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Executive Director's Note



*Prof. Charles Mgone,
EDCTP Executive Director*

The previous quarter was very busy and eventful at EDCTP. A series of stakeholder and constituency meetings kept our travel and other departments on a twenty-four-hour alert throughout the period. That is why I take this unusual step of publicly thanking and congratulating them for a job well-done. The outcome of the stakeholders meetings, progress of some projects and new grant calls are all announced in the current issue of the newsletter. As the result of this hard work, I am glad to announce that between July and August, EDCTP will launch eight new calls. These will be based on our new approach of integrating clinical trials with capacity development and networking activities to ensure successful and sustainable outcomes as well as utilisation of the developed capacity.

The Secretariat staff in collaboration with the High Representative continued their site visits. They visited EDCTP funded projects in Zimbabwe, where they met with the involved research scientists as well as relevant government leaders. These visits are very useful for not only assessing the progress of the projects but also for identifying capacity gaps and involving African leadership.

The EDCTP capacity building activities that were conducted (some of which are reported in the newsletter) include the GCP course at Banjul, the Gambia, the Project and Data Management Course at Johannesburg, South Africa, the launch of the ATM Clinical Trials Registry at Cape Town, South Africa and two Global Network Training Courses on Regulatory Affairs that were conducted in collaboration with WHO in Harare, Zimbabwe.

Therefore as we launch the current series of grant calls we look forward to a very busy time to come and wish everyone successful outcomes.

News about EDCTP Governance

During the General Assembly meeting that took place on 28 June, the following appointments of DCCC and PB members were approved:

Appointment of Developing Countries Coordination Committee (DCCC) members

- Dr Christopher (C.E.S.) Kuaban (Cameroon)
- Dr J. Johnstone Kumwenda (Malawi)
- Dr Mecky Isaac Matee (Tanzania)
- Dr Steven Velabo Shongwe (Swaziland)

Appointment of Partnership Board (PB) members:

- Dr Christian Burri (Switzerland)
- Dr Eric Gunnar Sandström (Sweden)
- Dr Rosemary Mubanga Musonda (Zambia)
- Dr Shabbar Jaffar (United Kingdom)

News about Calls and Grants

Funded projects

EDCTP is pleased to announce funding of the following projects:

Training Awards	Career Development
	Ifedayo Adetifa, Nigeria: "Immunologic, diagnostic and epidemiologic studies for improved phenotyping of Mycobacterium tuberculosis infection and disease for the purpose of a therapeutic trial of the Bacille Calmette Guerin (BCG) vaccine in The Gambia"
	Esperança Sevene, Mozambique: "Intensive safety monitoring of antimalarial and antiretroviral drugs in pregnancy"
	Senior Fellowship
Networking	Ambrose Otau Talisuna, Uganda: "Safety of artemisinin derivatives-based combination therapy in children with uncomplicated malaria and population-based pharmacovigilance: a capacity strengthening proposal for pharmacovigilance of antimalarial drugs in Africa"
	Badara Cisse, Senegal: "A Pilot Study of the Implementation of Seasonal Intermittent Preventive Treatment with Community Participation in Senegal"
Clinical Trials	Coordination and Networking of research activities in Africa
	Concepta Merry, Ireland: "Networking of European and sub-Saharan African research and capacity building in pharmacology"
	Capacity Building for the conduct of phase I/II and Phase III trials of vaginal microbicides against sexual transmission of HIV
	Richard Hayes, United Kingdom: "Site preparation and capacity strengthening for trials of vaginal microbicides in Tanzania and Uganda"
	Sheena McCormack, United Kingdom: "Establishing HIV microbicide clinical trial capacity in Mozambique and expanding an existing site in South Africa"
Clinical Trials	Capacity building and site development for the conduct of phase III trials of TB vaccines in high risk populations
	Anja van 't Hoog, The Netherlands: "Prospective epidemiological studies of TB in neonates and adolescents in Karemo Division, Siaya district, Western Kenya, in preparation for future vaccine trials"
Clinical Trials	Support of studies for the Prevention of Mother To Child Transmission of HIV, including prevention of transmission during breast feeding
	Marie Louise Newell, The Netherlands: "Impact of HAART during pregnancy and breastfeeding on MTCT and mother's health: The Kesho Bora Study"

Stakeholder and consultative meetings

Between May and June, EDCTP held a series of stakeholder and consultative meetings. A summary of the main recommendations of these meetings is summarised in the following table. Full reports of all meetings will be made available at our website very soon.

Theme	Main recommendations
Malaria vaccines	Launch an open call to support phase II malaria vaccines clinical trials in Africa, including age de-escalating trials. These may include safety, immunogenicity and efficacy trials in target populations including infants and children depending on transmission intensity and prior exposure.
Tuberculosis vaccines	Launch 2 open calls. The first call should be launched in 2007 with the main objective to support the conduct of Phase IIa or IIb clinical trials of tuberculosis vaccines in African countries. These may include safety, immunogenicity and efficacy trials in target populations such as infants or populations at high risk of exposure. The second call should be launched in 2008 with an emphasis on support of smaller proof of principle studies of around € 400,000 each with a focus on new upcoming TB vaccines such as recombinant vaccines that are not yet ready for testing in 2007.
Regional Networks of Excellence	Launch open call to support 4 regional consortia of research institutions to form Regional Networks of Excellence for Clinical Trials. The networks will be responsible for organising mentorship programmes and training of staff members working at African institutions where clinical trials will be conducted. They will also undertake epidemiological and demographic surveys that facilitate the planning of trials and support less established institutions to enable them to participate in multicentre clinical trials. Such support shall include design of trials, data management, quality assurance and any required laboratory techniques.
HIV/AIDS treatment	Launch open call for phase IV clinical trials with a focus on second line treatment. This should look into issues such as when to switch from first to second line treatment; what products to switch to; and monitoring of treatment. This should also address paediatric treatment issues such as fixed-dose combinations in children and possibly include PK studies.
Tuberculosis treatment	Launch brokering initiative for a clinical development programme to optimise the use of moxifloxacin and high dose rifamycins to shorten the duration of therapy to less than 4 months. This will be through a consortium formed to conduct the necessary Phase I and II trials that will culminate in pivotal Phase III trials.
Microbicides	Launch an open call for phase II cooperative clinical trials that are linked to phase III trials to answer various questions including identification of suitable biomarkers, immunology, effects of microbicides on sexually transmitted infections, timing of use in relation to the menstrual cycle, and frequency of use.
Ethics	Strengthening of ethics review mechanism where EDCTP is supporting clinical trials or likely to do so should be given priority. This should concentrate on making Ethics Review Committees operational and done in collaboration with all stakeholders. Furthermore there should be mapping of who is doing what and what kind of activities are currently taking place or already in place. The mapping exercise should have wide ownership and conducted through an open call or by outsourcing to organisations such as the Pan-African Ethics Initiative (PABIN).
Regulatory affairs	Outsource implementation of the priority activities to WHO after getting responses from other partners on activities of interest to be supported by them. It was further recommended that both the Department of Immunization, Vaccines and Biologicals; and Department Technical Cooperation for Essential Drugs and Traditional Medicine (TCM) of WHO should be involved.
Malaria treatment	To conduct phase IIIb trials which may include PK studies on special groups including children and HIV-infected individuals as well as phase II trials if new drugs become available.
Malaria in pregnancy	Conduct phase II clinical trials on case management and prevention of malaria in pregnancy through an open call. Case management investigations should emphasise on safety and efficacy. 4 million Euros should be earmarked for this. Clinical trials on prevention should have at least two arms and may include PK studies, testing of alternatives to SP, HIV-infected mothers and have birth weight as one of the end-points. 5mn Euros should be earmarked for this.
HIV vaccines	Will be held in Antwerp, Belgium on 7 September 2007.

Upcoming calls

EDCTP is happy to announce that the following calls have been launched on 6 July:

- Malaria vaccines
- TB vaccines
- Senior Fellowships

The following calls will be launched later this summer:

- Malaria treatment
- Malaria in pregnancy
- Regional networks of excellence for conducting clinical trials in sub-Saharan Africa.
- Support for Ethics Review Committee

In addition EDCTP will announce a brokering initiative for TB treatment. An alert will be sent out at the actual launch date.

All calls will be open for applications for a period of at least 4 months. With the exception of the call for support of Senior Fellowships, all calls are based on the main recommendations of the EDCTP stakeholder meetings on these topics that were held earlier this year (see article 'Stakeholder and consultative meetings' in this newsletter).

Please consult the EDCTP website (www.edctp.org) for more details on these calls and how to apply.

Focus on EDCTP grantees

Launch of ATM Clinical Trials Registry

We are delighted to announce that the HIV/AIDS, Tuberculosis and Malaria clinical trials registry (ATM Registry) was officially launched on 22 May 2007. The ATM Registry was launched during the inaugural African Cochrane Contributors' Meeting hosted by the South African Cochrane Centre in Cape Town. The registry was cofunded by EDCTP.

The registry is disease-specific and will serve the sub-Saharan African region. It is fully compliant with the clinical trial registration specifications set out by the International Committee of Medical Journal Editors as well as the World Health Organization's International Clinical Trials Registry Platform. In order to avoid duplication of efforts the registry will be working closely with the South African Department of Health, who have recently established a national clinical trials register, as well as other established registers around the world. It is now open for registration and the registry's website has gone live since the end of June 2007.

We hope that the registry will bring together researchers, health professionals, healthcare consumers and policy makers from all parts of Africa.

For more information go to www.atmregistry.org or contact Liesl Grobler at the South African Cochrane Centre (Email: liesl.grobler@mrc.ac.za; Telephone: +27219380506; Fax: +27219380836).

Good Clinical Practice (GCP) training course at MRC Gambia



Good Clinical Practice Training workshop, 07-11 May Banjul, Gambia: EDCTP, MRC and Swiss Tropical Institute collaboration

From 7 to 11 May 2007, a Good Clinical Practice training course took place at the MRC Gambia in Banjul. The course was a collaboration between EDCTP, the Medical Research Council and the Swiss Tropical Institute.

Lack of training in Good Clinical Practice (GCP) and Good Clinical Laboratory Practice (GCLP) has been repeatedly noted to be one of the main capacity gaps in the majority of the African institutions that were seen during the EDCTP site visits. To address this, EDCTP in collaboration with the Swiss Tropical Institute and the Medical

Research Council (UK) organised a GCP training workshop for research institutions in Africa that are conducting EDCTP funded projects.

The course was conducted over five days, with five half-day sessions of teaching and discussion of theoretical concepts, and three half-day workshops with practical case studies. The course covered the various topics including:

- Principles of drug and vaccine development with respect to HIV/AIDS, TB and malaria
- Current international ethical and regulatory guidelines for clinical research
- Clinical study designs and planning
- The roles and responsibilities of research personnel according to ICH-GCP guidelines
- Development of Standard Operating Procedures (SOP's) and GLP regulations applicable to field conditions
- Monitoring and auditing of clinical trial sites
- Basics of clinical data management and documentation skills.

The course was attended by a total of 35 participants including study clinicians, data managers, laboratory scientists and technologists and clinical trials nursing managers. The research institutions represented included Kigali National Malaria Control Programme (NMCP), Rwanda; Blantyre Malaria Programme (BMP), Malawi; Kilimanjaro Christian Medical Centre (KCMC) and Kibong'oto National TB Hospital, Kilimanjaro Tanzania; Centre Muraz, Bobo Dioulasso, Burkina Faso; University Teaching Hospital of Lusaka, Zambia; Tropical Disease Research Centre in Ndola, Zambia; and the University of Calabar, Nigeria.

Workshop for Project and Data Management for Clinical Trials

Twenty one delegates from a variety of organisations based in Europe and Africa came together in Johannesburg, South Africa on 20 to 22 June to discuss learning objectives for a training course for clinical trialists. This training course covered the topics on project management, data management and monitoring (Project title: Identifying the common learning needs of investigators working in poverty-related diseases in African settings, and the materials to address these, notably in the areas of project and data management).

Meetings and visits

Site visit to Zimbabwe

From 16 to 20 April, members of EDCTP staff visited a number of funded sites in Zimbabwe. The EDCTP team consisted of Dr Pascoal Mocumbi (EDCTP High Representative), Mr Simon Belcher (Director of Finance and Administration) and Dr Michael Makanga (Capacity Development Manager). Among the sites visited were the Biomedical Research and Training Institute (BRTI), the University of Zimbabwe Clinical Research Centre and the Medical Research Council of Zimbabwe (MRCZ).

The team had meetings with the scientists and management personnel from various institutions:

The Biomedical Research and Training Institute (BRTI), Harare

The team visited the clinical trial patient recruitment sites at Marondera Hospital and Beatrice Road Infectious Disease Hospital (BRIDH). The BRTI research will conduct an EDCTP supported clinical trial to evaluate high dose rifapentine and a quinolone in the treatment of pulmonary tuberculosis, with Dr Amina Jindani as Principal Investigator and Drs Ronnie Matambo and Elizabeth Corbett of Biomedical Research and Training Institute (BRTI) as the Zimbabwean investigators.

The University of Zimbabwe Clinical Research Centre - University of California in San Francisco Collaboration (UZ-UCSF), Harare

UZ-UCSF directed by Dr Peter Makuhunga, is involved in research interventions aimed at improving reproductive and sexual health. The team visited one of the five clinic facilities in Chitungwiza. The University of Zimbabwe is the hosting institution for Professor Lynn S. Zijenah, member of the Developing Countries Coordinating Committee (DCCC) for HIV/AIDS representing the southern African region.

The National Institute of Health Research (NIHR), Harare

The team visited the Malaria and HIV/AIDS unit. NIHR hosts the Medical Research Council of Zimbabwe (MRCZ).

The African Institute of Biomedical science & Technology (AIBST), Harare

AIBST is part of an EDCTP funded multicentre project on "Optimisation of tuberculosis and HIV co-treatment in Africa: Pharmacokinetic and pharmacogenetic aspects on drug-drug interactions

between rifampicin and efavirenz". Dr Collen Masimirembwa, the chief scientific officer of AIBST, is the Zimbabwean investigator for this study.

The Medical Research Council of Zimbabwe (MRCZ)

MRCZ is involved in two ethics capacity strengthening projects: (i) A project for building national capacities in health research ethics, ethical review and clinical trial monitoring in Zimbabwe; (ii) A project to strengthen the Medical Research Council of Zimbabwe, with Mrs Rosemary Musesengwa and Mrs Shungu Munyati as coordinators respectively.



Dr Pascoal Mocumbi and Mr Simon Belcher pose with the Medical Research Council of Zimbabwe (MRCZ) staff in front of their newly purchased vehicle

The Zimbabwe Medicines Control Authority (MCAZ)

The MCAZ is the legal body mandated for regulation of medicines and allied substances in Zimbabwe. The team met with the Director General, Dr MN Dauramanzi, Deputy Director, Dr Rutendo and the chair person of the National Ethics Committee of Zimbabwe (MRCZ) as well as the Director of Technical Services of MCAZ, Dr GN Mahlangu.

The EDCTP team had separate meetings with several officials including the Minister of Health and Child Welfare, Dr PD Parirenyatwa; the WHO Representative in Zimbabwe, Dr EK Njelesani; The First Secretary European Union, Delegation of the European Commission in Harare, Mr Bart Missinne.

Events

Update on the EDCTP Fourth Annual Forum

Preparations for the fourth EDCTP forum to take place in Ouagadougou (Burkina Faso) are well underway. EDCTP has received over 180 applications for registrations. It is envisaged that high government officials will attend the opening of the forum. EDCTP is grateful to European Member States who have indicated that they will contribute funding of bursaries at a cost of € 4,000 each. These include 10 from Irish Aid, 10 from MRC UK, 2 from Netherlands, 3 from Spain, 2 from Sweden, 3 from Italy, 10 from Belgium and 1 from Austria. More bursary support is being requested from other well-wishers. Information about the forum is continually being updated on the EDCTP website (<http://www.edctp.org/forum2007>).

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