

Note from the High Representative

Dear Readers,



It is my honour and privilege to introduce to you the second quarterly issue of the EDCTP newsletter for 2012. After approximately eight years of progression of the Partnership, EDCTP is now in its phase of consolidation while the second phase of the programme (EDCTP-II) is imminent.

This is a time to reflect upon and evaluate the past successes and challenges, sharpening focus and making strategic extensions of the vision of the future programme. The European Commission has made a head start on the preparatory arrangements by awarding EDCTP a Coordination and Support Action (CSA) grant, part of Framework Programme 7 (FP7), to facilitate laying the foundation for EDCTP-II. The title of this project is EDCTP-Plus.

I therefore call upon all EDCTP Partners especially political leaders and policy makers in Africa, Europe and other collaborating regions to renew and strengthen their alliance and commitment to this programme in the fight against poverty related diseases. EDCTP plans to hold a series of high level meetings both in Europe and Africa with the aim of raising political awareness, sharing progress made in the first phase of the programme and seeking country endorsement and ownership of EDCTP-II.

This newsletter features some of the ongoing EDCTP activities in the field and those under review; plans to strengthen collaboration with the Private Sector; and updates from the Governance, Advisory Partnership Structures and Executive Secretariat of EDCTP.

Enjoy your reading.

Dr Pascoal Mocumbi
EDCTP High Representative

Meetings

Symposium Europe and ACP against tuberculosis

In advance of World Tuberculosis Day 2012 the Tuberculosis Vaccine Initiative (TBVI) organised a symposium in which high level speakers from the group of African, Caribbean and Pacific states and Europe discussed how to support the fight against tuberculosis. The meeting was hosted in Brussels in the European Parliament by Member of Parliament Mr Charles Goerens.

Tuberculosis vaccine research is complex and costly and demands a global approach. Prof. Charles Mgone, EDCTP Executive Director held a presentation on 'How EDCTP strengthened North-South collaboration in tuberculosis clinical trials'. Dr Jelle Thole, Director of TBVI, presented the new research blueprint developed by the tuberculosis vaccine community: 'Tuberculosis Vaccines: a Strategic Blueprint for the Next Decade', following the Second Global Forum on TB Vaccines convened by Aeras and TBVI in 2010.

LSHTM Conference on Intervention Research

On 29 and 30 March the London School of Hygiene and Tropical Medicine held a symposium to celebrate 40 years of the MRC Tropical Epidemiology Group. The theme of the conference was 'Intervention Research to Improve Health in Developing Countries: Progress and Future Challenges'. The programme included sessions on HIV, tuberculosis and malaria as well as on maternal, neonatal and child health, vaccines and non-communicable diseases.

EDCTP Executive Director, Prof. Charles Mgone participated in the panel on 'Funder perspectives on intervention studies' together with representatives from the Medical Research Council, the Department for International Development, the Wellcome Trust and the Bill and Melinda Gates Foundation. Prof. Tumani Corrah (MRC The Gambia and member of the EDCTP Partnership Board) and Prof. Saidi

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EDCTP published on its YouTube channel two short videos as contribution to **World Tuberculosis Day, 24 March 2012**, and **World Malaria Day, 25 April 2012**, respectively.
(www.youtube.com/edctpmedia)

Kapiga (Harvard School of Public Health and coordinator of an EDCTP funded study) presented views from the field.

EDCTP Governance

EDCTP-Plus

EDCTP has received funding from the European Commission for a programme of activities known as EDCTP-Plus which will be carried out during 2012 and 2013. The aim of EDCTP-Plus is to ensure that the EU-Africa research partnership remains strong and to lay the foundation for implementing and managing the EDCTP-II programme in view of the proposed expansion of scope and increased budget. These activities, distinct from the current EDCTP research activities, will be funded by Framework Programme 7 through a Support Action Grant.

The EDCTP-Plus work programme aims to lay the foundation for the proposed EDCTP-II programme which is expected to start in January 2014. A number of related priority areas and activities have been identified. These include the mapping of national programmes and research activities related to major poverty-related and neglected infectious diseases in order to strengthen integration and alignment of African and

European research activities. Following on from the work to increase engagement with the private sector which was funded by the member states, EDCTP will work closely with a range of potential partners including Small and Medium sized Enterprises (SMEs), like-minded organisations, non-EDCTP partner countries and relevant funding agencies and stakeholders to identify priority areas for future research collaboration.

The current EDCTP programme has been praised for its contributions to capacity development and contribution to the coordination and networking of researchers and institutions in Africa and Europe. Related follow-on activities will consolidate and reinforce these achievements through continued support to ethics and regulatory institutions, the Pan-Clinical Trial Registry and the regional Networks of Excellence. Communications and advocacy activities will ensure the visibility of EDCTP-funded activities and that all stakeholders are informed during this critical period.

Finally, EDCTP's operational processes and systems will be improved and updated in order to ensure that the operational systems and management are ready for a programme of expanded scope and budget. In order to ensure that the impact of EDCTP-II can be closely measured a robust evaluation framework will also be developed.

In the coming months further information will be shared on stakeholder meetings, advocacy events and publications arising from these activities. To support this programme of work, EDCTP is currently in the process of recruiting new members of staff for the positions of Networking Manager, Networking Officer, and IT Officer who will be introduced in due course.

New staff members

A new Project Officer, Michelle Singh, has been appointed at the Africa Office. Wendy Morrill joined the EDCTP office in The Hague as Administrative Officer. Recruitment for all other vacancies is ongoing.



Michelle Singh - Project Officer

In April, the EDCTP Africa Office in Cape Town welcomed Dr Michelle Singh (South Africa) as the new Project Officer in the Calls & Grants team. Over the past ten years, she has

conducted research on the prevention of mother-to-child transmission of HIV. In 2010, she completed her PhD thesis at the University of KwaZulu-Natal on the subject of 'Pharmaco-immunological and virological dynamics of intrapartum HIV-1 transmission following single-dose Nevirapine for prevention of mother-to-child HIV-1 transmission'. Previously, Michelle Singh worked on various clinical and laboratory-based research studies in the fields of cancer, tuberculosis, STI's, infant feeding, and neonatal jaundice. She has a Master of Medical Science degree from the University of Natal (2003).



Wendy Morrill - Administrative Officer

Wendy Morrill (USA) joined EDCTP as Administrative Officer in April 2012. Wendy earned her Bachelor's degree in Sociology and

Women's Studies from the University of New Hampshire and her Master's degree in Sociology from the New School for Social Research in New York. Prior to joining EDCTP, she worked as Coordinator of Membership and Career Development at the European Haematology Association. Before moving to the Netherlands in 2007, Wendy lived in New York City and worked in various fundraising capacities at The Children's Aid Society, London School of Economics Foundation and American Committee for the Weizmann Institute of Science.

Partnership Board

The Partnership Board (PB), the independent scientific board that advises the General Assembly met in The Hague on 12 April 2012. The board discussed ongoing activities of the Secretariat and preparations for EDCTP-II. The PB also discussed the review of the 2011 applications for the calls Member States Initiated (MSI) projects, Ethics and Senior Fellowships, and procedures for monitoring the progress of ongoing EDCTP activities. Two new members were welcomed: Prof. Marie-Louise Newell and Dr Dawit Wolday. They bring considerable expertise in the areas of cross-cutting issues and HIV respectively. Their term of service will be effective as of February 2012.

Developing Countries Coordinating Committee

The 28th meeting of the Developing Countries Coordinating Committee (DCCC), EDCTP's independent advisory body of prominent African scientists and health professionals, took place at the EDCTP Africa Office in Cape Town (South Africa) from

15–16 March 2012. Two new members attended the meeting. Prof. Gita Ramjee of the Medical Research Council HIV Unit in Durban (South Africa) replaced Prof. Nkandu Luo (now honourable Minister of Local Government of the Republic of Zambia) as

HIV focal person for Southern Africa. Dr Abraham Aseffa Scientific Director of the Armaeur Hansen Research Institute in Addis Ababa (Ethiopia) replaced Prof. Mecky Matee as TB focal person for Eastern Africa.

At the meeting DCCC members provided advice to the Secretariat on the implementation of capacity building activities in the transition period between 2012 to the beginning of EDCTP-II in 2014. Preparations for the joint Seventh EDCTP Forum and the African launch of EDCTP-II were also discussed.

Regarding the EDCTP regional Networks of Excellence, the DCCC discussed the indicators developed for monitoring progress made by these networks. All members reported on their engagements with the Ministers of Finance and Ministers of Science and Technology in their respective countries. For the purpose of this engagement the DCCC has produced a draft strategy document. The work plan for 2012 also foresees DCCC participation in site visits by the Secretariat to EDCTP-funded projects.



Participants of the DCCC meeting on 15-16 March 2012

General Assembly

The upcoming meeting of the General Assembly (GA), the body that governs EDCTP, will be held at the Statens Serum Institute in Copenhagen, Denmark on 14 May 2012. The General Assembly will discuss the Annual Report 2011, ongoing business and preparations for the second programme.

On the following day, 15 May, the Danish Presidency of the European Union will host a meeting to present the opportunities and benefits of EDCTP membership. Representatives from EDCTP member states and European non-member states are invited to share their views regarding participation in the proposed second programme under Horizon 2020.



Winner of EDCTP photo contest

The First EDCTP photo contest closed on 16 April 2012. The total number of participants was 21 who submitted a total of 75 photos. EDCTP would like to thank them for their efforts. Through the contest EDCTP sought to capture different aspects of the many research, capacity building and networking activities from the perspective of project collaborators. Considering the quantity and quality of the submissions, it was decided to identify one winner irrespective of category. The winner of the First EDCTP photo contest is Dr Quique Bassat (CRESIB, Spain).

A young patient receives medication with an intravenous drop. She is a participant in a clinical trial for antimalarial drugs (Manhiça, Mozambique).



Calls and grants

Calls under review

MSI (August 2011)

The MSI grant scheme provides funding for networking and cooperation between two or more projects/programmes within the scope of EDCTP that have been independently initiated and/or are funded separately by Member States. Four applications were received by the 15 December 2011 deadline of the MSI 2011 Call. These applications are under review and final recommendations will be reviewed by the GA in May 2012.

Senior Fellowships (August 2011)

An open call for Senior Fellowships was launched in August 2011, resulting in 32 applications by the December deadline. The scheme supports mid-career to senior researchers capable of building and leading research groups at sub-Saharan African institutions. These applications are under review by an independent panel of scientific experts and the final recommendations will be reviewed by the GA in May 2012. Funds are available to support six fellowships.

Ethics NEC/IRB (August 2011)

An Ethics call for proposals to support the establishment and strengthening of National Ethics Committees (NEC) and Institutional Review Boards (IRB) in sub-Saharan Africa was launched in August 2011. The call sought applications from IRBs and countries that had not received EDCTP funding previously. A total of 28 applications were received. These applications are under review by an independent panel of scientific experts and the final recommendations will be reviewed by the GA in May 2012. Funding for ten awards is available.

Open call

Strategic Primer Grant (December 2011)

The Strategic Primer Grant Call for Proposals was published on 12 December 2011. The scheme provides pump-priming to allow researchers to explore novel and innovative lines of research that may lead to the development and testing of new or improved clinical interventions against HIV/AIDS, malaria or tuberculosis.

Applicants are requested to demonstrate how their proposal will:

- Generate results to inform future clinical trials
- Sustain and strengthen the capacity built up under EDCTP-I
- Increase networking of African and European Member States' research programmes

This Call for Proposals involves a two-step application process, with 89 Letters of Intent received by 14 February 2012. Of these, 74 Letters of Intent were found to be eligible for further assessment and were sent out for further review. 32 Letters of Intent were shortlisted for submission of full proposals. The full applications will be peer-reviewed, then considered by a Scientific Review Committee, whose recommendations will go via the Partnership Board to the GA for final approval by 31 July 2012. Successful applicants are expected to sign the EDCTP grant contracts by 30 September 2012. The quality of proposals received was high and this call is expected to be very competitive.

Funded projects

EDCTP is pleased to announce funding of the following projects:

Call: Establishment and Strengthening of African National Ethics Committees and Institutional Review Boards

Establishing a local Institutional Ethics Committee / IRB at the Faculty of Medicine, University 'Eduardo Mondlane' and the Maputo Central Hospital in Maputo, Mozambique

Project Coordinator: Prof. Albertino Damasceno (University Eduardo Mondlane Faculty of Medicine, Maputo, Mozambique)

Budget: €44,550

Duration of the project: March 2012–September 2013

Strengthening research ethics capacity of the Mbale Regional Hospital Institutional Review Committee

Project Coordinator: Dr Peter Olupot-Olupot (Mbale Regional Hospital Institutional Review Committee, Mbale, Uganda)

Budget: €42,922

Duration of the project: March 2012–March 2013

Capacity building programme for Centre Muraz Institutional Review Board of Bobo-Dioulasso, Burkina Faso

Project Coordinator: Abdoulaye Ouedraogo (Centre Muraz Research Institute)

Budget: €49,900

Duration of the project: March 2012–September 2013

Call: Senior Fellowships

Rifabutin with lopinavir/ritonavir in patients co-infected with tuberculosis and HIV in Burkina Faso: a pilot study of pharmacokinetics for definition of the minimum effective dose

Project Coordinator: Dr Seni Kouanda (Institut de Recherche en Sciences de la Santé, Ouagadougou, Burkina Faso)

Budget: €189,919

Duration of the project: March 2012–March 2014

Inflammatory determinants of risk of tuberculosis disease

Project Coordinator: Dr Thomas Scriba (University of Cape Town, South Africa)

Budget: €199,046

Duration of the project: March 2012–March 2014

A randomised controlled trial to explore adherence-failure relationships in a South African antiretroviral delivery site using an electronic adherence device and population pharmacokinetic sampling

Project Coordinator: Dr Catherine Orrell (University of Cape Town, South Africa)

Budget: €199,276

Duration of the project: February 2012–February 2014

Enhancing HIV prevention trial capacity in Eldoret, Kenya through baseline incidence study on two HIV prevention priority populations

Project Coordinator: Prof. Edwin Were (Moi University, Department of reproductive Health, Eldoret, Kenya)

Budget: €199,334

Duration of the project: February 2012–February 2014

Focus on Projects for Microbicide Trials

HIV still continues to spread rapidly especially among women in developing countries. In the fight against HIV/AIDS a recent approach is the development of microbicides that can be applied inside the vagina or rectum to prevent infection with HIV through sexual transmission. The availability of non-contraceptive microbicides in the form of a gel, cream, vaginal ring or suppository would greatly empower women to protect themselves and their partners as women could easily control its use.

The positive results of the CAPRISA 004 Phase IIb microbicide trial first conducted in South Africa suggested the feasibility of such an approach. EDCTP funded three studies aimed at the development of clinical, laboratory and field facilities and at training staff to conduct trials of vaginal microbicides. All projects have been successfully completed. While consecutive microbicide trials have yielded disappointing results, the achievements of these projects in terms of establishing cohorts and research capacity, will continue to contribute to HIV research in sub-Saharan Africa.

Preparing for phase III trials in Rwanda and Kenya

Dr Janneke van de Wijgert from the Centre for Poverty-related Communicable Diseases (CPCD) of the Academic Medical Center (AMC), University of Amsterdam in the Netherlands, led a project to prepare research sites in Kigali, Rwanda and Mombasa, Kenya. Phase III effectiveness trials of microbicides have to be conducted in female populations with a high incidence of heterosexually-acquired HIV. HIV incidence data is crucial in the planning, design and interpretation of microbicide trials and the target populations of such trials are generally HIV-negative, high-risk populations.

During the site preparation, HIV incidence was estimated by cross sectional and longitudinal cohort studies. The cohort studies evaluated the sites' recruitment and retention strategies, and assessed other relevant outcomes for microbicides studies, including reproductive tract infections and pregnancy rates. The HIV incidence studies in Kigali and Mombasa were completed successfully in 2010.

The project improved the clinical laboratory and data management infrastructure and provided training to a wide research community. The capacity building through this project also established the reproductive health clinic at the Kigali Teaching Hospital, increasing treatment options for cervical cancer and infertility. Moreover, the study results have been instrumental for the Rwandan Ministry of Health to develop a new HIV prevention policy focusing on female sex workers. The results from the human papilloma virus (HPV) study will be useful in the evaluation of the newly implemented

national cervical cancer screening and HPV vaccination program.

Project Ubuzima has received the 'best achiever awards' from the International Partnership for Microbicides (IPM) and has been selected as an IPM phase III clinical trial site. The successful Rwanda-Kenya-Belgium-Netherlands collaboration will continue in the next few years under the EDCTP funded Biomarkers project led by Dr Kishor Mandaliya entitled 'Characterisation of novel microbicide safety biomarkers in East and South Africa'.

Site preparation in Tanzania and Uganda

Prof. Richard Hayes of the London School of Hygiene and Tropical Medicine (United Kingdom) coordinated a project to expand the capacity for phase I, II and III clinical trials of candidate vaginal microbicides in Tanzania and Uganda. The project demonstrated that the study populations of women at high risk of contracting HIV in both Tanzania and Uganda are suitable for the implementation of future trials of microbicides or other HIV prevention tools, with high HIV incidence and high retention rates. As a result of the studies, the Medical Research Council MRC (United Kingdom) funded a project titled "Intravaginal practices in Tanzania and Uganda: Relationships with the vaginal microenvironment, HIV and other STIs" which was carried out in close collaboration with the EDCTP project. The research was to understand better the potential risk factors for HIV infection among women in Sub-Saharan Africa.

In Mwanza, Tanzania research infrastructure required to test new interventions, including microbicide trials, was successfully established. Research team members were trained to conduct research according to international scientific and ethical standards. A system to recruit and follow-up women working in these settings and retain them in active follow-up for a period of up to one year was developed. A strong community liaison system was established to ensure effective communication between researchers, the participants, and other local stakeholders. Collaboration between researchers and local health officials was a key to the success of research activities at the sites.

In Uganda, the first female high risk cohort which was set up, provided important information for policy makers and scientists. The new clinical trial site is ready to conduct studies while the established high-risk cohort will enable new multi-discipline HIV research.

Preparing for microbicide trials in Mozambique

Dr Sheena McCormack of the MRC coordinated a project to establish HIV microbicide clinical trial

capacity in Mozambique and expand on an existing site in South Africa. The objectives of this study were to conduct a microbicide feasibility and pilot study in Mozambique under the umbrella of the Microbicides Development Programme (MDP); and to build capacity at the Reproductive Health and HIV Research Unit (RHRU) in Johannesburg, South Africa. Clinical infrastructure was improved in order to complete this site's targets for the phase III MDP301 microbicide trial exploring the PRO 2000 vaginal gel. Regrettably, this MDP301 effectiveness trial, which enrolled almost 9,400 women in four African countries, found no evidence that the PRO 2000 microbicide, although safe, reduced the risk of vaginal transmission of HIV-1 infection.

On the basis of the experience already gained through the feasibility and pilot studies and the MDP 301 clinical trial, RHRU staff provided support to the Mozambique team to implement and co-monitor similar studies. Through this project, capacity for clinical trials has been built in two Mozambican research centres in Manhica and Maputo.

The TopUp study sought to determine the feasibility of conducting a microbicide trial of a daily vaginal gel and to study the way adherence should be assessed. Adherence measurement in microbicide trials relies heavily on self-reported data and although such data can be unreliable, a multi-method data collection strategy, comprising case report forms, in-depth interviews and coital diaries, was shown to provide more consistent estimates of adherence. The trial, the first related to microbicides in Mozambique, started in June 2010 and finished follow up of volunteers in November 2010. A total of 75 women were screened of whom 63 were enrolled. With respect to the daily placebo gel, women found it acceptable and the reported adherence was higher than expected at 79% overall, albeit lower than reported in MDP301 when women were instructed to use a single dose of gel prior to sex.

This feasibility study, which aimed to evaluate the population and study site in the Healthcare centres of Mavalane and Manhica in preparation for a possible Phase III vaginal microbicide trial, provided the first incidence data in Mozambique. These results complemented the national ante-natal data and raised awareness of the HIV health threat among policy makers.

The project was realised in collaboration with the International Partnership for Microbicides; the Community Development Foundation and the Instituto Nacional de Saúde (Mozambique); the Department for International Development, the Medical Research Council and the Imperial College London (United Kingdom), the University of Barcelona (Spain); the University of Witwatersrand (South Africa); and Endo Pharmaceuticals Solutions.

Focus on Ethics Projects

Since the ethics grant scheme took off in 2005, EDCTP has awarded a total of 64 grants for projects to strengthen ethics capacity in sub-Saharan Africa. Ten more grants are awaiting approval by the EDCTP General Assembly in May 2012 and under the EDCTP-Plus project further support is planned. The aim of the grant scheme is to strengthen the ethics framework of sub-Saharan institutions and countries. The ultimate aim is to develop the appropriate human resource and infrastructure required to enable functional, competent, independent and sustainable ethics review boards in Africa.

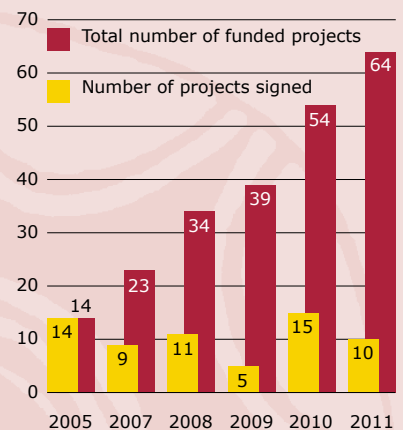
The funded projects fall into three categories, i.e. training projects, institutional development and networking. An example of each category is provided here. The training of members of ethics committees or institutional review boards is supported for instance through the development of online training programmes. Grants have been awarded to both European and African organisations such as TRREE for Africa (Training and Resources in Research Ethics Evaluation for Africa) and the ERECCA (Enhancing Research Ethics Capacity and Compliance in Africa) online courses on Good Clinical practice and Ethics Research Ethics Review led by Prof. K. Moodley (University of Stellenbosch, South Africa). More formal training courses resulting in a diploma or certificate have also been supported. For

example, ten members from the National Health Research Ethics Committee in Nigeria received support to obtain a diploma in research ethics. Moreover, courses on Good Clinical Practice (GCP) and Human Subjects Protection training are often part of larger projects.

Grants for support, establishment and strengthening of ethics capacity at both the institutional and national level form the second category. The purpose of these grants is to contribute to the establishment of independent and functional Institutional Review Boards and National Ethics Committees (NECs). For example, in 2005, EDCTP funded a project for the "Establishment and support of a National Ethics Committee in Gabon" awarded to the Ministry of Health of Gabon and was coordinated by Dr Pierre-Blaise Matsiegui. Today, the Gabonese NEC is leading initiatives on establishing an even broader network involving Ethics Committees in the Central African region.

The objective of the third group of projects is to network and coordinate and thereby support national ethics initiatives. For example, the first objective of the Southern African Research Ethics Network (SAREN) is to establish a network of Chairpersons of sub-Saharan Research Ethics Committees. The MARC (Mapping African Research Ethics and Drug Regulatory Capacity) project aims to create an interactive, online map of the capacity to conduct ethics review of health research in all African countries.

Number of ethics projects funded by year



Through this grant scheme, ethics research committees have been established in countries which previously had few resources for ethics, such as Benin, Democratic Republic of Congo, Liberia and Rwanda and have been strengthened in other countries. Grants contributed to improving infrastructure and office equipment. In many cases websites were set up to facilitate sharing of information, and documents such as Standard Operating Procedures which are essential to the operation of the ethics review committee and guidelines were prepared according to templates provided by the World Health Organisation. In total, 29 ethics projects have been successfully completed so far.

Websites:

TRREE: elearning.trree.org

ERECCA: t2000-05.sun.ac.za/erecca/index.html

MARC: researchethicsweb.org



Number of ethics projects funded per country

Five ethics grants are coordinated from European countries (Austria, Switzerland and United Kingdom).

The EDCTP Newsletter is available in three languages namely English, French and Portuguese in electronic format on our website (www.edctp.org). To receive the electronic format, please subscribe online (www.edctp.org, click on Newsletter sign up).

European & Developing Countries Clinical Trials Partnership

EDCTP – Europe Office

P.O.Box 93015, 2509 AA The Hague
The Netherlands
Tel: +31 70 344 0880
Fax: +31 70 344 0899

EDCTP – Africa Office

P.O.Box 19070, Tygerberg 7505, Cape Town
South Africa
Tel: +27 21 938 0819
Fax: +27 21 938 0569

E-mail: info@edctp.org

Web: www.edctp.org