

Note from the Africa Office

Dear readers,



It is a pleasure to present to you the current issue of the EDCTP newsletter featuring the progress and activities of EDCTP over the second quarter of 2010. The Partnership has continued to soar with activities matched with measurable progress, and a snap shot of these are highlighted in the recent release of the EDCTP 2009 Annual Report. An update on the new projects adding to the rapidly growing project profile is also covered in this issue. Moreover, a glance of one of the recently concluded projects on custom made treatments for HIV-infected children, lead by Professor Chifumbe Chintu from Zambia is cited. EDCTP also proudly recognises the outstanding

achievement of one of its grantees, Professor Marleen Temmerman who was awarded the British Medical Journal's group award for lifetime achievement. Additionally, you are encouraged to check out the two new calls, one on the evaluation of the impact of clinical trials in Africa and the second one, a repeat Member States Initiated call. Both calls will be launched mid-August 2010.

The recently concluded EDCTP Connecting the Chain II, meeting held in Brussels on 9 June 2010, whose theme was 'Linking Research and Development' features in this issue. EDCTP extends special thanks to all its stakeholders who participated in making this meeting a great success.

EDCTP has continued with site visits to EDCTP-funded projects and pursuing dialogue with policy makers in the countries where the research work is actually done. In the last quarter, an EDCTP team visited institutions in Rwanda and met with various officials as covered in this issue. Furthermore, an EDCTP delegation had a meeting with the African Union Commission Chairperson, an activity aimed at mutual sharing of information and strengthening strategic collaboration between the African Union and EDCTP.

As EDCTP continues to chart its course forward, the current period represents an important landmark for the organisation. This is a period of reflection, consolidation and continued harnessing of feedback and views of all our valued stakeholders. With this note I wish to draw your attention to the European Commission independent review panel evaluation report on the end-of-term review on the EDCTP programme which is available both on the EDCTP and European Commission websites. I also would like to take this opportunity to recognise and appreciate the enthusiastic support of all our stakeholders for participating in the ongoing public European Commission consultation.

I hope you enjoy reading this newsletter.

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

Events

Connecting the Chain II: Linking Research and Development

On 9 June 2010, more than 60 representatives of European and African research organisations and Universities, policy makers, development agencies, Product Development Partnerships (PDPs), Philanthropic organisations and other stakeholders in the fight against poverty-related diseases, met at the University Foundation in Brussels, Belgium to discuss the impact of the current EDCTP programme as well as discuss its future outlook. The deliberations of this meeting focused on the health development agenda in Africa, and how to explore and bridge gaps between development cooperation and research.

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Events (continued from page 1)

The main subject matter was the question on how to bridge the gap between research, policy and practice. The highly interactive sessions were facilitated by Chairperson Prof. Sir Andrew Haines, where the participants addressed six major issues:

1. How to develop effective strategies for engagement and coordination of research and development aid partners, and how to bridge the existing gaps between them
2. How to coordinate and improve synergies between clinical research and sustainable capacity development for health systems
3. How to strengthen governments to create good governance and good practice across research and aid

4. How to bridge the gap in translational research between generation and implementation of applied research, i.e. between products and delivery of new medicinal products to patients
5. Strategies for sustainable capacity building, utilisation and retention of expertise built within research and health care systems
6. The needs and role of Centres or Networks of Excellence.

The meeting was kicked off by seven speakers representing European and African research, policy and development organisations. In the animated discussion following the presentations, several recommendations were

made to improve and strengthen the impact of the EDCTP activities. One of the major points of discussion was the question on the role of EDCTP on health optimisation research.

Other valuable remarks concerned the role of EDCTP in advancing the implementation of research results, increasing the attention for ethical and regulatory aspects of health research and strengthening local communities by capacity building.

EDCTP will take all recommendations into consideration, and wishes to thank all those who participated in the meeting for their valuable inputs.

The meeting report and presentations will soon be available on the website www.edctp.org/connectingthechain.



Presentation from the *Gezellschaft für technische Zusammenarbeit (GtZ)*, Germany at the Connecting the Chain II

News about EDCTP governance

EDCTP Annual Report 2009



EDCTP is pleased to announce the release of its annual report 2009. 2009 proved to be yet another successful and rewarding year for EDCTP. In the course of the year the Partnership launched seven

calls for proposals including the new grant scheme of European Member State Initiated (MSI) projects. A total of 31 grants contracts were signed; these include 17 grants for Integrated Projects on clinical trials, four Senior Fellowships, six Ethics/IRB support, two Joint Programme Activities and three Networks of Excellence.

Additionally, in 2009 the average number of countries collaborating in EDCTP integrated projects was three for European and seven for sub-Saharan African countries. Furthermore, a significant proportion of clinical trials had a

greater involvement of European Member States with 35% of all EDCTP-funded clinical trials having four or more European Member States collaborating in a project. This represents a very good level of integration.

Another highlight of the year was the Fifth EDCTP Forum in Arusha, Tanzania, on 12 to 14 October 2009. The theme '*Fighting HIV/AIDS, tuberculosis and malaria – One World, One Partnership*' was well reflected by the wide participation which included 450 delegates from 49 different countries and the presentations from many EDCTP partners.

The Annual Report 2009 includes a summary in French and Portuguese, and is available on the website www.edctp.org. If you wish to receive a printed version please send your request to info@edctp.org.

Evaluation report of the end-of-term review on EDCTP programme released

The final evaluation report on the European and Developing Countries Clinical Trials Partnership (EDCTP) programme by an Independent External Evaluation Committee has been released. This review process, which started in July 2009, was commissioned by the European Commission aiming to deliver recommendations on the continuation of the programme after September 2010, when the EDCTP current constitution officially ends.

The full report is available on the EDCTP website at www.edctp.org.

News about calls and grants

Announcement of calls

The following calls for proposals will be launched in August 2010:

Call: Evaluating the impact of clinical trials in Africa

The purpose of this grant is to gain comprehensive insight into the impact of clinical trials on health services in sub-Saharan Africa, especially with regard to the quality of those services delivered to women and/or children.

In this call, emphasis is placed on evaluating the impact from the perspective of patients; health professionals; the community; and, public health services at the sites in sub-Saharan Africa, where the clinical trials are being conducted.

Call: Member States Initiated projects

European Member States often independently fund projects that fall within the remit of EDCTP. 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.

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

Calls open for applications

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, tuberculosis and malaria
- Postgraduate training awards
- Capacity building grants including ethics and establishment of networks of excellence.

For more details, please refer to the call text on the EDCTP website at www.edctp.org.

Funded projects

EDCTP is pleased to announce funding of the following projects:

Call: Support of clinical trials, capacity building and networking in new and improved diagnostics for tuberculosis

The evaluation of *Mycobacterium tuberculosis* specific host cytokine signatures in whole blood culture supernatants as diagnostic biomarkers for active TB infection

Project Coordinator: Gerhard Walzl
Budget: € 4,387,203 (€ 3,349,570 EDCTP)
Duration of project: June 2010-June 2013
African countries involved: Ethiopia, The Gambia and South Africa
Cofunding partners: BMBF (Germany), EU Research (Germany), Leiden University (Netherlands), LSHTM (United Kingdom), Makerere University (Uganda), Max Planck Institute (Germany), Medical Research Council (United Kingdom), NACCAP (Netherlands) and Stellenbosch University (South Africa)

Evaluation of new and emerging diagnostics for childhood tuberculosis in high burden countries (TB CHILD)

Project Coordinator: Fred Lwilla
Budget: € 3,309,885 (€ 1,532,586 EDCTP)
Duration of project: May 2010-May 2013
African countries involved: South Africa, Tanzania and Uganda
Cofunding partners: AISPO-Nsambya Hospital (Uganda), Federal Ministry of Education and Research (BMBF) (Germany), Foundation for Innovative New Diagnostics (FIND) (Switzerland), Klinikum der Universität München, Institute for Medical Bioinformatics (Germany), Ministry of Foreign Affairs (Italy), San Raffaele del Monte Tabor foundation (Italy), Swiss Agency for Development and Cooperation (SDC) (Switzerland) and Swiss National Science Foundation (Switzerland)

Evaluation of multiple novel and emerging technologies for TB diagnosis, in smear-negative and HIV-infected persons, in high burden countries (the TB-NEAT study)

Project Coordinator: Keertan Dheda
Budget: € 7,265,164 (€ 2,615,164 EDCTP)
Duration of project: May 2010-May 2013
African countries involved: South Africa, Tanzania, Zambia and Zimbabwe
Cofunding partners: Delft Imaging Systems BV (Netherlands), Federal Ministry of Education and Research (BMBF) (Germany), Foundation for Innovative New Diagnostics (FIND) (Switzerland), Klinikum der Universität München, Institute for Medical Bioinformatics (Germany), Medical Research Council (United Kingdom), Netherlands Organisation for Scientific Research (NWO) (Netherlands) and Swedish International Development Cooperation Agency (SIDA) (Sweden)

Call: Identification and Strengthening of Joint Programme Activities

Integrated training activities and IT infrastructures to improve capacities in eastern Africa area

Project Coordinator: Anders Sönerborg
Budget: € 282,908
Duration of project: May 2010-May 2013
African countries involved: Ethiopia, Kenya and Tanzania

Improved diagnostic and prognostic tools to combat tuberculosis in high endemic areas - from bench to clinical trials

Project Coordinator: Thomas Schoen
Budget: € 213,087
Duration of project: April 2010-April 2013
African countries involved: Ethiopia and Guinea-Bissau

Erratum

In the April 2010 newsletter, there was a mistake in the duration of project in the project '*Integrating capacity building and networking in the design and conduct of Phase I and II clinical trials of viral vectored candidate malaria vaccines in East and West African children and infants (Vectored Malaria Vaccines)*' (Egeruan Babatunde Imoukhuede). The correct duration of project is February 2010-February 2013.

Call: Establishment and strengthening of African National Ethics Committees or Institutional Review Boards

Strengthening ethical review capacity of the Joint Clinical Research Centre-IRB and collaborating IRBs in North and Western Uganda

Project Coordinator: Peter Mugenyi
Budget: € 49,759
Duration of project: May 2010-May 2012
African countries involved: Uganda

Strengthening of the National Ethics Committee in Gabon and creation of a Central African Ethics Committee Network (CAEN)

Project Coordinator: Pierre-Blaise Matsiegui
Budget: € 49,995
Duration of project: May 2010-May 2013
African countries involved: Gabon

Establishment and training of an Institutional Review Board (IRB) at the Kigali University Teaching Hospital (KUTH) to strengthen the ethical review capacities in Rwanda

Project Coordinator: Stephen Rulisa
Budget: € 47,850
Duration of project: May 2010-May 2011
African countries involved: Rwanda

Strengthening the capacity of UL-PIRE IRB

Project Coordinator: James Kollie
Budget: € 47,740
Duration of project: April 2010-April 2012
African countries involved: Liberia

Training and resources in research ethics evaluation for Africa

Project Coordinator: Dominique Sprumont
Budget: € 49,350
Duration of project: March 2010-March 2011
African countries involved: Mozambique, Nigeria and Senegal

Call: Senior Fellowships

Building research infrastructure and capacity to implement an HIV/STD prevention trial in post conflict Liberia

Project Coordinator: Stephen Kennedy
Budget: € 198,776
Duration of project: May 2010-May 2012
African countries involved: Liberia

Evolution of neutralizing antibodies among acute to early HIV subtype C infected individuals in Botswana: one year longitudinal study

Project Coordinator: Takafira Mdlulza
Budget: € 199,870
Duration of project: May 2010-May 2012
African countries involved: Botswana and Zimbabwe

A cluster-randomised controlled trial to assess the impact of combined strategies (impregnated bed nets plus home management of malaria oriented by Rapid Diagnosis Test) on severe malaria morbidity in children aged 6 to 59 months in Burkina Faso

Project Coordinator: Alfred Tiono
Budget: € 199,956
Duration of project: April 2010-April 2012
African countries involved: Burkina Faso

Evolution of HIV-1 ARV drug resistance mutations in the ART naïve during therapy; threshold frequency levels and linkage context associated with treatment failure in Uganda

Project Coordinator: Jonathan Kayondo
Budget: € 198,054
Duration of project: March 2010-March 2012
African countries involved: Uganda

Career development and strengthening institutional capacity for clinical research in TB at the Faculty of Health Sciences in Brazzaville

Project Coordinator: Sunny Okhaide Oyakhrome
Budget: € 200,000
Duration of project: April 2010-April 2012
African countries involved: Cameroon and Gabon

The risk of pulmonary tuberculosis associated with intestinal helminth infection among children at two tuberculosis vaccine trial sites in sub-Saharan Africa

Project Coordinator: Mark Hatherill
Budget: € 198,055
Duration of project: April 2010-April 2012
African countries involved: Kenya and South Africa

Focus on EDCTP grantees

Prof. Marleen Temmerman receives the BMJ's Group Award for Lifetime Achievement



Professor Marleen Temmerman, a Professor of Obstetrics and Gynaecology at the University Hospital in Belgium, has been honoured with the Lifetime

Achievement Award of the British Medical Journal (BMJ) at the ceremony that took place on 10 March 2010. This award is conferred upon an individual who has, over his or her working lifetime, made a unique and substantial contribution to improving health care, whether in clinical practice, health services, public health, health policy, medical education, or medical research. The jury selected 10 nominations from the 117 proposals that were put forward, where Prof. Temmerman exceeded all candidates and was selected the winner for her commitment to improving women's reproductive and sexual health and rights, especially in Africa.

EDCTP is proud to have Prof. Temmerman as a beneficiary of its funding both as principle investigator and as collaborator in various EDCTP-funded researches, and warmly congratulates her for this important achievement.

More information on the BMJ's Group Award: <http://groupawards.bmj.com>

Focus on EDCTP grantees

Project at a glance: Custom made treatments for HIV-infected children (Prof. Chifumbe Chintu, Zambia)

Lack of appropriate antiretroviral formulations for HIV-infected children has been one of the major constraints to scaling up of treatment in HIV-1 infected children in resource limited countries. Triomune Baby/Junior is a fixed dose combination of stavudine (d4T), lamivudine (3TC) and nevirapine (NVP) in a new formulation specifically developed for children.

Professor Chifumbe Chintu and his team in collaboration with the Medical Research Council (United Kingdom), Radboud University Nijmegen (Netherlands), University of Padova (Italy), University of Zambia and University Teaching Hospital Zambia, with an EDCTP grant studied the appropriate dosing of, and adherence to Triomune Baby/Junior in the project entitled '*Children with HIV in Africa-Pharmacokinetics and adherence of Simple Antiretroviral Regimens (CHAPAS-1 Trial)*'. This project, which started in November 2005, had a major breakthrough with preliminary Pharmacokinetics (PK) data

being shared with the Food and Drug Authority (FDA) of the United States of America. This data contributed to the approval of Triomune Baby/Junior for use in HIV-infected children, in August 2007. This approval has allowed these two Fixed-Dose Combination (FDC) drugs to be used in programmes and projects supported by US organisations. Triomune Baby/Junior FDC drugs are now widely used in Zambia, Uganda and Zimbabwe, and many sub-Saharan African countries may soon benefit from using these products.

The outcomes of this trial have resulted in World Health Organization (WHO) recommendations for the most optimal ratios of antiretroviral drugs in fixed dose combination solid formulas, and have been used as input for the definition of an optimal weight band for these drugs in children.

Future research plans

The CHAPAS-1 trial was completed in 2009.

The trial specifically aimed to address the complete lack of appropriate first-line antiretroviral regimens available for children in developing countries that was preventing children gaining access to treatment in 2005 when CHAPAS-I started. The next EDCTP-funded CHAPAS project, '*Expanding the availability of fixed dose combination antiretroviral formulations for first-line treatment of HIV-1 infected children - the Children with HIV-1 in Africa Pharmacokinetics Acceptability/Adherence of Simple Antiretroviral Regimens: CHAPAS-3 Trial*', is planned to be undertaken by the other CHAPAS-3 sites. This study aims to examine the PK of a new paediatric Lopinavir/ritonavir (LPV/r) sprinkle compared to paediatric LPV/r tablets and liquid. This is anticipated to be a useful second-line formulation appropriate for paediatric use.

More information: access the project profile for '*Children with HIV in Africa-Pharmacokinetics and Adherence of Simple Antiretroviral Regimens*' on the EDCTP website at www.edctp.org.



The CHAPAS-1 team group

Meetings and visits

Meeting with the African Union Commission Chairperson

On 26 April 2010, the EDCTP Executive Director, Professor Charles Mgone; the High Representative, Dr Pascoal Mocumbi; and the Director of South-South Cooperation and Head of Africa Office, Dr Michael Makanga visited the African Union Commission in Addis Ababa, Ethiopia. During this visit the EDCTP delegation had a meeting with the African Union Commission Chairperson, His Excellency Mr Jean Ping. Also in attendance were: the African Union Commission Director for Social Affairs, Dr Olawale Maiyegun; Chief of Staff of the Bureau of the Chairperson, Mr John Shinkaiye; Deputy Chief of Staff of the Bureau of the Chairperson, Mr Pierre Moussavou and the of Ambassador of Mozambique in Ethiopia, Mr Manuel Lubisse.

The objectives of this meeting were three fold:

1. Sharing information about EDCTP activities in Africa and the need to enhance African participation and contribution to the Partnership



From left to right: Dr Michael Makanga, Dr Pascoal Mocumbi, His Excellency Mr Jean Ping and Prof. Charles Mgone

2. Updating the African Union Commission Chairperson on EDCTP strategy for African representation at the General Assembly (GA) with focus on African Union involvement
3. Exploring ways of strengthening strategic collaboration between the African Union and EDCTP.

EDCTP site visit to Kigali, Rwanda

Rwanda is one of the African countries with increasing number of EDCTP-funded projects from 2005 to 2010. Currently, the following projects are either ongoing or recently completed:

1. Strengthening of the Rwanda National Ethics Committee (led by Dr Justin Wane)
2. Establishment and Training of an Institutional Review Board (IRB) at the Kigali University Teaching Hospital (KUTH) to Strengthen the Ethical Review Capacities in Rwanda (led by Dr Stephen Rulisa)
3. Project Ubuzima: Preparing for Phase III vaginal microbicide trials in Rwanda and Kenya : Preparedness studies, capacity building, and strengthening of medical referral systems (led by Dr Van der Wiggert and Dr Kishor Mandaliya)
4. The Monod Project multi-centre trial on simplifying paediatric ART (led by Dr Valerienne Leroy and Dr Corine Karema)
5. Safe and efficacious artemisinin-based combination treatments for African pregnant women with malaria (led by Prof. Umberto D'Alessandro)
6. Evaluation of 4 artemisinin-based combinations for treating uncomplicated malaria in African children (led by Prof. Umberto D'Alessandro)
7. Characterisation of novel microbicide safety biomarkers in East and South Africa (Dr Justin Ntirushwa)

From left to right: Dr Stephen Rulisa (Ethics Grantee for Kigali University Teaching Hospital), Dr Stephen Karengera (Director for Policy Planning and Capacity Building in Ministry of Health), Dr Gilles Ndiyasaba (Scientist at EDCTP-funded microbicide Project Ubuzima), Mr Simon Belcher, Hon. Dr Richard Sezibera (Minister for Health), Dr Pascoal Mocumbi, Prof. Omu Anzala and Dr Thomas Nyirenda

An EDCTP site visit to assess progress of the mentioned projects in Rwanda was conducted from 31 May 2010 to 4 June 2010. The EDCTP site visit team comprised of Dr Pascoal Mocumbi (High Representative), Mr Simon Belcher (Director of Finance and Administration), Dr Thomas Nyirenda (South-South Networking and Capacity Development Manager) and Professor Omu Anzala of Kenya AIDS Vaccine Initiative, an HIV expert and member of the Developing Countries Coordination Committee (DCCC) constituency of EDCTP. During this visit, the EDCTP delegation had meetings with the Minister of Health of the Republic of Rwanda, honourable Richard Sezibera; the WHO country Representative for Rwanda and other Programme Officers, as well as the co-Chair of the Health Sector at the Belgium Embassy.

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