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EDCTP Newsletter

February 2012

Note from the Executive Director

As this is the first newsletter of the year, I happily take the opportunity to wish all our



stakeholders and partners a happy and prosperous 2012. This year ushers the beginning of the transition period in preparation for EDCTP-II, which is now expected to commence in 2014 under Horizon 2020. In preparation for this, as noted in the newsletter, EDCTP has been awarded a Support Action grant. The purpose of the grant is to enable EDCTP to continue supporting the capacities and networks that it has helped to establish and strengthen, and to prepare the ground for EDCTP-II. In the coming two years EDCTP will use this grant to map the research landscape and hold a series of stakeholder meetings aimed at identifying needs and resources to enable smooth operations, particularly as the programme moves into an expanded scope that will include neglected infectious diseases and health services optimisation research.

EDCTP is also conducting a series of meetings with the private sector including industry, Product Development Partnerships (PDPs) and funders to explore how the parties can work together more closely and with greater synergy. In 2011 EDCTP contacted pharmaceutical companies to exchange views and information. The first months of this year meetings will be held with key representatives of several companies for exploratory talks that will culminate in a joint workshop in early May to determine the best way forward. One of the important issues is how to move forward together in the funding and undertaking of phase III clinical trials, which are becoming ever more expensive to conduct.

Furthermore, in order to pump prime EDCTP-II we have also launched a Strategic Primer Grant call aimed at studies preparing for the new programme. This has turned out to be a popular call as shown by the 89 applications that have been received. This call is a two-stage process, the first part being through letter of intent before inviting successful applicants to submit full proposals. The duration of these projects is not to exceed two years. Similarly EDCTP is planning to launch another joint member state initiated (JCMS) call in the near future. Please be on the lookout for this launch.

Charles S Mgone

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Events

Proceedings of Sixth EDCTP Forum published

The proceedings of the Sixth EDCTP Forum were published in February 2012. The Forum was held in Addis Ababa, Ethiopia from 9 to 12 October 2011 under the theme of Strengthening Research Partnership for Better Health and Sustainable Development. The report summarises the presentations and discussions of the Forum and is also available online. A complementary short video on the Sixth Forum can also be accessed online.

The report highlights the scientific results from EDCTP-funded projects and EDCTP collaborating partners, and their commitment to further health research. The report gives a summary of all research presentations on HIV/AIDS, tuberculosis and malaria, as well as on the cross-cutting areas of health research capacity development, networking, ethics and regulatory affairs.

The publication includes a CD ROM documenting the Sixth Forum. It contains a video on the Forum that gives an impression of the activities and discussions at the event in Addis Ababa. The Abstract book comprised of abstracts of all oral and poster presentations, is also available, both in interactive and PDF formats. All Forum presentations are included for download in PDF format.



Events (continued from page 1)

Private Sector Relations initiative

Through the years several large and smaller pharmaceutical companies have been involved in EDCTP-projects, mainly through providing compounds or drugs to specific clinical trials. The EDCTP private sector relations working group explores the possibilities of a broader involvement of the private sector in the EDCTP programme. The group is led by the Executive Director Prof. Charles Mgone and coordinated by Christa Janko, Private Sector Relations Coordinator.

In 2011, the working group contacted pharmaceutical companies to identify the major players engaged in EDCTP relevant research and other activities. In a second step Christa Janko conducted interviews with high-level representatives of large pharmaceutical companies and related industries (Clinical Research Organisations) to identify views, concerns and explore possibilities.

As of January 2012, EDCTP is involved in meetings with key representatives for exploratory talks to prepare for a joint workshop with up to ten major companies in early May 2012. The objective of the workshop is to shape a framework for stronger and broader public-private partnerships and an extended collaboration with large pharmaceutical companies in the second EDCTP programme.

EDCTP Governance

EDCTP staff

The European Commission has granted EDCTP support towards laying the foundation for the second EDCTP programme of expanded scope of activity. As part of this preparatory phase, EDCTP has opened four vacancies in February. For the important task of furthering research collaboration among the participating European countries EDCTP is reinforcing its staff with a North-North Networking Manager and a Networking Officer. The further development of its financial and project management systems requires an Information Technology Officer. The Africa Office needs an additional Project Officer. The post of Administrative Officer in The Hague has also opened up. EDCTP received applications until 24 February and will conduct interviews in March 2012.

EDCTP website redesigned

EDCTP launched its restyled website early January 2012. The new design and layout is intended to offer improved access to relevant information for all EDCTP stakeholders. The new features of the site include updated and expanded content, an improved database with summaries on EDCTP-funded projects and new interactive tools. Enhanced features and additional information will be introduced in the future as EDCTP moves towards its second phase.

The site (www.edctp.org) was restyled to achieve a fresh and cleaner look. It aims to be more intuitive, focusing on easy access to specific information about EDCTP and its activities. In addition to English resources, the website also provides summary content and relevant information in French and Portuguese.

The website now features a sharing tool, allowing visitors to email website content to friends, and to post any content to social media such as Facebook and Twitter. It also allows users to print easily and to convert pages into PDF format as appropriate. Different tools to stay up-to-date with EDCTP's activities – Twitter, Newsletter subscription, RSS feeds and email notifications - were added. (Readers of this Newsletter are invited to follow the EDCTP twitter account @EDCTP).

The Project Profiles, EDCTP's online database with summaries of funded projects, now offers a clearer design. The search facility has been modified making it easier to use and to extract any selection of information on projects more effectively. Projects can be searched by specific grants, topic, country, and year or by any keyword contained in the profile page.

Project Portfolio published

In addition to the project profiles, EDCTP created a comprehensive Project Portfolio, a compendium of technical information on all EDCTP-funded projects. The Project Portfolio provides details on collaborating scientists and institutions, compounds tested, clinical trial design, trial sites, capacity building, funding, networking efforts and other information for each project. The Project Profile is available on the EDCTP website for download in PDF format and will be updated quarterly.

You can access the Project Portfolio on the EDCTP website at www.edctp.org, under the Project profiles page.

EDCTP photo contest extended

We continue to invite all those working or collaborating in EDCTP-funded projects to enter photographs for the First EDCTP photo contest. The deadline for entry has been extended to 16 April 2012.

Through this contest EDCTP wants to capture different perspectives of the many research, capacity building and networking activities in the implementation of these projects. All those working or collaborating in an EDCTP-funded project can take part in the photography contest. These may include project coordinators, collaborators and all members of research teams.

Submissions will be judged in three categories: science, healthcare and capacity development and networking. A winner will be identified for each category. The winners, who give consent, will have their photographs used and recognised in EDCTP publications (including website, reports, newsletter and a photo book). In addition, winners will each receive a prize.

The contest entry form and photographs must be submitted electronically and follow the requirements and instructions as stated in the contest description. For more information, please visit www.edctp.org.

Calls and grants

Funded projects

EDCTP is pleased to announce funding that has been awarded to the following projects:

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

Strengthening the ethical review and oversight of health systems research and social science research in Zimbabwe

Project Coordinator: Farirai Mutenherwa (Biomedical Research and Training Institute)

Budget: €48,320

Duration of the project: February 2012-February 2013

Establishing a functional independent Institutional Review Board for trials conducted by the Africa Academy for Public Health (AAPH), Tanzania

Project Coordinator: Ramadhani Abdallah Noor (Africa Academy for Public Health, Tanzania)

Budget: €49,999

Duration of the project: February 2012-February 2013

Enhancement of awareness and implementation of ethics principles for research involving humans in the Republic of Congo

Project Coordinator: Honoré Ntsiba

(Comité d'Ethique de la Recherche en Sciences de la Santé, Congo)

Budget: €49,999

Duration of the project: January 2012-July 2013

Strengthening of the Institutional Review Board of the Council for Scientific and Industrial Research and capacity building on ethical review in Ghana

Project Coordinator: Mike Yaw Osei-Atweneboana (Council for Scientific and Industrial Research)

Budget: €49,942

Duration of the project: February 2012-August 2013

Documenting facilities and needs of ethics committees and implementing a training intervention to strengthen ethical review capacity in Central Africa

Project Coordinator: Godfrey Banyuy Tangwa

(Cameroon Bioethics Initiative)

Budget: €49,445

Duration of the project: February 2012-August 2013

Strengthening research ethics in Zambia

Project Coordinator: Esther M. Nkandu (University of Zambia)

Budget: €49,608

Duration of the project: February 2012-February 2013

Establishing and strengthening the Institutional Review Board at the School of Health Sciences, College of Health Sciences, Makerere University, Uganda

Project Coordinator: Isaac Okullo

(Makerere University, College of Health Sciences, Uganda)

Budget: €49,997

Duration of the project: February 2012-August 2013

Call: Evaluating the impact of clinical trials in Africa

Evaluating the impact of clinical trials on health services delivered to women and children in 3 countries of sub-Saharan Africa

Project Coordinator: Khátia R. Munguambe (Manhiça Health Research Center, Mozambique)

Budget: €248,457

Duration of the project: December 2011-April 2014

Call: Senior Fellowships

Impact of schistosomiasis hematobium on immunological and clinical aspects of P. falciparum malaria

Project Coordinator: Ayola Akim Adegnika (Albert Schweitzer Hospital, Gabon)

Budget: €199,976

Duration of the project: February 2012-May 2014

Early childhood transmission of viral hepatitis B among HIV- and non-HIV-infected mothers attending postnatal and immunisation clinic in Gulu hospital, northern Uganda

Project Coordinator: Ponsiano Ocama

(Infectious Diseases Institute, College of Health Sciences,

Makarere University, Uganda)

Budget: €199,976

Duration of the project: February 2012-May 2014

Focus on Ethics

MARC: Mapping ethics review and trial regulatory capacity

The MARC project (Mapping of ethics review and trial regulatory capacity in sub-Saharan Africa) is a three-year initiative funded by EDCTP. MARC aims to develop an interactive and continuously updated map of Africa's health research ethics committees (RECs) and to provide a web-based platform to increase contact and communication between these committees. A secondary objective is to map medicines regulatory authorities (MRAs) and facilitate a better contact between these authorities and research ethics review committees.

MARC is implemented through collaboration between the Council on Health Research for Development (COHRED) in Geneva, Switzerland and the South African Research Ethics Training Initiative (SARETI) at the University of KwaZulu-Natal, South Africa. This projected is coordinated by Prof. Carel IJsselmuiden, Director of COHRED. EDCTP supports this project because effective and efficient ethics review of health research, including clinical trials, is essential to develop medicines, interventions and medical technologies in and for Africa.

In September 2011, MARC hosted the first African Conference for Administrators of Research Ethics Committees (AAREC). The meeting was hosted in Kasane, Botswana, and brought together 40 REC administrators from 21 African countries. The meeting aimed at identifying the needs and challenges of REC administrators. To date MARC has mapped a total of 153 RECs in 33 African countries, while a further 46 RECs have been identified and are still to be mapped.

For more information, visit the MARC website: www.researchethicsweb.org

Focus on Projects

MiPPAD-1 malaria trial completed enrolment

A major milestone in the Malaria in Pregnancy (MiP) field was reached as one of the EDCTP-funded MiP studies completed recruitment. By January 2012, the Malaria in Pregnancy Preventive Alternative Drugs (MiPPAD) study had enrolled a total of 4,734 pregnant women in January 2012, after screening 17,947 women in Benin, Gabon, Mozambique and Tanzania. The study led by Prof. Clara Menéndez (Barcelona Centre for International Health Research, Spain) aims to evaluate the safety, tolerability and efficacy of an alternative drug for preventive treatment of malaria in pregnant women.

Worldwide malaria is an important cause of low birth weight and a major cause of severe anaemia contributing to maternal mortality. The study is part of a global effort by the Malaria in Pregnancy (MiP) Consortium to find effective ways of preventing malaria in pregnant women and their infants. Prof. Menéndez commented the information provided by the MiPPAD trials will be "essential for future policy decisions regarding the prevention of malaria in pregnant women in Sub-Saharan Africa".

The MiPPAD study aims to evaluate the safety, tolerability and efficacy of Mefloquine (MQ) as an alternative to the standard drug Sulfadoxine-Pyrimethamine (SP) used for Intermittent Preventive Treatment in

pregnancy (IPTp) in combination with Long Lasting Insecticide Treated Nets (LLITNs). For this randomised, controlled trial HIV-non-infected pregnant women were recruited and they will be followed up until their infants are one year old. It is conducted in 4 countries: Benin (Allada, Sékou and Attogon), Gabon (Fougamou and Lambaréné), Mozambique (Manhiça and Maragra), and in Tanzania (Makole and Chambwino). The trial is registered with the Pan African Clinical Trials Registry (PACTR2010020001429343).

Several institutions support the MiPPAD project: the Barcelona Centre for International Health Research (Barcelona, Spain); the Université d'Abomey-Calavi (Cotonou, Benin); the Albert Schweitzer Hospital (Lambaréné, Gabon); the Manhiça Health Research Centre (Manhiça, Mozambique); the Ifakara Health Institute (Dodoma, Tanzania); the Kenya Medical Research Institute/ Centers for Disease Control and Prevention (Nairobi, Kenya); the Vienna School of Clinical Research (Vienna, Austria); the Institut de Recherche pour le Développement (Paris, France); and the Institute of Tropical Medicine and University of Tübingen (Tübingen, Germany). The studies are co-funded by the Carlos III Health Institute (Spain), the University of Tübingen and the German Aerospace Center



Professor Clara Menéndez, MiPPAD project coordinator

(Germany), the Institut de Recherche pour le Développement (France), the Austrian Federal Ministry of Science (Austria), and the Malaria in Pregnancy Consortium, which is funded through a grant from the Bill & Melinda Gates Foundation to the Liverpool School of Tropical Medicine.

Enrolment completed for REMox TB treatment trial

The global REMox TB clinical trial made momentous progress as enrolment of volunteers was completed in January 2012. The study aims to establish the efficacy of moxifloxacin against tuberculosis in order to reduce treatment time from six to four months. It is conducted mainly in Africa (approximately 70% of the patients recruited globally come from Africa). Further data on cure rate will be collected during a follow-up period for patients of 18 months. If the results are positive, the TB Alliance and the pharmaceutical company Bayer will seek registration of moxifloxacin as part of a multi-drug regimen for drug-sensitive TB.

The project coordinator Prof. Stephen H. Gillespie of St. Andrews University, Scotland, points out the complexity of the project "Developing the systems for the trial and managing the multiplicity of ethical review boards and national regulators, making translations into multiple languages, delivering drugs to a range of high burden countries to a defined standard have proved to be an enormous challenge, but the REMox TB team has worked tirelessly".

REMox TB is a three-arm, double-blind Phase III study in which moxifloxacin substitutes for two different drugs in the current first-line standard TB therapy, ethambutol and isoniazid, and is administered for a total of four months. The trial will determine whether either of these two new, four-month regimens are not inferior to standard six-month therapy in terms of failure and relapse. The study is registered with ClinicalTrials.gov and with the Pan African Clinical Trials Registry (PACTR201110000124315). The African branch of the REMox TB study is also part of the Pan African Consortium for Evaluation of Anti-tuberculosis Antibiotics (PanACEA), a network of six European research organisations, twelve sub-Saharan clinical trial sites, and three pharmaceutical companies.

As part of the study, the capacity of African clinical trial centres to perform studies to the highest international regulatory standard was significantly developed at sites in Tanzania, Kenya, Zambia and South Africa.

Prof. Charles Mgone, EDCTP Executive
Director: "The REMox TB clinical trial
demonstrates what can be achieved through
partnerships and international collaboration.
It is also gratifying to note that in this global
trial African researchers recruited the
majority of patients, signifying an increasing
African capacity to conduct Good Clinical
Practice-compliant trials."

The study is funded by EDCTP, the Bill & Melinda Gates Foundation, Irish Aid, the Netherlands Organisation for Scientific Research, the Medical Research Council United Kingdom, the United Kingdom Department for International Development (DIFID), and the United States Agency for International Development (USAID). The pharmaceutical companies Bayer Healthcare AG and Sanofi provide the trial drugs and other support. In 2013, EDCTP will have contributed a total of €6.32 million to REMox TB.

Focus on projects (continued from page 4)

Simplified regimen for treating children with severe malaria works

EDCTP-funded phase II studies have proven that a shorter duration anti-malaria treatment is as effective as the longer standard regimen in treating children with severe malaria. This multicentre trial was conducted by the Severe Malaria in African Children network (SMAC) and coordinated by Prof. Peter G. Kremsner. It was shown that three doses over two days of the drug artesunate are as effective as five doses over three days. This alternative regimen is likely to lower the risk of incomplete treatment by the improved efficiency and reduced cost of administering the treatment. The results for the SMAC studies on artesunate treatment for severe malaria were published online in the Journal of Infectious Diseases in December 2011 (doi: 10.1093/infdis/jir724).

The phase II clinical trial conducted in hospitals located in Gabon and Malawi recruited 171 children between six months and 10 years old. All children with severe malaria that fulfilled the study recruitment

criteria were enrolled and randomised into two groups with different treatment regimens of intravenously administered artesunate. One group was given the current WHO recommended regimen of five doses over 72 hours; the other group received three slightly higher doses over 48 hours. All the children received the same overall quantity of artesunate. In all patients, parasite clearance occurred rapidly.

The WHO-recommended 5-dose regimen has been in place for a number of years. Prof. Kremsner: "Now we know the shorter treatment works as effectively, this could lead to improvements in the way we administer artesunate." The next step in further simplifying treatment regimens would be to study the delivery of artesunate intramuscularly instead of intravenously.

The SMAC network consists of five centres: the Royal Victoria Hospital/Medical Research Council (MRC) Laboratories in Banjul, The Gambia; the School of Medical Sciences at the University of Science and Technology in Kumasi (Ghana); the Albert Schweitzer Hospital in Lambaréné (Gabon); the Centre for Geographic Medicine (Coast) of the Kenya Medical Research Institute in Kilifi (Kenya); and the Queen Elizabeth Central Hospital in Blantyre (Malawi).

The trial was cofunded by the Federal Ministry of Education and Research (Germany); the Medicines for Malaria Venture (Switzerland); St.George's University of London (United Kingdom); the Vienna School of Clinical Research (Austria); the Bernhard Nocht Institute for Tropical Medicine (Germany), the Institute for Tropical Medicine (Belgium); the GlaxoSmithKline Foundation (United States); the Department for International Development (United Kingdom). The artesunate for injection was donated by the Walter Reed Army Institute of Research (United States).

MVVC 2012 Annual meeting and site visits

The 2012 Malaria Vectored Vaccines
Consortium (MVVC) held its second annual
meeting in The Gambia on 16-19 January
2012. The event brought together 32 project
collaborators from 4 African and 3 European
countries and was hosted by one of the
members of the Consortium, MRC Gambia.

The aim of MVVC is to develop a vectored malaria vaccine. The consortium is therefore carrying out Phase Ib clinical trials to assess the safety and immunogenicity of the candidate malaria vectored vaccines, AdCh63 ME-TRAP and MAV-TRAP, in healthy sub-Saharan African adults and children (2-6 years old). The results from the Phase Ib trials will open up the way for a Phase IIb clinical trial to assess the safety, immunogenicity and efficacy of these candidate malaria vaccines in prime-boost

The Keur Socé Research Centre in Senegal is now finished and has been fully equipped by MVVC with EDCTP funding



regimes in
healthy
sub-Sahara
African children
and infants
(5-17 months
old). The Phase
Ib trials are
being conducted
at sites in The
Gambia and

Kenya, while Phase IIb trials will be conducted in Kenya, Burkina Faso and Senegal. Capacity building (infrastructure and training) for conducting clinical trials according to ICH-GCP guidelines and all applicable national and international regulations is integrated in the project.

The meeting concluded that thus far the project has made good progress. Phase Ib trials conducted in Kenya and The Gambia showed good safety and immunogenicity profiles. In preparation for the Phase IIb trials, baseline epidemiological studies are being conducted in Burkina Faso and Senegal. Six scientists are already enrolled in long-term training programmes: one Post Doctoral Fellow, three PhD candidates, and two MSc students.

At the annual meeting, EDCTP Project Officer Jean-Marie Vianney Habarugira presented EDCTP's ongoing activities and the expected EDCTP-II programme. The meeting was



Participants at the MVVC workshop in The Gambia

followed by a visit to the recently refurbished trial site at the Sukuta Health Centre (The Gambia) and the new Keur Sossé Research Centre (Senegal), which was finished and fully equipped by MVVC with EDCTP funding.

The eight MVVC partners include academic institutions, collaborative research programmes, and a biotech spin-out: the Centre National de Recherche et de Formation sur le Paludisme (Burkina Faso); the European Vaccine Initiative (Germany); the Kenyan Medical Research Institute (Kenya); the Medical Research Council (MRC) Laboratories (The Gambia); biotechnology company Okairos (Italy); the Université Cheik Anta Diop (Senegal); the University of Oxford Centre for Clinical Vaccinology and Tropical Medicine (United Kingdom); and the Vienna School of Clinical Research (Austria).

Meetings

54th ECSA Health Ministers' Conference

The East, Central and Southern Africa Health Community (ECSA-HC) in collaboration with the Ministries of Public Health and Sanitation, and of Medical Services of the Republic of Kenya hosted the 54th ECSA Health Minister's Conference in Mombasa, Kenya on 21-25 November 2011. The Conference brought together Ministers of Health, senior health officials, experts, health researchers, and heads of health training institutions. Dr Thomas Nyirenda, South-South Networking and Capacity Development Manager, represented EDCTP.

The aim of the conference was to identify policy issues and make recommendations to facilitate the implementation of high impact interventions for improved health outcomes in the region. The general theme of the conference was "Consolidating the gains", while sub-themes included: 1) going to scale, revisiting the Paris Declaration and its implications for the health sector; 2) improving capacity for health research and its utilisation; 3) integration of programmes to reduce disease burden; and 4) accelerating the response to noncommunicable diseases (NCD) in the ECSA region. The conference also included a roundtable on the Maputo Plan of Action on reducing the incidence of unsafe abortions.

In the session on research capacity and utilisation Dr Nyirenda held a presentation on EDCTP activities in the ECSA-HC region. EDCTP has funded projects in ten of the fourteen member states of the ECSA Health Community to a total of almost 102M euro. The projects involve eighty research institutions, hospitals and clinics. Current, only Lesotho, Mauritius, Seychelles and Swaziland have no EDCTP funded projects and researchers from these countries are encouraged to respond to future EDCTP calls for proposals.

WHO-AFRO AACHRD meeting

From 17 to 19 November 2011 the African Advisory Committee on Health Research and Development (AACHRD) met in Brazzaville (Congo). EDCTP was invited to participate and represented by Dr Thomas Nyirenda. The AACHRD was established by the World Health Organisation African Regional Office (WHO AFRO) in 1979 to advise the Regional Director on research related to

health policies and development strategies.



The main objectives of the meeting were to review the progress made on the implementation of the recommendations of the Algiers and Ouagadougou declarations; to review the commitments of the Region within the context of the WHO Strategy for Health Research; and to review plans to attain the health research objectives of the WHO AFRO Strategic Directions 2010-2015.

ICASA 2011

The International Conference on AIDS and Sexually Transmitted Infections in Africa (ICASA) is a major international AIDS conference that takes place in Africa every two years. The conference provides a forum for the exchange of scientific knowledge, experiences and best practices on prevention and treatment of HIV/AIDS and STIs. The 16th ICASA was held in Addis Ababa, Ethiopia from 4-8 December 2011. Its theme was "Own, Scale-up, Sustain". The conference brought together political and national leaders, the scientific community, practitioners, communities, civil societies, the private sector and partners.

Dr Thomas Nyirenda represented EDCTP at ICASA. His presentation discussed the EDCTP model of funding HIV research and capacity development in Africa during a session on HIV and Biomedical Research in Africa on

7 December 2011. The session focused on the significance of biomedical research conducted in Africa for the African response to HIV and AIDS. The capacity to conduct sound research also relies on strengthening the biomedical research capacity in Africa, e.g. by ensuring that earmarked funding for HIV and AIDS is allocated toward establishing centres of excellence for biomedical research. EDCTP through its grants to projects integrating research and capacity building and to its Networks of Excellence is contributing to this effort.

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

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Participants at the 54th ECSA Health Ministers' Conference in Mombasa, Kenya

