

## Note from the Africa Office

*"What lies behind us and what lies before us are tiny matters compared to what lies within us."* Oliver Wendell Holmes



**Michael Makanga**  
Director of South-South Cooperation and Head of Africa Office

I am happy to introduce the October issue of the EDCTP newsletter covering an extremely busy quarter of 2009. This issue delivers updates on the fifth EDCTP Forum, the reinforcement of the EDCTP Africa Office, adverts for renewed memberships for the Developing Countries Coordinating Committee (DCCC) and the Partnership Board (PB). It also informs of the end-of-term review and impact assessment of EDCTP that are in progress.

During this quarter of 2009 a number of calls on thematic topics have been launched on TB vaccines, HIV treatment and Member States initiated calls. Moreover, a number of projects have been supported including capacity strengthening activities offering training opportunities. Also highlighted in this issue is the EDCTP funded Pan-African Clinical Trials Registry (PACTR) that was recently granted WHO primary registry status.

EDCTP has continued its site visit activities to EDCTP-funded projects and active engagement with African governments. During September, EDCTP representatives visited Congo, Brazzaville.

With the ongoing evaluated experience and the great commitment of EDCTP Secretariat staff and constituency members, EDCTP is set to deliver more and faster.

## Events



### Fifth EDCTP Forum

When you read this, the Fifth EDCTP Forum will be around the corner or maybe already in full swing. Full programme details are available on the Forum website ([www.edctpforum2009.org](http://www.edctpforum2009.org)). The first official Forum day starts on Monday 12 October and we are grateful that political speakers from both Europe and Africa are actively involved in the Forum agenda and will be expressing their political commitment towards the Partnership. We are honoured and extend a warm welcome to speakers from the Tanzanian government, WHO-AFRO, the Africa Regional Economic Communities and their health arms as well as our European Member States and the European Commission.

### Scientific presentations

The three Forum days are packed with scientific presentations to be held in plenary, parallel and poster sessions. This provides the delegates an opportunity to update themselves on the latest developments in HIV/AIDS, tuberculosis and malaria clinical trials as well as ethics and regulatory strengthening. Results of EDCTP-funded projects will be highlighted, including projects that establish Networks of Excellence such as CANTAM, mapping of ethics and regulatory review capacity in Africa (conducted by COHRED), and the recently launched WHO primary registry, the Pan African Clinical Trials Registry (PACTR; see under 'Focus on EDCTP grantees').

### Partnership presentations

On the third and final day, the Partnership idea will again be the focus of the presentations and discussion as a number of EDCTP partners present their collaborations. Delegates will be able to meet and exchange ideas with various global partners including Africa AIDS Vaccine Partnership (AAVP) and International AIDS Vaccine Initiative (IAVI), International Partnership for Microbicides (IPM), The Wellcome Trust, the Bill and Melinda Gates Foundation, Enhancing Support for Strengthening the Effectiveness of National Capacity Effort (ESSENCE), Africa Malaria Network Trust (AMANET), European Malaria Vaccine Initiative (EMVI) Medicines for Malaria Venture (MMV) and Aeras Global TB Vaccine Foundation, among others.

## Contents

### Note from the Africa Office

#### Events

- Fifth EDCTP Forum

#### News about EDCTP Governance

- Dr Michael Makanga appointed as Director of South-South Cooperation and Head of Africa Office
- End-of-term review and impact assessment of EDCTP
- Vacancy: Developing Countries Coordination Committee (DCCC) members
- Vacancy: Partnership Board (PB) members

#### News about Calls and Grants

- Calls open for application
  - TB Vaccines
  - HIV Treatment
  - MS Initiated projects
  - Call for Experts
- Funded projects

#### Focus on EDCTP grantees

- Pan-African Clinical Trials Registry (PACTR) awarded WHO primary registry status
- New online training programme on research ethics: TRREE
- Training workshop on "Molecular Diagnosis of Malaria"

#### Meetings and visits

- Site visit Congo



The EDCTP Newsletter is available in three languages namely English, French and Portuguese. It is available in electronic format on our website ([www.edctp.org](http://www.edctp.org)) and in print in English for distribution mainly in sub-Saharan Africa.



Persons who wish to receive the print format should subscribe on the website ([www.edctp.org](http://www.edctp.org), click on Newsroom).



EUROPEAN COMMISSION

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## Events

### Satellite meetings

Two satellite meetings will be held during the Forum. On Monday 12 October (12.00 - 14.00), the Switching the Poles" Clinical Research Network organises a satellite meeting on *Universal standards for clinical trials in practice*. The meeting focuses on the challenge of setting and implementing appropriate standards in externally funded clinical research projects carried out in resource-constrained settings.

On Tuesday 13 October (12.30 - 14.00) EDCTP and the Netherlands-African partnership for capacity development and clinical interventions against poverty-related diseases (NACCAP) jointly organise a meeting on *Ownership of research outcomes in sub-Saharan Africa*. This meeting will focus on the need to support African researchers and institutions to empower them in data management, handling of intellectual property related issues, creativity and innovation.

### Awards and social events

During the Wednesday closing session, EDCTP awards to outstanding Junior and Senior African scientists will be granted. Additionally, there will be an award giving ceremony to future scientists during the closing dinner, courtesy of our hosts in Tanzania, National Institute for Medical Research (NIMR) and the Ministry of Health of Tanzania.

EDCTP together with the local hosts have set up an ongoing social programme which starts on Sunday 11 October with a Welcome reception. Dinners and entertainment will be held every night.

### Keep updated through the Forum blog

Two sources of information will be available to keep updated on what's happening at the Forum. To keep updated on the daily proceedings, please check the Forum blog ([www.edctp.org/forumblog](http://www.edctp.org/forumblog)) regularly. The blog will be the central place for reports of sessions, audio and visual material, and interviews about salient research projects.

The Forum website ([www.edctforum2009.org](http://www.edctforum2009.org)) provides additional background information.

In addition, a selection of peer-reviewed abstracts will be published in journal of Tropical Medicine & International Health after the Forum.

### More information:

[www.edctforum2009.org](http://www.edctforum2009.org) and [www.edctp.org/forumblog](http://www.edctp.org/forumblog)

## News about EDCTP governance

### Dr Michael Makanga appointed as Head of Africa Office

Dr Michael Makanga was appointed as EDCTP Director of South-South Cooperation and Head of Africa Office. He is a medical and research doctor who trained from Makerere University, Uganda; Liverpool University and the Liverpool School of Tropical Medicine and Hygiene in the United Kingdom. He has several years of experience working with academic and health research institutions in Africa. In his previous function as Capacity Development Manager of EDCTP he was responsible for guiding the EDCTP organisation and grantees in building research capacity in sub-Saharan Africa. His earlier work and experience proved a firm basis for taking up his current position. As the Director of South-South Cooperation and Head of Africa Office, Dr Makanga is responsible for liaising with the African political leadership, policy makers and the scientific community with the aim of ensuring genuine African ownership, commitment and stewardship of the Partnership.

### End-of-term review and impact assessment of EDCTP

As the EDCTP programme in its current constitution officially ends on 1 September 2010, the programme is currently under review. This review aims to deliver recommendations on the continuation of the programme after September 2010. An Independent External Evaluation Committee commissioned by the European Commission started a programme of evaluation activities in July 2009. On 23 July the review committee and delegates from the EC visited the EDCTP secretariat in The Hague for a meeting with EDCTP members of the Secretariat and stakeholders. The report from the review committee is due by the end of November 2009.

In parallel, EDCTP has commissioned the Swiss Centre for International Health of the Swiss Tropical Institute (STI-SCHI) to conduct an impact assessment which evaluates the change that the EDCTP Programme has made both in Europe and in Africa. The results of this impact assessment are expected to become available by the end of 2009.

Additionally, the European Commission has announced to conduct an internal evaluation with the aim to collect views from internal and external stakeholders on the future of the programme and on the EU's involvement in poverty-related diseases in general.

We realise that these activities require input from our stakeholders and we wish to extend our sincere appreciation to those that invest time and effort in the evaluation of the EDCTP programme.

## News about calls and grants

### Calls open for application

#### TB Vaccines

Call for the support of clinical trials, capacity building and networking in tuberculosis vaccines development

#### Purpose of the call

The main objective of this call is to support the conduct of Phase II clinical trials of tuberculosis vaccines in African countries with a focus on new and upcoming TB vaccines such as recombinant BCG vaccines.

**Available funds:** €3,000,000\*

**Number of projects to fund:** 3-6

**Deadline of application:** 15 December 2009

*\* We expect the EDCTP contribution of €3,000,000 to be matched by at least an equivalent amount of cofunding from the EDCTP-EEIG Member States and possibly further contributions from third parties.*

#### Who can apply?

Participants in a proposal must be from at least two publicly funded institutions from the EDCTP EEIG Member States and at least two sub-Saharan African institutions. Preference will be given to proposals where the project coordinator is a sub-Saharan African national based in Africa.

#### HIV/AIDS Treatment

Call for the support of clinical trials, capacity building and networking on treatment of HIV/AIDS

#### Purpose of the call

The main objective of this call is to support the conduct clinical trials that aim to optimise the treatment of HIV infection by reducing the high early mortality.

**Available funds:** €5,000,000\*

**Number of projects to fund:** 2-4

**Deadline of application:** 15 December 2009

*\* We expect the EDCTP contribution of €5,000,000 to be matched by at least an equivalent amount of cofunding from the EDCTP-EEIG Member States and possibly further contributions from third parties.*

#### Who can apply?

Participants in a proposal must be from at least two publicly funded institutions from the EDCTP EEIG Member States and at least two sub-Saharan African institutions. Preference will be given to proposals where the project coordinator is a sub-Saharan African national based in Africa.

#### Member States initiated projects

Call for support of Member States initiated projects within the scope of EDCTP activity areas

#### Purpose of the call

The purpose of this grant is for EDCTP to provide funding and added value to these initiatives by acting as the locus of integration for various projects and programmes that have been independently initiated and or funded by Member States.

**Available funds:** €2,500,000\*

**Number of projects to fund:** 2-4

**Deadline of application:** 15 November 2009

*\* This is a new instrument whose primary objective is to increase the level of cofunding of EDCTP by Member States. EDCTP will contribute up to a maximum of 25% of the total funding. The EDCTP-EEIG Member State(s) and third parties will therefore contribute at least 75% of this grant. In addition, the EDCTP contribution to any single project will not exceed 1 million Euro for the entire duration of the grant, but there is no limit to the total project budget as contributed by all other funding parties.*

#### Who can apply?

The proposed project(s) must be supported by one or more 'initiators' who must be member(s) of the EDCTP General Assembly (GA). One of the GA members should act as the coordinating initiator. The application must however, be submitted by the project coordinator as mentioned in the guidelines for applicants.

#### Call for Experts

EDCTP invites applications from individuals wishing to serve on the EDCTP Scientific Review Committee (SRC) or as External Reviewers (ER) on the following subjects:

- Clinical trials for the diseases HIV/AIDS, malaria and tuberculosis
- Postgraduate training awards
- Capacity building grants including ethics and establishment of networks of excellence.

**For details on the calls and how to apply, please consult the relevant call texts on the EDCTP website: [www.edctp.org](http://www.edctp.org).**

#### Vacancy: Developing Countries Coordination Committee (DCCC) members

EDCTP is inviting applications for four members of the Developing Countries Coordinating Committee (DCCC). The DCCC is an independent advisory body comprising prominent African scientists and health professionals. Its general role is to ensure the commitment, ownership and leadership of the EDCTP programme by the participating sub-Saharan Africa countries.

EDCTP is looking for senior scientific experts and health professionals from sub-Saharan Africa with experience in one of the following areas:

- HIV/AIDS (1 position for Central African region)
- Tuberculosis (1 position from West African Region)
- Malaria (1 position for each of these African regions: Eastern and Southern).

**Closed for application:** 9 October 2009

**Position starting date:** 1 January 2010

#### Vacancy: Partnership Board (PB) members

EDCTP is inviting applications for two members of the Partnership Board (PB). The PB is an independent scientific expert panel comprising of members from both north and south. This advisory board is responsible for developing research strategy and overseeing scientific integrity of the EDCTP programme. It is also responsible for advising the General Assembly on all technical and scientific matters relating to the programme.

EDCTP is looking for senior scientific experts and health professionals with experience in one of the following areas:

- Malaria
- Tuberculosis

**Closed for application:** 15 November 2009

**Position starting date:** 1 January 2010

## Funded projects

EDCTP is pleased to announce funding of the following projects:

**Call: HIV/AIDS treatment  
(clinical trials, capacity building  
and networking)**

### **A multicentre Phase III trial of second-line antiretroviral treatment in African adults**

**Project Coordinator:** Eric Delaporte  
**Budget:** €4,040,245 (€1,970,367 EDCTP)  
**Duration of project:** July 2009 – July 2013  
**African countries involved:** Tanzania, Senegal South Africa  
**Cofunding partners:** Swiss National Science Foundation (Switzerland), IRD (France), ANRS (France), BMBF (Germany), ITM (Belgium), University of Antwerp (Belgium), University of Geneva (Switzerland)

### **The Eastern and Southern Africa research network for evaluation of second-line therapy in HIV**

**Project Coordinator:** Peter Mugenyi  
**Budget:** €4,872,368 (€1,858,914 EDCTP)  
**Duration of project:** September 2009 – June 2014  
**African countries involved:** Malawi, South Africa, Uganda, Zimbabwe  
**Cofunding partners:** MRC Laboratories (United Kingdom), DFID (United Kingdom), ISC III (Spain), ISS (Italy), ITM (Belgium), Irish Aid (Ireland), SIDA (Sweden)

**Call: Tuberculosis vaccines  
(clinical trials, capacity building  
and networking)**

### **A proof-of-concept Phase IIb clinical trial to evaluate the protective efficacy of a booster MVA85A vaccination administered**

**Project Coordinator:** Martin Ota  
**Budget:** €13,177,720 (€4,974,200 EDCTP)  
**Duration of project:** August 2009 – April 2012  
**African countries involved:** Belarus, South Africa, The Gambia  
**Cofunding partners:** Aeras Global TB Vaccine Foundation (USA), ITM (Belgium), DFID (United Kingdom)

**Call: Malaria treatment  
(clinical trials, capacity building  
and networking)**

### **Special populations and label expansion studies with the fixed dose combinations artemether-lumefantrine, amodiaquine-artesunate, and dihydroartemisinin-piperaquine in Zambia, Malawi and Mozambique**

**Project Coordinator:** Victor Mwapasa  
**Budget:** €5,082,544 (€2,826,808 EDCTP)  
**Duration of project:** July 2009 – July 2014  
**African countries involved:** Malawi, Mozambique, Zambia  
**Cofunding partners:** MRC (United Kingdom), ISCIII (Spain), ITM (Belgium), AMC (Netherlands), BMWF (Austria), ACT consortium & DNDi (United Kingdom)

### **An integrated approach to clinical trials, capacity building and networking in West Africa: Treatment in pregnancy (IPTp) in the context of insecticide treated nets**

**Project Coordinator:** Abdoulaye Djimde  
**Budget:** €5,359,268 (€2,824,118 EDCTP)  
**African countries involved:** Burkina Faso, Guinea, Mali  
**Cofunding partners:** MRTC (Mali), CNRFP and IRSS (Burkina Faso), CNFRSR (Guinea), MRC (United Kingdom) SIDA (Sweden), University Claude Bernard Lyon (France), BMBF Germany  
**Duration of project:** September 2009 – March 2013

**Call: Regional Networks of Excellence for conducting clinical trials and provide mentorship programmes in sub-Saharan Africa**

### **Capacity building to prepare West African sites for clinical trials on HIV, TB and malaria**

**Project Coordinator:** Soleymane Mboup  
**Budget:** €5,155,921 (€3,499,921 EDCTP)  
**African countries involved:** Burkina Faso, Ghana, Guinea-Bissau, Mali, Nigeria, Senegal, The Gambia  
**Cofunding partners:** NACCAP (Netherlands), MRC Laboratories (The Gambia), MRC Laboratories (United Kingdom)



## Focus on EDCTP grantees

### WHO provides primary status to the Pan African Clinical Trials Registry

The Pan-African Clinical Trials Registry (PACTR) has been accepted as a primary clinical trials registry – the first World Health Organization (WHO) endorsed trials registry in Africa. This registry will feed data into the global WHO International Clinical Trials Registry Platform (ICTRP) search portal facilitating African representation in the global picture of planned, ongoing and completed clinical trials. The Registry is currently funded by the European and Developing Countries Clinical Trials Partnership (EDCTP) and coordinated by the South African Cochrane Centre (SACC) at the Medical Research Council (MRC).

“We are delighted to be able to offer access to a WHO primary register to all trialists in Africa. We hope the PACTR will become the first choice for African trial registration,” says

Nandi Siegfried, co-director at the SACC. Professor Charles Mgone, EDCTP Executive Director, explained that since June 2009 the African registry has expanded from a disease-specific registry to cater for clinical trials on all diseases transitioning to the PACTR. Researchers conducting clinical trials in Africa who use PACTR as their registry of choice will meet international requirements for research transparency.

Davina Ghersi, head of WHO’s International Clinical Trials Registry Platform (ICTRP), says the approval of PACTR as a primary trials registry is a significant milestone in the quest for transparency. “Our hope is that the PACTR will make it easier to capture information about trials involving people in the region. We look forward to filling the gap in our knowledge about clinical trials in Africa.”

**PACTR online: [www.pactr.org](http://www.pactr.org)**

**Full press release available on [www.edctp.org](http://www.edctp.org)**

### Training workshop on “Molecular

A training workshop entitled “Application of Quantitative Real-time PCR method to Malaria Diagnosis and Parasite Density Estimation” was held at the Fajara Campus of the UK Medical Research Council (MRC) from 4-8 May 2009. This workshop, jointly sponsored by EDCTP and the UK MRC Laboratories (The Gambia), was organised for young Postdoctoral researchers and PhD candidates in the field of malaria research by Dr Davis Nwakanma, EDCTP Senior Fellow. Eleven participants from Nigeria, Senegal and Cameroon, drawn from research institutions and universities in the West African sub-region attended the workshop.

Training sessions covered the following subjects:

- Traditional microscopy
- Parasite DNA isolation methods
- PCR assays for malaria diagnosis
- Real-time PCR methods for parasite density estimation.

The workshop employed seminar-style presentations followed by practical demonstrations and hands-on laboratory sessions in which all participants took active part, with assistance from facilitators drawn from the MRC Research Programmes.



### New online training programme on research ethics: TRREE

TRREE-for Africa is a web-based training and capacity building initiative on the ethics of research involving humans conducted in African countries. It is very comprehensive, free, and easy to use for all those involved in clinical trials in Africa at all levels (researchers, ethics committees, institutions, research participants, regulators). Since its launch in June 2009, 390 persons from more than 36 countries have registered and the number is growing.

#### The training programme

The **e-Learning** component of the TRREE website (<http://elearning.trree.org>) provides a basic online free access training programme on biomedical research ethics and regulation, available in three languages (English, French and German). The training consists of three modules:

- Module 1 is an introductory module that presents the basics of research ethics evaluation and the broader context of research ethics
- Module 2 focuses on the training needs of members of Research Ethics Committees (RECs) and any support function
- Module 3 presents a comprehensive

overview of the relevant norms and regulations on a country-by-country basis for Mali (French only), Cameroon (French & English), Tanzania (English only), Switzerland (French and German). The number of countries is expected to expand in the coming years.

#### The TRREE Consortium

TRREE stands for Training and Resources in Research Ethics Evaluation, is a consortium of partners from Cameroon, Canada, Germany, Mali, Nigeria, South Africa, Switzerland and Tanzania working together for the promotion of high-quality research and the protection of research participants in Africa.

**Visit the TRREE website on <http://elearning.trree.org>**

#### Online resources

The **e-Resources** component is a participatory website making available international, regional and national regulatory and policy resources. It provides indexes and a quick search option to give access to relevant guidelines, databases, courses etc.



**Prof. Ogobara Doumbo (member of TRREE working group), Dr Théra (malaria researcher at Malaria Research and Training Center MRTCC), and Alassane Niaré (TRREE project collaborator at MRTCC in Mali)**

## Meetings and visits

### EDCTP site visit to CANTAM sites in Republic of Congo

EDCTP conducted a site visit to the Central African Network for TB, AIDS and Malaria (CANTAM) sites in Brazzaville, Republic of Congo from 17 to 21 August 2009. Four institutions that are now part of the network namely: Centre for Studies on Natural Plants or Centre d'Etudes sur les Ressources Végétales (CERVE), Marien Nguabi University Teaching Hospital of Brazzaville, Makelekele Hospital and the Public Health Laboratory were visited. In addition the team met with the local Ethics Committee at the University Teaching Hospital, the European Union (EU) Delegation to Congo, the World Health Organisation Representative to Congo, the Minister for Scientific Research and Innovative Technology, the Minister for Health, Family and Social Affairs and the Prime Minister.

CANTAM was the first Network of Excellence that was awarded EDCTP funding from December 2008. The project has started well

Ministry of Health, Family and Social Affairs to CANTAM.

The project also enjoys support of the local WHO Country Office. In his speech the Prime Minister of the Republic, Mr Mvoumba, mentioned that the diseases that EDCTP targets are the biggest cause of mortality in Congo and he thanked EDCTP for creation of an opportunity for less endowed states to carry out research activities in collaboration with neighbouring countries in the region. The EDCTP delegation also had a separate meeting with the Minister of Scientific Research and Innovative Technology.

The site visit team included Dr Pascoal Mocumbi (High Representative), Mr Simon Belcher (Director of Finance and Administration), Dr Thomas Nyirenda (South-South Networking and Capacity Development Manager) and Dr Veronique Penlap, DCCC member from Cameroon.



and infrastructure development is already underway. Management of the project is already embedded in the newly formed Fondation Congolaise pour la Recherche Médicale (FCRM) or Congolese Foundation for Medical Research at the Faculty of Public Health of Marien Nguabi University. Dr Mombouli and Professor Ntoumi are co-directors of this foundation.

There is much political will in support of the project in Congo. Through the involvement of Marien Nguabi University the Ministry of Scientifics Research and Innovative Technology has committed resources in terms of office space, bacteriology laboratory and access to the medical teaching facilities. Similarly the inclusion of Makelekele Hospital and the Public Health Laboratory into the project is additional resources from the

#### European & Developing Countries Clinical Trials Partnership

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### Diagnosis of Malaria"



#### Workshop participants at Seminar session

The one-week period of the workshop provided excellent opportunities for participants to interact with senior scientists at the MRC and to initiate potential collaborations and mentorship. In the post-training assessment, all participants expressed appreciation to the EDCTP and MRC for the training and adjudged the content of the workshop very relevant to their current research and future career plans. Many expressed the hope that opportunities for similar training would be extended to colleagues from their home institutions.

**Dr Davis Nwakanma**  
(Malaria Programme,  
MRC UK Laboratories)  
*EDCTP Senior Fellow*

### EDCTP news alerts and RSS

On the EDCTP website, you can now subscribe to the EDCTP Announcements to receive the latest EDCTP news (including calls for proposals on the date that they are launched, press releases, vacancies, events and any other important updates) either as an email alert or as an RSS feed. With these facilities, you will receive EDCTP news as soon as is published, without having to visit the EDCTP website to see if there is any news.



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