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**Executive Director's Note**

As we enter the last quarter of 2007 I am glad to note the continuing relentless pace of the EDCTP programme. Following the stakeholder meetings held during the previous quarters, we launched 8 calls worth nearly €130 million in July and August. EDCTP will launch three more calls to support clinical trials in the fields of HIV vaccines, microbicides and treatment before the end of the year. In keeping with the increased pace of rolling out grants and therefore increased activities in Africa, Dr Pascoal Mocombi has moved to the EDCTP Africa Office in Cape Town since September 2007. He will continue his role as the High Representative, and will focus on more closely engaging African leadership. To cope with the increased grant activity, and the departure of some staff, I am glad to welcome Dr Nnemdi Kamanu Elias, Dr Montserrat Blázquez Domingo and Ms. Lara Pandya in the Projects team and Ms Patricia Sáez in the Administration section. They all have proven to be very valuable additions to the Partnership.

EDCTP has continued with site visits to EDCTP funded projects. These visits collect information about ongoing EDCTP funded activities, identify capacity development requirements and provide an opportunity for the visiting team to meet with African leadership and policy makers. In the previous quarter, an EDCTP team visited institutions in Kenya and Uganda as reported in this current issue of the newsletter. In addition, there have also been several EDCTP supported networking meetings and training workshops. This includes a recent meeting for regional networks of excellence whose outcome we eagerly anticipate.

**News about EDCTP Governance**

**EDCTP welcomes new staff members**



**Dr Nnemdi Kamanu-Elias** has joined the EDCTP Secretariat as Projects Manager. She is a medical doctor and a citizen of Nigeria and the United States. She studied medicine at Yale University and obtained a Masters in Public Health from the University of California, Berkeley. She gained considerable experience in the treatment of HIV/AIDS patients while practicing in the United States. Before joining EDCTP, she worked in Tanzania with the Centers for Disease Control (CDC) as Programme Director for HIV/AIDS Care and Treatment in Dar es Salaam, within the framework of the US President's Emergency Plan for AIDS Relief (PEPFAR).

**Dr Montserrat Blázquez Domingo** has joined as Project Officer to be part of the Projects team. Born in Barcelona, Montserrat carried out BSc and MSc studies in biochemistry and molecular biology, and holds a PhD degree in cell and molecular biology. Previously, she has worked as scientific copy-editor and journal administrator for two international journals (FEMS Immunology and Medical Microbiology and FEMS Reviews) at the Publications Division of the Federation of European Microbiology Societies in Delft (Netherlands).



**Lara Pandya** was born in England and has joined EDCTP as Project Officer to be part of the Projects team. Lara studied Geography at the the University of Bristol and graduated with First Class (Hons) Master of Science. Following this, she worked at Kingston Hospital in Surrey where she was responsible for managing legal matters and handled clinical negligence claims made against the hospital. Lara moved to The Netherlands in September 2005 and worked for the Amsterdam office of Parexel firstly as Clinical Lead Assistant and later as Contracts Specialist, providing her with experience of Clinical Trials management and contracts negotiation.

**Patricia Sáez** was born in Spain, where she studied English Philology. After teaching English for several years, she moved to South Africa where she worked as a lecturer of Spanish at the University of South Africa and obtained a Diploma in Translation. Later on, she worked for different Diplomatic organizations as a secretary. She has recently arrived in The Netherlands to join EDCTP as an Administrative officer.



## News about Calls and Grants

### Calls open for application

In the previous EDCTP Newsletter we had announced calls that were launched on 6 July. On 3 August several more calls were launched. Shown below is an overview of all calls that are currently open for application.

#### Malaria

- Clinical trials, capacity building and networking in malaria vaccine development  
Available funds: a minimum of € 14,500,000  
Deadline for application: 19 November 2007
- Clinical trials, capacity building and networking in malaria treatment  
Available funds: a minimum of € 9,100,000  
Deadline for application: 26 November 2007
- Clinical trials, capacity building and networking in malaria in pregnancy  
Available funds: a minimum of € 9,100,000  
Deadline for application: 26 November 2007

#### Tuberculosis

- Clinical trials, capacity building and networking in tuberculosis vaccine development  
Available funds: a minimum of € 9,000,000  
Deadline for application: 5 November 2007
- Phase I, II and III clinical trials on new drugs and improved drug combinations for the treatment of tuberculosis  
Available funds: a minimum of € 14,000,000  
Deadline for application: 17 September 2007

#### Cross-cutting capacity building activities

- Senior Fellowship  
Available funds: € 1,200,000  
Deadline for application: 12 November 2007
- Establishment and strengthening of African National Ethics Committees or Institutional Review Boards  
Available funds: € 450,000  
Deadline for application: 05 November 2007
- Establishment of regional networks of excellence for clinical trials and South-South mentorship programmes  
Available funds: a minimum of € 10,000,000  
Deadline for application: 03 December 2007.

For more information about these calls and how to apply, please visit our website at [www.edctp.org](http://www.edctp.org).

## Funded projects

EDCTP is pleased to announce funding of the following projects:

<b>Capacity Building</b>	<b>Support establishing or strengthening of National Ethics Committees or Institutional Review Boards</b>
	Ministry of Public Health, Republic of Gabon: "Establishment and support of a National Ethics Committee in Gabon"
<b>Clinical Trials</b>	<b>Capacity building and site development for the conduct of phase III trials of TB vaccines in high risk populations</b>
	Howard Engers: "Capacity building for the conduct of ICH-GCP level TB vaccine trials in high risk populations in Ethiopia and East Africa"
	<b>Capacity building and site development for the conduct of phase III trials of TB vaccines in children under 1 year of age</b>
	Philippa Musoke: "Towards conducting phase III trials of novel TB vaccines in Ugandan infants and adolescents"

## EDCTP stakeholder meeting in HIV vaccines

The EDCTP stakeholders' meeting on HIV vaccines was the last in a series of such meetings focusing on specific disease topics within the EDCTP scope. The HIV vaccine stakeholder meeting was organised by EDCTP and the Prince Leopold Institute of Tropical Medicine, Belgium. The aim of this meeting was to help EDCTP to identify and prioritise potential products in the pipeline and suggest suitable sites to do the trials as well as make recommendations on the funding procedure for these projects. In addition, EDCTP wanted to have preliminary information about the financial commitment and participation of the Member States for clinical trials on HIV vaccines.

Although there was no clear cut recommendations, bearing in mind the scope and merit of EDCTP as well as the current landscape, the majority of the opinion seemed to favour conducting a phase II preventive vaccine trial.

The meeting was chaired by Dr José Esparza, Senior Advisor on HIV Vaccines at the Bill & Melinda Gates Foundation.

The report of the meeting is available on the EDCTP website at [www.edctp.org](http://www.edctp.org).

## Networking meeting for establishment of regional Networks of Excellence

EDCTP organised a meeting for potential institutional applicants for its call for proposals to establish regional networks of excellence. This call will support the development of networks of collaborating institutions or clinical trial sites to expedite the conduct of clinical trials on HIV/AIDS, tuberculosis

and malaria in sub-Saharan Africa. These networks will enable less developed institutions to participate in multicentre trials through mentorship and training programmes and will allow for facilitated planning of trials.



*Participants of the EDCTP regional networks of excellence meeting Cape Town – 20 September 2007*

The meeting was in response to the networks of excellence stakeholders' meeting recommendations that suggested availing an opportunity for regional discussions between institutions to come up with joint proposals. It took place at the EDCTP Africa Office in Cape Town, South Africa. EDCTP, through the Developing Countries Coordinating Committee (DCCC), invited participating institutions from all regions of Africa. 29 African institutions were represented at the meeting.

All regional networks are expected to submit their proposals to EDCTP before the 2 December 2007 deadline, after which the proposals will be subject to peer-review before selection for funding in the first quarter of 2008.

The networks of excellence meeting was followed by a DCCC meeting held at the same venue.

## Focus on EDCTP grantees

### Global Training Network (GTN) workshops

From 18 to 29 June, Global Training Network (GTN) workshops on authorisation and monitoring of clinical trials and Good Clinical Practice were held in Harare, Zimbabwe with the financial support of EDCTP. These important training workshops are part of the WHO Global Training Network (GTN) activities and are aimed at strengthening the regulatory framework to ensure appropriate oversight of clinical trials in Africa. The official opening and closure of this training was done by the WHO representative to Zimbabwe, Dr E.K. Njelesani.

The main goal of these workshops was to provide representatives of African National Regulatory Authorities (NRAs) and Ethics Review Committees with the necessary expertise and capacity to:

- Conduct scientific and ethical review of clinical trials applications that are submitted to ethical and regulatory bodies
- Authorise the importation of clinical batches
- Authorise the conduct of clinical trials

The first workshop on Authorisation of Clinical Trials was held in December 2006 in Ouidah, Benin. It targeted 11 French-speaking countries. The second course held in June in Harare was for English speaking countries that included Uganda, Ethiopia, Tanzania, Malawi, Mozambique, Botswana, Ghana, Nigeria, The Gambia and Zimbabwe. Participants from NRAs, Ethics Committees and Research Institutions from these countries attended the training.

Another workshop focussed on Good Clinical Practice (GCP). This GCP inspection course was delivered for the first time in Africa as a result of a collaboration between Developing Countries Vaccine Regulatory Network (DCVRN) with the national Department of Health, Medicines Regulatory Affairs in South Africa, National Agency of Drug and Food Control of Indonesia, the Collaborative Centre on Cold Chain Management in South Africa, University of Cape Town and the Ministry of Health in Turkey. The training material is based fully on adult learning methodologies.

### Meetings and workshops from EDCTP networking grant

With an EDCTP grant on networking of European and sub-Saharan African research and capacity building in pharmacology, Dr Concepta Merry organised a workshop at the Grand Imperial Hotel, in Kampala Uganda from 26 to 30 June. The workshop brought together delegates from a variety of organisations based in Europe and Africa to discuss their current research portfolio, key priority areas for research, identify opportunities for synergy and outline a strategy for future research applications.

A consensus paper on the role of clinical pharmacology in supporting the fight against HIV/AIDS, tuberculosis and malaria was drafted. As part of our ongoing commitment to capacity building, the workshop also provided a one-day training to staff and students at the Department of Medicine, Pharmacology and Pharmacy as well as at the Infectious Diseases Institute of Makerere University.

### Start of Phase II trial of intravenous artesunate for children with severe malaria

A multicentre Phase II trial of intravenous artesunate started recruiting patients in September this year. The €5.3 M trial, funded by EDCTP and sponsored by Medicines for Malaria Venture (MMV) is being conducted in Gabon and Malawi. It is evaluating the efficacy of two intravenous artesunate dosing regimens in clearing *Plasmodium falciparum* parasites in children with severe malaria. The trial protocol has been approved by the ethics committees and national regulatory authorities in Malawi and Gabon.

The Press release is available on the EDCTP website at [www.edctp.org](http://www.edctp.org)

### HIV/AIDS infected children can now benefit from a European and Developing Countries Clinical Trials Partnership (EDCTP) funded trial

In August, the United States (US) Federal Drug Administration (FDA) gave a tentative approval to a fixed-dose anti-HIV drug specifically formulated for paediatric use. The fixed-dose combination scored tablet of lamivudine 30mg, stavudine 6mg and nevirapine 50mg (Triomune Baby) and double this strength (Triomune Junior) is manufactured by CIPLA pharmaceuticals. It is administered twice daily, according to a simple weight-based table, allowing for easy prescribing. It can also be 'snapped in half' and dissolved in water for young children who cannot swallow tablets. As a result of this tentative approval, this FDC antiretroviral drug will be included in the World Health Organisation (WHO) Prequalification Programme and will become available for distribution under the Presidents Emergency Plan for AIDS relief (PEPFAR) and Clinton Foundation programmes. EDCTP, the funder of the pharmacokinetic study leading to this tentative approval, congratulates Professor Chifumbe Chintu from the School of Medicine and Department of Paediatrics, University Teaching Hospital, Lusaka and his Zambian team, along with research collaborators from the Netherlands and the Medical Research Council (MRC) Clinical Trials Unit, United Kingdom on their work. Triomune Baby and Junior have already been approved in Zambia and are currently being used to treat children there.

The Press release is available on the EDCTP website at [www.edctp.org](http://www.edctp.org)

## Meetings and visits

### EDCTP site visit to Kenya



*EDCTP visit to Ting'wang'i health centre in Karemo Nyanza province in Kenya*

From 16 to 20 July, EDCTP visited EDCTP supported institutions in Kenya. The EDCTP team consisted of Dr Pascoal Mocumbi (High Representative), Mr Simon Belcher (Director of Finance and Administration) and Dr Michael Makanga (Capacity Development Manager). The team had meetings with the scientists and management of Kenya Medical Research Institute (KEMRI)/Centre for Disease Control (CDC) Kisumu, The Kenya Medical Research Institute (KEMRI) headquarters, Pharmacy and Poisons Board, Ministry of Health, Kenya, and a number of high officials from various institutions.

#### **Kenya Medical Research Institute (KEMRI)/Centre for Disease Control (CDC) Kisumu**

The team visited KEMRI/CDC field research station in Kisian Kisumu and its clinical trial patient recruitment sites at Siaya-Gem and Karemo at Ting'wang'i Health Centre. KEMRI/CDC Kisumu is involved in a prospective epidemiological study of the prevalence and incidence of TB infection and TB disease in adolescents in Karemo division, Siaya district, Western Kenya; and a prospective epidemiological study of TB in neonates in Western Kenya.

#### **The Kenya Medical Research Institute (KEMRI) head quarters**

The team met with Dr Davy K. Koech the Director and Chief Executive of KEMRI and Dr Phoebe Josiah, the Chief Research Officer and Head of Corporate Relations. KEMRI provides scientific and ethical oversight for various EDCTP supported projects in Kenya.

#### **Pharmacy and Poisons Board, Ministry of Health**

The team met with Dr Ahmed I. Mohamed, the Deputy Registrar and Head of Training and Assessment, and Dr Jayesh M. Pandit the head of Pharmacovigilance. The Pharmacy and Poisons Board is the legal body mandated for the regulation of medicines and allied substances in Kenya.

The EDCTP visiting team together with the DCCC member Dr Walter Jaoko had separate meetings with several officials including the Permanent Secretary of the Ministry of Science and Technology, Professor Crispus M. Kiamba; the Chief Science Secretary, Dr Rispah N. Oduwo; the Head of the European Union delegation in Kenya, ambassador Eric van der Linden; the WHO Resident Representative to Kenya, Dr David O. Okello; the Vice Chancellor University of Nairobi, Professor G.A.O Magoha; Deputy Vice Chancellor University of Nairobi, Professor Jacob T. Kaimenyi; Director of the Office of International Programmes, Professor Kenneth Muema Mavuti; and the Chairperson of the University of Nairobi Institutional Ethics Committee, Professor Kirana Bhatt among others.

### EDCTP site visit to Uganda

From 13 to 17 August, EDCTP visited various institutions involved in EDCTP supported activities in Uganda. The EDCTP team consisted of Dr Pascoal Mocumbi, Mr Simon Belcher and Dr Michael Makanga. The team had meetings with the scientists and the management of the Uganda Virus Research Institute (UVRI), the Makerere University Medical School in Mulago, the Uganda Malaria Surveillance Project (UMSP), the Uganda National Council for Science and Technology (UNCST) and the Uganda National Regulatory Authority (UNRA).

#### **Uganda Virus Research Institute**

The team visited the Medical Research Council (MRC)/UVRI Uganda Research Unit on AIDS, the UVRI/International AIDS Vaccine Initiative (IAVI) HIV Vaccine Programme and the Centre for Disease Control (CDC)/UVRI Entebbe. MRC/UVRI is involved in two EDCTP supported projects namely site preparation and capacity strengthening for trials of microbicides in Tanzania and Uganda and pattern of HIV-1-specific CD8+ T-cell epitope recognition following HIV-1 infection.

UVRI/IAVI vaccine programme is involved in a project on 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. Dr Pontiano Kaleebu is the Ugandan principle investigator.

#### **Makerere University Medical School in Mulago**

Makerere University Institute of Infectious Disease (IDI) is involved in two projects namely towards the conducting phase III trials of novel TB vaccines in Ugandan infants and preparations for a phase III trial

of a TB vaccine in adolescents in Uganda.

The Department of Pediatrics is involved in a multicentre phase III double blind placebo/controlled trial of the efficacy and safety of infant peri-exposure prophylaxis with lamivudine to prevent HIV-1 transmission by breastfeeding (PROMISE-PEP trial)

**The Uganda Malaria Surveillance Project (UMSP)** which involves academic researchers and Uganda ministry of health, is involved in various EDCTP supported projects including evaluation of 4 artemisinin-based combinations for treating uncomplicated malaria in African children; evaluation of the best approach to retreatment recurrent malaria in Ugandan children; safety of artemisinin derivatives-based combination therapy in children with uncomplicated malaria; and population-based pharmacovigilance.

Other projects at Makerere include the KIDS-ART-LINC, a network of clinical centres treating HIV-infected children in Africa; a network for European and sub-Saharan African research and capacity building in pharmacology; and support of institution review board.



*Pascoal poses with Makerere University-University of California San Francisco research collaboration and malaria surveillance project-UMSP research group*

### **Authorities responsible for regulatory oversight of research projects in Uganda**

The team met with the executive secretariat staff of both the Uganda National Council for Science and Technology (UNCST) and the Uganda National Regulatory Authority (UNRA). They also met with several other officials including the Minister of State for Health, the honourable Dr Nduhuura B. Richard; Director Health Services (Clinical and Community), Dr Kenya-Mugisha Nathan; the first secretary and head of section of the European Union delegation in Uganda, Mr Tom Vens; the WHO resident representative to Uganda, Dr Melville O. George among others.

## **Events**

### **The Fourth Annual Forum**

Preparations for the upcoming EDCTP Fourth Annual Forum to take place in Ouagadougou, Burkina Faso, on 22-24 October 2007 are almost complete. The main objectives of the forum are to have an overview of ongoing clinical trials on the three main diseases of HIV/AIDS, malaria and tuberculosis in Africa and to promote networking. The forum that will be opened by a high ranking Burkinabe government official will consist of keynote addresses by invited speakers, plenary sessions, breakaway sessions, group workshops, and electronic posters presentations.

At least 165 people have registered for the forum. Participants are African researchers, European research collaborators, policy makers, and members of EDCTP constituencies. Some projects funded by EDCTP will present their on-going work. Sixty African scientists have been given bursaries to attend the forum and present their scientific work. The European member states that have contributed money for the bursaries are Austria (1), Belgium (10), Ireland (10), Italy (2.5), Netherlands (7), Spain (3), Sweden (2.5), UK (10); while the rest have been funded by EDCTP.

The programme of the forum can be accessed from the EDCTP website [www.edctp.org](http://www.edctp.org). The website will carry daily updates during the forum and also the report that will be produced four weeks after the forum.

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