

EDCTP is proud to announce that the electronic copy of the Newsletter is now available in three languages namely English, French and Portuguese. Additionally, the newsletter is also available in print in English for distribution mainly in sub-Saharan Africa. Persons who wish to receive the print format should send their request to the EDCTP Secretariat.



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### Head of Africa Office's note

On 15 September EDCTP celebrated its third anniversary and the Secretariat staff took time to reflect on gains that have been made in the past three years. Greatly missed was Dr Odile Leroy who has recently stepped down as the Partnership's Executive Director to take up the post of Executive Director of the European Malaria Vaccine Initiative (EMVI). Dr Leroy will be remembered as the person who has established a firm foundation for EDCTP including putting in place the current best practices being followed by the organisation such as standard operating procedures, transparent review mechanism, and quality control and quality assurance measures. We wish to put on record how much we have appreciated her hard work and guiding hand and wish her every success in her new post. The General Assembly of EDCTP hopes to identify a successor to Dr Leroy by the end of the year.

In the current issue of the newsletter, we report on the First EDCTP investigators' meeting that brought together policy makers, regulatory authority personnel and EDCTP funded scientists and other researchers working on poverty-related diseases. These met in Cape Town to share their experiences and to network. A detailed report of this meeting will soon be available including on our website. The investigators' meeting was followed by a very productive meeting of the DCCC members who deliberated on many issues including the establishment of centres of excellence. Among other very important functions, DCCC is responsible for identifying capacity gaps and research needs in Africa. This issue of the newsletter also has news of the recently awarded grants and advocacy activities of the High representative. We also report on the site visit that took place in Burkina Faso and on the First African Vaccine Regulatory Forum that was held in Accra, Ghana and organised in partnership with the World Health Organisation. There is good news of new funding from four EDCTP-EEIG member states (Sweden, Germany, Belgium and the UK) demonstrating the strong commitment of European states towards integration of national programmes.

### The Eleventh DCCC Meeting, Cape Town, 26-27 July

The eleventh meeting of the EDCTP Developing Countries Coordination Committee (DCCC) took place at MRC in Cape Town from 26 to 27 July 2006 soon after the Investigators' Meeting.

At the meeting members discussed the recommendations to EDCTP from the investigators that included:

- To extend senior fellowship projects with more funding
- To reinforce capacity building through training of personnel, ethics and regulatory bodies
- To foster collaboration between investigators and policy makers
- To promote and strengthen South-South and North-South networking
- To devise a strategy for accreditation of Clinical Trial sites
- To revisit co-funding and budget cuts associated with EDCTP grant.

Also addressed were:

- The need to involve more African countries in the newly proposed funding of large grants by EDCTP i.e. call strategies and co-funding modalities with both European states and African organisations
- Ways of enhancing regional capacity building and ownership of programmes in Africa; including link-ages with NEPAD initiatives such as the Biosciences Eastern and Central Africa (BecA)
- Ways of involving local ethical bodies while building their capacity within the grant applications without causing conflicts of interest in the process.

### Four Member States contribute to EDCTP with new funds

The EDCTP is based on Article 169 of the European treaty that allows the European Commission to co-fund the Joint Programme of the member states. Several member states have demonstrated their commitment towards integration of their national programmes, by committing additional funds for collaborative research within the EDCTP. The Swedish Agency for International Development Cooperation (SIDA) research board has recently approved 10 million Swedish Kronor (approximately 1 million €) per year over the next three years, with provision to provide the same level for a further two years. The funds will be disbursed directly to the EDCTP secretariat. Germany has enhanced its national participation in the EDCTP Joint Programme by earmarking 1 million EUR per year in its national budget lines for the next three years. The United Kingdom Medical Research Council is negotiating an additional 5 million UK pounds for EDCTP activities (about 7.5 million €) for the period 2007-2010. The Institute of Tropical Medicine in Belgium has committed 500.000 € per year from its institutional funding by the Belgian and Flemish governments for the period 2007-2010, negotiations are under way to obtain additional co-funding.

## News about calls and grants

### EDCTP is pleased to announce funding for the following projects

#### Capacity Building

#### Support for Ethics Courses and Seminars

University of Stellenbosh (South Africa): "Enhancing Research Ethics Capacity and Compliance in Africa"

Medical Research Council (Zimbabwe): "Building National Capacities in Health Research Ethics, Ethical Review and Clinical Trial Monitoring in Zimbabwe"

#### Support for the Establishment and Strengthening of African National Ethics Committees or Institutional Boards

Medical Research Council (Zimbabwe): "Strengthening the Medical Research Council of Zimbabwe"

Training Awards	<b>PhD Scholarships</b>
	Louis Marie Yindom (Gambia): "The role of human leukocyte antigen (HLA) and killer immunoglobulin – like receptor (KIR) in HIV-2 infection: a key component to HIV vaccine design and its evaluation in Africa"
	Getnet Yimer Ali (Ethiopia): "Anti tuberculosis – anti retroviral drugs induced hepatotoxicity and introduction of these drugs at the level of CYP 450 metabolism"
	Leah Mwai (Kenya): "Understanding the mechanism of resistance to lumefantrine by <i>Plasmodium falciparum</i> "
	Charles Arama (Mali): "Host immunogenetic factors involved in the susceptibility to malaria in sympatric ethnic groups (Dogon and Fulani) in Mali"
	Ramatouli Janha (Gambia): "Investigating the effects of inactive CYP2C19 alleles on chlorproguanil pharmacokinetics in adults and in children with mild malaria following Lapdap ® treatment"
Networking	<b>MSc Studentship</b>
	Sunny Oyakhirome (Gabon): "MSc in Public Health"
	Alasan Jobe (Gambia): "MSc in reproductive and sexual health research"
	<b>Workshops</b>
Clinical Trials	Dr Robert Colebunders, The Institute of Tropical Medicine, Antwerp (Belgium): Workshop on Tuberculosis Immune Reactivation Inflammatory Syndrome (TB IRIS)
	<b>Clinical Trials Registry</b>
	Prof. Jimmy Volmink, The South African Cochrane Centre: "Proposed HIV/AIDS, Tuberculosis and Malaria Clinical Trials Registry in Sub-Saharan Africa"
	<b>Phase II-III trials of drug regimens that shorten or simplify current treatment option</b>
	Dr Concepta Merry (Ireland): "Determining the optimal doses of antiretroviral and antituberculous medications when used in combination for the treatment of HIV/TB in co-infected patients"
	<b>Phase II-III drug trials for the treatment of severe malaria using artemisinin compounds</b>
	Prof. Peter G. Kremsner (Germany): "Artesunate for severe malaria in African children"

## Events

### First Investigators' meeting, Cape Town, 24-25 July

The First EDCTP Investigators' Meeting took place at the MRC in Cape Town from 24 to 25 July 2006. The goal of the meeting was to establish a South-South network of researchers and institutions for coordinating and synergizing activities related to clinical trials on the three major poverty-related diseases of HIV/AIDS, malaria and tuberculosis in Africa through the EDCTP platform.

The meeting brought together 88 participants: 43 African scientists (from research sites in Burkina Faso, Cote d'Ivoire, Gabon, Gambia, Kenya, Mali, Mozambique, Nigeria, Rwanda, South Africa, Sudan, Tanzania, Uganda, Zambia and Zimbabwe), 9 European collaborators (from research institutions in United Kingdom, Belgium, Ireland and USA), 13 invited guests (from bodies like Department of Science and Technology [South Africa], Medical Research Council [South Africa], Africa Malaria Network Trust [AMANET], World Health Organisation, European Commission and National Regulatory Officials from Zambia), 11 members of EDCTP Developing Countries Coordination Committee, a member of the European Network of National Programmes, 3 members of the EDCTP Partnership Board and 8 members of the EDCTP secretariat.

At this meeting participants shared experiences and exchanged information on existing projects, facilitated the establishment of South-South links (e.g. mentorship programmes, nodes of excellence, and sharing of facilities and expertise), explored common grounds of interest such as possibilities of joint grant applications, proposed a direction of research agenda to EDCTP as determined by the experiences from the ongoing projects, discussed regulatory issues, discussed the use of the established EDCTP clinical trial registry, and role of African institutions in clinical trials sponsorship.



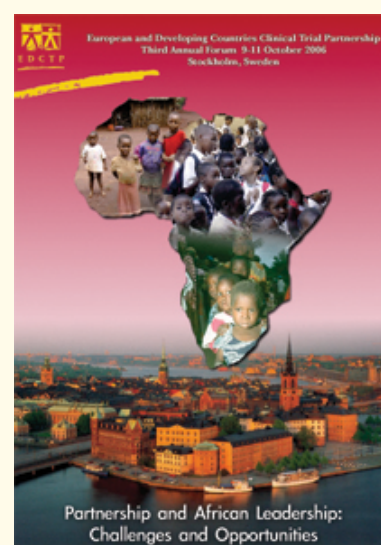
*Participants at the 2006 EDCTP investigators' meeting, South Africa*

A full report of the meeting will be available electronically on our website and in hard copies soon.

### **The Third EDCTP Annual Forum**

The Third EDCTP Annual Forum will take place in Stockholm on October 9-11. In September the Programme Committee selected recipients for 35 EDCTP bursaries, based on the submitted pragsters and names of the recipients are now available on our website. The Forum website has also been updated with new details of the programme, to which more details will be added accordingly. The programme, the submitted pragsters, and abstracts from the speakers will be published in a forum abstract book that will be distributed to all participants of the forum. Pragsters will also be loaded on to EDCTP USB memory sticks which will be available to Forum participants.

The Swedish Society for Medicine, where the forum will be held is a beautiful old building with antique wood furniture, and is very cosy and warm. The Karolinska Institutet in comparison is a modern building which features steel and white walls. The Scandic Sergel Plaza is the hotel where most guests will be staying and where the cocktail party will take place on 8 October. It is also the venue for the Round Table events. The hotel is modern in design, luxurious and welcoming. Guests to the Forum in October are advised to bring warm clothing since Stockholm in October is likely to be very cold.





### Advocacy conducted by High Representative

During the last quarter Dr Pascoal Mocumbi, the EDCTP High Representative (HR) represented EDCTP in various meetings. These included the Third National Health Conference on "Voice and Proposal: Policies for the Right to Health 2006-2011" that took place in Lima, Peru from 10-12 July 2006 where he spoke on "World Health and social determinants". This was followed by the Second Conference of Intellectuals from Africa and the Diaspora (II CIAD) in Salvador da Bahia, Brazil. In his presentation he highlighted EDCTP as an innovative partnership that would contribute in the retention of African health professionals in Africa and attract the diaspora to return home and contribute to sustainable development of the continent. At the meeting the HR also met with Professor Alpha Omar Konare, Chairperson of the African Union (AU) and Advocate Bience Gawanas, the AU Commissioner for Social Affairs and briefed them on EDCTP activities in Africa.

In August, Dr Mocumbi participated in the Geneva forum organised by the Geneva University Hospitals and the Medical School of the University of Geneva in collaboration with the Geneva International and Non-governmental Organisations active in health and care. At this forum that was dedicated towards global access to health, Dr Mocumbi spoke on public private partnerships as a possible solution for the future and discussed on the strengthening of the long-term capacity in the public sector.

September was equally busy for Dr Mocumbi. During the month he attended the Second Conference on Regulation in the Pharmaceutical Industry which discussed access to life-saving medication at the Basel Institute on Governance, Switzerland, and spoke on the development of new clinical interventions to fight poverty-related diseases. On 12 September Dr Mocumbi met with senior officials at the Directorate General of Development at the European Commission (EC) in Brussels to advocate for a better coordination of research and development and to explore opportunities for capacity development in non-established sites. This was complemented with the development agenda of EC in Africa where it was agreed to include capacity development in the agenda for the up-coming meeting between the African Union Commission and the EU Commission in Addis, Ethiopia in October 2006.

### Malaria treatment study to be conducted in Burkina Faso

Dr Pascoal Mocumbi (High Representative); Mr. Simon Belcher (Financial Manager), and Dr Michael Makanga (Capacity Development Manager), made a site visit to Burkina Faso from the 4-8 September 2006. The team visited Nanoro District Health Centre located in the centre of Burkina Faso and the Centre Muraz, a national institute of medical research located in Bobo Dioulasso. These sites are preparing to undertake an EDCTP supported multicentre study on the evaluation of three artemisinin-based combinations for treating uncomplicated malaria in African children, which will be conducted in collaboration with Professor Umberto D'Alessandro as a project coordinator and Dr Tinto Hamidou a Burkinabe investigator.



*EDCTP High Representative, Dr Pascoal Mocumbi, talking to study patients at Nanoro District Health Center, Burkina Faso*

The Centre Muraz is also part of two EDCTP networking grants that are coordinated by Dr Nicolas Meda. These include development of MSc Course in Burkina Faso and Ghana, in collaboration with the London School of Tropical Medicine and Hygiene and strengthening of laboratory capacity and nutrition skills in the context of clinical trial for the prevention of mother-to-child transmission of HIV. The later grant involves two African sites: The Centre Muraz in Bobo-Dioulasso (BurkinaFaso) and the International Centre for Reproductive Health in Mombasa (Kenya); and the European network consists of the University of Ghent (Belgium), the laboratory of bacteriology and virology, Université de Montpellier (France) and the Institut de Recherche pour le Développement (IRD), UR24 (Nutrition), Montpellier (France).

The team along with the Partnership Board Member from Burkina Faso, Dr Sodiomon Bienvenu Sirima had separate meetings with several officials including: The head of delegation of the European Union in Ouagadougou, Burkina Faso, Mme Sari Soumalainen; Deputy Minister of Research, honourable Eloi Bambara; Director in charge of Health Research in Ministry of Health, Dr Hien Sié Roger; Director General of Pharmacies, Medicines and Laboratories, Dr Mahamadou Compaoré; Representative of the World Health Organisation Country Representative, Dr Kane Ibrahim; the National Ethics Committee Chairperson, Dr Ouaba Bindi, and the Head of Research Collaboration at the Belgium Embassy in Ouagadougou, Mme Marie-Goretti Nyirakundo among others.

## WHO-EDCTP collaboration on national regulatory framework for Africa

On September 19-22, 2006, The AFRO Vaccine Regulators' Forum (AVAREF) held its first meeting in Accra Ghana. The forum was organised by the World Health Organisation (WHO) and as one of the collaborative activities aimed at strengthening regulatory capacity in Africa with funding from the EDCTP and the Netherlands-African Partnership for Capacity Development and Clinical Interventions against Poverty related Diseases (NACCAP).

The forum brought together 80 participants from 25 countries the majority of them being African regulators involved either in the ethical or regulatory review of clinical trials applications or related functions in the regulatory pathway of vaccine products. The forum was also attended by researchers, product developers and regulatory experts from the European Medicines Agency (EMA) and



*Participants at the first Afro Vaccine Regulator's Forum in Accra, Ghana*

the Food and Drug Authority (FDA) of the United States of America. The African countries represented included Botswana, Burkina Faso, Cameroon, Cote d'Ivoire, Ethiopia, Gabon, Gambia, Ghana, Kenya, Malawi, Mali, Mozambique, Nigeria, Rwanda, Senegal, South Africa, Tanzania, Uganda, Zambia, and Zimbabwe.

The launching of AVAREF is in response to the critical need to establish a system to support National Regulatory Authorities (NRAs) in the assessment of clinical trial applications, evaluation of clinical trial data, monitoring of clinical trials and evaluation of marketing authorisation dossiers in Africa.

The forum aimed at:

- providing scientific information to regulators of African countries that are involved in clinical trials of poverty related diseases, meningitis, rotavirus and other priority vaccines, on issues relevant to clinical trials evaluation and plans for registration in Africa
- promoting communication and collaboration between clinical trial sponsors, clinical research organisations, NRAs and ethics review committees both in Africa and developed countries
- identifying the need for expert support to the African NRAs for the regulatory review of clinical trials applications, evaluation of clinical data for registration purposes and other NRA functions
- identifying needs for developing regulatory guidelines and procedures for the evaluation of vaccines.
- identifying additional training needs to be facilitated by WHO;
- identifying capacity needs of NRAs in the evaluation of clinical trial application, monitoring, registration dossiers and post approval safety monitoring
- promoting of networking among African NRAs to facilitate sharing of expertise and skills in the review of clinical trials, monitoring and evaluation of vaccines and harmonisation of guidelines for these processes.

Professor Charles Mgone, Head of Africa Office and Dr Michael Makanga the Capacity Developing Manager represented EDCTP at the forum.

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