

European and Developing Countries Clinical Trials Partnership

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EDCTP newsletter

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Executive Director's Note



Professor Charles Mgone, EDCTP Executive Director

Reflecting on the year, the last quarter of 2007 was no different at EDCTP; it was a very busy and rewarding year. In the last quarter as is reported in the current newsletter there were many events, the highlights among them the closure of 8 calls and the launch of three new ones. It is very heartening and encouraging to note that in the recently closed calls many of the applicants who were principal investigators were scientists from sub-Saharan Africa. This underpins the equal participation and ownership of the Partnership. The newsletter also features successful stories of our grantees, workshops, meetings, site visits and of course the recently held Fourth EDCTP Annual Forum that was held in Ouagadougou, Burkina Faso. The Forum is rapidly becoming one of the most important meetings for diseases of poverty in Africa. It is certainly a very vital platform for networking, exchanging ideas, gathering and disseminating information on EDCTP activities. It is therefore fitting that the forum and the HIV calls released on the World AIDS Day week were among the highlights of EDCTP events as we come to the end of the year.

As the year draws to an end, the EDCTP Secretariat and constituents would like to extend our sincere gratitude to all our partners and stakeholders for their hard work, dedication and support. May you all have a happy year's end and a prosperous new year.

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News about calls and grants

TB treatment stakeholder meeting and the brokering process

In preparation for the launch of EDCTP's call for proposals for tuberculosis (TB) treatment, EDCTP held a stakeholder meeting on TB treatment in Dublin, Ireland. The meeting recommended to focus on shortening and simplifying the treatment of drug sensitive TB. Following this a call for expression of interest was launched on 1 August 2007, with a deadline of 17 September 2007. The applications received in response to this TB Treatment brokering call were considered by EDCTP's Partnership Board (scientific board). Of the eight eligible applications received, it was recommended that five successful applicants (consortia working on TB trials for shortening or simplifying treatment) should be invited to participate in the EDCTP TB Treatment brokering meeting and that the remaining three should be excluded. This TB Treatment brokering meeting took place in The Hague on 4 December 2007.

The main objectives of the meeting were to develop a "grand plan for TB drugs development" in order to progress towards clinical trials aimed at simplifying and shortening first line treatment of drugsensitive tuberculosis, to understand opportunities provided by potential participating clinical trial sites and to understand trial needs of potential participating drug development programmes. At the end the meeting agreed to produce a detailed clinical development plan defining three drugs in short order with clear milestones for advancement into subsequent studies. The studies will be phase III trials of moxifloxacin and phase I/II trials of high dose rifampicin, rifapentine and SQ109 respectively. The proposal, which will be written by a small group of the participants, is expected to be ready for submission to EDCTP by 3 March 2007.



The EDCTP Newsletter is available in electronic format in three languages namely English, French and Portuguese and in print in English.



If you wish to receive the EDCTP Newsletter in print or electronic format please go to www.edctp.org and subscribe.



News about calls and grants

Calls open for application

In the effort to combat the HIV/AIDS pandemic, EDCTP is announcing funding opportunities for HIV/AIDS researchers. In December 2007, three calls for proposals on HIV/AIDS treatment were launched. Please find below an overview of all calls that are currently open for application.

HIV Treatment

Call for the support of clinical trials, capacity building and networking for HIV/AIDS treatment in sub-Saharan Africa

The objectives of this call are:

- To support the conduct of clinical trials that evaluate second line treatment strategies, with a focus on what products to switch to when changing from first to second line treatment and when to switch.
- To improve ART in children, with a specific focus on using more optimal combinations and product formulations, and sub-studies on the pharmacokinetics of drug combinations.

Available funds:
Deadline of application:
Terms and requirements:

A minimum of € 6,500,000 1 April 2008 This call aims to fund 3 or 4 projects

HIV Microbicides

Call for the support of clinical trials, capacity building and networking for HIV/AIDS microbicides in sub-Saharan Africa

The objectives of this call are to support the conduct of clinical trials on microbicides that will yield data on safety, surrogate end-points of biological activity and surrogate markers that might correlate with safety or efficacy. In addition, proposals that evaluate the effect of barriers, concurrent sexually transmitted infections, frequency of microbicide use and stage of menstrual cycle on safety and efficacy are invited.

Innovative products or approaches are particularly encouraged.

Available funds: Deadline of application: A minimum of € 6,100,000 1 May 2008

HIV Vaccines

Call for the support of clinical trials, capacity building and networking in HIV/AIDS vaccines development

The main objective of this call is to support the conduct of phase I/II clinical trials of HIV candidate vaccines in African countries. Such studies should include safety and immunogenicity parameters and should ideally be designed to enable comparison of outcomes.

Available funds: Letter of Intent due: Deadline of application:

Awards

Training

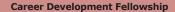
Clinical Trials

A minimum of € 7,000,000 1 February 2008 30 May 2008

For more information about these calls and how to apply, please visit our website at www.edctp.org.

Funded projects

EDCTP is pleased to announce funding of the following projects:



Dr Jennifer Serwanga: "Patterns of HIV-1-specific CD8+ T-cell epitope recognition determining plasma viral load trajectory and set point following HIV-1 infection"

Capacity building in preparation for the conduct of preventive HIV vaccine trials

Dr Pontiano Kaleebu: "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"

Current status of EDCTP calls for proposals 2007

Calls	EDCTP funding (€)	Launch date	Deadline	Number of eligible applications received
TB Vaccine	11.000.000	5 July 2007	5 November 2007	4
Ethics	4 <mark>50.000</mark>	1 August 2007	5 November 2007	17
Senior Fellowships	1.200.000	5 July 2007	12 November 2007	17
Malaria Vaccine	14.000.000	5 July 2007	19 November 2007	2
Mal <mark>aria T</mark> reatment	9.000.000	1 August 2007	26 November 2007	3
Networks of Excellence	10.000.000	1 August 2007	3 December 2007	8
Malaria in Pregnancy	9.000.000	1 August 2007	26 November 2007	3
TB Treatment Brokering	14.000.000	4 December 2008*	17 September 2007	10
HIV Treatment	6.500.000	1 December 2007	1 April 2008	-
HIV Microbicides	6.000.000	1 December 2007	1 May 2008	
HIV Vaccine	7.000.000	5 December 2007	30 May 2008	- * Brokering meeting

Focus on EDCTP grantees

Regional training on HIV viral load assay

Following the successful completion of a two year EDCTP Senior Fellowship awarded in 2004 to Dr Abraham Alabi of the Viral Diseases Programme, a further one year extension of the fellowship was approved earlier this year. A major thrust of this one year extension is capacity building and multicentre evaluation of a colorimetric HIV viral load assay developed by Dr Alabi and his team. To this end, some members of the team, Dr Alabi, Mr Pa Saidou Chaw and Modou Camara organised a one week training (24-28 September) on the assay for scientists from Central, Eastern and Southern Africa.

The training offered participants the opportunity of sharing experiences on the different commercial HIV-1 viral load assays being used at their centres. There were hands-on sessions during which participants were put through the entire process of viral load assay, which includes HIV RNA extraction from patients' plasma, reverse transcription and amplification of

Group picture of participants and facilitators at the closing ceremony



the RNA and detection of the target DNA product by enzyme oligonucleotide assay (ELONA).

The training was hosted by the HIV Laboratory, Centre for Virus Research, Kenya Medical Research Institute (KEMRI) in Nairobi. Although more than 50 scientists applied for the course, it was possible to take nine participants only. These were from Ethiopia, Uganda, Zimbabwe, Zambia and Kenya.

Financial training course for EDCTP grantees

A two week financial training course was held between 3 and 14 December. The course was attended by 16 invited participants directly involved in producing budgets and annual reports on EDCTP grants from 12 different sub-Saharan countries.

The course was designed and taught by Deloitte at their offices based in the Gambia and focused on:

- Practical elements of producing financial and management information
- Introduction and use of automated accounting systems
- Monthly management of accounts
- Internal control and tracking systems of
- grant expenditure.

Meetings and visits

Site visits to Ethiopia and Gabon

From 17-21 September 2007, EDCTP visited some of the EDCTP-supported institutions in Ethiopia. The EDCTP team consisted of 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 various institutions.

• Armauer Hansen Research Institute (AHRI) and Pan African Bioethics Initiative (PABIN) Secretariat

AHRI besides hosting the PABIN Secretariat manages several EDCTP projects including capacity building for conducting TB vaccine trials in high risk populations in East Africa; networking for strengthening the National Tuberculosis Research Network in Ethiopia (NTRNE) and establishing an African coordinating office for ethics through PABIN.

• Addis Ababa University

Addis Ababa University is involved in optimisation of tuberculosis and HIV cotreatment focusing on pharmacokinetic and pharmacogenetic aspects of drug-drug interactions between rifampicin and efavirenz. This is a multicentre study involving Ethiopia, Tanzania, Zimbabwe and Sweden. Another project is on hepatotoxicity and interactions of ART and TB drugs on CYP 450 metabolism, a PhD project of Dr Yimer Getnet, which is a sandwich programme at Addis Ababa University and Karolinska Institute.

• Ethiopian Health and Nutrition Research Institute (EHNRI)

EHNRI is involved in the strengthening the national tuberculosis research network in Ethiopia. EHNRI is one of the major partners of African Regional Capacity Building Network for HIV/AIDS prevention, Treatment and care project (ARCAN), sponsored by the World Bank.

The site visits in Gabon took place between 8 and 12 October 2007. The sites visited include the Medical Research Unit, Albert Schweitzer Hospital (MRU-ASH), Lambaréné and The University of Health Sciences in Libreville.



EDCTP site visit team meets with Dr Kouyate Amara Bintou, Chair of Lambarene Ethics Institutional Review Comittee (CERIL)

MRU-ASH

The medical research unit, Albert Schweitzer hospital, Lambaréné is involved in several projects including Artesunate for severe malaria in African children; Evaluation of 4 artemisinin-based combinations for treating uncomplicated malaria in African children; Establishing and support of a National Ethics Committee in Gabon; Ethics research training for members of African national ethics committees, physicians and investigator, (conducted with the Vienna School of Clinical Research); and in a networking project involving Ifakara, Lambarene and Manhiça.

Events Fourth Annual Forum: EDCTP looks to the future

EDCTP held this year's annual forum from 22 to 24 October in Ouagadougou, Burkina Faso. At the forum, stakeholders involved in EDCTP-funded research discussed their work. The Forum's theme, 'Building Bridges for Better Health', gained meaning when Charles Mgone, EDCTP's Executive Director, said that the partnership between Europe and Africa in fighting HIV/AIDS, malaria and tuberculosis "is now a reality".

Scientists from both Europe and sub-Saharan Africa presented an overview of ongoing clinical trials on the 3 povertyrelated diseases of HIV/AIDS, malaria and tuberculosis in Africa. They also identified future priorities, particularly with respect to the promotion of networking activities. Highlights of the scientific sessions included the presentation of the data that led to the tentative approval by the FDA of Triomune (a fixed-dose anti-HIV drug specifically formulated for paediatric use), and the presentation of unpublished data concerning prevention of mother-to-child transmission of HIV/AIDS through a combination of tenofovir and emtricitabine.

With so many of EDCTP's stakeholders present, Executive Director Charles Mgone shared his dream of a genuine partnership between Europe and Africa. Integration of European national research programmes into HIV/AIDS, malaria and tuberculosis in partnership with African programmes is the key to the EDCTP programme. This kind of partnership requires planning and coordination, as well as mutual understanding and respect. He concluded by saying "Let us decide and plan for the future with our HEADS, but commit ourselves to our decisions and the Partnership with our HEARTS."

The forum was officially opened by the Minister of Social Affairs in Burkina Faso, Honourable Pascaline Tamini, and was hosted by the Centre de Recherche et de Formation sur le Paludisme (CNRFP). It was attended by around 180 participants, which included researchers from both Europe and Africa, EDCTP grantees, policy makers, representatives from research funding organisations and members of EDCTP constituencies.

EDCTP's Fourth Annual Forum Report is currently in production and will be available soon both in print and on EDCTP's website www.edctp.org.



From left to right: EDCTP High Representative Dr Pascoal Mocumbi, EDCTP Chair Dr Diana Dunstan, Minister of Social Affairs in Burkina Faso Honourable Pascaline Tamini, EDCTP Executive Director Charles Mgone, Head of CNRFP Dr Sodiomon Sirima

Meetings and visits

Visit of the European Union Commissioner to EDCTP Africa Office



EU Commissioner Janez Potočnik with EDCTP High Representative Pascoal Mocumbi and MRC Cape Town President Professor Anthony MBewu

On 30 November 2007, European Union Commissioner Janez Potočnik paid a visit to EDCTP Africa Office (AO) in Cape Town, He was accompanied by Mr Ludewing Briet (EU Ambassador in South Africa), Ms Kristina Bole (Member of Commissioner's Cabinet), Ms Fadila Boughanemi (DG Research International Cooperation Programme) and Mr Daan du Toit (Senior Science and Technology Representative South African Mission to the European Union). The Commissioner was received by the EDCTP High Representative, Dr Pascoal Mocumbi, the President of the Medical Research Council of South Africa. Professor Anthony MBewu and EDCTP's Africa Office staff.

During the visit, Commissioner Potočnik was updated on the activities of the Africa Office and had a guided tour of the facilities. He applauded EDCTP for its good performance and the very important role of the Africa Office in pushing the agenda of EDCTP in Africa. He added that EDCTP has a great potential to do more and that the EC will continue to support it. European & Developing Countries Clinical Trials Partnership

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