

## Note from the EDCTP General Assembly Chairperson

Dear EDCTP Stakeholders,

Welcome to the October EDCTP newsletter as we pass through interesting times. Currently we are preparing for the second programme of EDCTP (EDCTP-II) and aim for new horizons. The draft strategic business plan for EDCTP-II has been published and the consultative process with our stakeholders continues for which we greatly appreciate your feedback. As part of this process, a high-level conference will be held to consult all our stakeholders in Cape Town, South Africa on 5 November 2012. The current partner countries have unequivocally joined hands and expressed their full support for EDCTP-II; and preparations for the political process of the European Union's legislative procedure are in progress.

As the wheel continues to turn, the organisation has maintained momentum with new activities commencing through the strategic primer grants, ethics grants, Senior Fellowships and capacity development activities made possible by an EU coordination and support action grant. This newsletter reports on some of the ongoing projects that are coming to fruition, EDCTP constituency activities and new staff members joining the Secretariat.

We hope that you will find this newsletter edition useful and will enjoy reading it.

**Prof. Hannah Akuffo**

EDCTP General Assembly chairperson



## Towards EDCTP-II

### Brussels meeting on implementation aspects of EDCTP-II

The European Commission discussed preparations for EDCTP-II with EDCTP-EEIG Member States, Associated Countries and prospective new partner countries during a two-day meeting in Brussels, 27-28 September 2012. The aim of this meeting was to discuss preparations for the legislative proposal regarding the second EDCTP programme by the Directorate General (DG) for Research & Innovation. In addition, participants discussed a wide range of issues pertaining to the practical implementation of EDCTP-II. This meeting was an important milestone in the preparation of the legislative proposal for EDCTP-II.

Strategic and operational issues related to the partnerships within EDCTP ranged from a global portfolio approach to joint programming. Topics covered comprised among others:

- Cofunding at project and programme level
- Partnership between EDCTP and other funders

- EDCTP's role in multi-funded large-scale trials
- Clinical trial ethics and sponsorship
- Scientific scope of EDCTP-II
- Further integration of the sub-Saharan African countries in EDCTP decision making processes
- Rules for participation in Horizon 2020.

Dr Ruxandra Draghia-Akli, Director for Health Research of the DG Research & Innovation, highlighted the work of EDCTP and concluded that looking at all the achievements of the previous programme, "the aim is to have a broader participation for the next EDCTP, in terms of partners, scope and funding".

The meeting was attended by representatives from Belgium, Denmark, France, Italy, Portugal, Spain, Sweden, Switzerland, United Kingdom, Finland and Latvia, the Bill & Melinda Gates Foundation, the European Investment Bank, and the DG Development & Cooperation – Europe Aid.

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**EDCTP published a short video on its capacity building activities. The video is available on the EDCTP YouTube channel**

[www.youtube.com/edctpmedia](http://www.youtube.com/edctpmedia)

## Towards EDCTP-II (Continued from page 1)

### High-Level Conference on EDCTP-II in Cape Town



**A high-level conference to consult African and international stakeholders on the second programme of EDCTP will be held in Cape Town, South Africa on 5 November 2012.**

The conference will be preceded by a meeting of the EDCTP General Assembly on 2 November. A special meeting on post-registration medicinal products' safety will be held on 4 November 2012. The objective of the meeting is to discuss with various stakeholders issues of post-registration programmes for medicinal products, such as effectiveness studies and product safety monitoring (pharmacovigilance) in sub-Saharan Africa. EDCTP aims to foster collaboration and reinforce partnership regarding post-approval programmes in sub-Saharan Africa.

On 5 November, the High-Level Conference will discuss the needs and expectations of

stakeholders regarding EDCTP-II as well as the opportunities the programme will create. Speakers, panellists and participants will include African, European and international representatives from policy, industry, non-governmental organisations, product development partners and the research community. Opening addresses will be held by, among others, Maire Geoghegan-Quinn, the European Commissioner for Research, Innovation and Science and Maria da Graça Carvalho, Member of the European Parliament who is a member of the Committee on Industry, Research and Energy and the Delegation to the ACP-EU Joint Parliamentary Assembly. Ministers from several African countries will address the participants. The Conference will be opened by the Minister of Science and Technology of South Africa, Derek Hanekom.

The day after the Conference, participants will have the opportunity to visit clinical trial sites/institutions in the Cape Town area, including the SATVI laboratories, the Khayelitsa TB vaccine site, The Groote Schuur Hospital and the Tygerberg Hospital. For more information see [www.edctp.org](http://www.edctp.org).



### Industry Workshop report published

EDCTP published the report of the one-day EDCTP Pharmaceutical Industry Workshop held in The Hague on 26 June 2012. The workshop is part of a broader EDCTP effort to foster cooperation of public and private partners for clinical research on poverty-related and neglected infectious diseases.

## EDCTP Governance

### New staff members



**Gabrielle Breugelmans - North-North Networking manager**

Dr Gabrielle Breugelmans joined the EDCTP Networking team in August 2012. She is a senior

infectious diseases epidemiologist with over ten years of experience in public health, programme management and research. Dr Breugelmans obtained an MPH and PhD in epidemiology from the Johns Hopkins Bloomberg School of Public Health in the U.S. She also holds a master's degree in health sciences from the University of Maastricht in the Netherlands and is a graduate of the European Programme for Intervention Epidemiology Training (EPIET).

Prior to joining EDCTP, she led for five years the vector borne disease and pharmaco-epidemiology programme at the Agence de Médecine Préventive (AMP) in Paris, France

where she was responsible for implementing epidemiological studies. Furthermore, in collaboration with the World Health Organization, she was closely involved in the implementation of surveillance systems for monitoring adverse events following immunisation in sub-Saharan Africa. Prior to joining AMP, Gabrielle Breugelmans spent several years in the private sector, working for a pharmaceutical company specialised in vaccinology.

As the North-North Networking Manager, Gabrielle Breugelmans will focus on increasing coordination and integration of European national programmes on poverty-related clinical research and spearhead EDCTP external relations with third parties, including the pharmaceutical industry, PDPs (Product Development Partnerships) and like-minded organisations. Her activities will include amongst others defining the framework for extended collaboration with industry and PDPs with the ultimate goal of increasing contributions from these sources to support clinical trials and capacity building.



**Lucien de Corte - IT Officer**

Lucien de Corte joined EDCTP in September 2012 as Information Technology (IT) Officer. He is responsible for managing all

EDCTP information technology systems for both EDCTP offices, in The Hague and Cape Town. He will also be involved in various projects to develop current and new systems to prepare the organisation for the second phase of the EDCTP programme.

Born in Delft, The Netherlands, Lucien de Corte earned a professional skills degree in Computer Science with a specialisation in systems administration. Since 1987, he has worked for both governmental and commercial organisations, including VSO, an international development non-governmental organisation, and the international branch of the military academy (Dutch Ministry of

## Focus on EDCTP-Plus

### Collaborative research on poverty-related and neglected infectious diseases

EDCTP published a report on research in poverty-related and neglected infectious diseases in the current EDCTP member states. It presents a summary overview of activities and programmes which are of relevance to the scope of EDCTP-II. The report is entitled *Charting Research: EDCTP Member State programmes and activities in the scope of EDCTP-II* and highlights available research capacities and expertise which will form the foundation for the second programme.

The report is intended to be part of a 'Charting research' series which will review past achievements and future opportunities for increased European integration and African partnership in the area of clinical research to address the burden of poverty-related and neglected infectious diseases. The report is available on [www.edctp.org](http://www.edctp.org)

Defence). Over the years he gained broad ICT experience, both as system administrator and as project manager of various ICT projects. Lucien is currently pursuing a degree in Business IT & Management at the University of Applied Sciences in The Hague.

### Joint meeting of DCCC and PB

The Developing Countries Coordinating Committee (DCCC) and the Partnership Board (PB), the independent scientific advisory bodies of EDCTP, will hold a joint meeting in The Hague on 9 October. The main focus of this joint meeting is to discuss the operational business plan for EDCTP-II.

### General Assembly

The EDCTP General Assembly (GA) will meet in Cape Town, South Africa on 2 November 2012, shortly before the High-Level Conference. The GA will discuss current affairs but focus on the preparations for the second EDCTP programme.

### Preparation of laboratories for future accreditation

EDCTP is supporting the development of the laboratory capacity of the Regional Networks of Excellence (NoEs) as part of the Coordination and Support Action (CSA) grant from the Seventh Framework Programme of the European Union.

Through a consultative process, the four NoEs have selected 24 clinical research and public health laboratories actively involved in EDCTP funded clinical trials in 19 sub-Saharan African countries namely Burkina Faso, Cameroon, Republic of Congo (Brazzaville), Ethiopia, Gabon, Ghana, Kenya, Malawi, Mozambique, Nigeria, Senegal, South Africa, Sudan,

Tanzania, The Gambia, Uganda, Zambia and Zimbabwe.

The selected laboratories will be systematically developed towards future accreditation by international laboratory accreditation agencies. The initial assessment of the selected laboratories to establish their baseline capacity and grading is currently in progress. The assessment will be based on frameworks established by the International Organisation for Standardisation (ISO) and the World Health Organisation-African Region (WHO-AFRO) stepwise Laboratory Quality Improvement Process (SLIPTA).

### Financial management training in Senegal



Participants of the Financial management training in Senegal

EDCTP organised a financial management workshop for finance staff of EDCTP grantee institutions in West and Central Africa in Dakar, Senegal from 10-15 September 2012. The objective of this workshop was to provide participants with the required knowledge and financial management skills to improve financial accountability and transparency at their respective institutions.

Forty-two participants from 11 countries, active at institutions involved in EDCTP-funded research activities in Western and Central Africa attended the training. Key topics covered during the training included:

- Accounting terms, concepts and standards
- Preparation of budgets
- Financial management of a research project
- Importance of designing a good chart of accounts structure

- Accounting for financial transactions
- Distinction between external and internal auditing
- Purpose and objectives of internal controls
- Procurement management objectives and procedures
- Introduction to the concepts behind current Bribery Acts
- Advanced features of Excel 2007
- EDCTP financial guidelines
- Factors to take into account in selecting an accounting system.

Attendees indicated that the workshop was useful and are convinced that the knowledge they have acquired will help them to strengthen financial governance at their different institutes. The initiative is part of capacity building in preparation of EDCTP-II.



## Calls and grants

### EDCTP Strategic Primer Grants: 14 Applications approved

The Strategic Primer Grants Call was published on 12 December 2011. The purpose of the call is to provide funding for research groups in sub-Saharan Africa and Europe to conduct innovative studies that will generate results to inform future clinical trials. The grants will also sustain and strengthen the capacity built under EDCTP-I as well as further the networking of African and European Member States' research programmes.

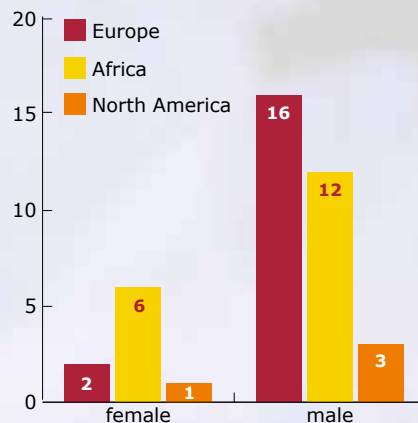
This scheme followed a two-step applications procedure, and a two-step peer-review process. On 14 February 2012, 89 Letters of Intent (LoIs) were received of which 74 applications were eligible and were peer-reviewed. Of the 74 LoIs, 32 received a high ranking by the reviewers and their authors were invited to submit full applications.

The 32 full applications went through another round of peer-review followed by a face-to-face meeting of the scientific review committee which recommended 14 applications for funding. The EDCTP Partnership Board agreed with the recommendation made by the Scientific Review Committee, and these 14 full applications were approved for funding by the EDCTP General Assembly.

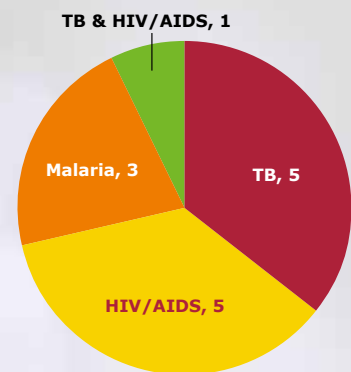
In total, 40 experts in the area of HIV/AIDS, tuberculosis, malaria, and clinical research ethics participated in the review of the Letters of Intent and Full Applications.

An analysis of the review teams shows that of the 40 experts, 18 are from African Research Institutions and 9 are women.

The 14 successful applications were submitted by leading scientists from Africa and Europe, some of whom are already linked to research networks funded by EDCTP and some are new grantees. These 14 projects include 6 clinical trials while the others are multidisciplinary capacity building studies that will contribute to future clinical trials. Preparations for these grant agreements are in progress.



**Figure 2.**  
SPG reviewers - gender and geographical origin



**Figure 3.**  
Projects by disease

### Funded projects

#### Call: Member State Initiated projects

Enhancing research capacities through the joint development of a multiplex flow cytometric bead assay for polyparasite detection in pregnant African women

**Project Coordinator:** Dr Andrea Kreidenweiss (Eberhard Karls Universität Tübingen, Germany)

**Budget:** € 414,613

**Duration of the project:**

October 2012–December 2013

### Capacity building for ethics: the 2011 call

The EDCTP 'ethics' call was launched on 15 August 2011, with a deadline for applications on 15 December 2011. The EDCTP budget available for the call was € 500,000 with a maximum budget per successful application of € 50,000. The purpose of the call is to support and promote the establishment and strengthening of National Ethics Committees (NEC) and Institutional Review Boards (IRB). The emphasis of this call was on supporting countries, institutions and ethics committees that had not received similar grants from EDCTP before.

A total of 28 applications were received, 25 of which were eligible. The eligible applications were peer reviewed by the Scientific Review Committee (SRC). The SRC's recommendations were supported by the Partnership Board and the EDCTP General Assembly approved funding for the 10 recommended projects on 15 May 2012. To date, contracts for nine projects have been signed.

It is gratifying that for the first time EDCTP will support a project in Togo. The National Health Research Ethics Committee of Togo (NHREC) was set up in early 2008, but has not been effective because of lack of funding, inadequate training and poor communication between healthcare workers in Togo and the ethics committee. Later in 2008, the Togolese government reconstituted the committee and developed guidelines for its functioning, which need to be operationalised.

The project titled 'Strengthening the National Health Research Ethics Committee of Togo' is coordinated by Dr Didier Koumavi Ekouevi. It aims to improve the communication between researchers and ethics committee members; develop standard operating procedures, guidelines and other materials needed to enable conducting ethical research; and ensure that the members are formally trained to review research projects according to national and international guidelines on bioethics.

A complete list of projects funded through this call is available at [www.edctp.org](http://www.edctp.org).

## Focus on Projects

### Children with severe malaria: SMAC clinical trial completes recruitment

The Severe Malaria in African Children network (SMAC) completed enrolment of patients for the phase III artesunate follow-up study led by Prof. Peter G. Kremsner (University of Tübingen). A total of 1,046 children with severe malaria were enrolled in this study. The follow-up period for the last patient enrolled is expected to end in October 2012. The primary objective of the study is to further evaluate simplification of the treatment of severe malaria by administering artesunate in a three-dose regimen intramuscularly rather than intravenously.

The overall goal of this Phase III Comparative, Open-Label, Dose and Regimen Optimisation Follow-up Study is to compare the efficacy, safety and tolerability of three-dose regimens: intravenous (i.v.) artesunate and intramuscular (i.m.) artesunate simplified dosing regimens

(4 mg/kg artesunate at 0, 24 and 48 hours; 12 mg/kg total dose) and the standard i.v. 5-dose regimen (2.4 mg/kg artesunate at 0, 12, 24, 48 and 72 hours; 12 mg/kg total dose).

If the outcome of this study is positive, further simplification of the treatment of severe malaria by administering artesunate in a three-dose regimen intramuscularly will contribute to reducing costs and improving severe malaria management in resource limited settings. These results will inform future policy and evidence-based changes in the WHO guidelines for malaria treatment.

The sponsor of the clinical trial is the University of Tübingen (Germany). The clinical trial sites are in Gabon (Albert Schweitzer Hospital in Lambaréné and the Université de Médecine et Science de la Santé in Libreville), Ghana (School of Medical Sciences, Kumasi), Kenya (KEMRI Coast in Kilifi and KEMRI Kondele Children's Hospital in Kisumu), Malawi (Queen Elizabeth Central

Hospital, Blantyre), and The Gambia (MRC laboratories, Banjul). Supporting sites are in Austria (University of Innsbruck, Innsbruck and the Vienna School of Clinical Research, Vienna), Germany (Institut für klinische Pharmacologie, Stuttgart), United Kingdom (St George's Hospital Medical School, London). The study is cofunded by the Federal Ministry of Education and Research (Germany).

The earlier SMAC phase II multicentre clinical trial, also coordinated by Prof. Kremsner, demonstrated that a shorter anti-malaria treatment is equally effective as the longer standard regimen in treating children with severe malaria. It was shown that three doses over two days of the drug artesunate delivered intravenously are as effective as five doses over three days. The results for the SMAC studies on artesunate treatment for severe malaria were published online in the Journal of Infectious Diseases in December 2011 (doi: 10.1093/infdis/jir724).



**A child who has just successfully completed a parenteral course of artesunate treatment for severe malaria in the SMAC clinical trial at the Albert Schweitzer Hospital in Lambarene, Gabon**

## Meetings

### Senegal site visit



**From left to right: Dr Samba Cor Sarr, Coordinator of Senegal National Ethics Committee; Professor Souleymane Mboup, WANETAM Network of Excellence coordinator; Dr Michelle Singh, EDCTP Project Officer; Dr Papa Amadou Diack, Director-General of Health; Hon. Professor Awa Marie Coll Seck, Minister of Health of Senegal; Mr Abdoulie Barry, EDCTP Director of Finance and Administration; Dr Michael Makanga, EDCTP Director of South-South Cooperation; and Professor Alioune Dieye, DCCC Chairperson**

On 5-7 September 2012, an EDCTP team comprising Mr Abdoulie Barry (Director of Finance and Administration), Dr Michael Makanga (Director South-South Cooperation and Head of Africa Office), Dr Michelle Singh (Project Officer) and Professor Alioune Dieye (Chairperson of the Developing Countries Coordinating Committee, DCCC) conducted site visits in Senegal. This is part of the ongoing EDCTP process of project monitoring and evaluation. The EDCTP team also had meetings with the honourable Minister of Health of Senegal, Professor Awa Marie Coll Seck; Dr Abraham Doi (Head of AIDS

National Programme) and a team of senior policy makers within the Ministry of Health of Senegal.

EDCTP supports the following projects in Senegal (with Senegalese investigators in brackets):

- Capacity building to prepare West African sites for clinical trials on HIV, tuberculosis (TB) and malaria (WANETAM and WANETAM Plus; Professor Souleymane Mboup)
- A multicentre phase II clinical trial evaluating safety and immunogenicity

trials of new TB vaccines in adolescents and adults with latent TB (Professor Souleymane Mboup and Dr Birahim Pierre Ndiaye)

- A multicentre randomised controlled trial of three strategies for the treatment of ARV-naïve HIV-infected patients with tuberculosis (RAFA study; Dr Mame Bocar Lo)
- A multicentre phase III trial of second line antiretroviral treatment in African adults (Professor Sow Papa Salif)
- Integrating capacity building and networking in the design and conduct of phase I and II clinical trials of viral vectored candidate malaria vaccines (MVA ME-TRAP/AdCh63 ME-TRAP) in East and West African children and infants (Dr Badara Cisse)
- Intermittent Preventive Treatment in children (IPTc) combined with home management of malaria in area with persisting high malaria prevalence in Senegal (Dr Jean Louis Ndiaye)
- Optimisation and standardisation of the new functional antibody dependent respiratory burst (ADRB) assay to evaluate anti-malarial immunity in endemic populations and merozoite based vaccine candidates (Dr Aissatou Toure)
- Programme for strengthening National Research Ethic Committee of Senegal (CNRS) and promoting ethics awareness in Senegal and in West Africa (Dr Samba Cor Sarr).

### BMGF/EDCTP satellite meeting at Global HIV Vaccine Conference

In 2006 the Bill & Melinda Gates Foundation (BMGF) and EDCTP launched a joint call on capacity building in preparation for the conduct of preventative HIV vaccine trials. (See also EDCTP Newsletter October 2012). At the AIDS vaccine 2012 meeting in Boston, BMGF and EDCTP organised a satellite meeting to present the results emanating from the grant as five of the six projects are now completed.

Dr Nina Russell, Deputy Director HIV at BMGF opened the meeting and spoke of BMGF's involvement with EDCTP and its future strategy in relation to tackling HIV. The EDCTP Operations Manager, Dr Pauline Beattie, explained what the next phase of EDCTP will have in store.

The Coordinators for the six projects are:

- Professor Linda-Gail Bekker from the Desmond Tutu HIV Centre in Cape Town
- Professor Muhammad Bakari from Muhimbili University College of Health Sciences, Tanzania
- Dr Saidi Kapiga from the Mwanza Intervention Trials Unit, National Institute for Medical Research, Tanzania
- Professor Pontiano Kaleebu from the Uganda Virus Research Institute (UVRI)
- Professor Tomáš Hanke from the University of Oxford
- Professor Jonathan Weber from Imperial College London (represented by Mr Roger Tatoud and Dr Sarah Joseph).

Each of them briefly presented project results and shared lessons learned regarding research and capacity building throughout the course of their experience.

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

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