

Note from the Africa Office

Dear readers,



Greetings and welcome to the October issue of the EDCTP newsletter bringing the latest news and information for the third quarter of 2010. Our stakeholders are informed of the sixth EDCTP forum that will be held from 9 to 12 October 2011 at the United Nations Conference Centre in Addis Ababa, Ethiopia. The theme for this Forum is **Strengthening Research Partnerships for Better Health and Sustainable Development** which takes into account the past, present and the future of EDCTP.

This newsletter edition provides updates on the newly funded EDCTP projects and highlights of selected project outcomes. It also draws your attention to the two recently launched calls for proposals; one on Member States initiated projects in the fields HIV/AIDS, tuberculosis and malaria; and the other on evaluation of the impact of clinical trials in Africa. EDCTP also continues to invite online applications from individuals wishing to serve on the EDCTP scientific review committees or as external reviewers. Applications from potential candidates to replace outgoing EDCTP Developing Countries Coordination Committee (DCCC) and Partnership Board members are also still open.

EDCTP has continued its site visits to EDCTP-funded projects and engagement with African institutions and governments. In this issue, visit to Zambia is featured. EDCTP also welcomes new staff members who have joined the Calls and Grants, and Finance teams.

Our readers are informed of the European Member States meeting of the Belgian European Union Presidency which took place in Brussels and focused on shaping the next phase of EDCTP. The European Commission also published the preliminary results of the public consultation on the impact and future of EDCTP. We wish to sincerely thank all EDCTP stakeholders who participated in the various EDCTP reviews and consultations for your feedback and valuable contributions. Lastly, all our readers are invited to participate and provide feedback in the EDCTP Annual Report 2009 survey.

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

Events

Sixth EDCTP Forum (9-12 October 2011): Strengthening Research Partnerships for Better Health and Sustainable Development

The sixth EDCTP forum will be held from 9 to 12 October 2011 at the United Nations Conference Centre in Addis Ababa, Ethiopia. The theme of the Forum is **Strengthening Research Partnerships for Better Health and Sustainable Development**, taking into account the past, present and the future of EDCTP. This Forum provides an international platform for the presentation and discussion of frontier research for everyone involved in combating the three main poverty-related diseases (HIV/AIDS, tuberculosis and malaria) and the appropriate capacity development and networking activities. It presents a unique opportunity to establish and reinforce cooperation and synergy among EDCTP stakeholders at various levels including scientific, policy, funding and political interactions. Scientists involved in EDCTP-funded projects are particularly encouraged to use this opportunity to share new developments and results from their projects.

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The EDCTP Newsletter is available in three languages namely English, French and Portuguese. It is available in electronic format on our website (www.edctp.org) and in print in English for distribution mainly in sub-Saharan Africa.



Persons who wish to receive the print format should subscribe on the website (www.edctp.org, click on Newsroom).



EUROPEAN
 COMMISSION

Supported by the EU DG Research

Events (continued from page 1)

The programme

The forum programme will include speakers from the scientific, policy, ethics and regulatory as well as political fields. The focus will be on advances in research, capacity development, networking and agenda setting for clinical research on HIV/AIDS, tuberculosis and malaria. Priority will be given to EDCTP-funded projects to share their results. The programme will contain a mix of:

- Keynote addresses by invited speakers
- Plenary and parallel sessions
- Roundtable discussions
- Oral presentations
- Posters sessions
- Satellite meetings
- Marketplace for research exhibitions.

Participating in the Sixth EDCTP Forum

EDCTP will invite keynote speakers for the plenary sessions. In addition, abstracts will be invited for oral and poster presentations to be selected based on scientific merit.

Presentations on EDCTP-funded projects are particularly encouraged. EDCTP will publish a call for abstracts on its website soon and will circulate the information through a number of channels. A selection of applicants with well rated abstracts especially from sub-Saharan Africa working on EDCTP-funded projects will be awarded scholarships. Details on how to submit abstracts and to apply for scholarships will be published together with the call for abstracts.

Sponsorship opportunities

The sixth EDCTP forum will offer organisations various possibilities to support the meeting and raise their visibility. Information on sponsorship packages and how to apply will be soon available on the website.

Forum updates and website

The sixth EDCTP forum website will be launched soon and will contain regular updates on the programme and on opportunities to join the Forum. For now, please check the EDCTP website (www.edctp.org) regularly for any updates.

EU Member States meets to propose a second phase of EDCTP

The Federal Science Policy Office (BELSPO/STIS), in collaboration with the European Commission and EDCTP, organised a meeting under the Belgian EU Presidency which aimed to seek agreement on a proposal to be submitted to the European Council and the European Parliament regarding the next phase of the European and Developing Countries Clinical Trials Partnership (EDCTP).

A proposal for the next phase of EDCTP is already being prepared, tentatively to run from 2012 to 2020. This proposal takes into account the current results and experiences, the internal assessments and Independent External Reviews that have taken place, as well as the feedback from the ongoing impact assessment and completed public consultations on the EDCTP programme.

This meeting aimed to find consensus on the proposal, with participation of the current EDCTP Member States and other Member States wishing to be part of the new phase.

More information about this meeting can be found on the website <http://www.belspo.be/Workshopedctp/meet.stm>.

News about EDCTP governance

EC publishes preliminary results of the public consultation regarding new EDCTP programme

The European Commission (EC) has published the preliminary results of the public consultation on the impact and future of the European and Developing Countries Clinical Trials Partnership (EDCTP).

The current EDCTP programme was established in 2003 and ends in 2015. This public consultation aimed at collecting views and opinions of all interested EDCTP stakeholders. The areas covered include the scope of the new programme, the development of possible future policy options, lessons learnt from current programme and identification of key issues for future consideration.

The questionnaire received in total 235 responses during the period of 8 April until 22 June 2010. Based on these preliminary data, the majority of the respondents are in favour of a new EDCTP programme.

The consultation results can be found online at http://ec.europa.eu/research/consultations/edctp/consultation_en.htm

Survey EDCTP Annual Report 2009: your views

EDCTP intends to make its annual report as informative, relevant and interesting as possible. In order to improve the quality of future EDCTP reports, we have designed a survey to collect your feedback on the EDCTP Annual Report of 2009. As a contributor to the Partnership, your views are valuable to us and will help us to improve the way the annual report is presented and assurance that we share with you the relevant information that you are looking for.

The survey will only take a few minutes to complete and can be accessible at www.surveymonkey.com/s/75F77FQ.

News about EDCTP governance (continued)

EDCTP welcomes new staff members

Hager Bassyouni Project Officer

Hager Bassyouni was born in Cairo, Egypt, raised in the Netherlands and completed her formal education in the UK. Hager successfully read International Relations at the University of Sussex and received her Master of Science in Health Policy, Planning &



Financing from the London School of Hygiene & Tropical Medicine and the London School of Economics. Throughout and after her studies she has held various posts

internationally in the field of education, law, finance, business and welfare/public health. She moved back to Holland in 2007 to work at the Organisation for the Prohibition of Chemical Weapons expanding on her experience of organisational management and policy, organising multiple implementation projects worldwide.

Dr Monique Rijks-Surette Project Officer

Monique was born in Canada, where she studied Biochemistry and Plant Sciences. In 2005, she went to the UK to pursue a PhD in Plant Molecular Virology at the University of Cambridge. Afterwards, she moved from the laboratory into science policy by taking up a position at the Royal Society of Chemistry in International Development, working on networking, building capacity and promoting best practices in the chemical sciences in Africa. In 2009 she relocated to the



Netherlands, where she managed a climate change-related project at TU Delft before joining the EDCTP.

Jing Zhao Grants Financial Assistant

Born in China, Jing Zhao graduated MSc Business Administration with a specialisation in Finance at the Rotterdam School of Management, Erasmus University in 2008. To consolidate her studies, Jing completed a six month internship at the Royal Bank of Scotland, where she gained experience in working in an international environment. Jing joined EDCTP as Grant Financial Assistant to deal with daily grant financial activities including budgets, financial reports and updates of donations on the EDCTP project database.



Sayma Siddiqui Financial Assistant

Born in India, Sayma pursued her Masters in Business Administration (MBA), specialising in Finance from Institute of Business Management, India in 2003. She also completed her Diploma in International



Business Management from NILEM, India. Before moving to the Netherlands, she has worked with ITI Exports as finance assistant for 3 years and with Aviva Insurance for one year.

Sayma joined EDCTP in 2010 as Financial Assistant handling day to day operations of the financial accounting function of the EDCTP.

Vacancy: EDCTP Developing Countries Coordination Committee (DCCC) members

The Developing Countries Coordination Committee (DCCC) of the European and Developing Countries Clinical Trials Partnership (EDCTP) is seeking four new members to replace those who have completed their tenure. Applications are invited from senior scientific experts and health professionals from sub-Saharan Africa with experience in HIV/AIDS, tuberculosis and malaria in the following areas:

- HIV/AIDS (1 position for Southern African region)
- TB (1 position for each of the following sub-Saharan Africa regions: Eastern Africa, Central Africa and Southern African).

Deadline for application:
20 October 2010

Position starting date:
1 January 2011

Vacancy: EDCTP Partnership Board (PB) members

The Partnership Board of the European and Developing Countries Clinical Trials Partnership (EDCTP) is seeking two new members to replace those who have completed their tenure. Applications are invited from senior scientists in the areas of malaria and Industry/Regulatory Affairs (preferably having worked or coming from such sector).

Deadline for application:
15 October 2010

Position starting date:
1 January 2011

For details on how to apply and further information about the obligations and duties of the PB and DCCC members, please refer to the detailed advertisement on our website www.edctp.org.

News about calls and grants

Calls open for applications

Member States Initiated projects on HIV/AIDS, TB and malaria

Available funds: € 2.5 million
 Open to application: 16 August 2010
 Deadline of application: 13 December 2010

Purpose of the grant

European Member States often independently fund projects that fall within the remit of EDCTP (clinical trials, capacity building and networking on HIV/AIDS, TB and malaria in sub-Saharan Africa). 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.

Evaluating the impact of clinical trials in Africa

Available funds: € 850,000
 Open to application: 16 August 2010
 Deadline of application: 15 November 2010

Purpose of the grant

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 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: Member States Initiated projects

Safety and efficacy of the universal use of the Efavirenz-Tenofovir-Emtricitabine and Zidovudine-Lamivudine-Lopinavir/Ritonavir combinations in pregnant and breast feeding women to prevent mother-to-child transmission of HIV-1 in resource-limited settings.

A multicentre randomised phase III clinical trial

Project Coordinator: Didier Koumavi Ekouevi
Budget: € 4,667,714 (€ 999,999 EDCTP)
Duration of project: August 2010-May 2013
African countries involved: Cote d'Ivoire and Zambia.

Assessment of the fixed-dose combination of Artesunate and Mefloquine as an alternative antimalarial treatment for children in Africa

Project Coordinator: Nathalie Strub-Wourgaft
Budget: € 2,000,090 (€ 380,989 EDCTP)
Duration of project: August 2010-May 2012
African countries involved: Tanzania.

Capacity and network strengthening measures within the framework of malaria research in Tanzania

Project Coordinator: Stephen Magesa
Budget: € 4,050,588 (€ 415,487 EDCTP)
Duration of project: July 2010-May 2013
African countries involved: Tanzania.

A joint initiative to sustain HIV vaccine trials and research capacity in the Republic of Guinea-Bissau, West Africa

Project Coordinator: Anders Fomsgaard
Budget: € 2,038,690 (€ 231,859 EDCTP)
Duration of project: July 2010-December 2011
African countries involved: The Gambia, Guinea-Bissau and Senegal.

Focus on selected EDCTP projects

Pan-African Clinical Trials Registry (PACTR): updates and developments

The Pan African Clinical Trial Registry (www.pactr.org) continues to develop into a continental resource and tool for clinicians, researchers and healthcare professionals throughout the region. In September 2010 PACTR marked its first anniversary as a member of the World Health Organization (WHO) Network of Primary Registers. PACTR continues to experience tremendous growth. To date the registry has more than doubled in application numbers, with 64 applications and 35 registered trials. Clinical trial research of the registered trials is taking place in nineteen African countries, with 30 of 42 listed principal investigators coming from African countries.

PACTR is widely represented both locally and internationally and continues to spread the message of the importance of clinical trial registration. PACTR is particularly committed to providing trialists in Africa with a reliable and user friendly platform to register their trials.

More information on the PACTR: www.pactr.org



Focus on selected EDCTP projects

Artemisinin-based combinations for treating uncomplicated malaria in African children: the 4ABC trial (Prof. Umberto D'Alessandro)

Malaria remains a major cause of illness and death in developing countries. With the burgeoning development of resistance of malaria parasites to most conventional antimalarial drugs, it is important to support development of new drugs and combination regimens. Currently, artemisinin-based combination therapies (ACTs) are recommended as first-line treatment by the World Health Organization (WHO) for uncomplicated *Plasmodium falciparum* malaria in all endemic countries. There is, however, limited safety and efficacy data for these products especially following repeated usage. This study was implemented to contribute to bridging this gap.

Prof. Umberto D'Alessandro and his study group in the Prince Leopold Institute of Tropical Medicine (Belgium) in collaboration with the Liverpool School of Tropical Medicine (United Kingdom), the Centre for International Health (Spain), the Epicentre (France), the Institute of Tropical Medicine (Germany), the Uganda Malaria Surveillance Project (Uganda), the Tropical Diseases Research Centre (Zambia), the Centre Muraz (Burkina Faso), the Manhica Health Research Centre (Mozambique), the Albert Schweizer Hospital (Gabon), the University of Calabar Teaching Hospital (Nigeria), and the Programme National de lutte contre le Paludisme (Rwanda), with an EDCTP grant, designed a clinical trial that compared the safety and efficacy of four different ACTs (amodiaquine-artesunate, ASAQ; dihydroartemisinin-piperaquine, DHAPQ; artemether-lumefantrine, AL; and chlorproguanil-dapsone plus artesunate, CD-A). These studies began in December 2005 and were carried out in ten sites distributed in seven African countries, representing different levels of malaria endemicity. Between July 2007 and December 2008, more than 10,000 children were screened for malaria of whom more than 4,000 were diagnosed with clinical malaria and included in the trial. Recruited children were

aged 6-59 months old and randomised to either ASAQ, DHAPQ, AL or CD-A, being the first three co-formulated combinations and the last one co-administered with artesunate. In February 2008, the recruitment for the CD-A arm was prematurely interrupted and stopped because of safety reasons. Children were actively followed up for 28 days and thereafter passively for the next six months. Preliminary results show that PCR-adjusted efficacy of DHAPQ, AL and ASAQ at day 28 was high and similar among the three treatments, while CD-A was less efficacious.

It is hoped that these studies will inform and help policy makers to estimate the relative value of three of the ACTs currently available, i.e. ASAQ and AL, as well as for DHAPQ, which is expected to be soon on the market. Importantly, the large safety data set from these studies will contribute substantially to the global database on ACTs safety.

Panacea: an African/European research collaboration to shorten and simplify TB treatment

The global tuberculosis burden

In 1993, the World Health Organization declared tuberculosis (TB) a public health emergency and remains a major cause of death worldwide. In 2005, an estimated 8.8 million people were diagnosed with TB among whom 1.6 million died of the disease.

Due largely to the lethal interaction between HIV/AIDS and TB, Africa suffers especially high burden. The urgent public health need for new TB drugs to shorten and simplify therapy is made apparent by the lengthy (6 months) and complex (4-drug) regimens currently required for TB treatment. Long treatment regimens are difficult to sustain because of the investment required by health services to supervise treatment and the commitment required by the patient to complete the course and attend follow-up outpatient appointments. Poor adherence to increases the risk of relapse and the emergence of drug resistance. Therefore, an effective response to the global emergency

requires new drugs to achieve shorter and simpler treatment regimens.

History of EDCTP funding

Faced with the challenge to contribute to the urgent need of simplifying TB treatment, the European and Developing Countries Clinical Trials Partnership (EDCTP) held a stakeholder meeting on 31 May 2007, in Dublin, Ireland. With the goal of shortening and simplifying treatment of drug-sensitive TB, the EDCTP stakeholders recommended a brokered programmatic strategy to conducting clinical trials for new drugs. This resulted in a call for expression of interest that was released on 1 August 2007. Following this, five applicants representing a collaboration of several institutions were invited to participate in a brokering meeting held in The Hague on 4 December 2007. This led to formation of the Pan-African Consortium for Evaluation of Anti-tuberculosis Antibiotics (PanACEA) which developed a joint proposal to conduct of regulatory standard phase IIa, IIb, and phase III clinical trials for Moxifloxacin, Rifamycins and SQ109 using a shared governance, administration and capacity development strategy. This network comprises of Aurum Institute for Health Research (South Africa), Ifakara Health Research and Development Centre (Tanzania), Kenya Medical Research Institute (KEMRI) (Kenya), Kilimanjaro Christian Medical Centre (KCMC) (Tanzania), Klinikum der Universität München, Institute for Medical Bioinformatics (Germany), Leiden University (Netherlands), Makerere University (Uganda), Mbeya Medical Research Programme (Tanzania), Medical Research Council South Africa (MRC), Medical Research Council (United Kingdom), National Institute for Public Health and the Environment (RIVM) (Netherlands), Radboud University Nijmegen (Netherlands), Sequella (United States), Stellenbosch University (South Africa), Swiss Tropical Institute (Switzerland), University College London (United Kingdom), University of Cape Town Lung Institute (South Africa), University of the Witwatersrand (South Africa), University of Tübingen (Germany) and University of Zambia.

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Prof. Umberto D'Alessandro and the 4ABC study group at the Investigators meeting in Kampala



Meetings and visits

EDCTP site visit to Zambia

Over the last five years, Zambia is one of the African countries with increasing number of EDCTP-funded projects. The following nine projects are currently in progress:

1. "Children with HIV in Africa - Pharmacokinetics and Adherence of Simple Antiretroviral Regimens" led by Dr Veronica Mulenga at University Teaching Hospital in Lusaka
2. "Rapid evaluation of Moxifloxacin in the treatment of sputum smear positive tuberculosis" and "PanACEA" at University Teaching Hospital in Lusaka, led by Professor Stephen Gillespie
3. "A phase III double blind placebo/controlled trial of the efficacy and safety of infant periexposure" at University Teaching Hospital in Lusaka, led by Dr Phillippe van der Perre
4. "Improving the balance between efficacy and development of resistance in women receiving single dose" at University Teaching Hospital in Lusaka, led by Dr Elton Kisanga
5. "TESA - Trials of Excellence in Southern Africa" at University Teaching Hospital in Lusaka, led by Dr Alexander Pym
6. "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)" at University Teaching Hospital in Lusaka, led by Professor Keertam Dheda

The three projects under the umbrella of PanACEA include:

- Rapid Evaluation of Moxifloxacin in Tuberculosis (REMox), sponsored by University College of London in United Kingdom
- Evaluation of a novel TB Drug (SQ109) to Shorten and Simplify Tuberculosis Treatment, sponsored by Klinikum der Universität München Department of Infectious Diseases and Tropical Medicine in Germany
- Rapid Evaluation of High Dose Rifampicin and Other Rifamycins in Tuberculosis (HIGH-RIF), sponsored by Radboud University Nijmegen Medical Centre in the Netherlands.

The total funding of this consortium is € 28,557,712 with a contribution of € 14,157,030 from EDCTP. The other cofunders for this project are TB Alliance, Bill and Melinda Gates Foundation, Sequella and the South African Medical Research Council.

Public health relevance

These regimens aim to reduce the duration of therapy by one third, which would have critical implications for public health. This will result in significant cost improvements to health services delivering TB treatment, allowing

7. "An assessment of the understanding of the informed consent process by participants in microbicide intervention trials in Zambia" by Dr Bornwell Sikateyo as a PhD project

8. "Safe and efficacious artemisinin-based combination treatments for African pregnant women with malaria" in Ndola, led by Professor Umberto D'Alessandro

9. "Special populations and label expansion studies with the fixed dose combinations artemether-lumefantrine, amodiaquine-artesunate, and dihydroartemisinin-piperazine in Zambia, Malawi and Mozambique" in Ndola, led by Dr Victor Mwapasa.

EDCTP conducted a site visit to Zambia from the 30 August 2010 to 3 September 2010. The visiting team comprised of Mr Simon Belcher (Director of Finance and Administration), Dr Thomas Nyirenda (South-South Networking and Capacity Development Manager) and two members of the Developing Countries Coordination Committee (DCCC) of EDCTP, Professor Nkandu Luo and Dr Modest Mulenga. In addition to the project specific visits, the EDCTP delegation had meetings with Dr Peter Mwaba, the Principal Secretary of the Ministry of Health in Zambia; Dr Olusegun Babaniyi the WHO Country Office for Representative and his team; Dr Kansonka, the Medical Superintendent at University Teaching Hospital; and all investigators involved.

more patients to be treated and the provision of higher-quality service. Importantly, for patients this will likely mean a reduced number of visits, which often impose a significant financial burden on a population that is least likely to be able to bear the costs. High treatment completion rates will significantly reduce the risk of the emergence of multiple drug resistant strains, which is an emerging threat in several parts of Africa. The studies and capacity development component will help ensure Africa's ability to successfully evaluate and register future improvements in TB treatments of public health importance through the conduct of high-quality clinical trials. This study directly addresses concerns about quality by ensuring that African TB clinical trials sites become world leaders in performing regulatory quality TB trials. The capacity and tools established through the PanACEA activities will establish an enduring framework for more effective and efficient development of new TB drugs as they progress through the development pipeline. Thus, the success of PanACEA will not only contribute to shorter and simpler regimens, but also build the infrastructure required for drug development.



Members of Community Advisory Board pose for a picture outside Kanyama Health Centre in Lusaka, Zambia. The board that targets populations of the suburb that is covered by the health in patient recruitment for studies funded by EDCTP and others funders at Lusaka Teaching Hospital

EDCTP news alerts and RSS

On the EDCTP website, you can subscribe to the EDCTP Announcements to receive the latest EDCTP news (including calls for proposals on the date that they are launched, press releases, vacancies, events and any other important updates) either as an email alert or as an RSS feed.



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