

European and Developing Countries Clinical Trials Partnership

Vol 5, No 1

EDCTP Newsletter

January 2010

2010: A new year of partnership in fighting HIV/AIDS, tuberculosis and malaria

Dear readers,

2009 has been a very eventful and prolific year for EDCTP. The current newsletter issue provides a snapshot of the activities in the fourth quarter of 2009. Included are highlights of the recently concluded Fifth EDCTP Forum and changes in the EDCTP governance structures. The EDCTP family also warmly welcomes Professor. Hannah Akuffo as the new GA Chair and greatly appreciates the outgoing Chair, Dr Diana Dunstan for the achievements and progress made. New appointments of DCCC office bearers, new DCCC members and changes in the North-North networking are covered.

EDCTP has continued to broaden its projects portfolio and this dispatch gives updates on the newly signed project grants, progress on the regional Networks of Excellence as well as the



Events

planned calls for applications for the first quarter of 2010. Moreover, in the spirit of strengthening African participation and contribution to the Partnership, EDCTP is engaging with various African governments, regional economic communities and high political structures including the African Union.

I wish you all a happy and highly productive 2010.

Charles Mgone, EDCTP Executive Director



Fifth EDCTP Forum: recommendations available online

The Fifth EDCTP Forum in October 2009 in Arusha, Tanzania brought together 450 scientific experts, policy makers, research funders and many other partners to network and plan for the continued fight against HIV/AIDS, tuberculosis and malaria in Africa. EDCTP wishes to thank all who attended and contributed to the success of this Forum. A broad range of research findings were shared through both oral and poster presentations, and valuable recommendations on the way forward were received.

The recommendations are available on the Fifth EDCTP Forum blog. EDCTP wishes to thank everyone that contributed to these as they help guide EDCTP's activities in the coming years.

Forum recommendations available on: www.edctp.org/forumblog

Reports of scientific sessions and satellite meetings

Report summaries of the scientific parallel and electronic sessions are now available online as

well as majority of the presentations on HIV/ AIDS, tuberculosis and malaria clinical trials and cross-cutting topics such as ethics and regulatory issues. In addition, reports were drafted for the satellite meetings *Universal standards for clinical trials in practice* organised by the "Switching the Poles" Clinical Research Network, and of *Ownership of research outcomes in sub-Saharan Africa* jointly organised by NACCAP and EDCTP.





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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) 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, click on Newsroom).



Events

Dr Alexis Nzila and Dr Dominique Pepper receive EDCTP awards for outstanding African scientist

The European & Developing Countries Clinical Trials Partnership (EDCTP) has given its Awards for Outstanding African Scientist to Dr Alexis Nzila and Dr Dominique Pepper.

Dr Alexis Nzila, Head of the Molecular Parasitology Group at the KEMRI Wellcome Trust Research Programme in Kilifi, received the Award for Outstanding Senior African Scientist. The award consists of a certificate of recognition together with a cash prize of EUR 20,000.

Dr Dominique Pepper of the Institute of Infectious Diseases and Molecular Medicine in Cape Town, South Africa, received the Award for Outstanding Junior African Scientist. This award consists of a certificate of recognition and a cash prize of EUR 10,000.

About the awards

The EDCTP Awards for Outstanding African Scientists will be extended on a biannual basis (once every two years). These awards are aimed at motivating and empowering African scientists to take scientific leadership and to stimulate building of research capacity in sub-Saharan Africa. There are two awards: one for a senior scientist, and one for a junior scientist (<30 years old). The next set of awards will be announced at the next

Partnership presentations

Various EDCTP partners participated in the Global Partnerships-session during the Forum. On the blog, you can now read about the work of Uganda Virus Research Institute (UVRI), Enhancing Support for Strengthening the Effectiveness of National Capacity Efforts (ESSENCE), Bill & Melinda Gates Foundation (BMGF), Wellcome Trust, European Vaccine Initiative (EVI), Medicines for Malaria Venture (MMV), International Partnership for Microbicides (IPM), African Malaria Network Trust (AMANET), Aeras Global TB Vaccine Foundation and the African AIDS Vaccine Programme (AAVP), These and other partners provide invaluable synergy and complementarities to EDCTP's work in fighting the three diseases on the African continent.

Read more about partnerships on www.edctp.org/forumblog

EDCTP Forum in 2011. A call for nominations will be published in the run-up to the Forum.

Please read the full article on the Forum blog: www.edctp.org/ forumblog



winner of EDCTP **Outstanding Junior Scientist Award**

Video message EU **Commissioner for** Science and Research

European Union Commissioner for Science and Research Dr Janez Potočnik addressed the audience at the opening ceremony through a video message. The EU Commissioner commented on the Dr Janez Potočnik, progress of research coordination **EU Commissioner** through EDCTP over the years, for Science and and referring to the independent evaluation of the EDCTP programme conducted in 2006, he remarks: "Because I have always believed in the noble purpose of this initiative. I decided to continue ... Now. almost three years later, it is paying off."

Watch the video message on www.edctp.org/forumblog



Dr Alexis Nzila (right), winner of EDCTP **Outstanding Senior Scientist award**

News about EDCTP governance

Professor Hannah Akuffo succeeds Dr Diana Dunstan as Chair of EDCTP General Assembly

The members of the General Assembly of the European & Developing Countries Clinical Trials Partnership (EDCTP) have elected Professor Hannah Akuffo as its Chair as of 1 January 2010. Prof. Akuffo succeeds Dr Diana Dunstan, who has chaired the Assembly between 2006 and 2009. Dr Gabriele Hausdorf was appointed and Professor Patrice Debré re-appointed as vice-Chair.

Professor Hannah Akuffo has a proven track record in research on the immunology of poverty-related diseases and has extensive experience with Euro-African research cooperation and funding. Prof. Akuffo was born in Ghana, trained in Ghana and the UK, and worked in among others Ethiopia and Uganda. She is currently Head of team of the Research secretariat of the Swedish International Development cooperation

Agency (Sida), and is known as a passionate advocate of research capacity building in low income countries. Before being elected as Chair, Prof. Akuffo was a member of the General Assembly for Sweden.

Changes in EDCTP governance: North-North networking

From 1 January 2010, EDCTP governance of North-North networking will change. Until 31 December 2010, European Networking Officers (ENOs) were in charge of these activities, and they were united in the European Network of National Programmes (ENNP). This Network of representatives of the European national programmes developed proposals to coordinate and join national research activities and funding.

In the new EDCTP governance structure, the representatives of the European national programmes will become a part of the General Assembly (GA), and will function as Deputy GA members. This change follows recommendations from various internal and

external stakeholders to simplify EDCTP governance and increase North-North research cooperation and integration. In the new organisation, the deputy-GA members will work closely with the GA members to develop a common coherent Member State strategy for integration and funding of research that falls within the scope of the EDCTP programme.



DCCC elects Chair and vice **Chairs and welcomes new** members

The members of the EDCTP Developing Countries Coordinating Committee (DCCC) have elected Professor Alioune Dieve as their



Research

News about calls and grants

Announcement of calls

In February 2010, three calls for proposals will be launched:

Senior Fellowships

Senior Fellowships NoEs

Senior Fellowship calls are intended to identify and support senior researchers capable of building and leading research groups at sub-Saharan African institutions that will be internationally competitive and capable of winning grants from international funding bodies. Two calls will be launched: one stand-alone Senior Fellowship call, and one call for Senior Fellows within the context of EDCTP-funded Networks of Excellence for clinical trials.

Ethics

Ethics calls are intended to strengthen local capacity in both Ethical Review and the National Regulatory framework in Africa,

These calls will be published in February on www.edctp.org

Funded projects

EDCTP is pleased to announce funding of the following projects:

Call: Establishment and the strengthening of African National Ethics Committees (NECs) or Institutional Review Boards (IRBs)

Strengthening African Research Ethics Committees' capacity for ethical review of HIV prevention research

Project Coordinator: Douglas Wassenaar

Project Coordinator: Okyere Boateng Budget: € 49,808 Duration of project: December 2009 -December 2010 African countries involved: Ghana

Research Ethic Committee of Senegal

Project Coordinator: Samba Cor Sarr

Duration of project: December 2009 -December 2011 African countries involved: Senegal

Call: Senior Fellowships

Immune reconstitution inflammatory syndrome (IRIS) in Schistosomiasis patients undergoing HAART

Project Coordinator: Pauline Mwinzi Budget: € 185,668.64 Duration of project: November 2009 -November 2011 African countries involved: Kenya

A randomised controlled trial of oral iron therapy for treatment of post-malaria iron-deficiency anaemia in Malawian children comparing immediate postdischarge versus delayed treatment on iron uptake and haematological response

Project Coordinator: Kamija Phiri Budget: € 199,145 Duration of project: September 2009 -September 2011 African countries involved: Malawi

new Chair, and Professor Nkandu Luo and Dr Veronique Penlap as vice-Chairs. In addition, four new members have joined the DCCC. Below, the new DCCC Chair and the new members are introduced.

EDCTP wishes to thank Dr Andrew Kitua (former DCCC Chair), Prof. Tumani Corrah, Dr Christine Manyando (former Vice Chair) and Prof. Peter Ndumbe for their commitment to making the voice of African researchers heard in the EDCTP partnership in the past few years.



Introducing the new DCCC **Chair: Professor Alioune Dieye** The DCCC welcomes Prof. Alioune Dieye as the new Chairperson. Prof. Dieye succeeds Dr Andrew Kitua as the DCCC's Chair.

Prof. Alioune Dieye

Prof. Dieye was trained and awarded a PhD (1984), DSc (1992) at the University of Dakar. He had

additional training programmes in advanced immunology. His research activities are mainly on malaria immunology.

Dr Dieye became Professor Agrégé of Immunology (CAMES, 1996) and full professor (CAMES, 2000). He was appointed Deputy Director of Institute Pasteur of Dakar (2001). From December 2002 to November 2005, he was appointed Seconded National Expert in the Directorate-General for Research (European Commission), and contributed to the establishment of the EDCTP partnership and its implementation in Africa. He managed the interaction between Health Research Direction and Developing Countries in particular sub-Saharan Africa.

New members

Dr Martin Antonio (TB expert Western Africa Region)

Bacterial Diseases Programme of the Medical Research Council (MRC), The Gambia

Dr Antonio obtained an MSc from the London School of Hygiene & Tropical Medicine (LSHTM) UK and a PhD in molecular microbiology from St. Bartholomew's and The Royal London School of Medicine UK. He joined the Medical Research Council Laboratories (UK), The Gambia, in 2005 as a Senior Scientist in Molecular Biology and Head of the Mycobacteriology Laboratory. He is also the Biological Safety officer and administratively in charge of the Unit's Containment level III facility housing HIV and TB laboratories. In 2008 Dr Antonio was appointed Honorary Lecturer at the LSHTM UK. Dr Antonio's research focuses on the leverage of new molecular technologies in clinical trials and he leads a wide range of projects dealing with clinical, epidemiological and laboratory science leading to large intervention clinical trials in West Africa.

Dr Martin Antonio replaces Prof. Tumani Corrah of the same institution.

Dr Modest Mulenga (malaria expert Southern Africa region)

Tropical Diseases Research Centre (TDRC), Ndola, Zambia

Dr Modest Mulenga obtained an MSc in Infection and Health in the Tropics (Clinical

Budget: € 49,500 Duration of project: November 2009 -November 2012 African countries involved: South Africa

Establishment of National Research Ethics Committee and strengthening of newly established IRBs/RECs in Ghana

Programme for strengthening National (CNRS)

Budget: € 50,000

The effect of HIV co-infection on the immune response to Mycobacterium tuberculosis in the lung

Project Coordinator: Wendy Anne Burgers Budget: € 199,980 Duration of project: October 2009 – October 2011 African countries involved: South Africa

Evaluating antiretroviral drug resistance in HIV-infected children in Africa

Project Coordinator: Cissy Mutuluuza Kityo Budget: € 196,900 Duration of the project: November 2009 – November 2011 African countries involved: Uganda

HIV/AIDS Vaccines

HIV vaccine trial capacity building in Tanzania and Mozambique by continued exploration of optimal DNA and MVA boosting strategies; TaMoVac II

Project Coordinator: Eligius Lyamuya Budget: \in 6,367,429 (\in 3,499,331 EDCTP) Duration of the project: November 2009 – June 2014

African countries: Mozambique, Tanzania Cofunding partners: SIDA (Sweden), DFID (UK), MRC (UK), Institute for Medical Bioinformatics (Germany), BMBF (Germany)

Regional Networks of Excellence

TESA - Trials of Excellence in Southern Africa

Project coordinator: Alexander Pym Budget: € 2,640,548 (€ 2,337,304 EDCTP) Duration of the project: November 2009 – November 2011

African countries involved: Botswana, Malawi, Mozambique, South Africa, Zambia, Zimbabwe

HIV/AIDS treatment

International Phase 2b randomised clinical trial to study a once-a-day maintenance

Project coordinator: Valeriane Leroy Budget: € 3,442,969 (€ 1,355,862 EDCTP) Duration of the project: November 2009 – August 2013

African countries involved: Burkina Faso, Cote d'Ivore, Rwanda

Cofunding partners: Ministry of Foreign Affairs (MAE) (Luxembourg), Treatment and Research AIDS Center (TRAC) (Rwanda), Fonds National de la Recherche (Luxembourg)

TB treatment: Support of phase I, II and III clinical trials on new drugs and improved drug combinations

Rapid evaluation of moxifloxacin in tuberculosis - REMox TB

Project coordinator: Stephen Gillespie Budget: € 8,413,760 (€ 4,206,880 EDCTP) Duration of project: September 2009 – February 2014

African countries involved: Kenya, South Africa, Tanzania, Zambia Cofunding partners: MRC (United Kingdom), TB Alliance (USA), Bill & Melinda Gates Foundation (USA), NACCAP (Netherlands)

Erratum

In the October 2009 newsletter, there was an error in the overview of African countries involved in the project *A proof-of-concept Phase IIb clinical trial to evaluate the protective efficacy of a booster MVA85A vaccination* (Martin Ota). The following countries are involved: The Gambia, Senegal, South Africa.

Tropical Medicine) (with Distinction), a PhD in Tropical and Infectious Diseases from the University of London, and a degree in Health Systems Management. Dr Mulenga is Director and Chief Executive Officer at the Tropical Diseases Research Centre, Ndola, Zambia (TDRC) and a member of various national research committees in the country. He is also the country representative and Board Member on the Joint Coordinating Board of the WHO/UNDP/UNICEF and World Bank Special Programme for Research and Training in Tropical Diseases (TDR). Dr Mulenga's clinical research interests are in povertyrelated tropical and infectious diseases, with emphasis on epidemiology and interventional trials, with an emphasis on malaria and HIV/ AIDS.

Dr Modest Mulenga replaces Dr Christine Manyando of the same institution as malaria expert from Southern Africa.

Professor Angélique Ndjoyi Mbiguino (HIV/AIDS expert Central Africa region) Department of Microbiology, Faculty of

Medicine, University of Health Sciences, Libreville (Gabon)

Professor Mbiguino obtained an MSc in medical microbiology at the University of Laval (Canada) and a PhD in virology at the University of Montreal (Canada). She returned to Gabon in 1992 to work for the Faculty of Medicine of the University of Health Sciences, Libreville. Currently, she is the head of the Department of Microbiology.

Professor Mbiguino's research focuses on microbiology, mainly on virology, immunology and molecular biology. She is an expert in AIDS and is a member of the Consultative Committee of antiretroviral therapy, contributor in the training of physicians on HIV /AIDS, and responsible for the diagnosis, follow-up and virological monitoring of people living with HIV.

Professor Mbiguino replaces Professor Peter Ndumbe of University of Buea in Cameroon as HIV/AIDS expert for Central Africa.

Professor Jasper Ogwal-Okeng (malaria expert Eastern Africa region) Department of Pharmacology of the Makerere University, Kampala, Uganda

Prof. Ogwal-Okeng obtained a medical degree (MBChB) at Makerere University and a PhD in Clinical Pharmacology at the University of Illinois in Chicago. He worked as lecturer at Makerere University from 1990 and became full professor of Pharmacology 2005. He is also founder Dean of faculty of medicine, Gulu University in Uganda.

In addition to his work at Makerere University, Prof. Ogwal-Okeng is involved in health research ethics and is also member of Pharmacovigilance Committee of the Uganda National Drug Authority.

Prof. Jasper Ogwal-Okeng replaces Dr Andrew Kitua, who was Director General of National Medical Research Institute (NIMR), Tanzania until May 2009, as malaria expert for Eastern Africa.

Focus on EDCTP grantees

Networks of Excellence for Western, Eastern, Central and Southern Africa now all in progress

All EDCTP-funded Networks of Excellence (NoEs) have started their activities. Each region of sub-Saharan Africa now has its own network: Western Africa has WANETAM, Eastern Africa has EACCR, Central Africa has CANTAM, and Southern Africa has TESA. The regional Networks unite institutions that collaborate on the basis of their complementary individual strengths such as in good practises for conduct of clinical trials (GCP and GCLP), data management and laboratory capacity. The networks have infrastructural development as well as human capacity development components. Through facilitation of collaborative research activities, training and mentorship schemes, these networks are anticipated to raise the quality of clinical research and practice in sub-Saharan Africa.

Collaboration and political support

To ensure sustainability and avoid duplication, the networks will strive to collaborate with similar initiatives such as the planned World Health Organization's (WHO) centres of excellence of WHO AFRO and its country offices. In addition, the networks actively seek political goodwill and financial support of African national governments and regional economic communities.

Introducing the networks

Western Africa: WANETAM

The West Africa NoE for TB, AIDS and Malaria (WANETAM) builds capacity to prepare West African sites for clinical trials on HIV, TB and malaria. The network started its activities on 31 July 2009 and is coordinated by Professor Souleymane Mboup. The Network includes institutions from Burkina Faso, The Gambia, Ghana, Guinea-Bissau, Nigeria, Mali, and Senegal.

Eastern Africa: EACCR

The East Africa Consortium for Clinical Research (EACCR) strengthens clinical trial sites in Eastern Africa. The Network started 14 May 2009 and is coordinated by Dr Pontiano Kaleebu. The Networks unites institutions from Ethiopia, Germany, Kenya, the Netherlands, Norway, Sweden, Sudan, Tanzania, United Kingdom and Uganda.

Central Africa: CANTAM

In Central Africa, the Central African Network on TB, HIV/AIDS and malaria (CANTAM)

joins institutions involved in clinical trials. The Network started its activities on 19 December 2008 and is coordinated by Prof. Francine Ntoumi. Partnering institutions in the Network are based in Cameroon, Congo, Gabon and Germany.

Western Africa: WANETAM

Eastern Africa: EACCR

Central Africa: CANTAM

Southern Africa: TESA

Southern Africa: TESA

The Trials of Excellence for Southern Africa (TESA) Network focuses on the Southern African region. It started on 23 November 2009 and is coordinated by Dr Alexander Pym. The Network's partners are based in Botswana, France, Germany, Malawi, Mozambique, Netherlands, South Africa, Sweden, the United Kingdom, Zambia and Zimbabwe.

Meetings and visits

Visit to AU commissioner for Social Affairs



On 1 December 2010 the EDCTP High Representative, Dr Pascoal Mocumbi and the Director South-South Cooperation and Head of Africa Office, Dr Michael Makanga visited the African Union's secretariat, the African Union Commission, in Addis Ababa, Ethiopia. The focus of this meeting was sharing information about EDCTP activities in Africa and the need to enhance African participation and contribution to the EDCTP Partnership.

During this visit the EDCTP delegation had a meeting the African Union Commissioner for Social Affairs, Advocate Bience Gawanas together with various African Union Commission Department of Social Affairs (AUC-DSA) representatives. Among the AUC-DSA officials were AUC-DSA expert for HIV/AIDS, tuberculosis & malaria, Dr Grace Kalimugogo; UNAIDS-AUC Liaison Officer, Dr Bernadette Olowo-Freers; Senior Health Officer for HIV/AIDS, tuberculosis & malaria, Dr Benjamin Djouldabaye; and Senior Health Officer-Health, Population & Nutrition, Dr Mabyuto Kango. Also in attendance was the Mozambican Ambassador to Ethiopia, His Excellency Mr Manuel Lubisse.

From right to left: Mozambican Ambassador to Ethiopia His Excellency Mr Manuel Lubisse, Dr Grace Kalimugogo, Dr Michael Makanga, Advocate Bience Gawanas (AU Commissioner for Social Affairs), Dr Pascoal Mocumbi, Dr Mabvuto Kango, Dr Bernadette Olowo-Freers and Dr Benjamin Djouldabaye

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