



European and Developing Countries Clinical Trials Partnership

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EDCTP Newsletter

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### Head of Africa Office's Note

In the current issue of the newsletter we proudly announce the new-look DCCC, which is now almost complete and has fourteen members. The Committee had a very productive meeting on 1-2 June in Arusha, Tanzania and EDCTP is grateful to have such able and committed members. We are equally proud to introduce to all our partners David Coles who has joined EDCTP as our new North-North Networking Officer replacing Stefan Wagener who has completed his tenure. David brings with him a wealth of knowledge and experience on European Commission research operational matters. David you are most welcome and Stefan we wish you good luck and thank you for a job well-done.

The newsletter contains information on three important meetings that EDCTP has been proudly associated with. These include the Brussels Stakeholder Forum, The African Partnership Forum and the Sub-regional Consultation Meeting on HIV Vaccines in Africa. There is also information on our collaboration with the World Health Organisation on capacity building activities for regulatory framework in Africa. We are also pleased to announce the awarding of capacity building and networking grants to various grantees and wish them productive work and outcomes. Finally, but certainly not least, we are glad to remind our partners of the coming First EDCTP Investigators' Meeting and the Third EDCTP Forum that will held in Cape Town and Stockholm, respectively. Those who are involved in these two events are most welcome to the meetings and we look forward to very productive deliberations.

### News about the EDCTP Governance

#### The Tenth DCCC Meeting, Arusha, Tanzania

The Tenth DCCC Meeting of EDCTP took place in Arusha, Tanzania on 1-2 June 2006. The committee welcomed its eight new members who were elected in 2006. The new DCCC members who took office from June 2006 and will serve until December 2007 are Dr Andrew Kitua (Tanzania), Dr Peter Ndumbe (Cameroon), Dr Tumani Corrah (Gambia), Dr Mathieu Ndounga (Congo), Dr Awono Ambene (Cameroon/OCEAC), Dr

Christine Manyando (Zambia), Dr Walter Jaoko (Kenya) and Dr Gatsha Mazithulela (South Africa). During the meeting the current fourteen members of the committee elected Dr Simon Agwale (Nigeria) to be the new DCCC Chair and Dr Christine Manyando the Vice-Chair.

Among other things discussed at the meeting the members proposed strategies for strengthening African leadership in EDCTP that included strong partnerships with other organisations working in sub-Saharan Africa, identification of gaps expressed by African scientists that can be addressed by EDCTP and stimulation of research funding from African governments. The members elected new focal persons for the six major activity areas namely Dr Jaoko (HIV), Dr Kashongwe (TB), Dr Kitua (malaria), Dr Corrah (capacity building), Dr Toure



*Front row (left to right): Souleymane Mboup, Pascoal Mocumbi, Lynn Zijenah, Simon Agwale, Christine Manyando and Charles Mgone. Back row (left to right): Getachew Aderaye, Tumani Corrah, Walter Jaoko, Kobus Herbst, Jean-Paul Kashongwe, Peter Ndumbe, Andrew Kitua, Mathieu Ndounga, Aissatou Toure, Awono Ambebe and Thomas Nyirenda*

#### **EDCTP welcomes new North-North Networking Officer**

Stefan Wagner seconded to the position of North-North Networking Officer by the German Federal Ministry for Education and Science leaves EDCTP after six months of excellent work and strong commitment. In his place, EDCTP warmly welcomes David Coles who is seconded by the UK Department of Health and brings to the EDCTP Secretariat his experience in dealing with health related policy development in Europe. With a background in physiology, chemistry, risk analysis and ethics, David has worked as a UK seconded national expert in the European Commission's Directorate General of Research for the last four years, where he developed and implemented the current EU system of ethical review for research proposals submitted to the Sixth Framework Programme (FP6). He has also managed FP6 research projects on ethics and research and contributed to development of EU policy on ethics.

Before joining the European Commission, David was assigned as Assistant Director at the UK Office of Science and Technology. He was responsible for implementation of guidelines on use of scientific advice in policy-making and the development of a code of practice for scientific advisory committees. Besides that, he was involved in the development of government policy on public confidence in science. Previously at the UK Department of Health, he managed the establishment of the Human Genetics Commission and was assigned as the Commissions Secretary. Other work experiences on governmental policies include the development of the UK Department of Health policy on medical ethics, research ethics committees, overseeing the work of the Human Fertilisation and Embryology Authority, international chemical risk analysis and the development of UK Government guidelines on risk communication.



*On taking up his role at EDCTP David said "I am looking forward to making a contribution to this important, yet challenging, initiative. Faced with the scarce resources available when compared to the huge task of developing treatments for poverty-related diseases such as HIV/AIDS, malaria and tuberculosis, the opportunity offered by the EDCTP for encouraging co-operation between national research programmes, has tremendous potential for making the most of valuable national research resources and for increasing the effectiveness of clinical trial initiatives in developing countries".*

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

Capacity Building Grants	<b>Support for Ethics Courses and Seminars</b>
	AMANET: "Creating web-based research training courses in biomedical research ethics for Africans"
Networking Grants	<b>Support for the establishment and the strengthening of African National Ethics Committees or Institutional Review Boards</b>
	Paulina Tindana: Navrongo Health Research Centre, Ghana
	<b>Sponsorship of meetings or workshops of sustainable networks on an EDCTP relevant subject</b>
Jenny Hill: "A North-South working group to support the design integrated research proposals for malaria in pregnancy"	
<b>Providing incentives for joint capacity building programmes in Africa with two or more European institutions</b>	
Marleen Temmerman: " Strengthening laboratory capacity and nutrition skills in the context of an ICH GPC clinical trial for the prevention of mother-to-child transmission of HIV"	

## Events

### Brussel's Forum gathers world's stakeholders against poverty-related diseases

On June 28, about a hundred participants from Europe, Africa, North-America and Australia gathered in Brussels to discuss the missing or broken links in the chain between early-stage drug discovery and accessible medicines against poverty-related diseases such as AIDS, TB and malaria for many millions of patients, most notably in Africa.



The Open Stakeholder Forum was sponsored by the European & Developing Countries Clinical Trials Partnership (EDCTP), the Dutch Ministry of Foreign Affairs and the Netherlands Research Organisation (NWO).

Titled 'Connecting The Chain', the forum brought together many high-level representatives from governments, private charities, pharmaceutical industries, NGO's and public-private product-development partnerships (PDPs). Among the participants were representatives of the WHO, the Bill & Melinda Gates Foundation, Médecins Sans Frontières, the World Bank, USAID, the European Commission, and many PDPs and pharmaceutical companies.

Among the problems that were identified: a lack of incentives for research between early-stage discovery and clinical trials; a rapidly growing need for health care and clinical trial capacity in Africa; a lack of commitment on the part of many governments, including the European Union, to really engage in the issue; a proliferation of players that could hinder co-ordination and make it increasingly complicated for donors to enter the game; the lack of firm supply chain management, making industries wary to invest in manufacturing capacity; the risk for industries lured by procurement funds to end up developing the second-best drug; and the potential for very long delays between drug registration and actual market penetration in Africa.

It was the first time many of the global players debated these complex issues at length.

The day was concluded by remarks from Mr Koos Richelle, Director-General of the EuropeAid Co-operation Office of the European Commission.

### **EDCTP grantees meet for the first investigators meeting: Cape Town, 24-25 July 2005**

African scientists working on EDCTP funded projects will attend the first EDCTP investigators meeting that will be held at the Medical Research Council in Cape Town (South Africa) on 24-25 July 2006. The aim of the meeting is to establish a South-South network of researchers and institutions for coordinating and synergising activities related to clinical trials on the three major poverty-related diseases of HIV/AIDS, malaria and tuberculosis in Africa through the EDCTP platform. This meeting will bring together over 60 participants from research sites in Gambia, Zambia, Burkina Faso, Gabon, Nigeria, Rwanda, Tanzania, Uganda, Mali, Ivory Coast, South Africa, Ghana, Kenya and Sudan. Also invited are the collaborating European Institutions from Italy, The Netherlands, UK, Belgium, France, Germany and Ireland. Other participants expected to attend the meeting include NEPAD regional representatives, officials of selected regulatory authorities from African countries, EDCTP constituency members and the secretariat. At this meeting, participants will share their experiences and exchange information on existing projects to facilitate the establishment of South-South links including mentorship programmes, nodes of excellence and sharing of facilities and expertise. Participants will also explore common grounds of interest such as possible joint grant applications, defining of research agenda and priorities as determined by the ongoing projects, discussing regulatory issues, the establishment of a clinical trial registry and the role of African institutions in clinical trials sponsorship.

### **Third annual EDCTP Forum**

The Organising Committee for the Third EDCTP Forum announces that it has launched a portal at the EDCTP website. The portal gives all information pertaining to the forum including travel, climatic conditions, local attractions and social events. The Organising Committee also informs interested parties that it will continue to accept pragsters (short electronic presentations) until 21 July 2006. Bursaries to attend the meeting will be offered to those with selected pragsters from African countries.

## **Meeting and visits**

### **Sub-regional Consultation Meeting on HIV Vaccines R&D in Africa**

As a follow on to the preparatory consultation meeting that was held on 11 May in Nairobi, Kenya between EDCTP, African AIDS Vaccine Programme (AAVP), World Health Organisation (WHO), International AIDS Vaccine Initiative (IAVI) and other partners, a consultation meeting on HIV vaccines R&D was held in Nairobi on 26 and 27 June. The meeting which was also attended by representatives from the Human Sciences Research Council (HSRC) of South Africa, the AU Commission for Social Affairs, Centre for Diseases Control (CDC) and members of the HIV/AIDS scientific community from the Common Market for Eastern and Southern Africa (COMESA) and other African Regional Economic Communities, reviewed the research capacity and current state of affairs in R&D of HIV vaccines. The meeting which took place ahead of the African Union consultation meeting with African Regional Economic Communities deliberated in depth on the integration of HIV vaccines into AIDS national vaccine control programmes, formation of regional networks and the establishing of a common advocacy strategy. Other matters that were discussed at the meeting include harmonisation of regulatory and ethical frameworks, conduct of multicentre clinical trials and collaboration of regional centres. Recommendations from the meeting will be discussed at the African Union consultation meeting with Regional Economic Communities that will be held in Addis Ababa, Ethiopia later this year.

At the meeting EDCTP was represented by Charles Mgone, the Head of Africa Office.

### **EDCTP High Representative, Dr Pascoal Mocumbi speaks on the development of new HIV/AIDS interventions at the African Partnership Forum, Mozambique, 5 May 2006**

On 5 May 2006 Dr Pascoal Mocumbi, the EDCTP High Representative attended the the Sixth African Partnership Forum Meeting that was held in Maputo, Mozambique. This was a follow-up meeting in response to a decision that was made by the Joint Chairs of the African Partnership Forum (AFP) meeting that was held in

Maputo on 24 March 2006 and decided to address the three priority challenges for Africa, namely Agriculture & Food Security, Infrastructure and HIV/AIDS. Dr Mocumbi spoke on the need to accelerate access to the treatment of HIV/AIDS and related infections. Other speakers at the meeting included Mr. El-Hadj Sy, the Director of HIV/AIDS Group from the Bureau for Development Policy, UNDP and Ambassador Dr Sigrun Mogedal, the AIDS Ambassador for Norway. The meeting offered opportunity to share information on EDCTP activities with Representatives of G8 and of NEPAD Heads of State and Government committees.

Participants underlined the need to incorporate and align the AIDS response with the development response, tackling poverty and optimising use of available funds through the implementation and linking of the Paris Declaration on Harmonisation of Development Aid and the AIDS specific "Three Ones" approach and the GTT recommendations. Best practices in this regard should be shared and programmes taken to scale. It was also agreed that there needs to be a rapid acceleration of efforts to address factors that make women and girls more vulnerable to HIV infection and to ensure that gender policies are AIDS sensitive and vice versa that AIDS policies are gender sensitive.

Participants also recognized the exceptional political and leadership challenges that the AIDS epidemic poses and the extraordinary opportunity that the APF offers AU/NEPAD and OECD/G8 to pull together and give leadership in the fight against HIV/AIDS. For instance, African Partnership Forum offers an important arena for reflection, mutual accountability and overcoming barriers in the AIDS response, including through the APF peer review mechanism.

The APF communiqué following the meeting included a commitment to accelerate global efforts and regional capacity for the development of a vaccine and the urgently needed new drugs and microbicides against HIV and AIDS.

## EDCTP staff visit clinical trial sites Zambia and Rwanda

EDCTP aims to develop new therapeutic and preventive interventions for HIV/AIDS, tuberculosis and malaria, which are appropriate for the African populations by doing high quality research in Africa, where African researchers and policy makers play a crucial role. In this endeavour EDCTP representatives have embarked on a strategic plan of visiting clinical sites and meeting researchers, African leaders, World Health Organisation and European Commission country representatives and heads of Public Health Institutions as well directors of the national regulatory authorities and Chairs of the ethics review boards among others.

From 8 to 12 May this year, Dr Pascoal Mocumbi (EDCTP High Representative), Mr Simon Belcher (Financial Manager) and Dr Michael Makanga (Capacity Building Manager) visited Zambia. During this visit two main clinical sites and one satellite site were visited. These included the University of Zambia, which is involved in two EDCTP supported projects namely 'Children with HIV in Africa: pharmacokinetics and adherence of simple antiretroviral regimens (CHAPAS) trial', whose principal investigator is Professor Chifumbe Chintu and 'The rapid evaluation of Moxifloxacin in the treatment of sputum smear positive tuberculosis (REMOxTB)', which has Professor Gillespie as the principal investigator and Dr Peter Mwaba as Zambian investigator. The others sites visited in Zambia were the Ndola Tropical Diseases Centre (main site) and Chipulukusu (satellite site), which will undertake the evaluation of four artemisinin-based combinations for treating uncomplicated malaria in African children, with Professor D'Alessandro as the principal investigator and Dr Modest Mulenga as Zambian investigator.



*Visiting the Chipulukusu Clinic, Ndola, Zambia*

The visit also involved meetings with various officials including the Minister for Health, the Honourable Sylvia Masebo; the Director for Public Health and Research in the Ministry of Health, Dr Victor Mukoka; the representative for the European Commission Country Office, Mr. Emilio Rossetti; World Health Organisation Resident Representative, Dr Stella Anyangwe and the WHO technical team; Dean of University of Zambia School of Medicine, Professor Yakub Mulla; University of Zambia Ethics Institutional Review Board (IRB) Chair person, Professor Joseph Karashani; Deputy Managing Director of University Teaching Hospital, Dr Theresa Kafula, representative of the Director of Ndola TDRC, Dr. Victor Mwanakasale and the EDCTP Developing Countries Coordinating Committee (DCCC) member from Zambia, Dr Christine Manyando, among others.

From 22 to 26 May 2006, Professor Charles Mgone (Head of Africa Office), Mr Simon Belcher and Dr Michael Makanga visited Rwanda. The team visited the main site at the Programme National Intégré de Lutte Contre la Paludisme (PNLCP) and two satellite recruitment sites namely Kicumiro and Rukara health centres. These sites will be involved in an EDCTP supported project for the evaluation of four artemisinin-based combinations for treating uncomplicated malaria in African children, whose principal investigator is Professor D'Alessandro and the Rwandese investigator Dr Daniel Ngimuje.



*Visiting children at a nutritional rehabilitation center, Rwanda*

The team also met with the Minister for Health, the Honorable Dr Jean Damascène Ntawukuliryayo; the Minister of State in Charge of HIV/AIDS and other Epidemics, the Honorable Dr Innocent Nyaruhirira; the Belgium Ambassador to Rwanda Mr Marc Gedoft; the Belgian Embassy International Cooperation Attaché in Charge of the Health Sector, Dr Dick de Clercq; Chef de la Section Economie et Gouvernance (EC Office Kigali) Consellor Jean Barbe; the Chair National Ethics Committee, Dr Kayitesi Kayitenkore; Directeur de la Pharmacie, Dr Vedaste Munyankindi; Director for the Treatment Research AIDS Centre (TRAC), Dr. Anita Asimwe; Dr. Walli van Deren and Dr Martine Toussaint, Medical Advisors to the Ministry of Health for malaria and tuberculosis respectively; and Dr Jean Bosco Ahoranyezu, from the WHO Country Office, Kigali.

## **A Significant EDCTP and WHO Collaboration Towards Strengthening the Capacity of National Regulatory Framework in Sub-Saharan Africa**

The establishment and strengthening of National Regulatory bodies in sub-Saharan Africa is an enormous and yet mandatory task in the development and rational use of products (drugs, vaccines, diagnostics and devices) in the fight against poverty related diseases. EDCTP is collaborating with the WHO to strengthen the capacity of national regulatory framework in sub-Saharan Africa. EDCTP has committed a total of 200,000 Euros with an additional 160,000 Euros co-funding from the Netherlands African partnership for Capacity development and Clinical interventions Against Poverty-related diseases (NACCAP) to kick start this collaborative initiative. Fifteen sub-African countries namely Tanzania, Kenya, Uganda, Rwanda, Mozambique, Malawi, Zambia, Gabon, Ghana, Nigeria, Burkina Faso, The Gambia, Cote d'Ivoire, Mali, and Ethiopia have been earmarked for capacity building in of the regulatory framework for 2006 and first half of 2007. This will be done through training activities targeting key managers of national regulatory bodies, representatives from national ethics committees, immunisation programmes and a selection of African investigators. The training will be done through in-country and inter-country workshops on regulatory pathway activities including joint review of clinical trials applications, regulatory forum on clinical evaluation of malaria and HIV vaccines and regulatory monitoring and inspection of clinical trials. This capacity-building strategy also includes giving support to the WHO-Global Training Network (GTN) course, providing training and empowering national regulatory bodies on authorisation and evaluation of clinical trials. The GTN training will be conducted both in English and French.

Different strategies to strengthen sub-Saharan African countries national regulatory expertise are being implemented which include, among others:

- An assessment of the national regulatory framework against a published set of indicators which contributes to the review of existing strengths and gaps and leads to the development of an Institutional Development Plan (IDP). The developed IDPs will provide basis for the planned training and capacity building regulatory activities.
- Establishment of a Regional Regulatory Network of African experts in order to optimise the use of regional resources and expertise, and to creatively establish an alternative regulatory mechanism for the assessment of clinical trial applications and monitoring of clinical trials. This will also ensure the quality of clinical trials that are being conducted and the establishment of a regional network of experts. This network will serve as a reference for interested countries and provide a platform where countries can discuss issues with peers as a means to build on the expertise available in the region and to strengthen the capacity of weaker countries. This will also facilitate the harmonisation process of guidelines and procedures across countries.

## Announcement

As part of EDCTP's strategic plan for quality assurance, EDCTP was elected as a member of EFQM on 1 May 2006, supporting its mission to be the driving force for sustainable Excellence in Europe and to create a world in which organizations in Europe excel.

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