no clear communication strategy on how to interact with interested medium sized enterprises. EDCTP provides no support for African researchers funded by EDCTP on how to deal with the pharmaceutical industry in their country. The IEE panel is aware that EDCTP is developing a project plan "Encouraging the participation and mobilization of funds from the private sector" to secure funds 2010-2015. EDCTP should set priorities on how to cooperate with business and be active in non-competitive market areas for public goods where so-called 'market failure' prevails.

Job opportunities created by EDCTP in Africa so far comprise: 90 African scientists funded by EDCTP, 21 African scientists have received scholarships for Distance Learning MSc in Clinical Trials and 27 Career and Senior Fellowships have been awarded. In addition 257 African researchers are involved in EDCTP supported projects as investigators receiving their core salaries form their hosting institutions or African governments. This is a start for quality job creation – but higher numbers are probably needed to create a significant impact and fill the current gaps in the 28 participating African states. Health professional migration and brain drain has a particular negative effect in sub-Saharan Africa, the region that faces the greatest shortage of human resources for health (so far 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).

Social impact

To assess (ex-post) EDCTP's social impact represents a significant challenge be-cause of the scarcity of available evidence. The evidence provided by EDCTP for the assessment focuses on programme performance indicators, on funding instruments development (e.g. Regional Networks of Excellence) and policy related issues (e.g. African ownership and partnerships). Another challenge is that social impact indicators are long term indicators that measure the positive or negative social changes produced, direct or indirect, as a result of EDCTP's activities. There is often a substantial time lag between new research findings, interventions or drugs and measured social impact. It is to be expected that EDCTP activities may have long term consequences (e.g. on population health) that may not be observable in the short or medium term.

During the interviews diverging opinions about the achievements, overall value and effectiveness of EDCTP were voiced. However, when asked to evaluate EDCTP's social impact, the majority of the interviewees stated - albeit in very broad terms - EDCTP's unique capacity building approach in Africa and its success in networking African researchers.

What is presented here is an opinion-based retrospective evaluation mainly based upon information on funded projects and policy implementation rather than on available independently verifiable data. Because only 28 out of 141 projects funded by EDCTP have been completed in 2009, it is fair to assume that EDCTP's social impact has been limited so far and is more a matter for the future

Below, areas are listed which have been identified to have a potentially positive social impact.

- Access to treatment and health monitoring for vulnerable and high risk groups such as: newborns and infants, pregnant women, 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.

The major challenge is the long term sustainability of the above listed potential improvements. It would be beneficial if EDCTP would implement an impact evaluation process that would allow prospective analysis of EDCTP achievements but would also consider advances in research conducted by other funders and capacity building strategies implemented by other funding institutions.

EDCTP lacks a comprehensive policy on how to reinforce and increase the role of women in its programme. There is no pro-active approach for implementing and monitoring the promotion of gender equality in its programme. Sex-disaggregated statistics of the funded female workforce are not included in its key performance indicators, nor was such a break down provided in EDCTP'S comprehensive briefing documents for the panel. Counting the rate of female participation is not enough. EDCTP could establish special fellowships or training inventory programmes for young female researchers. EDCTP could document and monitor the implementation of gender issues in its funded projects.

Environmental impact

The exercise is difficult for possible environmental impacts of ECDTP. Nevertheless, the panel took note of two guidelines on the EDCTP Website. The EDCTP has adopted an "Environmental Impact Policy" and developed guidelines on how to address environmental issues in grant proposals submitted to EDCTP calls.

Project coordinators have to address a basic set of environmental issues and how these are dealt with in the proposed project. EDCTP also provides a checklist for coordinators to screen the proposed project in regard to the following environmental issues: health/hygiene education for participants, infrastructure development, waste management, transport and fuel management, environmental risks, i.e., occupational risks for those working with HIV/AIDS.

By implementing an environmental assessment into the format of its grant proposals EDCTP clearly raises awareness among the project partners for environmental issues in relation to the specific sub-Saharan countries involved in the projects. How EDCTP controls the effective implementation of environmental issues during the funding period of a project remains unclear, it is also unclear how far project partners are held responsible for adequate management of environmental issues. However, an extra budget can be set aside within a project grant to address environmental issues.

Although there is currently no measurable evidence for a positive environmental impact of EDCTP funded projects in sub-Saharan Africa, it can be assumed that via health education and funding

environmental activities EDCTP will have a positive impact in the future. As such EDCTP activities are in line with overarching EU policies to address global health issues via development cooperation. Especially the Millennium Goals (4, 5, and 6) are providing a framework for addressing priority areas for joint development and health research actions in sub-Saharan Africa.

The potential environmental impact of EDCTP in regard to improved health highlights the need for further cooperation among DG Development and DG Research.

Highlights on researchers' feedback concerning EDCTP projects and their impacts

The majority of respondents to the questionnaire were academic persons, either projects leaders, principal or co-principal investigators who had sufficient and accurate knowledge on their own projects management and implementation process and were considered the best target group eligible to reply to the questionnaire.

As regards assessment of the impact of the projects, this was categorized into impacts on local community, researchers, and host institution. The findings indicate that in slightly more than half of the responses, the local population was well-informed about the project, and was accepting it. Most of the projects had written verbal consents, which should reflect awareness and acceptance of participation. They also promoted health services and ensured equity of participation and access to these services.

Furthermore, most projects created new job opportunities and provided appropriate on-job training. These results indicate that community awareness and participation need to be fostered in these projects. This seems to be possible since only less than one-third of the respondents mentioned the presence of barriers to community participation, and many suggested solutions to overcome such barriers.

As for the impact on researchers and research capacities, there was a unanimous agreement that these projects provided opportunities for young researchers, with no gender discrimination in the great majority of them. However, the project provided training to less than two-thirds of the respondents, and this training had a positive impact on the job of the majority of them. Other positive impacts reported by the great majority were on researchers' skills and knowledge, as well as personal capacities and transferable competencies as confidence, self-esteem, and team work. The findings point to a positive impact of the projects and their success in the area of building capacities.

The impact of the projects on the host institution was less prominent. Although the majority reported promotion of functional capacities such as promotion of sustainable development education and strengthening institution, less positive responses were reported regarding promotion of institutional structural capacities. Thus, less than half reported renovation of facilities, and only 18.8% reported establishment of new facilities. Nonetheless, about two-thirds of the projects involved new technologies. Therefore, more attention could be given to improve institutional structural capacities according to project needs and local situation analysis.

Only one (3.1%) respondent reported that the equipment and materials used in his/her project had hazardous effects on the environment. Also, two respondents (6.2%) reported that the materials or drugs used had known side-effects, and four (12.5%) reported possible side effects.

From another perspective, the questionnaire solicited respondents' opinions regarding the system of funding of their projects. About one-third of them had related problems, which were mainly due to tedious administrative procedures and co-funding. A similar percentage considered the procedures to acceptance of the project as lengthy. However, the median time to acceptance was only six months, and to receive funds five months. Meanwhile, about one-fifth of the respondents had the opinion that the EDCTP secretariat management needed improvement, and about one-half viewed that the administrative rules for management of grants could be improved. Nonetheless, the majority of the respondents affirmed that the EDCTP increased collaboration with researchers in Africa, and to slightly less extent with Europe.

In conclusion, the findings of the open and closed questions coincide and point to great success of the projects in achieving their goals in building capacities in research and in providing opportunities for learning and work for the young African researchers, as well as in bridging the gap between North and South. The only problem raised in both open and closed questions was related to financial and administrative procedures, as well as co-funding. A positive suggestion was that the EDCTP administration helps applicants to find European partners. In particular, the EDCTP has developed a Web tool named “Project Partners” (for more details, see annex 3).

PART 3

EDCTP CHALLENGES FOR THE FUTURE

(2010/2013 AND BEYOND)

- **EDCTP contribution to the AFRICA/EU Partnership**
- **Co-funding arrangements, the main bottleneck**
- **Problems with the management of EDCTP procedures**
- **Outstanding issues: Ethics, IPR, Industry**
- **Pre-requisites for a second EDCTP Programme (EDCTP2)**
- **Article 169 and other legal considerations**

EDCTP CONTRIBUTION TO AFRICA/EU PARTNERSHIP

There is consensus that strengthening research capacities in low-income countries is one of the most effective ways of advancing health and (economic) development in these countries. However, this needs not only commitment from funders but also political commitment and budget lines from African governments. Following the Lisbon Summit of December 2007, the need to increase health research in Developing Countries and in particular through EDCTP, was addressed. The action plan for Africa/European Union Strategic Partnership and the action plan relating to the Africa/EU Partnership on Science refer to EDCTP.

EDCTP programme objectives are addressing R&D objectives as well as developmental-aid objectives. With the implementation of the funding instrument for creating regional Networks of Excellence EDCTP is intensifying its commitment on developmental activities in sub-Saharan Africa. Because EDCTP is involved at the interface of two funding traditions and cultures - research funding and developmental aid funding – Research and Development funding institutions at Member States and Commission level need to improve collaboration and develop innovative two-track funding strategies. A policy is needed that ensures the future availability of two flexible funding streams one from research and the other one from development.

Three of the eight Millennium Development Goals directly address health issues[8]: MDG 4, 5 and 6. The major funding target disease in Africa is HIV followed by tuberculosis and malaria, with a shift towards capacity building in Africa as a major priority. By the size and number of funded projects, EDCTP is a niche player in an area where multiple international actors are involved, with much higher funding capacities. However, EDCTP funding activities have steadily increased since 2004.

The contribution EDCTP can make in relation to MDG 6 is evident, considering its target indicators (see annex 2).The successful combat of HIV/AIDS, malaria and tuberculosis, in part through improvements of the health system, will no doubt also improve maternal health (MDG 5: half of all maternal deaths occur in sub-Saharan Africa) and help to reduce significantly the under five child mortality rate (MDG4: Sub-Saharan Africa now accounts for half of all deaths among children under five).

Nevertheless, because most projects are still under way and in the absence of a comprehensive framework for systematically monitoring progress, output, outcomes and impact, it is not yet

[8] *http://www.un.org/millenniumgoals/pdf/MDG_Report_2009_ENG.pdf*

possible to assess the full impact of EDCTP on MDG 6, 5, 4, but EDCTP potential is clear and should be further developed and reinforced from 2010.

DG RTD has for years managed many research projects on poverty diseases under FP 5, FP 6, and now under FP 7. The activities under FP 6 started in parallel to EDCTP with a budget of around 250 million Euros, similar in size to the EDCTP allocation of EU funds. There was no detailed external evaluation of these activities other than a very general exercise covering the entire 6th Framework Programme. It is difficult therefore to compare the impact of the poverty research projects managed by the Commission to those of the EDCTP Programme.

After the initial difficult start-up phase, the EDCTP changed its approach and started offering larger awards that focus on product orientated clinical trials and built into the calls the networking (nodes of excellence, fellowships) and capacity development elements (ethical review, regulations). New efforts have been made to solicit third-party involvement and funding. A new database and tracking system that includes automatic alerts, countdowns and target milestones for contract negotiation have been developed and will be implemented. The EDCTP has initiated since 2007 a series of stakeholders meetings which resulted in a substantial increase of new calls.

These activities and EDCTP achievements were presented at a European Conference on research on HIV/AIDS, Malaria and Tuberculosis held in Brussels, on 13 and 14 October 2008. This conference underlined again the importance of keeping on track and reinforcing a programme such as EDCTP. In addition, the Commission has just started a wide public consultation on an issues paper entitled «EU role in Global Health«. This and other Commission documents show a strong and growing link between Development, Health and Research.

The EDCTP Executive Director stated that, in view of the teething problems that were encountered initially with the previously untested Article 169 mechanism for implementing EDCTP, the lack of flexibility of the European Commission during the earlier period did not help. A quicker decision-making process and creative repositioning by the Community was and is still necessary in order to maintain the credibility and continuity of EDCTP activities

It is important not only that EDCTP has good contacts with DG RTD and DG DEV separately but also that DGRTD and DG DEV keep in close touch. From the evidence available to the panel, the joint dialogue between DG RTD/DG DEV and EDTCP has not yet taken place. As the case study shows, EU Delegations do not seem to actively promote or support EDCTP activities. DG RTD has underlined that cooperation with DG RTD has recently improved. DG RTD recognized that additional efforts

should be made to include EDCTP in the picture and that EU delegations often lack expertise in the area of health research.

At the same time, African Governments need to take up more responsibility. They need to develop health research strengthening policies and start funding health research and capacity building. Sustainability of networks and capacities in Africa were questioned as long as African governments' financial commitment and support are missing.

CO-FUNDING ARRANGEMENTS, THE MAIN BOTTLENECK

The European Council and Parliament agreed to contribute €200 million from the European Research Area appropriation under FP6 to EDCTP[9]. The decision indicates that "the overall value of their national participation is estimated at EUR 200 million". In 2003, the Commission laid down contractual conditions for the EU subsidy to the EDCTP over 5 years.

The "Joint Programme of Action" (JPA) has a total cost of € 400 million. It limits the EU contribution to the same amount as that provided by the participating countries.

The Commission accepted in 2007 to extend the duration of the initial grant agreement until September 2010, at no extra-costs and with 4 conditions attached:

- The EU contribution to EDCTP management costs should not exceed € 15 million.
- EDCTP should provide a detailed roadmap and indicators of national programme integration.
- The Member States must match the EC contribution by co-funding or direct contributions.
- EDCTP plan must show an increase of clinical trials and capacity building in Africa.

The Member States co-funding was a crucial issue, from the beginning. It was flagged again in the IER 2007, but is still far from being solved. For the Independent External Evaluation panel the IER statements below remain entirely valid ad must be repeated again in December 2009, at a time when the Commission is about to extend the duration of the current programme by another 3 years to allow certain Member States to make their long awaited contribution to EDCTP.

[9] *Decision n° 1209/2003/EC*

The Commission should extend the EDCTP Grant agreement at no cost until 2013 and should request that the co-funding rules be made simpler, open and transparent.

It takes a lot of time and efforts to find sufficient co-funding for European partners, resulting in extra costs for manpower that could be avoided by Member States upfront funding. At the Arusha Conference, African Principal Investigators described how difficult it was to find European partners willing to apply for co-funding. These complex arrangements could prevent some relevant projects from being carried out. Moreover the co-funding policy could also be a barrier towards a real leadership emergence from Africa. In effect, the co-funding partners set up their own rules which may affect the project implementation process as originally defined by the research team.

The Head of the concerned financial Unit of DR RTD summarized the situation for the IEE Panel: "Member State commitment and coordination of activities has not materialized in the sense that was foreseen by Article 169 of the treaty. The streamlining of national activities to those of the EDCTP has not been attained. Although Member States claim expenditure in the form of an in-kind contribution when they launch EDCTP type of activities, these actions are managed and financed by the respective Member State. Furthermore these activities are not coordinated on the EDCTP level but directly by the authorities concerned. However, some Member States have provided cash contributions directly to the EDCTP and this demonstrates commitment to the EDCTP initiative and its planned actions. "

In its Communication of October 2008, the Commission envisaged the renewal of the EDCTP Programme, provided that most of the IER recommendations are met. The report states that, until the end of 2010, Member States will still have to contribute 104 million Euros and that a common co-funding pot might be difficult to achieve from national research funds, but that contributions from development aid agencies could become a solution.

The panel noted that, in spite of the IER 2007 recommendations, several Member States continue to apply severe restrictions to co-funding, with double evaluations and national discriminations, which seem to be in contradiction with the general principles of the EU Treaty. The EDCTP publishes on its website a table of Member States co-funding conditions and restrictions. This table reveals of the huge complexity for applicants. Some countries continue to apply national preference criteria. Some countries continue to require an additional national evaluation of projects evaluated by EDCTP (CH,

SP, FR, IT, LU, NL, NO). Additional restrictions have to be further searched on the Website, country per country.

The need for implementing a two track funding approach (national research funding plus development funds) sounds attractive but will have to be actively and strongly pursued. At national level members of the General Assembly must rearrange the sources for their Member State's contributions, at a time when certain countries seem to be about to disengage, because of the economic crisis. DG Development may offer support in approaching African governments to earmark EU Development funds for EDCTP projects, but this does not exonerate Member States from their financial obligations under EDCTP1.

In fact, the Member States contributions were very uneven, at least until April 2008. The reality that only a few Member States have so far respected their 2003 commitment to establish a joint Member States research programme should be publicly debated. The following figures are extracted from the October 2008 Commission staff working paper. Irrespective of the relative size of the countries, there are clearly four groups of contributors (in decreasing order of contributions):

- the contribution from the UK represented nearly 42%;
- 6 countries contributed 7 to 9% each: France, Sweden, The Netherlands, Belgium, Spain, Norway;
- 3 countries contributed together less than 10%: Denmark, Germany, Ireland;
- 6 countries' contribution was almost negligible: Switzerland, Italy, Austria, Greece, Portugal and Luxembourg.

Slovakia has joined the EDCTP only recently and no contribution has been mentioned so far.

A rough calculation shows that if all concerned countries had followed the example of the group of six countries (7 to 9%), national contributions would have matched the EU. In addition, if all concerned countries had followed the lead of the UK, the co-funding of EDCTP2 would be assured by now. It is clear that the "active partners" should impose much stricter solidarity from the '"dormant" ones, taking into account the size of each country, if they want the EDCTP to survive and prosper.

EDCTP GOVERNANCE AND AFRICAN PARTICIPATION

The EDCTP governance appears to be working better than in earlier years and in closer cooperation with the European Commission. This is widely attributed to the combined efforts of Diana Dunstan, Chair of the General Assembly and of Charles Mgone, appointed Executive Director in April 2007, after having served as the Head of the Cape Town Office.

The Director of Health of DG RTD confirmed that EDCTP had improved in comparison to the situation, a few years ago. The general management has improved. The management of the scientific aspects also has improved. The activity on capacity building is getting better. In the Arusha conference, several promising clinical results have been presented. There are some negative aspects:

- The funding system (especially the support in kind) is not sufficiently clear;
- The implementation of the projects remain quite slow and have to improve;
- The management costs of EDCTP appear to be high.

Two key bodies have contributed to the EDCTP recent positive developments: the advisory Partnership Board (PB) (12 independent experts from Europe & Africa), and the Developing Countries Coordinating Committee (DCCC) giving the views of 14 scientists from developing countries on institutional and human capacity development.

The High Representative, Pascoal Mocumbi, acting as an EDCTP advocate for political support and funding has moved from The Hague to Cape Town in 2007, in order to improve links with African governments and regional organizations.

The General Assembly (GA) is the decision making body made up of representatives of the Member States and observers (Chairs of the PB, DCCC; EU Commission). The GA has just dissolved the European Network of National Programmes (ENNP), and reclaimed the previously delegated North/North and North/South networking tasks for the deputy members of GA.

The Partnership Board Chair has criticized the malfunction of ENNP, saying that most relevant propositions to PB have been issued by DCCC, who brings a consensus on the priorities of African countries. Their counterparts in Europe fail to obtain a scientific community consensus on research priorities before coming to ENNP meetings. This confirms the difficulties in integrating national research programmes, 6 years after the creation of EDCTP.

Before starting a Second EDCTP Programme, the General Assembly should review again the number of EDCTP bodies, clarify their respective roles, improve effectiveness and decrease operating costs.

The Secretariat led by the Executive Director facilitates the work and implements the EDCTP plans, in compliance with the legal and financial obligations of the EU and other sponsors.

As recommended in the IER 2007 Report, a G.A. Steering committee has been put in place to reinforce collaboration with the Executive Director. The principle of appointing General Assembly members from higher position at home to be able to supervise all relevant national activities and to mobilize national funds directly has not yet been followed up by most countries. There is clearly a conflict of interest for several General Assembly members who have to look after the financial interests of their own research institute first, before trying to solve EDCTP co-funding problems.

The final minutes of EDCTP governing bodies are not accessible on the EDCTP Website. This is now the normal practice for other European Agencies who want to show transparency and good governance to their stakeholders and the public. Other relevant information relating to the management of proposals cannot be found on the Website. As a consequence, repeated contacts have to take place with the Secretariat, generating inefficiency and increased costs.

The present legal entity created to run the EDCTP, the "European Economic Interest Group"", does not allow voting rights for representatives from outside Europe. Neither Commission, nor Developing Countries can participate in the decision-making of the General Assembly. Nevertheless the EDCTP wants to have high-level Africa presence at the General Assembly.

The WHO AFRO Regional Committee held in Kigali in September 2009 has decided to participate in EDCTP General Assembly with 2 countries in rotating order. Regional Economic Communities have agreed to have two representatives, a GA member and deputy, on a rotational basis. The West African Health Organization (WAHO) has an annual research fund of about 600 000 US$ and expressed their interest to directly co-fund EDCTP projects particularly in networking and capacity building. In associating with regional organizations, EDCTP could gain visibility with Heads of State and Ministers attending various summits where policy-makers discuss regional priorities.

The IEE Strongly supports the intention of the General Assembly to include at least 4 high level political decision-makers from African governments as associate members in the General Assembly; if not appointed by WHO AFRO or regional organizations active in the field, they should come from countries conducting the most research activities of HIV, TB and Malaria.

PROBLEMS WITH THE MANAGEMENT OF EDCTP PROCEDURES

Discussions in Arusha and the case study in Burkina Faso revealed that researchers were often frustrated with EDCTP processes, besides the more fundamental co-funding issue. This comes out very clearly in the internal assessment carried out by the Swiss Centre for International Health.

The IEE has been provided with a series of SOPs and Guidelines. Nevertheless, applicants complain about the EDCTP Website because it does not provide easy access to all the tools needed. They have to contact a member of the secretariat who ultimately detains the knowledge.

The panel felt that the EDCTP office should improve its work as follows:

- The contact person (scientific officer) for specific calls or current projects should be easily identifiable for national contact points as well as for researchers;
- A help desk for researchers, specifically from Africa, wanting to submit a grant proposal should be implemented and a "how to find a partner" site could be published on the homepage;
- Overall the web-site could be less self-referential and more user friendly especially the guidelines for submitting a grant proposal should become easily understandable for researchers from Non-EU countries (e.g. explain/define in more detail terms employed);
- Management costs should be firmly contained and not exceed a defined percentage of budget.

Some complaints heard at the Arusha Conference are listed below as examples:

- The contract negotiation timeline is still too long and needs to be shortened. Better and user-friendly financial templates are welcomed.
- More flexibility between budget lines and some autonomy in the purchases and investments relating to local needs would be welcomed by senior researchers in Africa.
- No support from EDCTP when dealing with industry in regard to drug development.
- Too many administrative hurdles and constraints; EDCTP funding regulations are perceived as being too inflexible from the point of view of African partners.
- Overheads are too low and should be reconsidered to help African universities, in line with DG RTD practices.

It is not possible for the IEE to check all the facts, but clearly, a big EDCTP conference like Arusha could have been an occasion to collect views and discuss improvements, both during the plenary session and in dedicated organizational workshops. EDCTP should implement a policy of 'quality management'' and a culture of continuous improvements, given the complexity of issues in a multicultural environment. The EDCTP should better use existing meetings and conferences for that purpose.

Monitoring and impact evaluation indicators would help to measure EDCTP performance and impact and pick up critical issues before it is too late. The outcome of this regular assessment should serve to adjust performance and research funding strategies where needed, and to better communicate priorities and achievements to Member States, Commission, third parties, industry.

Systematic performance and impact evaluation by the EDCTP Secretariat will help to ensure that resources are well spent, will control whether EDCTP funded projects make a difference on HIV/AIDS, malaria and tuberculosis disease burden and help to empower African health research capacities as well as to improve coordination of Member States research activities. EDCTP should develop a comprehensive framework for process monitoring and evaluation that uses appropriate standard methods and tools and is flexible enough to allow for revisions as needed, based on results of monitoring and evaluation activities.

In the spirit of internal assessments and quality improvements, the panel welcomed the self-assessment of the EDCTP (2003-2009) by the Swiss Center for International Health Institute. The content of this report was made available to the panel at the end of October, covering:

- quality and ownership and sustainability of the partnership with Africa and third parties;
- improvement in cooperation and cooperation between the Member States;
- perception in Africa and internationally of the EDCTP partnership with Africa; empowerment of African partners to set priorities and drive research agenda.

The EDCTP should review the way it handles the proposals in the light of critical remarks brought to the attention of the panel and raised also in the recent self-assessment exercise and publish revised procedural guidelines on its Website.
The EDCTP General Assembly should adopt a transparent information and communication strategy and publish, on an annual basis, performances and outcomes.

OUTSTANDING ISSUES: ETHICS, IPR, AND INDUSTRY

Review procedures were improved over the years in line with DG RTD practices. On the EDCTP Website, there are guidelines for reviewers and on conflicts of interests. Eligibility and selection criteria for applications are stated in the call publication. All proposals are reviewed by two independent external experts as well as two members of the Scientific Review Committee (SRC). The SRC meeting produces a ranking of proposals, submitted to the Partnership Board with a full SRC report. The General Assembly makes the final decision on the basis of Partnership Board recommendations. It takes 6 to 9 months, overall, between receiving the proposal and the final decision. The results and reports are accessible to national agencies but not to the general public.

Clinical trials evaluation process at EDCTP

The review of EDCTP clinical trials has shown the following trends:

- Fulfilment and adherence to the principles and guidelines for ethics and safety related issues are stated in the majority of the clinical trials projects[10].
- The role of each participating institution is clearly stated in all the projects.
- There is an improvement in EDCTP form for proposal submission. Recent proposals (2008, 2009) have a better systematic way of presenting activities with work packages, clear deliverables and milestones.

Some suggestions for improvements:

- Community preparedness; providing them with proper information before being involved in research projects.
- Establishing community advisory boards to bridge the gap between researchers and community.
- Promoting the role of local leaders who have more influence on the community and could encourage their participation in clinical trials.

[10] *Including human rights, SOPs, case records, good clinical practice regulations, protection and processing of personal data and guidelines on storage and use of biological specimens.*

- Better understanding of the ethical-legal, human rights as well as knowledge, attitude and practice of each participating community.

None of the projects have included the outcome evaluation measures as final indicators of success or failure in achieving their goals. Outcome assessment of each project should be planned for and added to the original CT proposals with definite deliverables and milestones.

Sustainability could be achieved through the following:

- Infrastructure development with either renovation of existing facilities or establishment of new facilities,
- Supporting national programs implementation,
- Data presentation on a national level,
- Strengthening and improving research capacities of participating African institutions,
- Building capacities of young African researchers to take over the responsibilities of continuing the mission for the development of new treatment or vaccines,
- Securing links with international organizations to develop and implement international guidelines for new treatment or vaccines, g. encouraging community participation to clinical trials and promoting awareness.

EDCTP, through the European Commission, should seek guidance from EMEA on how to reinforce its own GCP overview and responsibilities. Article 58 of Regulation (EC) No 726/2004 allows the Agency's Committee for Medicinal Products for Human Use (CHMP) to give opinions, in cooperation with the World Health Organization (WHO), on medicinal products for human use that are intended exclusively for markets outside of the EU.

Medicines eligible for this new procedure are used to prevent or treat diseases of major public health interest. This includes vaccines used for protection against a public health priority disease, as well as medicines for WHO target diseases such as HIV/AIDS, malaria, or tuberculosis. The CHMP carries out a scientific assessment of applications submitted under Article 58, and, after consultation with the WHO, adopts a scientific opinion. A summary of opinion is published at the time of adoption of the opinion. Procedural guidance for companies intending to apply for a CHMP opinion in the context of WHO cooperation is provided.

In future, EDCTP will naturally have to give a growing attention to "pharmacovigilance": adverse effects during clinical trials, which are of direct relevance to EDCTP activities, and post-marketing surveillance. It is interesting to note that the WHO Uppsala Centre of reference for pharmacovigilance is working in Africa with the Centre for Clinical Pharmacology of the Medical School of the Ghana University at Accra[11], which has been appointed as a WHO collaborative centre for pharmacovigilance training. An African Society for Pharmacovigilance has just been established[12].

Ethical review process

Clinical trials that breach ethical guidelines in the developed world should not be permitted in developing countries. The EU, US and Japan, in the framework of the International Conference on Pharmaceutical Harmonisation (ICH) and in collaboration with WHO, adopted in 1995 a major guideline on good clinical practices which incorporates the CIOMS Helsinki Declaration on Ethics.

All trials in Europe must conform to these rules. Unethical trials conducted elsewhere in the world are not accepted in a submission for marketing approval of a medicinal product in the EU[13]. The European Medicines Agency (EMEA) held a Conference in London in October2007 to reinforce the protection of clinical trials subject both inside and outside the European Union, with the participation of EDCTP.

A quarter of patients in pivotal trials submitted to the EMEA between 2005 and 2008 were recruited in Latin America, Asia and Africa. In December 2008, the EMEA adopted a strategy for clinical trials conducted in third countries, including verification of compliance with good clinical practice (GCP) and ethical standards, foreign inspections, protocol assistance. The compliance with ethics and GCP of foreign data will be recorded in the European Pharmaceutical assessment report (EPAR) published on the EMEA Website[14] together with guidelines for GCP compliance and inspection.

At the EDCTP, all clinical trials require previous ethics clearance through a national ethical board and projects that do not meet ethical criteria are rejected. One reviewer in the scientific committee is responsible to verify national ethics clearance. All clinical trial projects are registered with the South

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[11] *Headed by Dr Alex Dodoo, Chairman of the International Society for Pharmacovigilance, alexooo@yahoo.com*

[12] *Chairperson: Pr Rachida Bencheikh, Centre de Pharmacovigilance, Rabat, Maroc, gbcherkaoui@yahoo.fr*

[13] *Directive 2001/20/EC and Directive 2004/27/EC*

[14] *www.emea.europa.eu*

African Cochrane Centre (Pan-African Clinical Trials Registry, recognized by WHO). EDCTP also actively supports the work of various ethical committees in Africa (33 ethics projects in 17 countries).

Strict compliance with ethics is clearly very important for the protection of patients and healthy volunteers and for the reputation of EDCTP and the EU as a whole. A major ethical controversy is a serious risk factor as it could put into question the future of EDCTP. Besides, insufficient attention to GCP and ethics could mean that a product investigated through EDCTP could be rejected at marketing authorization stage. The EDCTP's guideline on ethics was revised and expanded in August 2008. It is still merely a cross reference to ICH and WHO documents. The actual EDCTP policy and procedures should be spelled out in more detail in a future revision.

The panel suggests that summary of how ethical judgements were carried out on major EDCTP projects should be prepared by sponsors and reviewers and made available on the Website, for scrutiny and international peer review.

There are many national ethics committees involved for ethical clearance of EDCTP each project. The diversity of committees for ethical clearance could delay the start of the projects. Also the amendments sometimes required for the original proposals could be refused by one or more of the ethics committees and this could lead to regulatory confusion. There is a need for harmonized and consistent ethics practices in the context of the diversity of ethics committees of participating African countries.

The panel noted with interest that EDCTP had outsourced the establishment of a dynamic data basis to COHRED for the mapping of ethics review and trial regulatory capacity in Sub Sahara Africa. The suggestion was made in the panel that EDCTP might establish in due time a research ethics committee formed of representatives from African and European experts in the field of clinical trial ethics. The committee should be officially approved by the General Assembly and assigned by the EDCTP to perform the following tasks:

- Revise all CT protocols before their final approval;
- Provide clearances or suggest modifications according to the ethics rules and protocol for clinical trials ethics that the committee set;
- Communicate with participating countries ethics committees to get their preliminary approvals;
- Monitoring the performance as regards ethics application during the CT implementation.

The EDCTP should, as soon as possible, publish on its Website more detailed information, on how it intends to verify compliance with internationally recognized ethical principles.

Intellectual Property Rights (IPR) and communication with industry and other partners

The rules regarding the protection dissemination and use of knowledge were re-defined in 2002 for the 6th Framework Programme. Decision N° 1209/2003/EC makes EDCTP funding conditional on the formulation of the provisions relating to intellectual property rights in such a way that they also aim at ensuring that the people of developing countries have easy and affordable access to the research results produced by activities under the EDCTP Programme and to the products directly deriving from its results. The basic principle is that the EDCTP will favour the transfer of IP-rights to ensure production and availability of affordable medicines to the people in need in developing countries.

EDCTP had announced in 2007 that a policy paper on Intellectual Property Rights (IPR) would be adopted as soon as possible to address tiered pricing agreements, availability and easy access to affordable new medicines. The EDCTP also stated that a general policy is difficult to define given the various combinations of potential partners and that specific IPR issues should be addressed on a project–by–project basis. It seems that the EDCTP policy on IPR has been discussed at great length in a special working group and that it might not be ready at the end of 2009.

In April 2007, the Commission Health Directorate of DG SANCO organized with WHO Europe an important seminar on Public Health, Innovation and Intellectual Property, with the participation of the EDCTP. The discussions held during this seminar[15] could help the EDCTP to formulate its future policy. Also relevant are the DNDi's (Drugs for Neglected Diseases Initiative) Intellectual Property Policy document published in December 2004 and the report produced on the subject by a special WHO commission in 2006. The best practices as discussed by WHO will serve as examples in making interventions readily available at an affordable price to people in developing countries, in accordance with the policy on tiered product pricing under Regulation EC/ 953/2003.

EDCTP urgently needs a clear strategy on how to deal with intellectual property rights and this is a pre-requisite for any cooperation with the pharmaceutical industry. The absence of a general policy

[15] http://ec.europa.eu/health/ph_international/int_organisations/who_en.htm

impacts negatively on alternative funding opportunities. EDCTP has yet no clear communication strategy how to interact with interested enterprises. EDCTP provides no support for African researchers funded by EDCTP how to deal with pharmaceutical industry in their country. Although industry has been invited to take part in consultation meetings leading to EDCTP calls, the main players in pharmaceutical R&D do not seem very interested and they see several problems:

- The application process is complicated and requires considerable efforts;
- The rules of co-funding are too complex;
- There is fierce competition with other sources (BMG Foundation, NIH, AVI);
- For these other sources, the procedures are more simple and effective.

The industry has to be sure that the funds will be guaranteed until the end of the project in clinical trials. In the case of GSK, the Malaria vaccine project was subject to earlier discussions but they were not conclusive. There are several potential possibilities of working together, above all in the TB field.

The IEE panel is aware that EDCTP is developing a project plan "Encouraging the participation and mobilization of funds from the private sector" to secure funds 2010-2015. EDCTP should set priorities on how to cooperate with business. Such a public/private partnership is crucial in non-competitive market areas for public goods where so-called 'market failure' is an obstacle and where public health interventions and 'priority medicines'' may need the know-how from industry.

In the field of infectious diseases all partners have to share the risks since research in this area requires huge investments. Some Member States Institutes seem reluctant to engage with the pharmaceutical industry which is responsible for a vast majority of clinical trials around the world. An extra -effort from both sides is required to facilitate EDCTP/Industry relationship in future.

In addition, only a few EDCTP grants are linked to Product Development Partnerships. EDCTP must define EDCTP's strategic niche, in relationship to similar research funding initiatives in Africa.

Recommendations to EDCTP
The EDCTP should, as soon as possible, publish on its Website its detailed guidelines on Intellectual Property Rights.
By mid 2010, the general Assembly should have adopted a realistic and viable strategy for private

sector collaboration; the Executive Director should start to implement a concrete business plan, attractive to the research-based industry, including a clear Intellectual Property Rights policy.
By mid 2010, the EDCTP should forge strategic alliances with major international funding agencies, given the high costs of phase III clinical trials; in a highly competitive funding environment, the EDCTP should pursue a proactive agenda for operations and translational research, focusing on clinical trials (e.g. TB vaccine trials, antiretroviral prevention of HIV).

PRE-REQUISITES FOR A SECOND EDCTP PROGRAMME (EDCTP2)

Two thirds of the clinical trials will end after the present official date of termination of EDCTP in September 2010. Therefore, the Commission is ready to accept a no-cost extension until 2013 to accompany the ongoing trials, if only to allow Member States to realize their co-funding pledge.

But clearly, in the absence of a second EDCTP Programme from 2010 onwards, all new projects would have to be stopped already in 2010. It is therefore imperative and urgent for the General Assembly to mobilize its Member States, or a least those willing to commit to the continuation of this important activity for African/EU partnership in the field of Research, Health and Development.

A firm commitment from Member States is urgently needed

To be successful, EDCTP should be fully owned and funded by Member States and should become a very long-term common enterprise. Within countries, national institutions often compete for the same limited funds. Some governments did not make fresh funds available for participation in the EDCTP Programme. In October 2008, the Commission reported back to Council and Parliament about current difficulties and possible solutions.

It is the responsibility of the Member States who own the EDCTP to enhance true ownership and reinforce their mutual commitment towards the common structure and programme they accepted to create in 2003. This was partly achieved when several Research Ministers replied to a letter sent by Commissioner Potočnik to all of them, following the IER 2007.

The first question is therefore how much money or resources are they ready to invest in a second Programme, so that the Commission could match the Member States contributions with a new EU

subsidy. This should be accompanied by multi-annual committed up-front funding by Member States for both research and capacity development, as already discussed in the General Assembly.

Secondly, Member States should now accept that programme integration must really take place in terms of a single EDCTP procedure for planning, launching and evaluating calls, with no national strings attached. The interested Members States should jointly revisit the EEIG statutes to define the mutual commitments in terms of budget and programme integration. An acceptable key for contributions from Member States reflecting their contributive capacities should be negotiated amongst all interested parties. The value and process for endorsing "in kind contribution'" should be agreed and codified[16] in advance.

At this stage, it does not seem advisable to review the form of the EDCTP legal entity, or the two locations of the Secretariat, since this will inevitably disrupt and delay the new Programme. Some preliminary thoughts are given in the last part of this report on long term considerations.

EDCTP2 decision-making at the General Assembly should be restricted to the donor European countries represented at the highest possible level and opened to representative African partners. Other EDCTP countries not yet ready to accept these new conditions could retain an observer status, besides the Commission and the African representatives, until they decide they are ready to join EDCTP2.

A draft for a second EDCTP Programme is urgently needed

The mapping of all national activities running in parallel to EDCTP activities is to a certain extent, provided by the national certificates which allow the EDCTP to measure the extent of programme integration.

At the General Assembly, each EDCTP Member State should identify in advance their national programmes or projects to be fully integrated. After consultation with both ministries of science /research and health and development funders, they should be in a position to inform each other and the Secretariat about a specified level of financial support they are ready to guarantee throughout the duration of EDCTP2. The representation from Africa with observer seats on the General Assembly should have been settled in the meantime.

[16] *The recent experience of the "Innovative Medicines Initiative" could serve as a model.*

Based on reflections of the Partnership Board, the Executive Director of EDCTP should present as soon as possible for endorsement by the General Assembly a detailed and visionary draft for a new Programme, which should not be a simple repetition of the first Joint Programme Activities designed back in 2003.

There is a need to have increased funding and strengthening of the Secretariat for dealing in parallel with EDCTP 1 and EDCTP2, as well as taking an expanded role for monitoring and evaluation (staff and management costs). However management costs for the Secretariat should be capped and should not exceed a defined percentage of the total costs of the Programme. The bureaucratic burden associated with contracts should be reduced for the next phase.

As for the content, the panel was informed that:

- There is wide agreement on the need to extend the scope of the core programme to Phase 1 trials in Africa and to phase 4 (health services research) trials.
- Additional programmes outside sub-Saharan Africa could be included – MSs would need to indicate their wish to be involved in this work and to allocate additional resources above their core contribution to EDCTP.
- Other neglected diseases could be included on a similar add on (with additional resource commitment) basis.
- The Partnership Board has close links with the Member States representatives and the Developing Countries Coordinating Committee so a more detailed strategy and planning for a new programme can be carried out efficiently at the appropriate time.

According to the panel, before the start of the Second Programme, EDCTP must put in place:

- A reinforced ethical and regulatory overview ,
- A strong Intellectual Property Rights policy,
- Attractive and mutually acceptable terms for productive cooperation with the research based pharmaceutical and biotech industry.

Recommendations to EDCTP in view of a Second Programme (EDCTP2)
The General Assembly should finalize proposals on how each country intends to fund EDCTP2 and each member should consult accordingly with their Minister(s) in charge.
The EDCTP should engage in a profound outreach activity towards Member States who are not substantially contributing to the Programme and towards EU countries not yet members of the EDCTP.
For the purposes of EDCTP2, the General Assembly composition and voting rights should be restricted to representatives from countries that have made the necessary financial commitments in cash or in kind, as it is the case in several EU research projects based on Article 169.
GA members must be able to operate with a political and financial mandate from their government and be in a position to effectively coordinate EDCTP with relevant national activities.
General Assembly members and the Commission should actively seek to expand the financial commitments through the use of additional financial resources such as national development funds and EU funds for Africa.
The General Assembly should continue to review the number of EDCTP Bodies, clarify their respective roles and review the number of meetings in order to reduce costs and improve the efficiency of its communication, especially on the Website, where all corporate minutes should be made public.
The Chairperson of EDCTP General Assembly must have the authority to discuss financial and policy matters with the Commissioner and relevant Ministers.
The EDCTP General Assembly should adopt, as soon as possible, a coherent Second Programme (EDCTP2) with a clear strategy linked to the EU Health Research and existing national policies on poverty diseases. The EDCTP should continue to focus on clinical trials and operational research on introduction of new technologies for HIV/AIDS, TB, and Malaria.

The future, and much expected, Commission proposal

It is clear that the Commission would need a draft new EDCTP2 Programme, endorsed by the GA and a reasonable assurance about the Member States future commitments towards EDCTP, before submitting a proposal for a new funding decision to Parliament and Council. Given the time taken by

EU decision making, it is imperative that the new Programme and member States commitments are communicated to the Commission as soon as possible, if the new funding decision was to be taken at the end of 2010 (presently, the official term of EDCTP).

The Commission and the Member States should strive to achieve synergy between Development and FP 7 Research activities, at EU as well as national level.
The Commission should urgently implement a proactive plan to seriously address the earlier IER recommendations on the use of joint DG Research / DG Development platform to engage a genuine dialogue with EDCTP. Commission (DG DEV) delegations in African countries should promote synergies with EDCTP in terms of capacity building.
The Commission should define a sound rationale for a central role for EDCTP in the context of the Africa/EU Partnership on research, development and global health, for example through a new specific Communication to Parliament and Council, making reference to the present Report.
The Commission should prepare guidelines (soft law), based on experience with Article 169: ***• on the way the "common or virtual pot" should be operated,*** ***• on the use of national funds before the start of EDCTP2,*** ***• on the inclusion of non-national researchers in national co-funding schemes.***

The Commission should only submit a new proposal for EDCTP2 if there is ***• a satisfactory Implementation by EDCTP of the IEE recommendations for EDCTP1,*** ***• an agreement with EDCTP on annual performance criteria for EDCTP2,*** ***• a solid upfront financial commitment by individual participating Member States,*** ***• an agreement between the Commission and each of the concerned Member States on a common financial pot for cash contributions and on rules concerning in kind contribution.***
The future Council and Parliament decision should strictly define the new co-funding arrangements and should exclude double evaluations and national researchers' exclusivity clauses.

Additional suggestions for future monitoring of EDCTP2 activities

The key performance indicators implemented so far by EDCTP were a good start. For EDCTP2, they are too broad and unspecific. There should be a clear plan for the intended inputs (e.g. funds, personnel, material), and strategies needed for:

- Capacity building in Africa,
- The development of new interventions and products against HIV/AIDS, malaria and tuberculosis,
- The financial and scientific integration of MS national programmes.

It is recommended that EDCTP implements a systematic needs assessment approach (involving multiple African stakeholders) to identify needs for capacity building in targeted sub-Saharan African countries/regions and assesses the ability of these countries/regions to benefit in an intermediate and long-term perspective from EDCTP funded capacity building.

Needs assessment, through a rational, epidemiological assisted approach could help to provide evidence-based information to plan, introduce and beneficially change public health (and research) capacities in sub-Saharan Africa in a way that will promote sustainability and enable local populations to better control HIV/AIDS, tuberculosis, and malaria. Needs assessment based capacity building strategies that take into account the specific national and local contexts of the targeted countries/regions, including political, cultural and socio-economic implications, will help to employ appropriate indicators to measure improvement/change and to guide the planning of a funding process for capacity building that follows the assessment of needs.

Recommendations to EDCTP on future indicators
The IEE Panel supports the current efforts and encourages EDCTP to develop more comprehensive indicators for assessing EDCTP's activities. According to the panel, this assessment should include two complementary components: ***• Monitoring the performance of the Programme*** ***• Evaluating the impacts on research capacity, with a view to reduce the disease burden of HIV/AIDS, Malaria and Tuberculosis in sub-Saharan Africa.***

In particular, the EDCTP GA should develop more specific key performance indicators and monitor, on an annual basis, the EDCTP Key performances, including:

Number, quality of implementation and output of clinical trials

Number, quality of implementation and output of capacity building projects

Number, quality of implementation and output of networking activities

Performances of EDCTP Secretariat in The Hague and Cape Town

Measuring cost efficiency and effectiveness,

Number and quality of EDCTP links with other global health initiatives in the field

Number and quality of EDCTP links with industry in the field.

ARTICLE 169 AND OTHER LEGAL CONSIDERATIONS

The IER Report from July 2007 made clear that the EDCTP started in 2003 without fulfilling the basic criteria of Article 169 of the Treaty and recommended critical issues to be considered by the European Commission for the next Article 169 initiatives, namely:

- Set out future Article 169 pre-conditions, preferably in a guidance communication.
- There must be pre-existing national programmes, strong commitment by Member States to provide funding and irreversible national support.

Before EU money becomes available, there must be:

- a common work-plan;
- sound governance structures;
- fixed national financial contributions;
- clear evaluation criteria and procedures;
- clear deliverables;
- a solution for the liability issue.

An informal internal working group on Article 169 programs has been set up. The financial scenario of the EDCTP is different from that of the newer programmes. More "financial integration" among MS is now required. The Commission has not yet been able to produce an official doctrine document on the lessons learnt from EDCTP. Several article 169 programs are still under negotiation[17]. The 169 initiative "EUROSTARs" is seen as a good model where the stakeholders are:

- the European Commission;
- the EUREKA Secretariat (ESE) is the implementing structure;
- National Funding Bodies (NFB) designated by the participating countries;
- Project participants.

In the meantime, the Commission has followed most of the IER recommendations. In several case, member States are reluctant to implement the “common pot’ but are ready to provide resources in kind’’.

The IEE panel reviewed the legal modalities and alternatives to Article 169 with the Commission services. Any EU initiative in the field of research has to be based on articles 163 to 173 of the Treaty.

Article 169 supports the integration and synergies among Member States and with the Framework Programme. Under Article 169, the European Union aims at stimulating intergovernmental actions without the Commission (EC) being involved in their management. On the contrary, article 171 allows the EU to set up and lead directly new community bodies involved in research activities or programmes (as it has been the case with the Joint Undertakings like IMI, ARTEMIS, etc.).

During the last few year the Commission started new initiatives to obtain greater involvement of the Member States, e.g. through the ERA-Net Scheme or the Joint Programming Initiative.

The panel discussed the models described which all have advantages and disadvantages. Going for a mixture of Article 169 and 170 does not solve the issue fundamentally. Choosing Article 171 would imply that the EC is paying the whole budget and the contributions of Member States would disappear, which is not desirable given the past investments some have made in EDCTP. Following

[17] *EUROSTARS; Ambiant Assisted Living, AISBL international non profit under Belgian law; EMRP (metrology), EURAMET non profit under German law; BONUS-169 (Baltic Sea), EEIG.*

Article 300 would mean that the current EDCTP structure would also have to disappear. Changing the legal basis for the EDCTP now for a period of 4 years is not realistic.

Given the aim of EDCTP, article 169 remains probably the best option, but what could be changed in theory is the so called Dedicated Implementation Structure: the European Economic Interest Group, through which the cooperation among Member States has been put in place and managed. Actually, this particular instrument (EEIG) does not allow full membership of Third Countries. This may possibly need more in depth reconsideration among the Member States participating in EDCTP, and in view of the experience gained in the medium term with the presence of African governmental observers.

Well before the end of the extended EDCTP1 Programme, the General Assembly should explore, in consultation with the Commission, alternatives to the present EEIG legal structure, in order to give equal voting rights to the African Government Representatives.

ANNEXES

TO THE

INDEPENDENT EXTERNAL EVALUATION

REPORT

OF THE EUROPEAN AND DEVELOPING COUNTRIES

CLINCICAL TRIALS PARTNERSHIP

(EDCTP PROGRAMME)

- **Follow-up to IER Report 2007**
- **Some facts and figures**
- **Questionnaire to researchers: methods and results**
- **IEE panel discussions in Arusha**
- **Capacity building**
- **Clinical trials: SWOT analysis**
- **Clinical trials: Descriptive data and results**
- **Burkina Faso Case Study**
- **Documentary sources**

ANNEXE 1

FOLLOW-UP TO THE EDCTP

INDEPENDENT EXTERNAL REVIEW

OF JULY 2007 (IER 2007)

A number of answers were given to the main recommendations issued by the Independent External Review panel in July 2007. They were given by the Commission in its Communication, COM (2008)688 of 20 October 2008, by EDCTP and EDCTP representatives and by interested Member States.

The replies from EDCTP, the European Commission (EC) and the Member States (MS), have been regrouped and expressed in general terms.

They are summarized below, after each IER recommendation.

Opinion of a majority of members of the IER Panel (July 2007):

"The difficulty for the EDCTP Programme in combining two major tasks should not be underestimated: integrating national clinical trials programmes and working with scientists and clinicians in Africa. This is a very long-term ambition, which can only produce progressive results if all interested partners understand their responsibilities and respect their commitments, which must be renewed from time to time. The EDCTP is unique in providing a strong influence to African scientists and this should be reinforced and institutionalized in future.

1. The EDCTP must strictly comply with its mandate under Annex 1 of Parliament and Council Decision N°1209/2003/EC and focus on the following activities:

a) Effective coordination of product clinical investigations within a clearly defined public health strategy and involving strong partners in Europe (including industry) and in Africa to avoid fragmentation.

b) Improving the general conditions for conducting clinical trials in Africa, taking into account the existing regulatory and ethical constraints.

c) Studying the optimal conditions of use of drugs and vaccines against the three diseases in an African context (access, affordability and distribution), in comparison with other public health interventions.

2. For the EDCTP Programme to continue, the Member States who created and own the EDCTP should endeavor to take all necessary measures to provide the promised levels of financial support and to drastically improve the EDCTP governance and performance.

3. If by end of 2008, the EDCTP did not improve significantly in terms of visible and tangible outputs and results, in line with key recommendations 1.1 to 1.5 (see table), the panel does not recommend the renewal of the financing decision under FP7, based on Article 169 of the Treaty."

Follow-up to key recommendations from the IER panel (EDCTP, MS and EC)

IER recommendations to EDCTP ***and replies from EDCTP***

IER recommendations ***and replies from EDCTP Member States***

IER recommendations on future EDCTP activities ***and replies from the Commission***

IER recommendations on new Article 169 initiatives ***and replies from the Commission***

1. *IER recommendations to EDCTP* ***and replies from EDCTP:***

1.1. "Define a clear, convincing and realistic EDCTP strategy with a common shared vision, clearly defined contributions from each partner and equitable sharing of results."

EDCTP: GA redefined in June 2007 the EDCTP strategy until 2010 and made recommendations, in early 2009, for a future strategy beyond 2010, such as:

-extend the scope from phase II-III to Africa phase I and health services strategies for delivery

- improve prospective information on NP mapping, MS certificates, in a public database,

- include other neglected diseases if additional resource commitments.

1.2. "Make the General Assembly more political and create an Executive Steering Committee."

EDCTP: making GA more political is under way in certain countries (NL, BE, UK, FR); the Executive Director visited several MS, including 5 new MS and also Finland to seek political commitment from each MS. A minimal national programme is promoted by Deputy GA members.

A Steering Committee (Chair, Vice-Chairs and ED was mandated by GA and meets regularly

1.3. "*Expand association with major Product Development Public/ Private Partnerships for access to know-how and to provide visibility. Keep an inventory of and contacts with other similar programmes, to avoid unnecessary duplication."*

EDCTP: ED/GA working group is reviewing engagement with private partners (industry, PDPs), IPR, funding, pricing, publications. Better results since 2008, can be improved during Arusha conference.

1.4. "*Renew calls for appropriate projects to be submitted rapidly to attract the best public/private partnerships and to participate in major R&D initiatives such as MVI, IAVI and on TB."*

EDCTP: There is a significant increase in calls since 2007, following "enabling" stakeholder meetings: 11 calls totaling 180 million EUR (90 million EC), including Medicines for Malaria Venture and Global TB Alliance.

1.5. "*Simplify and streamline co-funding, from a virtual to an actual common pot (by 2009), in order to reduce operational complexity and allow African initiation of EDCTP projects."*

EDCTP: co-funding to be legally re-defined for EDCTP II

Each MS should commit to minimum annual contribution for the entire EDCTPII, and to upfront funding each year (from research development or other sources) and accepts to fund African and other European researchers (common pot for African researchers?)

There are still some open questions: amounts per MS, annual Art. 169 fees, co-funding rules (50 or 75 %)?

2. IER recommendations ***and replies from EDCTP Member States:***

2.1. "*Interested Member States should renew their "EDCTP vows" in Council; accept reforms to EEIG structures, and directly finance an EDCTP "common funding pot".*

Six countries (CH, SP, UK, IRL, DK, FR, and DE) confirmed support, in response to Commissioner's letter. True common pot is only a long term goal. It is difficult in many countries to fund foreign researchers from national research funds.

2.2*. "In the General Assembly, the decision making should be restricted to Member States who provide financial contributions with representation at the highest appropriate national level and to African representation; other member would become observers, starting in 2008."*

GA did not agree. Most decisions, made by consensus, can also include African representatives.

2.3. "*The African presence in the General Assembly should be reinforced, with decision-making status for representatives from African countries or regional organizations."*

African personalities are already present in GA: DCCC chair (and also PB Chair). In future, four representatives from regional bodies will be invited as observers. Formally, EEIG decision-making is limited to EU countries.

2.4. "*Member States should refrain from imposing national criteria, and accept one integrated scientific and ethical evaluation conducted by EDCTP, utilizing a pool of the best national experts."*

Some countries (SP, NL, DE, NO, IT, LU, FR) still carry out their own evaluation before co-funding. MS have agreed to accept a single EDCTP independent peer-reviewed evaluation after 2010.

2.5. "*Member States should enforce the Article 169 concepts in their own countries on a sustainable basis, involving national parliaments when required, and report back annually to the EDCTP and the Commission on progress in implementation."*

EDCTP "prototype" is different from more recent Art 169 initiatives because of its African dimension. MS now accept the need for important internal national changes in view of EDCTP II.

The main difficulties are due to the heterogeneity of MS funding mechanisms and rules. The bureaucratic approach and lack of flexibility of the Commission did not help.

We need a stronger commitment of all MS with up-front funding for research and capacity development and single EDCTP administered peer review.

3. IER recommendations on future EDCTP activities ***and replies from the Commission:***

3.1. "*Report to the Council and Parliament about the current status, in anticipation of the 2008 review."*

See Communication from the Commission to EP and Council, COM (2008)688 of 20.10.2008.

3.2. "*Create a joint DG Research / DG Development platform to engage in a dialogue with the EDCTP."*

Commission services have agreed to participate actively in GA and PB and are using the "inter-service group on communicable diseases for poverty reduction".

3.3. "*Reformulate health research strategy before any new decision to finance EDCTP from FP7, in particular on the three diseases."*

The new health strategy for FP7 focuses on translational health research on the 3 diseases. It refers to possible further support to EDCTP, depending on final evaluation and impact studies before any decision is proposed on EDCTP II.

3.4. "*Consult African Governments on EDCTP future and international health research under FP7."*

The EDCTP High Representative began consulting African governments and other stakeholders in 2007. Commission has participated in Global Ministerial Forum on Research for Health (Bamako, November 2008).

3.5. "*Involve African Governments at an early stage to link capacity strengthening to national strategies, in order to ensure sustainability."*

More efforts are needed to ensure sustainability on capacity in Human resources and laboratories.

3.5."*Submit a new funding proposal to the Council and Parliament, before FP 7 mid-term review, provided that:*

Interested Members States political/budgetary/administrative commitments are clear.

The EDCTP programme integrates the relevant national ones, with a common funding pot.

The EDCTP governance is properly adjusted and more open to African partners.

The EDCTP performance complies with targets from the EDCTP Roadmap."

4. *IER recommendations on new Article 169 initiatives* ***and replies from the Commission:***

4.1. "*Set out future Article 169 pre-conditions, preferably in a guidance communication."*

The ***new Article 169 initiatives (AAL, BONUS, EMRP, EUROSTARS) closely follow the IER recommendations and include a specific set of preconditions to be met.***

4.2. "*For an Article 169 Programme to become and remain successful there must be pre-existing national programmes, strong commitment by Member States to provide funding and irreversible national support*."

This is one of the main pre-condition set by the Commission.

4.3. "*Before EU money becomes available, there must be: common work-plan; sound governance structure; fixed national financial contributions; clear evaluation criteria and procedures; clear deliverables; solutions for the liability issue."*

These are also pre-conditions set by the Commission.

ANNEX 2

SOME FACTS AND FIGURES ABOUT:

EDCTP ACTIVITIES,

MILLENIUM DEVELOPMENT GOALS,

AND AFRICA/EU PARTNERSHIP

EDCTP KEY PERFORMANCE INDICATORS (EDCTP Website, November 2009)

Thousand EUROS						
YEAR	**2004**	**2005**	**2006**	**2007**	**2008**	**HALF 2009**
GRANTS % OF EXPENDITURE	1%	36%	54%	73%	79%	92%
GRANTS VALUE	46	8276	14680	21921	23392	32626
MS CO-FUNDING	0	824	5774	20833	28200	2970
RICAN EXPENDITURE	96	6677	11657	18915	18450	24070
EUROPEAN EXPENDIT;	3181	4528	7003	7460	7805	10437
N° CLINICAL TRIALS	5	7	14	24	42	45
N° CAPACITY PROJ.	0	6	47	59	163	181
AFRICAN INSTITUTIONS	1	20	86	98	124	124
AFRICAN COUNTRIES	1	13	21	21	26	26

EDCTP APPROVED PROJECTS (Source: EDCTP)

Disease/Programme	Number	million Euros
HIV/AIDS clinical trials	21	89.1
TB clinical trials	14	76.9
Malaria clinical trials	10	63.6
Networking, excellence centers	11	12.0
Career and senior fellowships	27	6.5
Ethics & regulatory	41	3.4
Scholarships (Msc & PhD)	11	1.4
Joint Programme activities	2	0.6
Clinical trials registry	4	0.2
Total	141	253.7

In October 2008, the Commission gave a progress report to Parliament and Council, including the financial situation (2003 to May 2008, covering 145 projects, 26 African countries and 123 institutions):

EDCTP expenditure: 37, 4 million EUR

EC Funding to signed grants: 146, 5 million EUR

MS Contributions: 94, 7 million EUR (in cash, direct and in kind)

Third Party contributions: 34, 1 million EUR (including Gates Foundation).

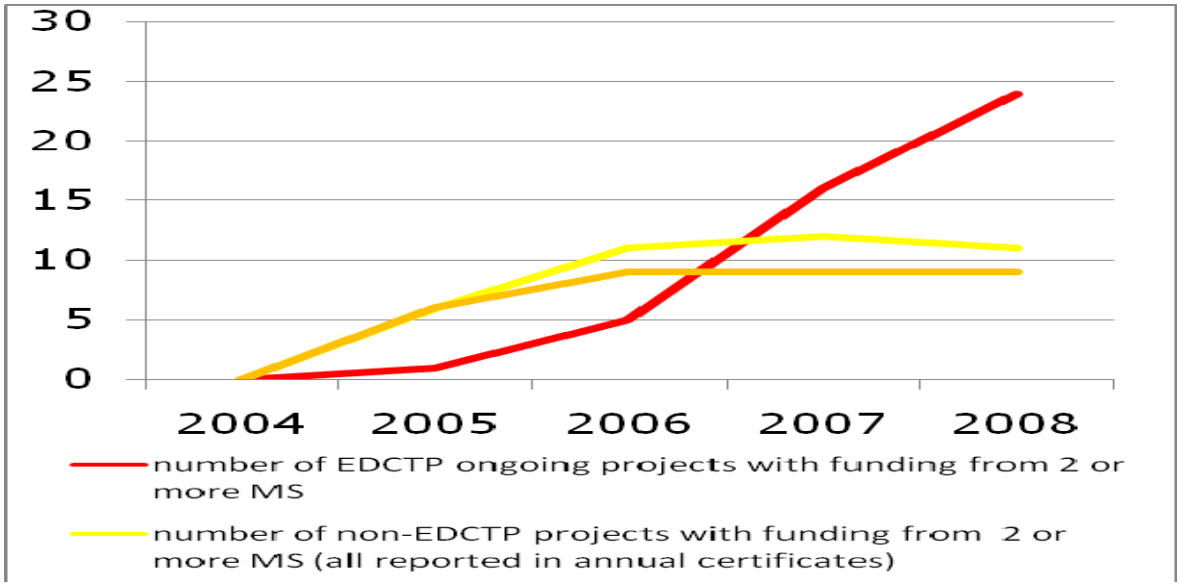
MEMBER STATES CONTRIBUTIONS, UNTIL APRIL 2008 (Source: EU Commission)

MS contributions/commitments to EDCTP (000 EUR), extracted from Commission staff working document, 30.10.2008, p. 36				
Member State	**Cash**	**Direct**	**In kind**	**Total**
1.UK	22170	814	3008	25992
2. FRANCE	9	5294	675	5978
3.SWEDEN	3832	0	1403	5235
4.NETHERLANDS	2020	0	2908	4928
5.BELGIUM	53	2000	2335	4389
6.SPAIN	3191	509	494	4194
7.NORWAY	2	3302	782	4086
8.DENMARK	2	113	2618	2734
9.GERMANY	9	539	1772	2321
10.IRELAND	1309	3	7	1318
11.SWITZERLAND	198	145	36	379
12.ITALY	21	116	235	371
13.AUSTRIA	7	140	57	205
14.GREECE	4	0	3	7
15.PORTUGAL	6	0	0	6
16.LUXEMBURG	1	0	3	4
TOTAL	**32835**	**12975**	**16335**	**62145**

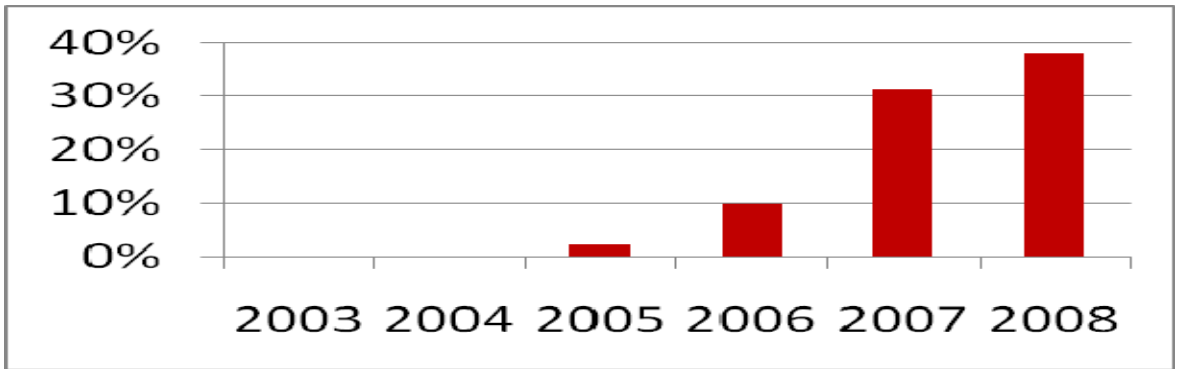
MEMBER STATES ADDITIONAL CONTRIBUTIONS, NOVEMBER 2009 (Source: C. MGONE)

The current level (November 2009) of co-funding stands at nearly €175,000,000 as follows:

Signed projects, staff secondment, bursaries, etc €79,305,109; committed funds to projects under negotiation €15,727,964; additional MS funds given to ongoing projects 2,324,000; and joint (at least two member states) funding to activities within EDCTP scope €74,921,571. This does not include the current call on Member State Initiated activities which may raise around €13,000,000. EDCTP funded clinical trials average around 3 member states and up to 15% of them 5 or more member states working together with their African counterparts. Number of EDCTP and non-EDCTP projects with funding from 2 or more member states is increasing since the inception of EDCTP showing how the programme is facilitating the integrations:



Furthermore, by 2008 more than 40% of the member state funding of activities within the scope of EDCTP were channel through the programme. The funding spent on EDCTP activities by member states as a proportion of the overall member states activities within the scope of EDCTP according to their annual certificates is shown in the histogram below. This shows increasing channel of funds through the programme.



EDCTP AND THE MILLENNIUM DEVELPOMENT GOALS

Three of the eight Millennium Development Goals directly address health issues: MDG 4, 5 and 6. The contribution EDCTP can make in relation to MDG 6 is evident, considering its target indicators:

- Combat HIV/AIDS, malaria and other diseases,
- Halt by 2015 and begin to reverse the spread of HIV/AIDS,
- Achieve, by 2010, universal access to treatment for HIV/AIDS for all in need,
- Halt by 2010 and begin to reverse the incidence of malaria and other major diseases.

The successful combat of HIV/AIDS, malaria and tuberculosis, in part through improvements of the health system, will no doubt also improve maternal health (MDG 5: half of all maternal deaths occur in sub-Saharan Africa) and help to reduce significantly the under five child mortality rate (MDG4: Sub-Saharan Africa now accounts for half of all deaths among children under five).

MDG 6: HIV/AIDS (summarized extracts)
Worldwide the number of people newly infected with HIV declined to 2.7 million in 2007. The number of AIDS deaths declined to 2 million in 2007, partly due to better access to antiretroviral drugs in poorer countries. Over one third of new HIV infections and 38% of AIDS death in 2007 occurred in Southern Africa. Altogether, sub-Saharan Africa is home to 67% of those living with HIV (Women: 60%). In 2007, about 33% of HIV positive pregnant women received antiretroviral treatment. The most significant gain in coverage has been in sub-Saharan Africa.

MDG 6: Malaria (summarized extracts)
A million people died of malaria in 2006: 95% in sub-Saharan Africa, and the vast majority, children under 5. Between 190 million and 330 million episodes of malaria occurred in 2006, 88% in sub-Saharan Africa. Major progress has been made in the fight against malaria in recent years, due in large part to increased funding and focus control of malaria: insecticides-treated bed nets, use of diagnostics to better target treatment. Countries that have reached a high coverage with two or more malaria interventions (e.g. Eritrea, Rwanda, and Zanzibar) have seen declines of more than 50% in severe malaria cases and deaths in health facilities.

MDG 6: Tuberculosis (summarized extracts)
Tuberculosis prevalence has fallen globally, but prevalence is still rising in sub-Saharan Africa. Of the new 9.3 million tuberculosis cases in 2007, an estimated 1.4 million (15%) were among people who were HIV-positive, most of whom (79%) live in Africa. The diagnosis and treatment of multi-drug resistant tuberculosis and the implementation of TB-HIV initiatives, plus research and development activities need funding.

EDCTP clearly supports projects supporting MDG directly, such as:

- 33 Clinical Trials projects: 17 HIV, 6 Malaria, 8 TB, 2 HIV/TB
- 4 regional Networks of Excellence to build capacities in all three target diseases.
- 22 Senior Fellowships: 8 Malaria, 7 HIV, 4 TB, 3 non-specific
- 5 Career Development Fellowships (3 HIV, 1 malaria, 1 tuberculosis).

IMPLEMENTATION OF THE JOINT AFRICA-EU STRATEGY

Joint Africa-EU Strategy **Thematic partnerships of the first Action Plan (2008-2010)** *Extracts from progress report of 9/10/2009*
• EU Programme for Action to Confront HIV/AIDS, Malaria and Tuberculosis Through External Action (2007-2011), including action to enhance access to safe and affordable quality medicines in Africa, address the critical shortages of health care workers and contribute to bridging the financing gaps for the three diseases. • Medicines registration programme (Pharmaceutical Manufacture Plan for Africa) • Global Fund to fight AIDS, Tuberculosis and Malaria; EC: € 100 m per year in 2008 and 2009, of which 60% for Africa, through thematic financing and intra-ACP funds, and 9.5 million in 2008 to the Global Fund for Vaccines and Immunization. • EC support to the review processes of the Maputo Plan of Action on Sexual and Reproductive Health and rights of African countries. • MDGs through the 7th Framework Programme (FP7) and its international cooperation on health research. The 2007-2008 call for proposals: allocated €121 m, with €27 m for neglected diseases and €16 m for improving reproductive health, access to medicines, Innovation and IP, integrating diseases surveillance and health systems response. The 4th call of FP7's Health Theme (July 2009) includes a call on –"Better health for Africa" - with an indicative budget of €39 m, building on the Global Ministerial Summit on Heath Research held in Bamako in November 2008.

ANNEX 3

QUESTIONNAIRE

FOR THE ASSESSMENT

OF EDCTP FUNDED PROJECTS

(Researchers' Opinion)

Randa Kamal,

On behalf of the EDCTP Independent Evaluation panel

27 October 2009

Questionnaire for the Assessment of EDCTP Funded Projects

Objective

This self-administered questionnaire was developed to assess investigators' feedback regarding EDCTP projects and their impact, and to solicit their suggestions for improvement.

Method

The questionnaire included 41 multiple choice questions. A total number of 45 forms were sent by E-mail to participants to be filled and a reply was requested within 10 days to be sent to a specific e-mail address (edctp2009@gmail.com). Additional 12 forms were distributed during the Arusha forum. The number of respondents was 35, but three of them had invalid forms due to missing data, which makes a response rate of 71.1%. Most of the respondents were academic persons, either projects leaders, principal or co-principal investigators who had sufficient and accurate knowledge on their own projects management and implementation process and were considered the best target group eligible to reply to the questionnaire.

Data management

Data entry and statistical analysis were done using SPSS 14.0 statistical software package. Quality control was done at the stages of coding and data entry. Data were presented using descriptive statistics in the form of frequencies and percentages for qualitative categorical variables, and means and standard deviations and medians for quantitative variables.

Table 1. Titles and project job positions of respondents (n=32)

	Frequency	Percent
Respondent title:		
Academic	26	81.2
Technical	3	9.4
Missing	3	9.4
Respondent position:		
Principal investigator	12	37.5
Co-investigator	18	56.2
Missing	2	6.2

Table 2. Distribution of respondents according to countries (n=32)

	Frequency	Percent
South Africa	4	12.5
Gambia	3	9.4
Uganda	2	6.2
Mali	2	6.2
Tanzania	2	6.2
Nigeria	2	6.2
Ethiopia	2	6.2
Kenya	1	3.1
Ghana	1	3.1
France	1	3.1
Mozambique	1	3.1
United kingdom	1	3.1
Denmark	1	3.1
Netherlands	1	3.1
Spain	1	3.1
Zambia	1	3.1
Multicenter	6	18.8
Category:		
African	21	65.6
European	5	15.6
Multicenter	6	18.8

Table 3. Current status and duration of studied projects (n=32)

	Frequency	Percent
Current status of the project:		
Just beginning	6	18.8
Implementation phase	14	43.8
Data management phase	1	3.1
Report submission	1	3.1
In process of publication	7	21.9
Published	3	9.4
Project duration (years):		
Mean(SD)	3.2(1.0)	
Median	3.0	

Table 4. Types of activities and locations of studied projects (n=32)

	Frequency	Percent
Project activities:[@]		
Capacity building	29	90.6
Networking	20	62.5
Clinical trial	19	59.4
Facilities where the project is implemented (*Not mutually exclusive*)		
Research center	26	81.2
Lab	24	75
Clinic	23	71.9
Hospital ward	13	40.6
Other	4	12.5

Table 5. Target populations and groups involved in studied projects (n=32)

	Frequency	Percent
Project target population: [@]		
Women in childbearing period	13	40.6
Children	11	34.4
Infants	10	31.2
Pregnant women	10	31.2
Men	10	31.2
Senior men/women	9	28.1
Adolescents	8	25
Newborns	7	21.9
Lactating women	5	15.6
Project engages specific groups:	10	31.2
Groups engaged (n=10):		
Poor communities	2	20.0
Poor communities/unemployed	1	10.0
Poor communities/unemployed/disabled/religious minorities	1	10.0
Other (pregnant/children/etc.)	6	60.0
Project considers needs of disadvantaged population and minority groups	10	100.0

(@) Not mutually exclusive

Table 6. Potential side effects and hazards of studied projects (n=32)

	Frequency	Percent
Materials/drugs used in project:		
Completely safe	2	6.2
Possible side effects	4	12.5
Known side effects	2	6.2
Not applicable	24	75
Equipment and materials used in the project have hazardous effects on the environment:		
Yes	1	3.1
No	30	93.8
Do not know	1	3.1

Table 7. Ethical aspects in implementation of studied projects (n=32)

	Frequency	Percent
Local population well-informed of the EDCTP project and its importance:		
Yes	17	53.1
No	7	21.9
Do not know	8	25
Local population accept the concept of drug trials:		
Yes	18	56.2
No	1	3.1
Do not know	6	18.8
Not applicable	7	21.9

Types of consents project provides to target population for ethical clearance:[@]		
Written	25	78.1
Informed	24	75
Verbal	6	18.8
Other	3	9.4

(@) Not mutually exclusive

Table 8. Impact of studied projects on local communities (n=32)

	Frequency	Percent
Project provides equity for participation:		
Yes	25	78.1
No	2	6.2
Do not know	5	15.6
Project promotes health services provision:		
Yes	18	56.2
No	6	18.8
Do not know	4	12.5
Not applicable	4	12.5
Project activities create inequalities in health services provision:		
Yes	4	12.5
No	24	75.0
Do not know	4	12.5
Project creates new job opportunities:		
Yes	23	71.9
No	5	15.6

Do not know	3	9.4
Not applicable	1	3.1
Project provides appropriate on-the-job training	30	93.8

Table 9. Impact of studied projects on local research capacities (n=32)

	Frequency	Percent
Project provides opportunities for young researchers	32	100.0
Project provides equal chances for researchers from both genders without discrimination:		
Yes	29	90.6
No	1	3.1
Do not know	2	6.2
Respondent received training/education for the project:	20	62.5
Training was funded by ADTCP (n=20)	15	75.0
Training had a positive impact on job (n=20)	18	90.0
Project ascertained skills and filled gaps in knowledge:		
Yes	30	93.8
No	1	3.1
Do not know	1	3.1
Project built confidence, self-esteem and capacity of working individuals:		
Yes	30	93.8
No	1	3.1
Do not know	1	3.1

Table 10. Impact of studied projects on host institution (n=32)

	Frequency	Percent
Project provides and promotes sustainable development education:		
Yes	24	75.0
No	4	12.5
Do not know	4	12.5
EDCTP strengthened institution:		
No	2	6.2
Yes	26	81.2
Do not know	4	12.5
Project involves new technologies:		
Yes	21	65.6
No	10	31.2
Do not know	1	3.1
Project involves renovation of facilities:		
Yes	14	43.8
No	16	50.0
Do not know	2	6.2
Project involves establishment of new facilities:		
Yes	6	18.8
No	23	71.9
Do not know	3	9.4

Table 11. Barriers to community participation in studied projects and means to overcome these barriers (n=32)

	Frequency	Percent
There are barriers to community participation in the project	10	31.2
Types of barriers (n=10):		
Lack of information	*1*	*10.0*
Lack of trust	*1*	*10.0*
Cultural barriers	*1*	*10.0*
Lack of trust and geographic barriers	*1*	*10.0*
Lack of credibility of health services + cultural barriers	*1*	*10.0*
All the above	*3*	*30.0*
Other	*2*	*20.0*
Project considered ways to overcome barriers to participation:	14	43.8
Ways used (n=14):		
Health education	*4*	*28.6*
Health education + access to services	*3*	*21.4*
Financial incentives	*1*	*7.1*
All three	*4*	*28.6*
Other	*2*	*14.3*

Table 12. Obstacles faced in studied projects' funding and implementation (n=32)

	Frequency	Percent
Project had problems in funding:	11	34.4
Types of problems (n=11): [@]		
Tedious administrative procedures	*8*	*72.7*
Co-funding problems	*4*	*36.4*
Late receipt of fund	*3*	*27.3*
Budget lower than claimed	*2*	*18.2*
Other	*3*	*27.3*
Time between project submission and acceptance (months):		
Mean (SD)	8.8 (6.3)	
Median	6.0	
Time between project acceptance and receiving funds (months):		
Mean (SD)	6.1 (5.5)	
Median	5.0	
Project took a long time until it was accepted:		
Yes	11	34.4
No	18	56.3
Do not know	3	9.4
Obstacles encountered during implementation of project:		
Yes	19	59.4
No	9	28.1
Do not know	4	12.5

(@) Not mutually exclusive

Table 13. Respondents' opinions about ECTCP work (n=32)

	Frequency	Percent
Opinion about secretariat management of calls for proposals:		
Good	24	75.0
Can be improved	7	21.9
Do not know	1	3.1
Opinion about the EC/EDCTP administrative rules for managing grant:		
Efficient	17	53.1
Can be improved	14	43.8
Do not know	1	3.1
EDCTP has increased collaboration with researchers in Africa:		
Yes	30	93.8
No	1	3.1
Do not know	1	3.1
EDCTP has increased collaboration with researchers in Europe:		
Yes	25	78.1
No	1	3.1
Do not know	6	18.8
EDCTP should:[@]		
Remain limited to AIDS, TB, malaria	16	50.0
Fund clinical trials on other infectious diseases	11	34.4
Fund clinical trials on non-communicable diseases in Africa	8	25.0
Fund health system trials	6	18.8
Other	1	3.1

(@) Not mutually exclusive

Quotations from respondents' open comments

"EDTCP has changed the research field in Africa for the better. I give EDTCP a lot of credentials demonstrating what a true partnership looks like. .. The issue of co-funding is however a stumbling block that needs critical review." "Securing co-funding from European countries is extremely difficult for African project coordinators. I would suggest that EDTCP secretariat and partnership board and DEEE be involved in finding a common pot of co-funding." "EDTCP is an excellent undertaking which filled a gap which existed since long time."

"Many lessons have been learnt in the last few years of the current EDTCP phase. It is now time and great opportunity to consolidate what has been learnt and utilize these opportunities in EDTCP phase II. It is important that the focus remains on sub-Saharan Africa because current capacity might not be sufficient to expand to other regions."

"As a matter of urgency, EDTCP should improve the capacity building of young African scholars by providing many fellowships, scholarships, and grants for training. Finally, other funding agencies should emulate and double EDTCP's efforts in providing opportunities for African scholars. KUDOS for the 5th EDTCP 2009 forum. Keep it up."

"EDTCP is evolving and refining its operations and administration funding guidelines which a certain percentage be given at the end of the study should be revisited."

"EDCTP fills a very valuable niche, funding specifically clinical trials for important diseases in Africa. This is something that almost no other funding agency does. Research organizations focus on research, Aid funding agencies focus on implementation. Prior to EDCTP it was extremely hard to find agencies (and even harder to find commercial partners) to cover the gap between promising early discoveries and products ready for final commercial development. This aspect should at all costs be retained."

"I believe EDCTP has performed creditably well within its relatively short time of existence and limited resources at its disposal. However, there is always room for improvement in any human endeavor; therefore this external evaluation should take a closer look at EDCTP operations and try to identify possible areas that can be improved upon. One particular area that I think requires improvement is the area of funding i.e. how to substantially increase EDCTP core funding to enable it make more impact in promoting research culture and in conducting medium to large scale clinical trials in sub-Saharan Africa."

"EDCTP is following the right track to address the health needs of the poor and the needy countries and I do believe that it is all being done well so far."

"The bureaucracy is beyond belief. There must be more admin staff at EDTCP than researchers funded. There is little understanding of research by office staff who seem to think their job is to "catch out" researchers. … This is the most bureaucratic grant I have ever had and least user friendly. Furthermore, the holding back[18] of 20% of the grant until final reports have been accepted has placed an impossible burden on me and my university in a developing country."

[18] *In fact, the hold back is 10% till final report, in accordance with FP6 rules.*

ANNEX 4

IEE PANEL DISCUSSIONS

WITH PRINCIPAL INVESTIGATORS

Summary by Irmgard Nippert

Venue: Fifth EDCTP Forum
Ngurdoto Mountain Lodge Arusha, Tanzania

Date: October, 14th, 2009

Duration: 12:30-14:15

IEE Panel Discussion with PIs in Arusha

PIs attending from:	Belgium, Botswana, Congo, Gabon, Gambia, Germany, Mali, Nigeria, Senegal, Uganda (one PI from South Africa was interviewed separately)
EC:	Ruxandra Draghia–Akli, Manuel Romaris
EDCTP:	High Commission Pascoal Mocumbi, in addition, GA members/GA deputies from Germany, Austria, Sweden and the United Kingdom were present.
IEE:	Nicholas Meda, Irmgard Nipppert

PIs were asked to outline the strengths, weaknesses, opportunities and threats of EDCTP.

Strengths:

EDCTP was unanimously considered a unique funding agency, which connects African scientists, fosters south-south networking and capacity building ("Never seen a group that brings Africans together in this way"). It was pointed out that other funding agencies, such as the Bill and Melinda Gates Foundation, move away from capacity building.

Overall opinion is that EDCTP is a funding agency that successfully builds African partnerships and capacities and as such needs to be kept.

Major strengths: Networking, capacity building, Senior Fellowship funding ("Integrated Project funding helped me to stay in Africa" PI, Mali).

Weaknesses:

Contract management (time it takes to sign the contract much too long)

Co-funding/regulations:

- Difficult for African PIs to find European partners willing to apply for Co-funding ("an obstacle that is blocking")
- For European partners from some countries that contribute to the common pot (e.g. Sweden) it is difficult to find co-funding ("Not always optimal – it is more a double edged sword. When you apply it is hard to know whether there will be any money at all available, nor the amount available. You often have to start underfunded and are left to trust your ability to raise funds from 3rd parties. You won't get any money from Swedish International Development Cooperation Agency (SIDA) because they have already contributed to the common pot and the common pot mainly goes to Africa. However, the EDCTP secretariat has been very forthcoming in trying to help out." Scientist, Karolinska Institute, Sweden). Co-funding procedures were generally described as "a real pain", "a nightmare", "and a gun to your head «to» go and find a partner"."Cut the fake in kind funding"

  Funding period of 3 years for Networking programmes were considered too short by African PIs, more flexibility is also needed when Clinical Trials are funded.

No support from EDCTP available when dealing with industry for instance in regard to drug development (PI, Mali, had to deal on his own with pharmaceutical industry).

Micro-management from EDCTP is not optimal: too many administrative hurdles and constraints, which are not always well understood by African partners. EDCTP funding regulations are perceived as being too inflexible from the point of view of African partners.

Overheads are too small and should be increased to help African universities to improve their infrastructure (PI, South Africa).

Opportunities:

Building south-south partnerships, providing training for African young scientists – although more outreach is needed to bring in young scientists, difficult to get into the networks (PI, Uganda).

Improving standards including ethical standards, harmonization of standards for clinical trials among African partners. EDCTP activities hopefully will lessen inequities in research capacity (long-term), overall improvement of the research infrastructure in Sub-Saharan Africa which is – with the exception of South Africa – hardly developed at all. Keeps (young) researchers in Africa

The integration of MS national programmes is inching forward because of the "needs to find a partner" policy

Opportunities were mainly voiced by African PIs, however, south-north partnerships were seen as difficult to be obtained, whereas the opportunities of south-south partnerships were generally emphasized.

Threats:

African Governments need to take up more responsibility. They need to develop health research strengthening policies and start funding health research and capacity building. Sustainability of networks and capacities in Africa were questioned as long as African governments' financial commitment and support are missing.

ANNEX 5

EDCTP PERSPECTIVE

FOR CAPACITY BUILDING

By Nicolas Meda,

On behalf of the EDCTP Independent External Evaluation Panel

9 November 2009

Health research capacity building in developing countries:

Analysis of an EDCTP perspective

Capacity building concept & key definitions

Capacity building is a process by which a person, a group/organization/institution, a society/system increase its ability to perform core functions to meet stated objectives effectively, efficiently and sustainably. Fundamentally, capacity building addresses needs expressed by beneficiaries. Research capacity building is an ongoing process of empowering individuals, institutions, organizations and nations to: 1) define and prioritize problems systematically; 2) develop and scientifically evaluate appropriate solutions and 3) share and apply the knowledge generated (Lansang & Dennis, 2004).

Health research capacity strengthening is the process by which an individual researcher, a research group, a research institution increase his/its ability to define health problems, set objectives and priorities, build sustainable good research practices to identify solutions to key national health problems (Pang et al. 2003). Building health research capacity has been recognized internationally as important in order to supply essential inputs of evidence-based decision-making at policy level, at programme management level, and at practitioner level. Activities to increase research capacity for, within, and by practice include initiatives to support individuals and teams, organizations and networks (Cooke, 2005).

EDCTP strategy for capacity building

The European & Developing Countries Clinical Trials Partnership (EDCTP) was founded in 2003 in response to the overwhelming global burden caused by the three main diseases of poverty, namely HIV/AIDS, Tuberculosis and Malaria (Mgone & Salami, 2009). To date, EDCTP is a partnership between 17 European countries and sub-Saharan Africa that work closely with third parties (private foundations, pharmaceutical industries, etc.)**.** EDCTP aims to accelerate the development of new or improved diagnostics, drugs, vaccines and microbicides against HIV/AIDS, malaria and tuberculosis, with a focus on phase II and III clinical trials in sub-Saharan Africa.

To ensure successful and sustainable outcomes, the partnership is paying great attention to capacity development and strengthening of an enabling environment for conducting clinical trials in Africa using best practices. The purpose of EDCTP capacity building and strengthening activities is to create and maintain sufficient capacity within Africa to formulate and conduct clinical research.

EDCTP founds its capacity building agenda on the concept of integrated projects. Each clinical trial funded has to include personnel incentives, infrastructure/laboratories improvement, and initial (MSc, PhD) and continued (short-term) training activities. Additional grants offer opportunities for senior and career development fellowships. EDCTP also proposes training grants to ethics review committees and to national regulatory agencies and has supported the establishment of clinical trials registration system in Africa. Finally, networking is part of the critical EDCTP strategies for capacity building in Africa. EDCTP facilitates North-South and also South-South networking.

The establishment of sub-regional networks of excellence in Western, Central, Eastern and Southern parts of Africa is the central component of EDCTP South-South networking strategy (Kitua et al. 2009). The networking component is also supposed to facilitate north-south technology transfer and south-south mentorship allowing proliferation of the developed capacity and enhancement of the critical mass of knowledgeable researchers and research institutions.

EDCTP achievements in capacity building in Africa

To date EDCTP has already funded 141 projects worth around 255 million € which involve 126 institutions from 28 sub-Saharan countries, 43 European institutions and 51 other partners – non-profit organizations and private sector partners mainly from the North. These projects are divided into 45 clinical trials, 4 networks of excellence, 27 senior and career development fellowships, 51 ethics & regulatory framework support, 14 training and joint programme activities, particularly the setting up of a registration system for clinical trials conducted in Africa. Currently, 52 projects are in contract negotiation phase. Each clinical trial funded is supposed to train at least one MSc and one PhD student. The total sum spent on capacity building in the member states during 2003-2008 is 113 233 515 €.

Unfortunately, it was impossible to find in a report or in EDCTP key performance indicators, the total number of students (MSc, PhD) trained in some research disciplines (epidemiology, biostatistics, immunology, microbiology, etc.) or the total number of training workshops held in research core functions (research priority setting, grant proposal writing, scientific paper writing, research management, etc.). The same can be said for the inventory of personnel and infrastructure support. Networks of excellence are recent and have not yet delivered something.

How to improve EDCTP capacity building strategy?

EDCTP is a partnership between European and African countries and other parties to advance the development of new clinical interventions against HIV/AIDS, Tuberculosis and Malaria. A partnership is a voluntary, mutually beneficial arrangement between partners for the purpose of accomplishing mutually agreed objectives**.** Its purpose and nature may vary but partnerships can be usefully seen to range on a continuum from networking through collaboration (see box).

It is not clear in reviewing EDCTP documents that the concept of partnership is fine-tuned. All the components of a partnership are used interchangeably in EDCTP's communication.

The following process is the one highly recommended to those who want to establish a genuine partnership. (See an example[19] in health promotion easy to adapt for partnership in health research). Seven actions have to be cyclically accomplished:

(1) Determine the need for the partnerships;

(2) Choose, twin, or network partners fitting well with needs expressed;

(3) Decide on management style and structure to make sure partnerships work;

(4) Participatory plan collaborative actions;

(5) Appropriately implement collaborative actions;

(6) Find ways to minimize the barriers to partnership;

[19] http://www.vichealth.vic.gov.au/en/Resource-Centre/Publications-and-Resources/Mental-health-and-wellbeing/Mental-health-promotion/Partnerships-Analysis-Tool.aspx

(7) Regularly reflect on and decide to pursue or end the partnership.

In reviewing EDCTP documents, it appeared that a partnership analysis tool was not properly applied at the beginning phase. This is important in determining the agenda of capacity building. As said before, capacity building addresses needs expressed by beneficiaries. No EDCTP document presents the needs assessment exercise for capacity building.

In fact, EDCTP concept of capacity building is heavily focused on training. In reality, health research capacity building is a compact of five building blocks:

(1) Facilitating education and training of individual researchers, research administrators, and research regulators;

(2) Providing "logistical" support to institutions;

(3) Modifying behavior of researchers towards integrity, professionalism and accountability;

(4) Providing financial and non-financial incentives to keep researchers motivated;

(5) Acting on national research system to ensure it enhances both research activities (stewardship, financing, organization, procedures), and researchers promotion and career development (Pang et al. 2003; Potter & Brough 2004).

Box: The continuum of partnership

- **Networking** involves the exchange of information for mutual benefit. This requires little time and trust between partners.
- **Coordinating** involves exchanging information and altering activities for a common purpose.
- **Cooperating** involves exchanging information, altering activities and sharing resources. It requires a significant amount of time, high level of trust between partners and sharing the turf between parties.
- **Collaborating**. In addition to the other activities described, collaboration includes enhancing the capacity of the other partner for mutual benefit and a common purpose. Collaborating requires the partner to give up a part of their turf to another party to create a better or more seamless service

If this compact is not satisfied, all well trained researchers by EDCTP will join inevitably international organizations and NGO for good working conditions and better salaries. If there is a **new EDCTP business plan, it needs to consider this compact**.

How to improve EDCTP capacity building implementation?

The major problem with the implementation of EDCTP capacity building strategy is the lack of a business plan with clear targets. How and when to know if something is met or missed? There is a real need for a capacity development plan.

The training sub-component of capacity building exemplifies the need of targets. Many authors suggest that 1.5 researchers and engineers per 1000 inhabitants is the minimal critical mass of researchers needed to push research and development agenda in Africa (Tchinda, 2002; Coloma & Harris, 2009). Sub-Saharan Africa population is around 750 million inhabitants in 2009. So, 1 125 000 researchers are the target for all sectors of

research and development. This number is realistic. In USA only, there are 2.5 million foreign-borne high-qualified immigrants, with around 100 000 coming from sub-Saharan Africa. The health research sector in sub-Saharan Africa can probably advocate for researchers in a range between 50 000 and 100 000. We don't know the actual needs for MSc and PhD degrees in sub-Saharan Africa.

In reviewing the performance of Welcome Trust and Fogarty International Clinical, operational, and health services research and training award program, it appears that from each organization around 125 scientists are trained per year at PhD level. In Uganda only, Fogarty trains 10 MSc/PhD per year and supports annually 500 training workshops on research core functions (see Fogarty Global health matters September/October 2008). As capacity development is one of the EDCTP core goals, a target of at least 100 PhD theses per year can be set for the future.

Personnel incentives and logistic (office construction, laboratories equipment, IT equipment & supply, etc.) support are already part of EDCTP capacity building agenda but EDCTP has no institution grant to support institutional capacity strengthening. Networks of excellence help but are not enough to cover all institutional capacity needs. This kind of grant in addition to infrastructure support can better focus on behavior and systems. Coaching, mentoring using channels of North-South and South-South networking can advance the agenda of accountability, professionalism and integrity. Twinning research institutions can facilitate the transfer of best practices in research governance and management and also in communication for research dissemination. Involving national governments, international partners can help to influence the national research system governance and functioning towards the facilitation of research activities and promotion of researchers' career development. In acting on national research systems, EDCTP focuses only on ethics and regulatory bodies' needs. That, only, cannot maintain trained researchers in sub-Saharan Africa. EDCTP needs to propose some forms of country grants to help develop in each sub-Saharan country a health research policy framework able to sustain the core functions of a national research health system.

Recommendations

1) EDCTP must urgently conduct a partnership analysis with an appropriate tool as the proper way to determine with all beneficiaries the agenda of capacity building.

2) EDCTP must broaden its health research capacity building strategy to involve individual, institutional and country level activities with its grant schemes; integrated projects can support part of individual and institutional capacity strengthening needs but not all. Integrated project grants can be well complemented by institutional and country level grants.

3) EDCTP capacity building strategy needs a business plan with clear targets. How and when to know if something is met or missed without targets? One ambitious target can be to train from 2010, at least 100 PhD students per year.

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ANNEX 6

A SWOT ANALYSIS

ON EDCTP CLINICAL TRIALS

By Randa Kamal

On behalf of the EDCTP Independent External Evaluation panel

23 October 2009

Forty five EDCTP clinical trial proposals and fourteen progress reports were reviewed, the projects were coded and data were collected, tabulated and analyzed (see attached annex) A SWOT analysis was performed, and the following points are emphasized.

Strengths:

1. Progressive increases in the number of accepted proposals; (60%) of accepted proposals during the last 2 years.

2. More than half of the accepted projects (57.8%); have integrated type of **activities** including clinical trials, capacity building and networking.

3. Many clinical trials (33%) offer integrated type of **services** including diagnostic, therapeutic and follow-up services.

4. Preparedness studies constitute (42.9%) of the AIDS clinical trials projects. Those studies include many crucial activities for planning and organization of future trials for example; setting preparation, capacity building and cohort expansion through the involvement of new sites, increasing acceptability of the community to clinical trials, improving community recruitment, and promoting and monitoring adherence to participation.

5. Concrete efforts are evident in the majority of the projects for African scientific capacity building with development of training programs in all vital aspects of clinical trials including technical training, development of SOPs, and establishment of internal quality assurance, recruitment strategies, ethics and regulatory procedures. There are 10 projects with exclusive capacity building activities.

6. Progress has been made in the field of Malaria treatment as (50%) of Malaria clinical trials have reached phase 3 and (20%) phase 4.

7. Fulfillment and adherence to the principles and guidelines for ethics and safety related issues are stated in the majority of the clinical trials projects. Those principles include human rights, SOPs, case records, good clinical practice regulations, protection and processing of personal data and guidelines on storage and use of biological specimens.

8. Equity in participation of African (48.8%) and Non-African (51.2%) researchers in EDCTP funded projects. Approximately (55.5%) of projects' coordinators and project leaders or principal investigators are African researchers.

9. There is good representation of female researchers in most of the projects; approximately (40%) in AIDS projects and (25%) in TB and Malaria projects.

10. There are a great number of specialized institutions participating in EDCTP projects with equity in participation of African (51.4%) and non-African (48.6%) institutions.

11. The role of each participating institution is clearly stated in all the projects.

12. North to South and South to South networking activities are evident in (75%) of the projects. The number of participating institutions could reach up to 11 African and 10 Non-African institutions in one project.

13. The UK could be considered a good model for other EU countries as it is participating in (70%) of the clinical trials with parallel financial contribution.

14. A total of 38 countries (23 African and 15 non-African countries), are participating in EDCTP clinical trials. This is considered a unique achievement in the field of clinical trials in AIDS, Malaria and TB that no other project or funding agency was able to accomplish, and gather all those countries in collaborative networking activities.

15. There is good representation of specific groups in clinical trials. The groups include neonates and infants in (17.8%), children in (24.4%), adolescents in (8.9%), pregnant and lactating women in (15.6%) of the projects.

16. There is an improvement in EDCTP form for proposal submission. Recent proposals (2008, 2009) have a better systematic way of presenting activities with work packages, clear deliverables and milestones.

Weaknesses:

1. Only few projects (11%) address the need for community health education and measures for community approach in clinical trials. Only one study addresses the ethical-legal rights and social-behavioral issues including knowledge, attitude and needs of the selected target group. The role of community involvement and advocacy in clinical trials should be highlighted. The community should be engaged at an early stage of any clinical trial.

   Suggestions:

   a. Community preparedness; providing them with proper information before being involved in research projects.

   b. Establishing community advisory boards to bridge the gap between researchers and community.

   c. Promoting the role of local leaders who have more influence on the community and could encourage their participation in clinical trials.

   d. Better understanding of the ethical-legal, human rights as well as knowledge, attitude and practice of each participating community.

2. Delay in cohort recruitment after the start of the clinical trials (from annual progress reports).

3. None of the projects have included the outcome evaluation measures as final indicators of success or failure in achieving their goals. Outcome assessment of each project should be planned for and added to the original CT proposals with definite deliverables and milestones.

4. Only few projects (15%) started their clinical trial with epidemiological studies to determine either the incidence or prevalence of the disease in the selected community.

5. Many researchers are participating in 3 or more projects at a time. This might affect the quality of work and minimize the opportunity for other researchers to participate in such projects.

Opportunities:

1. Infrastructure development with innovation and renovation of labs, clinics and other health facilities.

2. Building capacity and skills of African partners and preparing them to take the lead afterwards.

3. Learning opportunities; MSc. Studentships and PhD. Scholarships.

4. Forming consortia from specialized group of expertise in the field, working in renowned academic and research institutions.

5. Involvement of national policy makers.

6. Development and strengthening of collaborative North to South and South to South networking for the benefits of promoting and developing clinical trials.

7. Promoting progress in the field of clinical trials (so far only 4 projects on phase 3 AIDS trials and none phase 4); encouraging and preparing for transition from phase 2 to phase 3 and 4 clinical trials.

8. There is progressive increase in partnership with the private sector especially in phase 3 clinical trials.

9. Sustainability could be achieved through the following: **a**. Infrastructure development with either renovation of existing facilities or establishment of new facilities, **b.** Supporting national programs implementation, **c.** data presentation on a national level, **d.** strengthening and improving research capacities of participating African institutions, **e**. Building capacities of young African researchers to take over the responsibilities of continuing the mission for the development of new treatment or vaccines, **f.** securing links with international organizations to develop and implement international guidelines for new treatment or vaccines, **g.** encouraging community participation to clinical trials and promoting awareness.

10. Better knowledge on the magnitude of the problem of the three main poverty related infectious diseases in sub-Saharan African countries.

11. Better understanding of the knowledge, attitude and behaviors of the vulnerable and affected groups.

Threats:

1. Property rights protection including intellectual and copy rights. Although EDCTP contracts have clauses relating to protection of intellectual and copy rights; this important issue should be stated clearly in each proposal.

2. Ethical clearance for clinical trials. There are so many ethics committees involved for ethical clearance of each project. The diversity of committees for ethical clearance could delay the start of the projects. Also the amendments sometimes required for the original proposals could be refused by one or more of the ethics committees and this could lead to regulatory confusion. Accordingly insuring harmonized and consistent ethics practices in the context of the diversity of ethics committees of participating African countries.

   Suggestion: To establish a research ethics committee formed of representatives from African and European experts in the field of clinical trial ethics. The committee should be officially approved by the GA and assigned by the EDCTP to perform the following tasks:

   a. Revise all CT protocols before their final approval

   b. Provide clearances or suggest modifications according to the ethics rules and protocol for clinical trials ethics that the committee set.

   c. Communicate with participating countries ethics committees to get their preliminary approvals

   d. Monitoring the performance as regards ethics application during the CT implementation process.

3. Except for few projects; monitoring and auditing of projects are done by an internal participating organization while this should be done by an external contract organization to avoid bias and to insure transparency.

4. Co-funding is a big problem that could hamper the whole process of projects' acceptance. It is a burden on the researchers who are responsible of securing co-funding before applying for a grant from the EDCTP.

5. Some EU countries have minimal contributions in EDCTP funded projects.

6. Approximately 65% of the clinical trials will end after the official date of termination of EDCTP. To insure sustainability the gap between 2010 (the official termination date of the project) until the end of 2013 must be filled. Suggestion: EDCTP should plan for a new EDCTP 2 project.

ANNEX 7

DESCRIPTIVE DATA OF

EDCTP APPROVED CLINICAL TRIALS PROPOSALS

By Randa Kamal,

On behalf of the EDCTP Independent External Evaluation Panel

23 October 2009

The overall number of approved clinical trials proposals is 46:

One is on clinical trial registry. The project is called ATM registry in Sub-Saharan Africa and the proposal; it was submitted in June 2004 and is directed by the South-African Cochrane centre.

There are 21 HIV projects:

- Four HIV mother to child transmission clinical trials
- Seven on HIV vaccines
- Five on HIV microbicides
- Five on HIV treatment

There are ten Malaria projects:

- Five on Malaria treatment
- Three on malaria in pregnancy
- Two on Malaria vaccines

There are fourteen tuberculosis projects

- One on TB diagnosis
- Six on TB vaccines
- Seven on TB treatment

Number of projects with integrated activities including clinical trial, capacity building and networking:

AIDS: 12 = 57% **Malaria:** 9 = 90% **Tuberculosis:** 7 = 50%

- Number of projects that are only capacity building:

AIDS: 6 = 28.6% **Tuberculosis:** 4 = 28.6% **Malaria:** None

- Preparedness for clinical trials projects:

AIDS: 9 = 42.9% **Tuberculosis:** 4 = 28.6% **Malaria:** None

Projects that have diagnostic activities, with development of new techniques and capacity building in the lab for diagnostic infrastructure development:

AIDS: 5 = 23.8% **Malaria:** 1 = 10% **TB:** 5 = 35.7%

Clinical trials phases:

Projects	Phase 1	Phase 2	Phase 3	Phase 4
AIDS	7	5	4	0
%	33.3%	23.9%	19.1%	0.0%
Malaria	3	8	5	2
%	30%	80%	50%	20%
TB	1	5	1	0
%	7.1%	35.7%	7.1%	0.0%
Total & %	11 = 24.4%	18 = 40.0%	10 = 22.2%	4.4%

NB: Numbers are not mutually exclusive

Starting dates of projects:

Projects (n=45)	2004	2005	2006	2007	2008	2009	Total
AIDS	1	0	2	5	7	6	21
%	4.8%	0.0	9.5%	23.8%	33.3%	28.6%	100.0%
Malaria	1	1	0	0	6	2	10
%	10.0%	10.0%	0.0%	0.0%	60.0%	20.0%	100.0%
TB	0	1	4	2	6	1	14
%	0	7.1%	28.6%	14.3%	42.9%	7.1%	100.0%
Total & %	2 = 4.4%	2 = 4.4%	6 = 13.3%	7 = 15.6%	19 = 42.3%	9 = 20%	45 = 100.0%

Projects' duration:

Field	2 Y.	3 Y.	4 Y.	5 Y.
AIDS	0	11	8	2
%	0.0%	52.4%	38.1%	9.5%
Malaria	0	1	4	5
%	0.0%	10%	40%	50%
TB	1	4	9	0
%	7.1%	28.6%	64.3%	0.0%
Total & %	1 = 2.2 %	16 = 35.6%	21= 46.7%	7 = 15.6%

Projects ended: **AIDS:** 3 **Malaria:** 1 **TB:** 4

Projects ending after 15 September 2010 (The end of the EDCTP project):

- **AIDS:** 14 = 67%
- **Malaria:** 8 = 80%
- **TB:** 7 = 50%

There are projects expected from the currently open 2009 calls and last set of calls planned for early first half of 2010.

Proportion of African & Non-African researchers participating in EDCTP clinical trials projects:

Researchers	AIDS	Malaria	TB	Total
African	133= 43.8%	100= 54.6%	98= 51.3%	331= 48.8%
Non-African	171= 56.2%	83= 45.4%	93= 48.7%	347= 51.2%
Total	304	183	191	678

NB: many researchers are participating in more than one research.

Number of projects where coordinators, principal investigators and work package leaders are African:

- **ADS projects**

  Coordinators: 11

  PI or work package leaders: 4

  Total & %: 15 = 71.4%

- **Malaria projects**

  Coordinators: 3

  PI or work package leader: 3

  Total & %: 6 = 60%

- **TB projects:**

  Coordinators: 3

  PI or work package leader: 1

  Total & %: 4 = 28.6%

- **Overall number and %:** 25 = 55.5%

Proportion of females to males researchers participating in EDCTP projects:

Researchers	AIDS	Malaria	TB	Total
Females	124 = 40.8%	47 = 25.7%	48 = 25.2%	219 = 32.3%
Males	180 = 59.2%	136 = 74.3%	143 = 74.8%	459 = 67.7%
Total	304	183	191	678

Range of female and male researchers participating in each project (minimum and maximum number):

- **AIDS:**

Female researchers: 1 to 13

Male researchers: 2 to 19

- **Malaria:**

Female researchers: 1 to 12

Male researchers: 8 to 21

- **TB:**

Female researchers: 0 to 8

Male researchers: 2 to 16

Number and percent of African and non-African institutions participating in clinical trials EDCTP projects:

Institutions	AIDS	Malaria	TB	Total
African	90 = 47%	57 = 54.3%	57 = 55.8%	204 = 51.4%
Non-African	100 = 53%	48 = 45.7%	45 = 44.2%	193 = 48.6%
Total	190	105	102	397

NB: Some institutions are collaborating in several projects, so the total number of institutions in each field is much less, considering that it could be repeated in many projects. The exact overall number of institutions is159 institutions (126 African institutions, 43 Non-African institutions from 15 European countries and 51 other partners (NGO's and private organizations).

Range of African and Non-African institutions participating in each project:

- **AIDS:**

African institutions: 1 to 11

Non-African institutions: 0 to 10

- **Malaria:**

African institutions: 3 to 11

Non-African institutions: 2 to 7

- **TB:**

African institutions: 2 to 7

Non-African institutions: 2 to 6

Number and percent of African and non-African countries participating in EDCTP clinical trials funded projects:

Countries	AIDS	Malaria	TB	Exact total #
African	14 (50%)	16 (61.5%)	13 (52%)	**23** (60.5%)
Non-African	14 (50%)	10 (38.5%)	12 (48%)	**15** (39.5%)
Total	28	26	25	**38**

NB: Participating countries are considered according to the location of the participating institution.

African countries participating in EDCTP funded projects; ranking according to the extent of participation:

AIDS projects:

1. Tanzania TZ (10 projects)
2. South Africa ZA (9 projects)
3. Uganda UG (6 projects)
4. Kenya KE (5 projects)
5. Mozambique MZ (5 projects)
6. Zambia ZM (5 projects)
7. Rwanda RW (4 projects)
8. Burkina- Faso BF (3 projects)
9. Malawi MW (2 projects)
10. Cameroun CM (1 project)
11. Cote D'Ivoire CI (1 project)
12. Gambia GM (1 project)
13. Senegal SN (1 project)
14. Zimbabwe ZW (1 project)

Malaria Projects:

1. Burkina Faso BF (7 projects)
2. Gabon GA (6 projects)
3. Mozambique MZ (5 projects)

4. Tanzania TZ (5 projects)
5. Malawi MW (4 projects)
6. Zambia ZM (4 projects)
7. Gambia GM (3 projects)
8. Ghana GH (3 projects)
9. Kenya KE (3 projects)
10. Benin BJ (2 projects)
11. Mali ML (2 projects)
12. Rwanda RW (2 projects)
13. Uganda UG (2 projects)
14. Guinea GN (1 project)
15. Nigeria NG (1 project)
16. Senegal SN (1 project)

TB projects:

1. South Africa ZA (12 projects)
2. Tanzania TZ (6 projects)
3. Kenya KE (4 projects)
4. Ethiopia ET (3 projects)
5. Uganda UG (3 projects)
6. Mozambique MZ (2 projects)
7. Zambia ZM (2 projects)
8. Gabon GA (1 project)
9. Gambia GM (1 project)
10. Guinea-Bissau GW (1 project)
11. Madagascar MG (1 project)
12. Senegal SN (1 project)
13. Zimbabwe ZW (1 project)

Non-African countries participating in EDCTP funded projects; ranking according to the extent of participation:

AIDS Projects:

1. United Kingdom UK (15 projects)
2. The Netherland NL (10 projects)
3. Belgium BE (6 projects)
4. Italy IT (6 projects)
5. Spain ES (6 projects)
6. USA (6 projects)
7. France FR (5 projects)
8. Sweden SE (5 projects)
9. Germany DE (4 projects)
10. Switzerland CH (3 projects)
11. Ireland IE (2 projects)
12. Denmark DK (1 project)
13. Luxembourg LU (1 project)
14. Norway NO (1 project)

Malaria Projects:

1. United Kingdom UK (8 projects)
2. Austria AT (7 projects)
3. France FR (4 projects)
4. Germany DE (4 projects)
5. Spain ES (4 projects)
6. Belgium BE (3 projects)
7. Denmark DK (3 projects)
8. Italy IT (2 projects)
9. The Netherlands NL (2 projects)
10. Sweden (1 project)

TB projects:

1. United Kingdom UK (8 projects)
2. The Netherlands NL (7 projects)
3. Belgium BE (4 projects)
4. Sweden SE (3 projects)
5. USA (3 projects)

6. Denmark DK (2 projects)
7. Germany DE (2 projects)
8. Spain ES (2 projects)
9. Austria AT (1 project)
10. Ireland IE (1 project)
11. Italy IT (1 project)
12. Switzerland CH (1 project)

Range of African and Non-African countries participating in each project:

- **AIDS projects:**

African countries: 1 to 6

Non-African countries: 2 to 7

- **Malaria projects**:

African countries: 3 to 8

Non-African countries: 2 to 5

- **TB projects:**

African countries: 1 to 4

Non-African countries: 1 to 4

Selected target groups in projects:

Field	Neonates & Infants	Children	Adolescents	Pregnant & Lactating women	Adult women	Adults Males & females
AIDS projects	5	3	2	4	5	6
%	23.8%	14.3%	9.5%	19.0%	23.8%	28.6%
Malaria projects	0	7	0	3	0	2
%	0.0%	70.0%	0.0%	30.0%	0.0%	20.0%
TB projects	3	1	2	0	0	11
%	21.4%	7.1%	14.3%	0.0%	0.0%	78.6%

Total & %	8 = 17.8%	11 = 24.4%	4 = 8.9%	7 = 15.6%	5 = 11.1%	19 = 42.2%

NB: Numbers are not mutually exclusive

Most common participating institutions in EDCTP projects:

African institutions:

- Kilimanjaro Christian medical college (TZ), 6 projects
- Muhimbli university of health and allied sciences (TZ), 3 projects
- Mbeya medical research program (TZ), 5 projects
- Mwanza intervention trials unit (TZ), 5 projects
- Makarere university (UG), 7 projects
- Joint clinical research center (UG), 3 projects
- University of Cape town (ZA), 9 projects
- Kwa-Zulu Natal (ZA) 3 projects
- International center for reproductive health (KE) 4 projects
- Manhica research center (MZ) 6 projects
- National institute of health Maputo (MZ) 6 projects
- University of Ouagadougou School of Health Sciences, Centre Muraz (BF) 7 projects
- University teaching hospital Lusaka (ZM) 8 projects
- Albert Schwitzer hospital Lamberne (GA) 6 projects

Non-African institutions:

- Medical research council, London (UK) 15 projects
- Imperial college, London (UK) 6 projects
- London school of hygiene and tropical medicine (UK) 7 projects
- Liverpool university (UK) 6 projects
- University of Montpellier (FR) 4 projects
- Karolinska institute, Stockholm (SE) 7 projects
- Prince Leopold institute, Antwerp (BE) 5 projects
- Ghent university (BE) 3 projects

- Academic medical center-poverty related communicable diseases (NL) 5 projects
- Radboud university (NL) 3 projects
- Munich university (DE) 5 projects
- Tubingen university (DE) 4 projects
- FCRB (ES) 7 projects

Researchers participating in 3 or more clinical trials projects n = 12:

- Sheena McCormack, 5 (UK)
- Christa Janko, 5 (AT)
- Clara Menendez, 4 (ES)
- Janneke Van de Wijggert, 4 (NL)
- Michael Hoelscher, 4 (DE)
- Diana Gibb, 3 (UK)
- Leonard Maboko, 3 (TZ)
- Nicolas Meda, 3 (BF)
- Philippe Van de Perre, 3 (FR)
- Khalifa Bojong, 3 (GM)
- Umberto D'Alessandro, 3 (BE)
- Feieko Ter Kuile, 3 (UK)

Coding of clinical trials proposals

Code #	Title
	HIV Mother to Child Transmission
11	Improving the balance between efficacy and development of resistance in women receiving single dose nevirapine (**Vi**ramune®, NVP) for the prevention of mother-to-child transmission in **Ta**nzania & Zambia (VITA studies)
12	Impact of HAART during Pregnancy and Breastfeeding on MTCT and Mother's Health: The Kesho Bora Study
13	A phase III double blind placebo/controlled trial of the efficacy and safety of infant periexposure prophylaxis with lamivudine to prevent HIV-1 transmission by breastfeeding (PROMISE-PEP trial)
14	Back-up with Combivir (AZT/3TC) or single dose Truvada (FTC/TDF) in order to avoid Non Nucleoside Reverse Trascriptase Inhibitor (NNRTI) resistance after single dose Nevirapine for the prevention of mother-to-child transmission (MTCT)
	HIV vaccines
15	HIV vaccine trial capacity building in Tanzania and Mozambique by continued exploration of optimal DNA priming and MVA boosting strategies; TaMoVac II
16	African-European HIV Vaccine Development Network
17	Feasibility Of And Capacity Building For Adolescents HIV Vaccine Trials In South Africa
18	HIV vaccine trial capacity building in Tanzania and Mozambique by continued exploration of optimal DNA priming and MVA boosting strategies
19	Strengthening of long term clinical and laboratory research capacity, cohort development, and collection of epidemiological and social science baseline data in Uganda and Malawi to prepare for future HIV vaccine trials
110	Capacity development and strengthening in preparation for HIV vaccine trials in Tanzania and Burkina Faso
111	Building capacity of Infant HIV-1 Vaccine Clinical Trial Centers in Nairobi, Kenya and Fajara, The Gambia.
	HIV microbicides
112	A project to complement and contribute to a trial to assess the safety and effectiveness of tenofovir 1% gel applied daily, or prior to sex, in the prevention of vaginally acquired HIV infection in comparison to placebo.
113	Characterization of novel microbicide safety biomarkers in East and South Africa
114	Establishing HIV microbicide clinical trial capacity in Mozambique and expanding an existing site in South Africa

115	Preparing for phase 3 vaginal microbicide trials in Rwanda and Kenya: Preparedness studies, capacity building and strengthening of medical referral systems.
116	Site preparation and capacity strengthening for trials of vaginal microbicides in Tanzania and Uganda
	HIV treatment
117	CHAPAS Trials: Children with HIV in Africa - Pharmacokinetics and Adherence of Simple Antiretroviral Regimens
118	The Eastern and southern Africa Research Network for Evaluation of Second Line Therapy in HIV infection: The EARNEST Trial
119	Expanding the Availability of Fixed Dose Combination Antiretroviral Formulations for First-line Treatment of HIV-infected Children - the Children with HIV in Africa Pharmacokinetics and Acceptability/Adherence of Simple Antiretroviral Regimens CHAPAS-3 Trial
120	A multicentre phase III trial of second-line antiretroviral treatment in African adults.
121	International phase 2b randomized clinical trial to study a once-a-day maintenance strategy after a 15-month induction antiretroviral therapy among HIV-infected children diagnosed early between age 6 and 52 weeks and in virologic success in Africa: the MONOD project
	Malaria treatment
21	An integrated approach to clinical trials, capacity building and networking in West Africa
22	Artesunate for severe Malaria in African children
23	Development of Fosmidomycin and Clindamycin, in a Fixed Dose Combination, for the Treatment of Acute Uncomplicated Plasmodium falciparum Malaria
24	Evaluation of 4 artemisinin-based combinations for treating uncomplicated malaria in African children
25	Special populations and label expansion studies with the fixed dose combinations artemether-lumefantrine, amodiaquine-artesunate, and dihydroartemisinin-piperaquine in Zambia, Malawi and Mozambique.
	Malaria in pregnancy
26	Evaluation of alternative antimalarial drugs to sulfadoxine-pyrimethamine for intermittent preventive treatment in pregnancy (IPTp) in the context of insecticide treated nets.

27	Safe and efficacious artemisinin-based combination treatments for African pregnant women with malaria.
28	Optimization of the existing dose and regimen of intermittent preventive treatment with sulfadoxinepyrimethamine for the prevention of malaria in pregnancy in the context of high coverage of insecticide treated nets and highly seasonal malaria transmission.
	Malaria Vaccines
29	Integrating capacity building and networking in the design and conduct of Phase I and II clinical trials of viral vectored candidate malaria vaccines in East and West African children and infants.
210	Fostering research capacity, networking and project management through phase I-IIB clinical trialsof candidate malaria vaccine GMZ2.
	Tuberculosis diagnostics
31	Surrogate markers to predict the outcome of antituberculosis therapy
	Tuberculosis Vaccines
32	Prospective epidemiological studies of TB in neonates and adolescents in Karemo Division, Siaya district, Western Kenya, in preparation for future vaccine trials.
33	Capacity building for the conduct of ICH-GCP level TB vaccine trials in high risk populations in Ethiopia and East Africa
34	A proof-of-concept Phase IIb clinical trial to evaluate the protective efficacy of a booster MVA85A vaccination administered to healthy, HIV-infected adults in South Africa, Senegal and The Gambia.
35	A Multicentre Phase II Trial of a New TB Vaccine in African Infants
36	Conduct of ICH-GCP level Phase II TB vaccine trials in high risk populations in Africa
37	Toward conducting phase III trials of novel TB vaccines in Ugandan infants and adolescents
	Tuberculosis treatment
38	A controlled clinical trial to evaluate high dose Rifopentine and Moxifloxacin in the treatment of pulmonary tuberculosis

39	Optimisation of tuberculosis and HIV co-treatment in Africa: Pharmacokinetic and pharmacogenetic aspects on drug-drug interactions between rifampicin and efavirenz.
310	Evaluation of a novel TB drug (SQ109) to shorten and simplify TB treatment
311	Rapid Evaluation of Moxifloxacin in the treatment of sputum smear positive tuberculosis: REMoxTB
312	Determining the optimal doses of antiretroviral and antituberculous medications when used in combination for the treatment of HIV/TB coinfected patients
313	Rapid evaluation of high dose rifampicin and other rifamycins in tuberculosis (HIGHRIF)
314	Rapid Evaluation of Moxifloxacin in Tuberculosis

ANNEX 8

BURKINA FASO CASE STUDY

Dr. Nicolas MEDA,

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On behalf of the

EDCTP Independent External Evaluation Panel

9 November, 2009

Acknowledgments

We are grateful to all stakeholders and researchers that have take in their busy time to welcome our survey team. We thank Dr. Malick Coulibaly, medical epidemiologist, for his invaluable help in data collection and compilation, interpretation of results and preparation of the report.

List of abbreviations

AMANET	African Malaria Network Trust
ANRS	Agence Nationale de Recherche sur SIDA et les hépatites
CERBA	Centre de Recherche Biomoléculaire Pietro Annigoni
CHUSS	Centre Hospitalier Universitaire Souro Sanou
CIFRA	Centre International de formation en Recherche-Action
CNRFP	Centre National de Recherche et de Formation sur la Paludisme
DCCC	Developing Countries Coordination Committee
EDCTP	European and Developing Countries Clinical Trial Partnership
EU	European Delegation
GDP	Gross Domestic Product
INDEPTH	International Network of field sites with continuous Demographic Evaluation of Populations and Their Health in developing countries
INSD	Institut National de la Statistique et de la Démographie
INSSA	Institut supérieur des Sciences de la Santé
IRSS	Institut de Recherche en Sciences de la Santé
ISHReCA	Initiative to Strengthen Health Research Capacity in Africa
ISSP	Institut Supérieur des Sciences de La Population
LNSP	Laboratoire National de Santé Publique
MESSRS	Ministère de l'Enseignement Secondaire Supérieur et de la Recherche Scientifique
RAFT	Réseau d'Afrique Francophone de Télémédecine
UFR-SDS	Unité de Formation et de Recherche en Sciences de la Santé
WAHO	West African Health Organisation

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EXECUTIVE SUMMARY

The European and Developing Countries Clinical Trials Partnership (EDCTP) was established in 2003 by the European Commission as a response to the health crisis caused by diseases of poverty such as HIV/AIDS, malaria and tuberculosis, selected in the Millennium objectives for development.

It was planned that after five years of existence, an external evaluation should be conducted to locate the European Commission on progress and results achieved by the EDCTP.
Hence, a panel of six experts was convened by the European Commission to conduct the EDCTP external evaluation: Wim Van Velzen, Fernand Sauer, Professor Peter Piot, Dr Nicolas Meda, Professor Irmgrad Nippert and Professor Randa Kamal Raouf.

Burkina Faso, a West-African developing country, has been selected for a case study in order to examining the EDCTP reality in the field in Africa. This qualitative study should be carried out in the Ministry of health, the Ministry of Secondary, Higher Education and Scientific research, the Ministry at the office of the President in charge of Analysis & Prospective, the European Union delegation, the research institutions, as well as with individual researchers.

One epidemiologist carried out the interview in a total of 14 institutions, using semi-structure questionnaires. Data analysis was implemented manually.

It was found that the Ministries are not aware of the letter of the African Union (initiated by the EDCTP High Representative) to the head of state introducing the EDCTP and only the Ministry of Health knew the existence of the programme.

The European Union Delegation does not receive briefing notes or reports from the Headquarter in Brussels. They did not undertake actions to raise the EDCTP profile, in addition to their financial contribution.

As regard research institutions, they do not have much link with the EDCTP boards, but they work in networks with a few sub-regional or regional institutions. They operate to gain and retain partner by strengthening their institution through human resources development, well-tailored communication and advocacy, efficiency and good management practices.

Their success in gaining EDCTP grants are related to the scientific pertinence of their proposal and their partnerships. However, the low competence of some young researchers sometimes constitutes a barrier to success.

On the whole, the EDCTP programme helped implement more than eight integrated projects in Burkina Faso in five years, and greatly contributed in capacity building. The initiative is acknowledged by all the research institutions and needs to be strengthened.

Nevertheless, some criticisms have been raised and could be taken into consideration through the following recommendations:

- The collaboration between the EC Headquarter in Brussels and Burkina Faso EC delegation should be strengthened; it is essential that EC delegation in the country has the important role to raise the EDCTP profile with the government and other partners in support to the High Representative advocacy activities.

- The co-funding policy should be revised and some exceptions or percentage reduction could be envisaged if relevant in order to avoid gift principal investigators awarded by European researchers to African counterparts and really facilitate the leadership of African researchers in grant proposal writing.

- EDCTP Africa Office needs to be more active in sharing information, organizing capacity strengthening and networking workshops, and motivating individual researchers and research institutions to submit their research proposals and results.

- EDCTP must assure that each integrated project has necessary funds for MSc and PhD trainings. This is not the case for the majority of projects funded in Burkina Faso.

- EDCTP project management should be more flexible and the time allocated for negotiation procedures reduced.

INTRODUCTION

The European and Developing Countries Clinical Trials Partnership (EDCTP) was established in 2003 by the European Commission as a response to the health crisis caused by diseases of poverty such as HIV/AIDS, malaria and tuberculosis, selected in the Millennium Development Goals. The programme is a funding mechanism for clinical research conducted by research teams in Europe and Africa (http://www.edctp.org/). Its initial budget was set at 600 million Euros. The European Commission has allocated 200 million Euros over five years for its funding. A group of interest comprised of 14 European Union country members, associated with Switzerland and Norway, participated in cash or in kind to this effort to the tune of 200 million Euros as well. This participation is through co-funding of projects won by researchers in the EDCTP tenders. Finally, the pharmaceutical industry, private foundations and other agencies are supposed to help finance the EDCTP up to 200 million Euros to complete the total budget announced at the launch of the program.

The goal of EDCTP is to accelerate the development of new clinical interventions to fight HIV/AIDS, malaria and tuberculosis in developing countries, particularly in sub-Saharan Africa. The EDCTP is led by a General Assembly composed of the European Union Member States. It is the body that makes all the decisions. The EDCTP is advised by a "Partnership Board which is actually, in fact, a scientific advisory committee. The EDCTP is managed by a Secretariat led by an Executive Director supported by a High Representative, for advocacy. It has an Africa Office based in Cape Town (South Africa) for networking, capacity building and support on-site projects funded.

The EDCTP conducts open calls for integrated projects. As illustrated in Figure 1, the main activity of the EDCTP is funding clinical trials in order to develop new drugs and new therapeutic, diagnostic and preventive strategies of HIV/AIDS, malaria and tuberculosis. But each clinical research project funded also became part of the networking activities North-South, North-North and South-South and capacity building (training, Master, PhD, scholarships for junior investigator initiation, senior researcher awards, support the establishment and operation of ethics committees and regulatory agencies for clinical research staff, salaries, purchase of research infrastructure, etc..). In late 2008, the EDCTP has funded 42 clinical trials and 163 networking activities and capacity building in 26 African countries federating 124 research institutions.

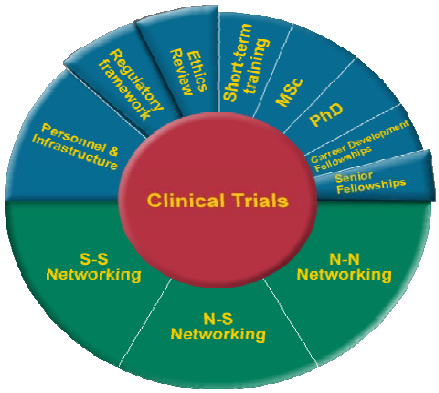

Figure1: Representation of EDCTP 2007-2010 integrated tenders.

The EDCTP was established on September 15, 2003 by the European Commission for a period of five years. It was planned that after five years of existence, an external evaluation should be conducted to locate the European Commission on progress and results achieved by the EDCTP. The findings of this report would help the Commission to consider the appropriateness of continuing the initiative or its cancellation when the

projects already funded would be completed.

Hence, a panel of six experts was convened by the European Commission to conduct the EDCTP external evaluation: Wim Van Velzen, Fernand Sauer, Professor Peter Piot, Dr Nicolas Meda, Professor Irmgrad Nippert and Professor Randa Kamal Raouf. As Dr Meda is the only member among the panel of selected experts who is coming from a sub-Saharan country, namely Burkina Faso, this country was considered for a case study.

Burkina Faso

Burkina Faso is a land locked nation located in West Africa. It is surrounded by six countries: Mali to the North, Niger to the East, Benin to the South East, Togo and Ghana to the South, and Côte d'Ivoire to the South-West. Its size is 274,222 km² (INDS, 2007). Formerly called the Republic of Upper Volta, it was renamed on August 4, 1984, by President Thomas Sankara to mean "the land of upright people" in Moré and Dioula, the major native languages of the country. On administrative plan, the country is divided in 13 regions, 45 provinces, 49 urban communes and 302 rural communes (INSD, 2007). Ouagadougou is the capital city of the country and Bobo-Dioulasso the second largest city.

The climate is tropical with two seasons: a dry season and a rainy season. The average rainfall varies between 300 mm in the North and 1 200 mm in the South. This rainfall is low and poorly distributed throughout the country. This greatly influences the availability of food and consequently the nutritional status of populations. The country is drained by three rivers: the Mouhoun, the Nazinon and Nakambé (INSD & ORC MACRO, 2004).

The population was estimated at 13,117,147 in 2006 with 48.28% of men and 51.72% of women (INDS, 2007). Life expectancy at birth was 55.8 years for men and 57.5 years for women, in 2006 (**INDS**, 2009).

The country currently occupies the second-last place on the Human Development Index. It has one of the lowest Gross Domestic Product (GDP) per capita incomes in the world: 1,200 International $ (PPP). Agriculture represents 32% of its GDP and occupies 80% of the working population. It consists mostly of livestock but also, especially in the South and Southwest, of growing sorghum, pearl millet, maize (corn), peanuts, rice and cotton (WIKIPEDIA, 2009).

The national research system is the result of the realization of two goals: the creation of an institutional framework for research activities and the creation of a higher education system. We can currently count roughly 13 research institutions involved in the field of health research in the country and located in Ouagadougou, Bobo-Dioulasso, Nanoro and Nouna (See in figure 2, the map of Burkina Faso below for the precise location of major health research centers).

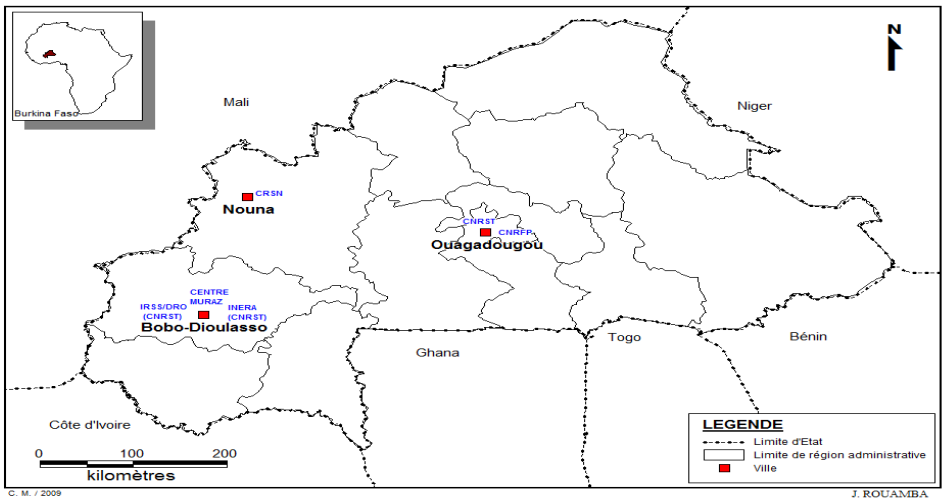

Figure 2. Localization of major research institutions in Burkina Faso, 2009

Objectives of the Burkina Case Study

Firstly, the objectives of external evaluation are:

1. To examine the performance of the EDCTP as:

driver of the integration of national programmes of EU Member States for research on HIV/AIDS, malaria and tuberculosis
operational structure (clinical trials funding, networking and capacity building activities)
symbol of partnership between Europe and African states in scientific research

2. To examine the role of the EDCTP in the broader international research and development agenda, taking into account the nature and values of the Programmes and its comparative advantages

3. To assess the economic, social and environmental impacts of EDCTP

4. In light of this assessment, draw possible lessons to be learnt and formulate recommendations for future initiatives of the European Commission in the same field.

The case study consisted in examining the EDCTP reality in the field in Africa, by considering Burkina Faso as a model country. This case study was planned to capture necessary information with the Ministry of Health, the Ministry in charge of scientific research, the Office of the Head of State, the European Union delegation in Burkina Faso, research institutions, and individual researchers.

METHOD

It is a qualitative study where four semi-structured questionnaires were designed according to the terms of reference, to conduct the interviews (Annex 4). One epidemiologist was selected to carry out the field work which consisted most of the time, of face-to-face interviews, completed with telephone and e-mail exchanges. The field work started from September 22nd, to October 18th. Data analysis was implemented manually.

RESULTS

1) List of visited institutions

Number	Institution name	Appointment for interview	Interview
1	Ministry of health	Obtained	Carried out
2	Ministry of Secondary, Higher Education and Scientific research	Obtained	Carried out
3	Ministry at the office of the president in charge of Analysis and Prospective	Not obtained	Not carried out
4	European Union delegation	Obtained	Carried out

5	University of Ouagadougou (UFR-SDS)	Obtained	Carried out
6	Saint Thomas d'Aquin University	Obtained	Carried out
7	University of Bobo-Dioulasso (INSSA)	Obtained	Carried out
8	Centre de Recherche Biomoléculaire Pietro Annigoni	Obtained	Carried out
9	Biomedical laboratory of Saint Camille	Obtained	Carried out
10	Institut de Recherche en Sciences de la Santé	Obtained	Carried out
11	Centre Muraz	Obtained	Carried out
12	Centre de Recherche en Santé de Nouna	Obtained	Carried out
13	Centre National de Recherche et de Formation sur le Paludisme	Obtained	Carried out
14	Centre International de Formation en Recherche-Action	Obtained	Carried out
15	West African Health Organisation	Not obtained	Not carried out
16	Institut Supérieur des Sciences de La Population	Not obtained	Not carried out
17	Laboratoire National de Santé Publique	obtained	Carried out

Among the 17 institutions visited, the interview was carried out in 14, representing a percentage of 82.35%.

2) List of independent researchers interviewed

Number	**Name**	**Appointment for interview**	**Interview**
1	Dr Seydou Ouattara	Obtained	Carried out

2	Dr Somé Eric	Not Obtained	Not Carried out
3	Dr Traoré Isidore	Obtained	Carried out
4	Dr Traoré Hugues	Not obtained	Not Carried out
5	Prof Lassana Sangaré	Obtained	Carried out
6	Dr Bicaba Abel	Not obtained	Not carried out
7	Dr Fao Paulin	Obtained	Carried
8	Mr Barro Seydou	Obtained	Carried out

A total of eight researchers were contacted and five of them were interviewed, i.e. 62.5%

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3) Concept of EDCTP in Ministries

3. 1 Ministry of Health

An appointment has been set up with an advisor of the Minister and he is well aware of the EDCTP programme. The Adviser is, in fact, the Director of the National Malaria Training and Research Centre who is also part of some EU ad hoc Scientific Review Committees.

The Secretary General and the Director of Studies and Planning were not available during the study period. The letter of African Union introducing EDCTP to the Heads of States is not known from the Ministry. Burkina Faso does not participate in the EDCTP programme with a co-funding, but it could be envisaged in the future. The national health research system tries to strengthen its research institutions, by motivating researchers, providing salaries, grants for training and equipments.

3. 2 Ministry of Secondary, Higher Education and Scientific research

The investigator met the Director General of Education and Scientific Research, and the Secretary General of the Ministry. They were not neither aware of the EDCTP programme before receiving the technical note, nor of the African Union letter introducing EDCTP to the Heads of States. They also mentioned the possibility of the government to be involved in EDCTP co-funding process in the future.

3. 3 Minister at the office of the President in charge of Analysis and Prospective

It has not been possible to set up an appointment with the Minister at the office of the President in charge of Analysis and Prospective, during the allocated time of the study.

4) Involvement of the European Union Delegation in EDCTP

The investigator was welcomed by the officer in charge of programmes, Economy division and social sectors. She has been appointed since February 2009 and is well aware of the EDCTP programme for being involved in her previous position. She explained that delegation of European Union in Burkina Faso did not receive briefing notes or reports from Brussels. However, she underlined that for the EU directly funded (FP6 for example) she was invited at QUALMAT project launching, entitled "Health care intervention research – improving pre-natal and maternal care", in Heidelberg (Germany) in 2009 and the project will involved Burkina Faso.

As regard strengthening the EDCTP profile with Burkina Faso government and other technical and financial partners, the European Union has not undertaken any action. The Officer at European Union delegation in Burkina Faso promised to improve this aspect.

The European Union delegation in Burkina Faso concluded by assuring us that they will manage to ameliorate communication with the Headquarter in Brussels. They wish they could be informed about projects currently implemented in the country and be invited to attend new projects launching.

5) Links of research institutions with the EDCTP Africa Office, the DCCC and the network of excellence

Except the *Centre National de Recherche et de Formation sur le Paludisme* (CNRFP) that has links with the EDCTP Africa Office and the Developing Countries Coordination Committee (DCCC), the Partnership Board Chair is part of its staff, other institutions do not collaborate with these boards. They do not have the opportunity to set up links and they are not familiar enough with the DCCC or General Assembly members to name them. EDCTP Africa Office has probably no mailing list of research institutions and individual researchers from Africa. As for sub-regional or regional networks, a few networks pompously called nodes of excellence have been mentioned by the interviewees:

- Réseau d'Afrique Francophone de Télémédicine (RAFT)
- Afro-immunoassay Network
- African Malaria Network Trust (AMANET)
- Agreement with University of Lomé
- Consortium Volta
- Réseau Corus-résistance
- INDEPTH (International Network of field sites with continuous Demographic Evaluation of Populations and Their Health in developing countries)
- ISHReCA (Initiative to Strengthen Health Research Capacity in Africa)

6) Gaining and retaining partners

Partnership is a key element of institution success as it allows useful exchanges for the benefit of all parties. Partnerships constitute centers of excellence, and synergize strengths of the partners. Therefore gaining and retaining partners should be included among priorities of research institutions.

Gaining partners can be achieved through institution strengthening framework which requires:

- Human resources development plan;
- Development/adaptation of technical and managerial tools and curricula;
- Adaptation, promotion and use of evidence-based best practices and strategies;

- Design of objectives and outputs based on institutional strategic and/or action plans;
- Development and implementation of well-tailored communication and advocacy plans. This point includes institutional lobbying, participation in conferences and scientific presentations, papers published in high impact journals.
- Improving management and financial systems and capability;
- Strengthening training approaches in key technical, managerial and leadership areas.

Retaining partners involves:

- Good management and financial system especially transparency;
- Seriousness in work and delivery in terms of scientific production;
- Efficiency in carrying out research projects.

7) Overview of projects submitted

Funded Projects

N°	Project title	Submission year	Partnership for submission	Project duration	Total cost (€)
1	Understanding the mechanisms underlying the difference in susceptibility to malaria in an area of hyper endemic malaria in Burkina Faso: The potential role of regulatory T cells		Principal Investigator (PI) CNRFP		
2	Capacity building to prepare West African sites for clinical trials on HIV, TB and Malaria	2005	PI Prof Mboup and CNRFP collaborators		99,800
3	Integrating capacity building and networking in the design and conduct of Phase I and II clinical trials of viral vectored candidate malaria vaccines in East and West African children and infants		PI Babatunde EMVI and CNRFP collaborators		
4	Fostering research capacity, networking and project management through phase I-IIB clinical trials of candidate malaria vaccine GMZ2.	2007	PI Ramadani Noor , AMANE and CNRFP collaborators		5,140,147

N°	Project title	Submission year	Partnership for submission	Project duration	Total cost (€)
5	Public health benefit of artemisinin-based combination therapies for uncomplicated malaria	2004	PI Abdoulaye Djimdé MRTC Mali CNRFP collaborators, Malaria Research and Training Center, DEAP, FMPOS, University of Bamako, Mali		
6	Evaluation of 4 artemisinin-based combinations for treating uncomplicated malaria in African children	2004	Institute of Tropical Medicine (ITM), Antwerp, Belgium	3 years	2 million
7	Safe and efficacious artemisinin-based combination treatments for African pregnant women with malaria	2008	Institute of Tropical Medicine (ITM), Antwerp, Belgium	4 years	3 million
8	Capacity development and strengthening in preparation for HIV vaccine trials in Tanzania and Burkina Faso	2008	Mwanza Intervention Trial Unit (Tanzanie), Kilimandjaro Christian Medical School (Tanzanie), Centre Muraz (Burkina), Université de Ouagadougou (Burkina), Université de Montpellier (France) Université de Milan (Italy), London School of Hygiene and Tropical Medicine (United Kingdom) Immuclin (France)	3 years	1 294 034

Project not funded

N°	Project title	Submission year	Partnership for submission	Project duration	Total cost (€)
1	Evaluation of the impact of the Intermittent Preventive Treatment of malaria with Sulfadoxine Pyrimethamine during pregnancy on infants malaria morbidity in a stable transmission setting : a randomized control trial				

8) Financing projects

Facilitators to success

- Scientific relevance and quality of projects submitted
- Quality of results
- Partners established
- Credibility of researchers
- Confidence of partners

Barriers to success

- Call for proposals are limited in term of research areas, preventing some researchers to submit projects;
- Call for proposals circuit mechanism is not well known;
- Low competence of young researchers;
- Deadline for submitting short.

9) EDCTP Project Management

Although the EDCTP project management rules are found to be acceptable by some interviewees, most of them described them as rigid and difficult. Negotiation procedures take a lot of time and the budget forms are very complicated. There is a lack of flexibility as regard funds using. The management is even seen as implemented at a micro-management level, without taking into consideration some local realities.

It had also been underlined that some project budgets accepted were further reduced, causing implementation problems. **Some MSc and PhD budgets were not allocated in the total budget although been accepted during the project submission**.

10) Comments and criticisms

In addition to the critics related to project management, it has been pinpointed the problem of co-funding. This rule could prevent some relevant projects to be carried out because of lack of co-funding. Moreover the co-funding policy could also be a barrier towards a real leadership emergence from Africa. In effect the co-funding partners set up their own rules which may affect the project implementation process as originally defined by the research team.

Another point is related to the Secretariat which manages the calls for proposals. Some researchers are not informed about the calls and wish it could be improved.

Notwithstanding these critics, Burkina Faso researchers globally appreciate the EDCTP programme and wish it could be strengthened.

11) Needs

11.1 In terms of research funding

Many projects have still to be validated by the scientific review committee

- Project “African-European HIV Vaccine Development Network II (AfrEVacc II)” costing 3,923,004.00 Euros;
- Project in the field of malaria treatment;
- Project related to malaria immunopathogeny;
- Infrastructure strengthening (laboratories, clinics, archive rooms etc.).

11.2 In terms of strengthening human resources

Strengthening human resources is a key element of capacity building which is a process that improves the ability of a person, group, organization, or system to meet its objectives or to perform better. In other words, it is a process that aims to instill commitment and improve fundamental management and technical skills within an organization, thereby making the institution more effective and sustainable.

In Burkina Faso research institutions, the needs in terms of strengthening human resources are:

- Training for Masters of Science and PhD;
- Capacity building in the fields of administration, finances, medical statistics, research ethics, data management and project management;
- Training in English.

11.3 In terms of networking

In term of networking, there is a need of broaden the partnership between the country institutions with other ones, as well as in the sub-region and in the world. Furthermore, means of telecommunication such as internet and telephone should be improved. Some institutions request more computers and information system software.

12) Expectations and suggestions

In order to improve the secretariat management of calls for proposals, it is suggested that a mailing list of all the research institutions be established and be used accordingly.

The management process could be improved with more collaboration between scientific and financial team during the follow-up period.

It is expected that EDCTP programme be extended. Thereby other infectious diseases or relevant public health problems which can be studied through clinical trials or operational researches could be taken into consideration. As regard the fighting against malaria, it had been suggested that medical entomology be considered.

Finally, the institutions that are not currently working with the EDCTP wish they could be involved in the programme and promise to submit proposals in forthcoming calls.

CONCLUSIONS AND RECOMMENDATIONS

In conclusion, the EDCTP programme helped implement more than eight integrated projects in Burkina Faso in five years, and greatly contributed in capacity building. The initiative is acknowledged by all the research institutions and needs to be strengthened. Nevertheless, some criticisms have been raised and could be taken into consideration through the following recommendations:

- The collaboration between the EC Headquarter in Brussels and Burkina Faso EC delegation should be strengthened; it is essential that EC delegation in the country has the important role to raise the EDCTP profile with the government and other partners in support to the High Representative advocacy activities.

- The co-funding policy should be revised and some exceptions or percentage reduction could be envisaged if relevant in order to avoid gift principal investigators awarded by European researchers to African counterparts and really facilitate the leadership of African researchers in grant proposal writing.

- EDCTP Africa Office needs to be more active in sharing information, organizing capacity strengthening and networking workshops, and motivating individual researchers and research institutions to submit their research proposals and results.

- EDCTP must assure that each integrated project has necessary funds for MSc and PhD trainings. This is not the case for the majority of projects funded in Burkina Faso.

- EDCTP project management should be more flexible and the time allocated for negotiation procedures reduced.

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INDS (2007) Le Burkina en chiffres.

INDS (2009) Annuaire statistique. Edition 2008.

INSD (2003) Annuaire statistique.

INSD & ORC MACRO (2004) Enquête Démographique et de Santé du Burkina Faso 2003. Calverton, Maryland, USA: INSD et ORC Macro.

WIKIPEDIA (2009) Burkina Faso.

APPENDICES

1) Terms of reference

Burkina Faso case study: framework of method and questions to interviewees

1. **Visit Ministries in Burkina Faso** to check awareness (Africa Union letter to all Heads of States introducing EDCTP), visibility and potential efforts of the government of Burkina Faso to strengthen EDCTP programme (co-funding?) and national health research system?

   Ministry of Health

   Ministry of Secondary, Higher Education and Scientific research

   Minister at the Office of the President in charge of Analysis & Prospective

2. **Visit EU Delegation** in Burkina Faso to check awareness, briefing from Brussels, visibility of EDCTP programme in Burkina Faso and potential efforts of the EU delegation to raise EDCTP profile with national governments and other financial and technical partners

3. **Map all the research institutions** in Burkina Faso

   Check awareness, visibility and any attempt to win EDCTP grant

   Check any link to EDCTP Africa Office main activities

   Check their needs in terms of research financing

   Check their needs in terms of capacity building and they operate to strengthen institutions and individuals?

   Check their needs in terms of networking and how they operate to gain and retain partners?

4. **List successful institutions** to EDCTP grants

   Check facilitators to success

   Check any link to EDCTP Africa Office

   Check any link to DCCC?

   Check any link to sub-regional node of excellence?

   Check how easy is it in running EDCTP project?

   Request from evidence of results already obtained?

   Request comments, critics, suggestions, needs, expectations in order to improve the management of EDCTP project?

5. **List unsuccessful institutions** to win EDCTP grants

   Check barriers to success

   Check any link to EDCTP Africa Office

   Check any link to DCCC

   Check any link to sub-regional node of excellence

Request from comments, critics, suggestions, needs, expectations in order to improve their ability to win EDCTP grant

6. **Find individual researchers involved** in EDCTP activities

   Check facilitators to join EDCTP programme

   Check any link to EDCTP Africa Office

   Check any link to DCCC

   Check any link to sub-regional node of excellence

   Request from evidence of results already obtained or any achievement?

   Check for their views, concerns, needs, critics, suggestions and expectations

7. **Find individual researchers not involved** in EDCTP activities

   Check barriers to join EDCTP programme

   Check any link EDCTP Africa Office

   Check any link to DCCC

   Check any link to sub-regional node of excellence

   Check for their views, concerns, needs, critics, suggestions and expectations

2) Supporting documents

PROJETS FINANCES PAR EDTCP AU BURKINA – OCT.2009

MALARIA

1. **Intermittent preventive therapy with SP for the prevention of malaria in pregnancy: Regimen optimization studies in Africa**

Type of Grant: Integrated Projects

Title of call: Malaria in Pregnancy (2007) : 12.08-12.12

EU contrib.: € 3,648,811

Total cost : € 6,243,458

2. **Fostering research capacity, networking and project management through phase I-IIB clinical trials of candidate malaria vaccine GMZ2**

Type of Grant: Integrated Projects

Title of call: Malaria Vaccines (2007) : 01.09-01.14

EU contrib. : € 5,140,147

Total Budget: € 9,863,901

3. **Ant malarial treatment for African pregnant women**

Type of Grant: Integrated Projects

Title of call: Malaria in Pregnancy (2007) : 02.09 – 02.13

EU contrib. : **€ 2,953,678**

Total Budget: € 5,993,753

HIV

1. **Capacity development and strengthening in preparation for HIV vaccine trials in Tanzania and Burkina Faso**

Type of Grant: Clinical Trial

Title of call: Preventive HIV vaccine trials (2006) : 03.08 – 11.11

EU contrib.: **€ 2,435,071**

Total Budget: € 5,138,535

2. **Placebo-controlled trial of the efficacy and safety of infant peril-exposure prophylaxis with lamivudine to prevent HIV-1 transmission by breastfeeding**

Type of Grant: Clinical Trial

Title of call: Mother to child transmission of HIV prevention (2006) :04.08–03.12

EU contrib. : **€2.800000**

Total Budget: €12,199,421

Total investment of EU in health projects in Burkina Faso: €16.98M (by 08.10.09).

3) List of persons met

N°	Name	Institution
1	Pr Sawadogo Mamadou	Université de Ouagadougou
2	Pr Jacques Simporé	Université Saint Thomas d'Aquin, Laboratoire Biomédical Saint-CamilleCentre de recherche Biomoléculaire(CERBA)

3	Mr Yé Luc	Ministère des Enseignements Secondaire, Supérieur et de la recherche Scientifique (MESSRS)
4	Pr Sanou Salaka	MESSRS
5	Pr Dao Blami	Université de Bobo Centre Hospitalier Universitaire Souro Sanon (CHUSS)
6	Dr Kouyaté Bocar	Ministère de la Santé Centre National de Recherche et Formation sur le paludisme (CNRFP)
7	Dr Sirima Sodiomo	CNRFP
8	Dr Ouattara Seydou	Centre Muraz
9	Dr Tinto Halidou	Centre Muraz Institut de Recherche en Sciences de la Santé (IRSS)
10	Mrs Lorraine Gallagher	Délégation de la commission Européenne au Burkina Faso
11	Dr Dabiré K. Roch	Centre Muraz, IRSS
12	Mrs Sombié Djamilat	Centre International de Formation en Recherche-Action (CIFRA)
13	Dr Ky/Ba Absétou	Laboratoire National de Santé Publique (LNSP)
14	Dr Coulibaly Sheick Oumar	LNSP
15	Dr Sangaré Karim	Centre Hospitalier Universitaire Souro Sanon (CHUSS)
16	Mr Barro Seydou	CHUSS
17	Dr Traoré Isidore	Site ANRS Burkina/UFR-SDS/Université de Ouagadougou Association KASABATI
18	Dr Fao Paulin	Centre Muraz
19	Dr Ali Sié	Centre de Recherche en Santé de Nouna

ANNEX 9

Documentation for the

Independent External Evaluation of EDCTP

Documents received during the evaluation were put on a dedicated internal Website (CIRCA/EDCTP Independent External Evaluation) accessible to the panelists and to the Commission services concerned.

The CIRCA site was also used to archive the agendas, minutes and internal documents exchanged between the members of the IEE Panel. An indicative list of the main source material received by the IER panel is given below.

1) List of EDCTP documents

1.1) Establishment of EDCTP

Co-Decision N°. 1209/2003/EC, 16 June 2003

Incorporation EDCTP-EEIG, 26 June 2003

Grant Agreement F169-CT-2003-980429, 15 December 2003

1.2) Internal Regulations and self-assessment

Internal Regulations 2004 and revised Internal Regulations, 09 Aug 2006

Internal Assessment of the 2003/2009 EDCTP Programme, SCIH 28/10/2009

1.3) No-cost extension and roadmap

Request for extension of term from Chair, D. Dunstan, to the Commission

DCTP Roadmap approved by the GA, 22 Nov 2006 (submitted along with JPA and JPB 2006, Dec 2006)

1.4) Activities of EDCTP

Annual report 2005 to 2008

Interim Technical Report 2004 to 2008

Minutes of all EDCTP governing bodies meetings since July 2007

1.5) Court of Auditors

Court of Auditors report 2005

Court of Auditors report 2008

Court of Auditors Special Report N 10 EC development assistance to health services in Africa

1.6) Additional documentation provided by EDCTP to the IEE panel

D. Dunstan, Chair GA_EDCTP- Comments for IEE Group, 3/09/2009

From C. Mgone_EDCTP Executive Director

EDCTP briefing to the European Commission Independent External Evaluation Panel, 15/07/2009

Annexes to briefing 15/07/2009

Further Briefing for IEE Panel_31/07/2009_

Recommendation from the EDCTP-EEIG for a second EDCTP Programme

EDCTP Forum 2009_Programme at a glance

EDCTP: Business plan and national certificates

EDCTP Plan encouraging participation and funding from the private sector

Personal communications from A. Kitua, Chair DCCC: P Chinok and Dirk Van Drost, Chair ENNP:

From W. Salami: Overview of Approved Budgets.pdf

SOP02_Development_of_Call_for_Proposals_Aug_2008_Approved.pdf

SOP04_Review_Procedure_Aug_2008_Approved.

SOP06_Activation_of_Projects_Aug_2008_Approved.pdf

SOP07_Monitoring_and_Reporting_Aug_2008_Approved.

SOP10_Cancellation_of_Projects_Aug_2008_Approved.

EDCTP guidelines for ethical reviews and full documentation on clinical trials (request by R. Kamal).

Site visits reports, Approved Clinical trials proposals and reports.

2) Documents provided by the Commission

Independent External Review Report, 12/07/2007

Communication on Progress of EDCTP, COM (2008)688 of 30/10/2008

Commission staff working document SEC (2008)2723 of 30/10/2009

First Action plan (2008/2010) for the Africa EU Strategic Partnership

The EU role in Global Health, Issue paper, 14/10/2009

3) Press on EDCTP (non exhaustive selection)

Article in Nature Medicine on EDCTP and EU HIV vaccine, Aug 2005

Lehner et al "EU and EDCTP strategy: recommendations for preventive HIV vaccines research", Vaccine, 2005

Lancet editorial "Europe's science bureaucrats should learn from Gates' success", Jul 2005

G8 St. Petersburg – Fight against infectious diseases, July 2006

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