

Note from the Africa Office



On behalf of the broader EDCTP family I welcome you all to the April Newsletter which addresses updates of EDCTP activities.

Let me start with highlighting the second annual meeting of the Trials of Excellence in Southern Africa (TESA) network in Maputo (Mozambique) on 23-25 February 2011. This EDCTP-funded regional network of excellence in conducting clinical trials in HIV, tuberculosis and malaria held its meeting to review results, to share experiences and to plan for future activities. Twenty-five representatives from the institutions integrated in TESA attended and visited CISM – the Manhica Health Research Centre.

On progress made, the meeting noted that to date more than 80 clinical students and clinical research staff in 10 institutions attended short courses, conference and workshops organized by TESA.

The section on selected projects brings to your attention the project investigating Artesunate plus Mefloquine (ASMQ) as an alternative antimalarial treatment for children in Africa. Moreover, as part of the more than forty ethics capacity strengthening projects in Africa, the successful efforts to strengthen health research ethics in Ethiopia by Professor Beyene Petros are shared.

This edition of the newsletter also reports on how the Kesho Bora study results offer new hope for substantially reducing the risk of mother-to-child transmission of HIV during breastfeeding. In addition it announces the Master course in clinical trials to be launched in various francophone universities in sub-Saharan Africa.

You may also wish to look at news about the calls for proposals launched so far in 2011 and about the recently funded projects. The section on EDCTP governance will give you an update on changes in the staff to meet the challenges of the next phase of the organisation.

On a personal note, I would like to inform you that as of January 2011 I continue to contribute to the goals of EDCTP from Maputo, Mozambique.

Dr Pascoal Mocumbi

EDCTP Ambassador and Advisor to the EDCTP General Assembly

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The EDCTP Newsletter is available in three languages namely English, French and Portuguese in electronic format on our website (www.edctp.org). Persons who wish to receive the electronic format should subscribe online (www.edctp.org, click on Newsroom).

Events: Sixth EDCTP Forum

Sponsorship opportunities

The EDCTP Forum has become one of the major conferences in Africa on the three poverty-related diseases of HIV/AIDS, tuberculosis and malaria. The Forum provides excellent possibilities to highlight key activities to a diverse audience including representatives from research institutions, universities, like-minded organisations, governments, regional bodies and industry.

The theme of the Sixth EDCTP Forum is 'Strengthening Research Partnerships for Better Health and Sustainable Development'. The programme will take into account the past, present and future of EDCTP, and will stress the need for effective and sustainable partnerships for health research and development in the fight against diseases of poverty. The forum will be held at the United Nations Conference Centre in Addis Ababa, Ethiopia, from 9 to 12 October 2011.

EDCTP is now inviting interested organisations to sponsor the event. Sponsorship packages have been developed, offering sponsors different opportunities to support the Sixth EDCTP Forum and raise their organisation's visibility during the event. The possibilities for sponsorship are explained on the Sixth EDCTP Forum website (www.edctforum.org). Organisations interested in presenting their activities are requested to complete the sponsorship interest form, also available on the forum website.



Events (continued from page 1)

Programme overview

The forum programme includes contributions by high-profile speakers from the fields of science, policy, ethics, regulation and strategic partnerships. A wide range of research topics on HIV/AIDS, tuberculosis and malaria, as well as cross cutting issues such as ethics and regulatory affairs will be covered in keynote addresses by invited speakers from North and South. Plenary and parallel sessions, roundtable discussions, oral presentations, poster sessions and satellite meetings will elaborate on these subjects. A Forum marketplace offers room for research exhibitions.

The official opening will take place on Sunday 9 October 2011, between 15:00 and 17:00 hrs, followed by a cocktail reception.

On Monday 10 October, African and European leaders will speak on the need for and commitment to clinical research to fight the main three poverty-related diseases in a forum prologue session. Thereafter the programme will focus on actual project outcomes from completed and ongoing

research activities in sub-Saharan Africa. Tuesday 11 October starts with the 'Meet the Professor' session for junior scientists. This session is aimed at giving career guidance to junior scientists and to advise on specific research projects and will take place in smaller parallel groups based on different thematic areas. During the plenary morning session a variety of speakers will present an overview of recent advances in HIV/AIDS, tuberculosis and malaria clinical trials followed by parallel sessions in the afternoon.

A satellite meeting will be organised by "Switching the Poles" Clinical Research Network. The satellite meeting discusses 'Clinical trials in practice: how to achieve the best protection of the study subjects?' and will take place at the forum's venue from 12:30 to 14:00. It focuses on the challenge of achieving appropriate protection of patients that participate in clinical trials carried out in resource-constrained settings.

The day will round off with a parallel session on future strategy for clinical research and research capacity development in the three

poverty-related diseases. This includes a cross-cutting session jointly organised by EDCTP and NACCAP – the Netherlands-African partnership for capacity development and clinical interventions against poverty-related diseases, on capacity strengthening. It aims at improving the impact of EDCTP grants by sharing experiences and formulating best practices in capacity strengthening for health research and clinical trials.

On the morning of Wednesday 12 October, EDCTP research partners, funders and donors will present an overview of their work and collaborative efforts with EDCTP. This will be followed by the continuation of parallel sessions on HIV/AIDS, tuberculosis and malaria clinical trials, as well as capacity building and networking for health research, ethics and regulatory framework in Africa. The programme will end with a summary of recommendations and future outlooks.

For more information about the forum programme, please download the Programme at a Glance available at www.edctpforum.org.

EDCTP Governance

EDCTP welcomes new staff members



Christa Janko
Private Sector Relations
Coordinator

Ms Christa Janko graduated from the University of Vienna in 1998, holding a degree in philosophy and translation sciences with specialties in economics and medicine. She has gained extensive experience in clinical trials during her almost decade-long employment within pharmaceutical industry. Between 2001 and 2009, Christa was in

charge of the general management and strategic development of the Vienna School of Clinical Research, one of EDCTP's grantees for training and education activities. In previous years, she was member of the EDCTP General Assembly (GA) and also of the European Network of National Programmes (ENNP) up until 2009. This broad spectrum of experiences and understandings will help her to fulfill her current role at EDCTP. As Private Sector Relations Coordinator, Christa is responsible for coordinating, consolidating and expanding the private sector relations of EDCTP.



Gert Onne van de Klashorst
Communications Officer

Mr Gert Onne van de Klashorst has an academic background in cultural history and worked as a researcher on the history of political ideas and as a teacher of cultural history at Utrecht University in the Netherlands. Between 1998 and 2001 he was in management and communications (public relations and communications consultancy firm). Thereafter he was head of

the communications department and press officer of the Dutch Data Protection Authority, dealing with dossiers concerning a great variety of issues of e.g. police and justice, banking, internet, social security, and health care.

Calls and grants

Calls open for application

Call: Senior Fellowships
Available funds: € 1,200,000

Call: Senior Fellowships linked to regional networks of excellence
Available funds: € 400,000

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 for those looking to return to the continent (re-entry grant). For the Senior Fellowship at Networks of Excellence call, EDCTP specifically seeks to contribute towards building sustainable capacity through training and networking with linkage to the EDCTP supported regional networks of excellence in sub-Saharan Africa.

Call: Establishment and strengthening of African National Ethics Committees (NECs) and Institutional Review Boards (IRBs)
Available funds: € 500,000

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 their sustained optimal functioning 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.

Funded projects

EDCTP is pleased to announce funding of the following projects:

Call: Senior Fellowships

Pre-clinical Evaluation of Dendritic cell targeted consensus B, C, CRF02-AG and MOSAIC HIV gag protein vaccines in PBMC from chronically infected Patients in Central Africa

Project Coordinator: Godwin Nchinda

Budget: € 199,036

Duration of project: 10 March 2011-
10 March 2013

African countries involved: Cameroon

Focus on Projects

Artesunate plus Mefloquine (ASMQ) as an alternative antimalarial treatment for children (Nathalie Strub Wourgaft)



Plasmodium falciparum malaria kills over one million people and results in up to 500 million cases annually affecting mainly young children and pregnant women. Malaria is curable and preventable. The principal control strategies include rapid diagnosis, effective treatment, malaria control and prevention in pregnancy and personal protection with insecticide treated bed nets.

Two of the most widely used anti-malaria drugs, Chloroquine and Sulfadoxine-Pyrimethamine, are no longer effective in many parts of the world due to drug resistance. The World Health Organisation currently recommends use of Artemisinin-based combination therapies (ACTs) for treatment of uncomplicated *falciparum* malaria. In order to prevent drug resistance to artemisinins and to cope with their relatively short half-life, it is recommended to give artemisinins in combination with an appropriate partner anti-malarial agent.

This project is a collaborative initiative cofunded by EDCTP and the Drugs for Neglected Diseases (DNDi). It is coordinated by DNDi medical director Nathalie Strub Wourgaft and is one of the pivotal studies in the development of a fixed-dose combination of AS and MQ for international registration.

It aims to assess ASMQ as an alternative antimalarial treatment for children in Africa. Additionally, simple dose regimens facilitate treatment adherence, which is critical for effectiveness. In a multicentre clinical study the efficacy and safety of ASMQ is being compared with Artemether-Lumefantrine (Coartem®) in children under the age of five with uncomplicated *falciparum* malaria. Approximately 1,000 affected children will be treated (target patient number is 940).

The study is being performed in Tanzania (National Institute for Medical Research - NIMR), Kenya (Kenya Medical Research Institute - KEMRI) and Burkina Faso (Centre National de Recherche et de Formation sur le Paludisme - CNRFP) in partnership with the Centre de Recherche Public de la Santé - CRP Santé (Luxembourg), the Centre Hospitalier Universitaire Vaudois - CHUV (Switzerland) and Cardinal Systems (France). Patient recruitment started in December 2010 at the CNRFP sites in Balonghin and Ouagadougou, in Burkina Faso.

If the study demonstrates excellent efficacy for ASMQ, national programmes could consider adopting a multiple first-line therapy policy that includes ASMQ as part of the armamentarium towards malaria control and elimination.

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

Establishment of Institutional Research and Ethics Committee (IREC) in Western Kenya

Project Coordinator: Wellington Otieno

Budget: € 52,348 (€ 49,720 EDCTP)

Duration of project: 3 March 2011-
31 January 2013

African countries involved: Kenya

Call: HIV treatment

A randomized controlled trial of 3 strategies for the treatment of ARV-naïve HIV-infected patients with tuberculosis (RAFA)

Project Coordinator: Corinne Merle

Budget: € 2,766,767 (€ 1,768,737 EDCTP)

Duration of project: 21 January 2011-
21 January 2014

African countries involved: Benin, Guinea, Malawi, Senegal and South Africa.

Focus on Grantees

London School of Hygiene and Tropical Medicine: Master course in clinical trials translated for Francophone institutions

The distance learning master course (MSc) in clinical trials offered by the London School of Hygiene and Tropical Medicine (LSHTM) and cofunded by EDCTP has its materials now available in French to students from Francophone African research institutions.

The MSc in Clinical Trials programme was initially launched in English at the School of Public Health in the University of Ghana. Prior to the launch, the University of Witwatersrand in South Africa organised a workshop for universities and institutions. The aim was to develop their capacity to use the learning materials of the programme for face-to-face teaching of clinical trial methods and to incorporate this in existing or new training courses.

A similar workshop based on the materials translated into French was conducted to



Students at the Master course class in Ouagadougou, Burkina Faso

launch the MSc course for African Francophone universities. The workshop was held from 6 to 10 December 2010, and hosted by the Centre Muraz in Bobo-Dioulasso, Burkina Faso, in partnership with the University of Montpellier. It involved 24 trainers from 11 institutions of higher learning in Francophone Africa which included representation from Benin, Burkina Faso, Cameroon, Cote d'Ivoire, Democratic Republic of Congo, Madagascar, Mali and Senegal. Several Francophone universities, including those in Bobo-Dioulasso and Ouagadougou in Burkina Faso, are expected to launch the Master course in clinical trials in the academic year 2011-2012.

Strengthening the ethics of health research in Ethiopia (Prof. Beyene Petros)

Effective delivery of health services can best be accomplished when supported by local health research. Health research can only properly serve the population if it is conducted in an ethically responsible manner. This can only be assured if research proposals are reviewed by independent, competent ethics review committees. EDCTP plays an important role in strengthening the capacities of both institutional and national ethic committees.

One example is the case of Ethiopia where the National Ethical Clearance Committee (NERC) was established in 1990 by the National Health Science and Technology Council. Until recently NERC used to review almost all major research protocols. Although the NERC maintains oversight, it has now delegated some of this responsibility to competent institutional review boards in Ethiopia.

Professor Beyene Petros of Addis Ababa University in Ethiopia coordinates an EDCTP-funded project that aims to strengthen existing institutional review boards and establishing new ones in Ethiopian health research institutions and universities. Extensive training on health ethics research is provided to staff of universities in the country,

and the infrastructure is developed to make these committees operational and independent. The Ethiopian Bioethics Initiative (ETBIN) provides the overall administrative and managerial support to the project.

By end of 2010, this project had succeeded in forming a new network of health research ethical review committees in an extensive part of Ethiopia. A total of 47 trainees from the newly established institutional review boards

and 64 members from 12 existing review boards were trained. Four existing institutional review boards were also provided with office equipment. Furthermore, a manual on Human Participant Protection and Good Clinical Practice (GCP) was developed in Amharic for distribution in Ethiopia.

Participants at the training workshop on Health Research Ethics in Addis Ababa, Ethiopia



Focus on Grantees (continued from page 4)

An initial grant from the Bill & Melinda Gates Foundation enabled the LSHTM to develop a distance learning master course for students from developing countries. The course programme was designed to enhance the capacity of African scientists to conduct high quality clinical trials of interventions against endemic diseases of major importance. The MSc provides them with a theoretical and practical understanding of the design, conduct, analysis and interpretation of randomised controlled trials of health interventions. This is critical for designing and implementing cost-effective public health programmes that will have maximum impact on the burden of disease in developing countries.

Currently, few institutions in Africa have the substantial in-house capacity required to run a full distance-based master course in clinical trials. Through this programme, the capacity of African universities and institutions to develop and deliver masters level degrees and short courses in clinical trials will increase substantially. It will now also strengthen the capacity of Francophone institutions to support future trials and to successfully submit grant proposals.



Mother and baby study participant

Kesho Bora study: hope for cutting risk of mother-to-child transmission of HIV during breastfeeding

The Kesho Bora study – ‘A better future’ in Swahilli – is led by WHO Department of Reproductive Health and Research. Its partners in this project are the French National Agency for Research on AIDS and Viral Hepatitis (ANRS), US Centers for Disease Control and Prevention (CDC) and Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) of the National Institutes of Health.

A study published in *Lancet Infectious Diseases* of 14 January 2011 shows that giving a triple antiretroviral therapy (ART) during pregnancy, delivery and breastfeeding cuts the risk of mother-to-child transmission (MTCT) of HIV by 43% compared with the standard regimen of zidovudine and niverapine recommended by World Health Organization (WHO) from 2004. This new approach will increase the chances of mothers living with HIV to breastfeed with reduced risk of passing on the virus to their babies.

The Kesho Bora study offers a new hope for preventing HIV infection and death among infants in low-resource settings where many mothers with the virus breastfeed. The study was a randomised controlled trial in

antiretroviral-naïve pregnant woman infected with HIV-I conducted in five sites in Africa. It aimed to assess the efficacy and safety of a triple antiretroviral therapy compared with zidovudine and single-dose nevirapine prophylaxis in pregnant woman, which was the regimen recommended by WHO guidelines. The findings of the Kesho Bora study have strongly influenced the revised WHO guidelines on prevention of mother-to-child transmission of HIV, and infant feeding.

The study was funded by the ANRS, the Belgian Directorate General for International Cooperation, CDC, WHO Department for International Development, Development and Research Training in Human Reproduction (WHO/HRP), EDCTP, NICHD (National Institutes of Health), the Thrasher Research Fund, UNDP/UNFPA/World Bank/WHO Special Programme of Research and by UNICEF.

Meetings and visits

ESSENCE initiative: harmonising research funding

The research funding platform ESSENCE is a new initiative to harmonise internationally funded research programmes. EDCTP aims to develop new and important interventions to fight HIV/AIDS, tuberculosis and malaria, and to maximise the effectiveness of the delivery of these interventions once available. This is to be done in collaboration with platforms such as ESSENCE. Harmonisation of donor practices and the prevention of unmanageable funding systems will benefit the policy makers and researchers of the countries where these diseases are endemic. They will have a stronger voice in determining the priorities of internationally-funded global health programmes.

ESSENCE stands for Enhancing Support for Strengthening the Effectiveness of National Capacity Efforts. Its membership consists of international health institutions, government research agencies and philanthropic societies. The initiative is building on the principles of the Paris Declaration on Aid Effectiveness and the Accra Agenda for Action, which set standards for good practice in international aid. The Secretariat of ESSENCE is well-positioned at the WHO Special Programme on Research and Training on Tropical Diseases (TDR). This global health research organization both gives and receives donor funds. Its relationship with funders as well as country stakeholders, gains TDR an operational understanding of the issues that ESSENCE is aiming to address.

ESSENCE made its first major step with the development of a framework document that is designed to harmonise the planning, monitoring, and evaluation of international health research programmes. ESSENCE also sponsors an ongoing review of funding practices, which aims to identify disparities, redundancies and overlaps between agencies. A first pilot study in Tanzania will facilitate the dialogue between international donors and representatives from all Tanzanian health research institutes on how to harmonize international research funding to the country. Most recently, ESSENCE engaged in the new Medical Education Partnership Initiative (MEPI) for Africa.

For further information on ESSENCE please visit:
<http://apps.who.int/tdr/svc/partnerships/initiatives/essence>



ESSENCE on Health Research members meet after the MEPI Conference in Johannesburg, South Africa, 10 March 2011



Participants at the Second TESA Annual Meeting in Maputo, Mozambique

TESA Network of Excellence for Clinical Trials: Second Annual Meeting

The Trials of Excellence in Southern Africa (TESA) held its second Annual Meeting at the Centro de Investigação em Saúde da Manhica (CISM) in Maputo, Mozambique from 23 to 25 February 2011. TESA is funded by EDCTP and is the first project of the Southern African Consortium. It is the 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 researchers, clinicians and laboratory technicians to conduct trials in line with ethical guidelines and Good Clinical Practices.

Participants from nine institutions within six Southern African countries, namely Botswana, Malawi, Mozambique, South Africa, Zambia and Zimbabwe, were present. Some of the achievements of the first year of TESA were highlighted. The network exceeded the milestones set for capacity development in terms of human resources. For the second year, the need to focus on better networking and for the execution of a baseline study was emphasized.

During the two day meeting TESA partners made considerable progress in networking and in exploring new areas for research and clinical trials. For each disease a baseline study was defined. Project management strategies were established to seek funding and to put in place the supervision and training of Masters and PhD students. The question of the network's sustainability was the focus of most discussions. Strategies to engage new regional and international funders were devised.

**More information
about TESA can
be found at
www.tesafrica.org.**

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Supported by the EU DG Research