

Note from the Africa Office

Dear readers,



EDCTP started 2010 with sustained momentum and focus on the Partnership's strategic objectives. This newsletter issue gives highlights of the activities of the first quarter of the year. An overview featuring the imminent second connecting the chain meeting with spotlight on linking clinical research and health development agendas in Africa is provided. Proceedings from this very important meeting will complement preparations for the future activities of EDCTP by addressing the critical link between research and development.

In this edition, the EDCTP family warmly welcomes to the Partnership Board the new members and extends appreciation to the former members for their dedication and invaluable contributions to the EDCTP programme. We also wish to draw your attention to the report by the Swiss Centre for International Health at the Swiss Tropical Institute following an internal assessment of the EDCTP programme. We value such open and constructive feedback and appreciate all EDCTP stakeholders who contributed to this exercise.

EDCTP launched another round of call for proposals on 22 February 2010. This new round includes three calls: stand-alone Senior Fellowships, Senior Fellowships linked to regional networks of excellence and grants to support establishment and strengthening of African National Ethics Committees (NECs) and Institutional Review Boards (IRBs). New projects added to the rapidly increasing EDCTP project profile are also reported on. This issue specially features the launch of the East African Consortium for Clinical Research (EACCR) and Trials of Excellence in Southern Africa (TESA), regional networks of excellence; the Pan African Clinical Trials Registry (PACTR) updates; and the EDCTP-COHRED collaborative activities on African ethics review and regulatory capacity mapping activities. Furthermore, you are informed of our continued networking and capacity development activities in Africa, a visit to the Central African Network for TB, AIDS and malaria (CANTAM) and other partners in Cameroon is covered.

We wish to thank all EDCTP stakeholders for your continued support to the Partnership in the fight against HIV/AIDS, tuberculosis and malaria.

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

Events

Connecting the Chain II: Linking Research and Development

EDCTP plans to hold a meeting with key representatives from European National Development agencies or their equivalent to explore pragmatic and workable strategies for collaborating most effectively in line with the Declarations of Paris (2005) and Bamako (2007). The meeting will take place on 9 June 2010 at the University Foundation in Brussels, Belgium, and will discuss how to better coordinate clinical research and health development agendas in Africa in order to facilitate effective delivery of interventions.

The purpose of the meeting is to inform European Development agencies of the relevance of the EDCTP programme to their health development agenda in Africa; to better understand existing gaps between current research and development agendas and obstacles to better collaboration; to explore how integrated capacity development and networking can be achieved; and to explore how the outputs from clinical trials can be utilised in better coordinated and effective ways, promoting translation of results into policies.

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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.



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News about EDCTP governance

PB welcomes new members

EDCTP warmly welcomes to the Partnership Board (PB) two new members, Professor Tumani Corrah and Professor Robert Sauerwein. They bring to the board considerable expertise in the areas of tuberculosis and malaria respectively, and their term of service was effective from beginning of January 2010. After four years of service, Professor Peter Kremsner and Professor Richard Adegbola stepped down from the PB in December 2009 to make way for new members. EDCTP sincerely appreciates their dedication and invaluable contributions to the EDCTP programme.

Professor Tumani Corrah (CBE) is the Unit Director & Chairman of The Gambia's Executive Management Board of the Medical Research Council (MRC) and Visiting Professor at the University of Oxford. He has served EDCTP in various capacities over the years, including as a member of the Developing Countries Coordinating Committee (DCCC). With over twenty-five years of progressively senior-level research work experience in Africa on tropical and infectious diseases, Prof. Corrah brings considerable scientific, clinical and networking expertise to the Partnership Board. His interests span clinical research, capacity building and research ethics, with particular expertise in the area of tuberculosis

(early diagnosis; diagnosis of TB in difficult situations, such as in patients with HIV and low CD4 counts; and shortening the duration of treatment for TB). Prof. Corrah also has interest in HIV and malaria and currently serves on a number of committees for organisations such as the African AIDS Research Network, WHO Task Force for TB Control in Africa, the Royal Society of Tropical Medicine & Hygiene and the Malaria Eradication Research Agenda. In 2007, he was awarded the honorary title of CBE in Her Majesty Queen Elizabeth II's honours list, in recognition of his long and distinguished career as a consultant physician, researcher and leader. Prof. Corrah looks forward to contributing further to EDCTP's vision of encouraging African scientists to lead the clinical trials so urgently needed in sub-Saharan Africa.

Professor Robert Sauerwein is the Head of the Division of Medical Parasitology and Centre for Clinical Malaria Studies (CCMS), Nijmegen, and a full Professor of Medical Parasitology. He has got a good track record as a clinical investigator in malaria vaccine development and long experience in epidemiological studies in Africa. His interests are in the development and conduct of clinical malaria research and trials in Africa, in particular, on clinical testing of malaria vaccines, immune correlates of

protection and induction of protective immunity. Prof. Sauerwein has been a member of a number of committees such as the AMANET Scientific Coordinating Committee, and is a current member of WHO MalVAC committee and the Scientific Advisory Committee of the Swiss Vaccine Institute. Additionally, he is a member of the board of WOTRO Science for Global Development, chairman elect of the Dutch Society of Parasitology, and is actively involved in several EU networks in this area.

EDCTP 2003-2009 Internal Assessment

In July 2009, EDCTP commissioned the Swiss Centre for International Health at the Swiss Tropical Institute to undertake an internal assessment of the EDCTP programme covering the period from its inception in 2003 to 2009. The goal of the assessment was to gauge the progress that EDCTP had made by the end of 2009 and to collect views on the future direction. The EDCTP family thanks all those who participated and would like to reassure all concerned that their participation was not in vain since EDCTP will address all their valuable suggestions. Findings of this review are accessible at the EDCTP website (www.edctp.org).

News about calls and grants

Calls open for application

Senior Fellowships

Available funds: € 1,200,000

Number of projects to fund: 6 projects

Open to application: 22 February 2010

Deadline of application: 28 June 2010

Senior Fellowships linked to regional networks of excellence (NoEs)

Available funds: € 800,000

Number of projects to fund: 4 projects

Open to application: 22 February 2010

Deadline of application: 28 June 2010

Purpose of the grants

Through these calls, EDCTP intends 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. This grant is both available for researchers already working in Africa as well as those looking to return to the continent (re-entry grant). For the Senior

Fellowship NoE call, EDCTP specifically targets to contribute towards building of sustainable capacity through training and networking with linkage to the EDCTP supported regional networks of excellence in sub-Saharan Africa.

Establishment and strengthening of African National Ethics Committees (NECs) and Institutional Review Boards (IRBs)

Available funds: € 750,000

Number of projects to fund: 15 projects

Open to application: 22 February 2010

Deadline of application: 28 June 2010

Purpose of the grant

EDCTP wishes to promote the establishment and strengthening of National Ethics Committees (NEC) and Institutional Review Boards (IRB) that are competent and independent. The NECs and the IRBs

are encouraged to establish themselves administratively and financially so as to ensure sustained optimal function beyond the EDCTP funding. Strengthening of NEC or IRB aims at making them operational and gives support to their ongoing functions. Networking and training is encouraged and supported. Additional support in the form of online literature access, documentation, access to websites on ethics and GCP will be facilitated.

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

For details on these calls and how to apply, please refer to relevant call texts on the EDCTP website: www.edctp.org

News about calls and grants

Funded projects

EDCTP is pleased to announce funding of the following projects:

Call: Malaria vaccines

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)

Project Coordinator: Egeruan Babatunde Imoukhuede
Budget: € 9,543,311 (€ 7,882,536 EDCTP)
Duration of project: February 2010 – February 2011
African countries involved: Burkina Faso, Kenya, Senegal, The Gambia
Cofunding partners: SIDA (Sweden), Medical Research Council (United Kingdom), Department of Foreign Affairs (Ireland), KEMRI (Kenya), University of Oxford (United Kingdom), Okairos s.r.l (Italy), Vienna School of Clinical Research (Austria), Centre national de recherche de Formation sur le Paludisme (Burkina Faso), Medical Research Council Laboratories (The Gambia), Austrian Federal Ministry of Science (Austria), European Vaccine Initiative (Germany) and Université Cheikh Anta DIOP de Dakar (Senegal)

Call: Malaria treatment

Development of fosmidomycin and clindamycin, in a fixed dose combination, for the treatment of acute uncomplicated *Plasmodium falciparum* malaria

Project Coordinator: Saadou Issifou
Budget: € 4,917,381 (€ 3,252,381 EDCTP)
Duration of project: January 2010 – January 2013
African countries involved: Benin, Gabon, Mozambique and Tanzania
Cofunding partners: Jomaa Pharma GmbH (Germany), IRD (France), BMBF (Germany) and Instituto de Salud Carlos III (Spain)

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

Strengthening of the Botswana IRB, and establishment of Health Institutions and Health Districts Ethics Committees

Project Coordinator: Mary Kasule
Budget: € 47,200
Duration of project: February 2010 – February 2012
African countries involved: Botswana, Uganda and South Africa

Building capacity of laypersons on IRBs to review research protocols and provide constructive feedback

Project Coordinator: Morenike Oluwatoyin Ukpong
Budget: € 45,799
Duration of project: January 2010 – January 2011
African countries involved: Nigeria

The Mzadi project: strengthening research ethics capacity in the Republic of Congo and the Democratic Republic of Congo

Project Coordinator: Bavon Mupenda
Budget: € 40,800
Duration of project: December 2009 – December 2010
African countries involved: Democratic Republic of the Congo

Strengthening the capacity of the Uganda Virus Research Institute Science and Ethics Committee (SEC) and preparing it for WHO recognition

Project Coordinator: Edward Katongole Mbidde
Budget: € 50,000
Duration of project: February 2010 – February 2012
African countries involved: Uganda

Consolidation of a National Ethic Committees network in Mozambique by promoting training collaboration with African and European networks

Project Coordinator: João Fumane
Budget: € 47,250
Duration of project: February 2010 – February 2012
African countries involved: Mozambique

Strengthening Capacity for Ethics Review and Monitoring of Approved Projects at the Kenya Medical Research Institute

Project Coordinator: Christine Wasunna
Budget: € 49,500
Duration of project: December 2009 – December 2011
African countries involved: Kenya

The Palabre project: developing national research ethics guidelines for the Democratic Republic of Congo

Project Coordinator: Emile Okitolonda Wemakoy
Budget: € 48,700
Duration of project: February 2010 – February 2011
African countries involved: Democratic Republic of the Congo

Call: Senior Fellowships

A multi-site double-blind placebo controlled randomized clinical trial to prevent immune reconstitution inflammatory syndrome with non-steroid anti-inflammatory drugs

Project Coordinator: Jean Nachega
Budget: € 189,197
Duration of project: February 2010 – February 2012
African countries involved: South Africa

Training in mucosal immunity and the evaluation of KIR: HLA genes in HIV-1 clade C infection: key components to HIV vaccine design

Project Coordinator: Photini Kiepiela
Budget: € 198,000
Duration of project: March 2010 – March 2012
African countries involved: South Africa

Malaria baseline studies towards characterising and establishing a clinical trial site at Mutengene, South West Region of Cameroon

Project Coordinator: Eric Akum Achidi
Budget: € 199,199
Duration of project: March 2010 – March 2012
African countries involved: Cameroon

Erratum

In the January 2010 newsletter, there was an error in the overview of cofunding partners involved in the project International Phase 2b randomised clinical trial to study a once-a-day maintenance (Valeriane Leroy). The following cofunding partners are involved: Ministry of Foreign Affairs (MAE) (Luxembourg), Treatment and Research AIDS Center (TRAC) (Rwanda), Fonds National de la Recherche (Luxembourg) and National Agency for AIDS Research (ANRS) (France).

Focus on EDCTP grantees

Launch of the EACCR and TESA Networks of Excellence for clinical trials

The **East African Consortium for Clinical Research (EACCR)** launched its regional Network of Excellence for Eastern Africa on 21-22 January 2010. The EACCR is an EDCTP-funded project with the ultimate goal of integrating and synergising efforts to:

- Strengthen research capacity
- Design, conduct, evaluate and communicate large multi-centre clinical trials under best international practices in this region
- Network amongst partners and improve south-south and north-north collaborations
- Facilitate EDCTP's vision of accelerating development of new drugs and tools to control HIV/AIDS, tuberculosis and malaria.

The regional networks unite institutions that collaborate on the basis of their complementary individual strengths such as in good practice 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.

The EACCR is coordinated by Dr Pontiano Kaleebu and unites African institutions from Ethiopia, Kenya, Sudan, Tanzania

and Uganda in collaboration with European institutions from Germany the Netherlands, Norway, Sweden and United Kingdom.

The **Trials of Excellence in Southern Africa (TESA)**, the first project of the Southern African Consortium, is a collaborative effort of ten southern African research institutes and universities involved in clinical trials of HIV/AIDS, tuberculosis and malaria. The aim of the project is to build clinical trials' capacity and infrastructure by mentoring and training the existing capacities among the researchers, clinicians and laboratory technicians to conduct trials in line with ethical guidelines and Good Clinical Practice. The project will focus on building capacity for clinical trials and infrastructure among its partner organisations, in addition to improving the cooperation and networking of the clinical research teams through conducting of baseline studies on infectious diseases of HIV/AIDS, tuberculosis and malaria.

TESA was officially launched on 22 February 2010 in Durban, South Africa, followed by the first meeting of the network collaborators.

TESA is coordinated by Dr Alexander Pym and unites African institutions from Malawi, Mozambique, South Africa, Zambia and Zimbabwe, in collaboration with European Institutions from France, Germany, Netherlands and United Kingdom.



Group session during the launch of TESA and MRC Tuberculosis Research Unit in Durban in South Africa from 22 to 23 February 2010



Meetings and visits Focus on EDCTP grantees

EDCTP visit to CANTAM research sites in Cameroon

EDCTP representatives conducted a site visit on 1 to 6 February 2010 to Central African Network for TB, AIDS and malaria (CANTAM) research sites located in Yaoundé and Buea. The delegation comprised Dr Pascoal Mocumbi (High Representative), Mr Simon Belcher (Director of Finance and Administration) and Dr Thomas Nyirenda (South-South Networking and Capacity Development Manager), Dr Veronique Penlap (DCCC members from Cameroon) and Dr Awono Ambene (DCCC member from OCEAC). Four institutions that are now part of the network namely University of Yaoundé 1 Biotechnology Centre, Jamot Hospital, International Centre for Reference – Chantal Biya (CIRCB) and University of Buea were visited. Additionally, the team met with the national ethics committee, the institutional ethics review board at CIRB, Coordinator of Poverty Related Diseases University project, the University of Yaoundé, Delegation of European Union (EU) to Cameroon, welcomed by Head of Operations and Cooperation, Mr Emile Jeannee; the World Health Organisation Representative to Cameroon, Dr Charlotte Faty Ndiaye and her team; Dr Nicolas Dologuele, the representative of the Secretary General of OCEAC; Director of Pharmacy and Medical Products, Dr Jean-Rollin Ndo; Professor Mol Nang, representative of Ministry of Higher Education; Dr Andre Mama Fouda, the Minister of Public Health; officials and Dr Biyiti Bi Essam Lucie who is the General Inspector representing the Ministry of Research, and the Prime Minister, Mr Philemon Yang.

CANTAM project has started well in Cameroon and enjoys support from all the three ministries in charge of research and institutions including the office of the Prime Minister. CANTAM displays excellent collaboration between the researchers and policy makers a feature that needs to be emulated in other regions.

Recent data analysis reveals positive steps forward for the PACTR

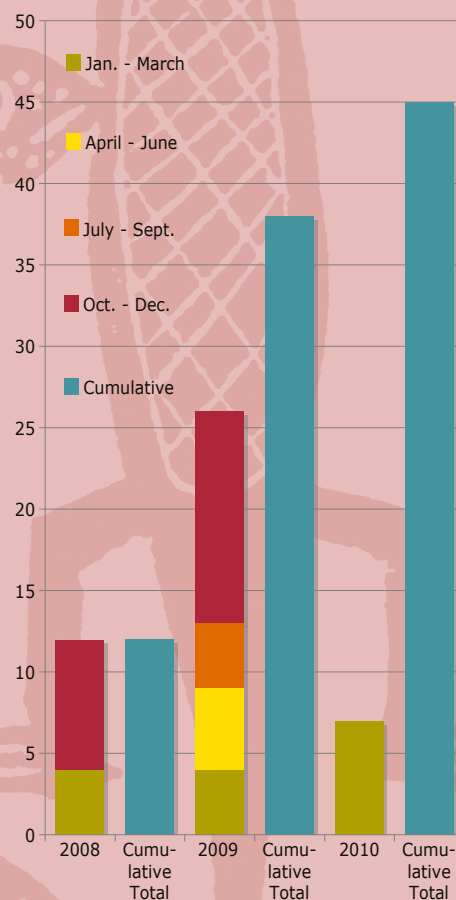
The Pan African Clinical Trials Registry (PACTR), an EDCTP supported initiative, is the first WHO-endorsed primary registry on the African continent. The PACTR aims to increase clinical trial registration on the continent, with the ultimate goal of assisting in the harmonization of the regulation, registration and ethical oversight of clinical trials in Africa. This project has grown in scope and breadth since its initial inception as the EDCTP AIDS, Tuberculosis and Malaria Registry (ATM).

In June 2009, the ATM expanded its scope to include all diseases and was renamed the Pan African Clinical Trials Registry. In September 2009, the PACTR was formally launched as a WHO-primary registry. Since that time the registry's database has nearly doubled; of the total applications received over the last three years, 45% have been received since September.

Additionally, the PACTR has embarked on developing a strategy to achieve the increased registration of clinical trials recruiting children in Africa as part of a larger World Health Organization initiative to increase child-focused trial activity throughout the world. Data analysis shows that of the 19 registered trials, nine deal with issues affecting the health of children (47%). Trial activity specifically dealing with children is present in 13 African countries, including Benin, Burkina Faso, Egypt, Gabon, Gambia, Kenya, Mozambique, Nigeria, Rwanda, South Africa, Tanzania, Uganda and Zambia.

The PACTR excitedly looks forward to future growth and development.

More information on the PACTR: www.pactr.org



EDCTP team with Cameroonian scientists involved with CANTAM Project



Meetings and visits

Strengthening Pharmaceutical Innovation in Africa

On 18 to 20 February COHRED and NEPAD jointly organised a meeting to consider the results of the study on *Strengthening Pharmaceutical Innovation in Africa*. EDCTP participated at this important meeting which is reported in details at the following links:

- COHRED project profile:
www.edctp.org/Project-Profiles.245.0.html
- Pretoria Expert meeting:
www.cohred.org/African_Innovation
- Full report and "Pharmaceutical Innovation Framework & Grid":
www.cohred.org/Report-Strengthening_Pharmaceutical_Innovation_Africa
- The meeting statement can be downloaded from:
www.cohred.org/Meeting_Final_Statement

In addition to the very productive discussions on Africa's problems and challenges on access to medicines and the review and evaluation of a new tool, the "Pharmaceutical Innovation Framework and Grid", the activities of the Health Research Web were shared.

Health Research Web is a web-based platform for use by countries and institutions interested in doing exactly this: *assessing own status of research and innovation, monitoring progress, identifying gaps and comparing with relevant others*. It is developed by COHRED for use by countries, institutions and individuals interested in

putting low and middle income countries in the 'driver's seat' as far as research for health is concerned. Not surprisingly, HRWeb will play a key role in enabling countries to monitor their own progress – and by displaying this information regionally and globally – to allow cross-country, region and continent comparisons to be made.

EDCTP supports a key component of *Health Research Web: the pages on ethics review and medicine regulation*. Already over 93 African Ethics Committees have their contact details listed on **HRWeb** – while the work for medicine regulation is just starting. EDCTP appeals to all ethics committees and national drug regulatory authorities in Africa to 'log in' and 'create their information pages'. It is free – and the more people use it, the better it is – for research, for medicines regulation and access, and for health of all.

Please visit www.healthresearchweb.org and click on 'Ethics Review' to get a global picture, or simply click on a country and then on 'Ethics and Research Regulation' to find information, to enrol and to upload information.

For further information, please contact:

- ethics@healthresearchweb.org
(for research ethics committees)
- MRA@healthresearchweb.org
(for medicines regulatory authorities)

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