



EDCTP

EDCTP NEWSLETTER

European & Developing Countries Clinical Trials Partnership



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CRUCIAL PERIOD AT HAND

Esteemed Stakeholders,

We have entered crucial and exciting years for the second programme. As we roll up our sleeves to advance, it is timely to take stock first and then look ahead at the task at hand.

Last year, 2016, was a very productive year. We successfully closed the first EDCTP programme with the appropriate reports and audits. Under the new programme, our total of grants awarded rose to a cumulative figure of 60 projects which involve 15 European countries and 30 countries in sub-Saharan Africa. Nine calls for proposals were launched in 2016. Solid support for our partnership was demonstrated at the Eighth EDCTP Forum in Lusaka, Zambia in November 2017. A report on this Forum is available and its abstracts will be published in a supplement of the *BMJ Global Health* in February.

Importantly, EDCTP nominated two High-Representatives to advocate for the programme at the highest levels. Our implementation structure was strengthened with the Monitoring & Evaluation Team and an independent EDCTP Audit Committee. In order to enhance the visibility of the programme, we rebranded EDCTP and refined our communication strategy.

On the scientific and strategic front, following a consultative process we published a revised and concise version of the EDCTP2 strategic business plan with clear indication of our funding priorities. In addition, we released the first EDCTP annual strategic research agenda for 2017. Two stakeholder meetings on new areas within our scope also contributed to this agenda. Both documents



guide the drafting of the annual work plans. Moreover, the Scientific Advisory Committee (SAC) was renewed with eight new members (and another two still advertised). We are sincerely grateful to all former and current SAC members for their very valuable advice. Our special thanks go to the former SAC Chair, Professor Tumani Corrah, and a warm welcome to the new Chair, Professor Catherine Hankins.

The start of 2017 ushers the EDCTP programme into a critical and exciting period. The 2017 strategic research agenda revealed high-priority research and capacity gaps which call for accelerated efforts to address these priorities. It also urges us to scale up our international engagement with like-minded public and private partners with consequent tangible joint actions.

Currently, the first interim evaluation of the programme is taking place. It will provide valuable feedback to enable informed course corrections in the execution of the programme. I am confident that working together we will achieve our overall objectives and targets for EDCTP2, provided we remain fully concentrated on our mission and nimble enough to exploit emerging opportunities of high value. In conclusion, I wish all our stakeholders a healthy and productive year ahead.

Dr Michael Makanga
Executive Director

Eighth EDCTP Forum: highlights

The highlights of the Eighth EDCTP Forum, held in Lusaka, Zambia, from 6 to 9 November 2016, have been published. The publication gives a summary of the themes discussed during the Forum's plenary sessions, and it highlights the discussions that took place during the parallel sessions and scientific symposia.

The Forum welcomed 434 attendees from 48 countries. The programme included 156 abstract-based presentations, of which 32 were oral presentations, and 133 were poster presentations.



The abstracts of the presentations in the plenary and parallel sessions as well as the posters will be published in a supplement to *BMJ Global Health* in February.

The highlights of the Eighth EDCTP Forum can be downloaded at www.edctp.org.

Switzerland fully associated to Horizon 2020

Effective from 1 January 2017, Switzerland is associated to the entire Horizon 2020 programme, the Research and Innovation programme of the European Union. This means that for all EDCTP2 projects for which the grant agreements are signed from 1 January 2017 onwards, Swiss participants are eligible for funding and may count towards the minimum number of participants required for a project. The status of Swiss legal entities in all on-going projects, i.e. for which the grant agreements have already been signed before 1 January 2017, remains unchanged.

“THIS IS A GREAT STEP TOWARDS STRENGTHENING AND FURTHER DEVELOPING SWISS PARTNERSHIP WITH THE EU AND PARTICULARLY HORIZON 2020 AND EDCTP. THE RE-ASSOCIATION OF SWITZERLAND IS TRULY MOTIVATING. IT OFFERS A LONG-TERM PERSPECTIVE FOR OUR JOINT GOALS AND INCREASES OPPORTUNITIES TO CONTRIBUTE TO HEALTH AND WELL-BEING THROUGH PARTNERSHIPS ACROSS SYSTEMS AND CULTURES.”

Marcel Tanner, EDCTP High Representative North

It is important to note that Swiss entities do not count towards the **minimum** number of participants required for an EDCTP-funded project as Switzerland is not a member of the EDCTP Association, i.e. an EDCTP Participating State. For more information on EDCTP grants, please access www.edctp.org.

UK Parliament hosts EDCTP meeting on African-European partnership for global health

The meeting ‘African-European partnership for global health benefit’ will take place on 27 February 2017 at the Houses of Parliament in London, United Kingdom. Organised by EDCTP, the meeting is hosted by Dr Daniel Poulter MP on behalf of the UK All-Party Parliamentary Group on Global Health.

This meeting aims to share first-hand information on some of the life changing outcomes from EDCTP. A case study on development of paediatric fixed-dose combination therapy for HIV-infected children will be presented by researchers from Zambia and the UK. The agenda will be followed by a panel discussion on the value of EDCTP in generating valuable new evidence on medical interventions against poverty-related diseases.

Members of the UK Parliament, as well as representatives of UK-based funders, UK researchers, NGOs, private foundations, private sector are expected to attend the meeting.

WHO-AFRO meeting on SDGs and universal health coverage

The technical leaders of Ministries of Health, representatives of development partners, funders, donors, NGOs, civil society and members of the United Nations system attended the first Regional Forum on Strengthening Health Systems for Sustainable Development Goals (SDGs) and Universal Health Coverage (UHC) in Windhoek, Namibia, on 12-13 December 2016. Dr Thomas Nyirenda, South-South Networking and Capacity Development Manager, represented EDCTP at the meeting.

The meeting was organised by the World Health Organisation Regional Office for Africa (WHO-AFRO) under the theme: “Health Systems, Healthy People: Making Universal Health Coverage Work for Africa.”

It is a recognised fact that health (under SDG 3) is linked to all SDGs, but each country has its own priorities for social and economic development. The objective of the meeting was to provide a platform to review and discuss health system strengthening efforts to meet the SDGs and UHC in the context of different country priorities.

Many partners have a role to support countries meet the SDG targets. Organisations such as WHO assist countries to produce tangible plans, build health systems capacity, improve governance in health systems, building better monitoring and evaluation systems and implement UHC. Organisations such as EDCTP provide support to enable African institutions to conduct collaborative clinical research for medicinal products and their practical implementation, as well as build human and institutional capacity to conduct relevant research according to the highest international standards. .

It is envisaged that such a meeting will be an annual event. WHO-AFRO is committed to organising these meetings and publishing their communities of practice on a dedicated website.



Dr Matshidiso Moeti, Regional Director for WHO-AFRO, speaks at the meeting in Windhoek, Namibia

EDCTP welcomes new SAC members and chairperson

Professor Catherine Hankins has been appointed as the new Chair of the EDCTP Strategic Advisory Committee (SAC) as of January 2017.



Prof. Catherine Hankins is Deputy Director Science of the Amsterdam Institute for Global Health and Development, Scientific Chair of the institute's international INTEREST conference on HIV, and Honorary Professor at London School of Hygiene & Tropical Medicine. She chairs the Scientific Advisory Board of CAPRISA, KwaZulu-Natal and the USA National Institutes

of Health's HIV Prevention Trials Network's Scientific Advisory Group. She was principal investigator of studies involving women, prisoners, and people who inject drugs and of population-based epidemiological studies. As Chief Scientific Adviser to UNAIDS, she led the scientific knowledge translation team focused on ethical and participatory HIV prevention trial conduct, convening mathematical modelling teams, and supporting country implementation of proven biomedical HIV prevention modalities. Prof. Hankins was the editor of the popular UNAIDS' science blog HIV This Week. A trustee of the UK HIV Research Trust and member of the International AIDS Society Industry Liaison Forum, she was named to the Order of Canada in 2013.

Prof. Hankins succeeds Prof. Tumanii Corrah (Medical Research Council, The Gambia), who has given invaluable contribution to EDCTP as a member of its Developing Countries Coordinating Committee (DCCC), Partnership Board, and later the SAC.

Additionally, from January 2017, the SAC welcomes seven new members.



Professor Christian Burri is a member of the Directorate of the Swiss Tropical & Public Health Institute, Head of the Department of Medicines Research and Professor for pharmacy & clinical pharmacology at the Department of Pharmaceutical Sciences, University of Basel. He has been involved in the management and conduct

of clinical trials on drugs and vaccines against neglected tropical and poverty related diseases for 20 years. The trials are mainly executed in low-income countries, but also in Europe. Prof. Burri has significantly contributed to the improved treatment of parasitic diseases with a particular passion on sleeping sickness (human African trypanosomiasis). He has published over 40 peer reviewed papers, and numerous reviews and book chapters.



Professor John Gyapong, a Public Health Physician and an Epidemiologist, is the Vice Chancellor of the University of Health and Allied Science in Ghana. Professor Gyapong had his basic medical education in Ghana, and later pursued a Master of Science in Public Health in Developing Countries, and a PhD in Epidemiology at the London School of Hygiene and Tropical Medicine,

University of London. He practised as a doctor in rural Ghana for nine years. His main area of research is infectious disease epidemiology,

especially lymphatic filariasis, other neglected tropical diseases and malaria. He established and managed the Ghana Neglected Diseases Control Programme for 8 years. He has over 120 publications in peer-reviewed journals and a book on neglected tropical diseases in sub-Saharan Africa.



Professor Martin Meremikwu is a tenured Professor of Paediatrics and Child Health at the College of Medical Sciences University of Calabar in Cross River State Nigeria where he also leads the clinical trials and evidence-based healthcare program of the Institute of Tropical Diseases Research and Prevention. He obtained MBChB at the University of Calabar

in 1985 and the Master of Science in Mother and Child health at Institute of Child Health, University London in 1993. He holds specialist fellowship of the Faculty of Paediatrics of the National Postgraduate Medical College of Nigeria and is a Fellow of Royal College of Paediatrics and Child Health UK. He pioneered the Cross River Health and Demographic System which became an INDEPTH member site in 2013. Professor Meremikwu is the Director of Cochrane Nigeria and current Chair of the Nigerian National TB/HIV Technical Working Group. He was awarded the Kenneth Warren Prize for excellence in developing Cochrane systematic reviews in 2009.



Dr Jutta Reinhard-Rupp is Head of the R&D Translational Innovation Platform for "Global Health" at Merck Serono. Her focus is the discovery and development of new drugs and health solutions for children suffering from poverty-related diseases such as malaria and schistosomiasis. Jutta Reinhard-Rupp studied

Biology in Mainz and Tübingen and received her PhD at the Max-Planck Institute in Tübingen. After her postdoctoral training at Novartis, she was lab head at Evotec Biosystems in Hamburg. In 1997, she joined Aventis in various assignments in Research and Development. Since January 2008, she works with Merck Serono in Switzerland with main responsibilities on the implementation of key strategic initiatives in drug discovery and development, including the lead of several "Global Health" programs. The current flagship program is the development of a new paediatric formulation of praziquantel to treat young children in schistosomiasis endemic areas.



Professor Peter Smith is Professor of Tropical Epidemiology at the London School of Hygiene & Tropical Medicine (LSHTM) and a member of the Board of Directors of PATH. He graduated in mathematics and statistics from City University, London and in 1965 joined the Medical Research Council's Statistical Research Unit in London. Prof. Smith's research

interests include large-scale intervention studies against tropical diseases, including vaccine trials. He was involved in research on the link between Bovine Spongiform Encephalopathy (BSE) and Creutzfeldt-Jakob Disease in humans.



Professor Halidou Tinto is Regional Director of Institute for Health Research (IRSS) in Burkina Faso. From 2003 to 2006, he worked as PhD fellow in Medical Sciences at Institute of Tropical Medicine (ITM) in Antwerp, Belgium, where he studied the epidemiology of malaria drug resistance in Burkina Faso and the mechanism of the resistance in Rwanda. After obtaining his PhD in 2006, he returned to Burkina Faso, where he created in 2008 a Clinical Research Unit. The unit has successfully conducted several trials including a malaria phase three vaccines trials (RTS, S), and has about 200 people working on several research projects. Prof. Tinto graduated in July 2016 as Professor of Parasitology at the Polytechnic University of Bobo-Dioulasso, Burkina Faso. He is the author and co-author of 93 publications in international peer-reviewed journals.



Professor Marleen Temmerman is Chair of the Department of Obstetrics and Gynaecology, Aga Khan University (AKU) Hospital Nairobi, and Director of the Centre of Excellence in Women, Child and Adolescent Health, AKU-East-Africa. From 2012-2015, she was the Director of the Department of Reproductive Health and Research (RHR) at the World Health Organization (WHO), Geneva. She is also a full Professor Obstetrics and Gynaecology at Ghent University in Belgium. As an obstetrician she supervised over 18,000 births in many parts of the world. Her interest is women's health and rights. She has a strong academic background with over 500 publications and books in the area of women's health, many PhD students in Europe, Africa (mainly Kenyan scientists), Latin America and China, and several awards and honours.

Prof. Eleni Aklillu (Karolinska Institute, Sweden), Dr Maryline Bonnet (Institute of Research for Development, France), Prof. Maria Fraga Oliveira Martins (Institute for Hygiene and Tropical Medicine, New University of Lisbon, Portugal), Prof. Clara Menéndez Santos (Barcelona Centre for International Health Research (ISGlobal), Spain), Prof. Philippe Sansonetti (Pasteur Institute, France), and Prof. Ali Zumla (University College London, United Kingdom) will continue their term as SAC members in 2017.

Currently, EDCTP is seeking two high-level experts in the fields of implementation research and ethics to join the SAC in 2017. The call for applications is open until 9 February 2017.

The SAC is an advisory panel of independent scientific experts from Europe and Africa. Working with the Secretariat, the SAC develops the strategic framework for EDCTP and advises the General Assembly on technical and scientific matters relating to the EDCTP programme. The SAC is not involved in the review of applications submitted to EDCTP calls for proposals. For more information about the SAC and its members, please visit www.edctp.org.

Diagnostic tools to eliminate sleeping sickness

The EDCTP-funded DiTECT-HAT project is evaluating new diagnostic tools for Human African trypanosomiasis (HAT), also known as sleeping sickness. HAT is a neglected infectious disease affecting rural populations in sub-Saharan Africa. Started in February 2016, the DiTECT-HAT project is the first grant funded under EDCTP on a neglected infectious disease.

HAT is caused by infection with the parasites *Trypanosoma brucei gambiense* (Tbg) or *Tb rhodesiense*, and transmitted by tsetse flies. In the last decade, the prevalence of Tbg HAT has dramatically decreased and HAT has been targeted for elimination by 2020. However, integration of diagnosis and case management into the general health system, sustainable monitoring of eliminated foci and development of safe and efficacious drugs, remain important challenges. Approximately 97% of all cases are caused by Tbg infection, leading to a chronic fatal disease. Control of Tbg HAT mainly relies on case detection and treatment.

Led by Dr Veerle Lejon of Institut de Recherche pour le Développement (IRD) in France, DiTECT-HAT aims to determine the diagnostic performance and cost-efficiency of rapid diagnostic tests performed in peripheral health centres, and of diagnostic algorithms combining rapid diagnostic tests with serological and/or molecular tests on filter paper performed at regional reference centres.



“DITECT-HAT INDEPENDENTLY EVALUATES NEW TESTS FOR SLEEPING SICKNESS. AS A RESULT, HEALTH CENTRES WILL PICK UP MORE PATIENTS AND DETECT THEM AT AN EARLIER DISEASE STAGE. I AM PROUD THAT WITH THE DITECT-HAT PROJECT, WE CONTRIBUTE TO SUSTAINABLE ELIMINATION OF SLEEPING SICKNESS.”

Dr Veerle Lejon, DiTECT-HAT project coordinator

Diagnostic algorithms with high positive predictive values will improve cost-effectiveness of passive case detection and might, depending on the result, allow scenarios of testing and treating without the need for parasitological confirmation.

The project also aims to determine the feasibility and cost-efficiency of different diagnostic algorithms with serological and molecular high-throughput tests. General health workers performing house to house visits in eliminated HAT foci can easily collect blood on filter paper and send it to regional HAT reference centres for analysis. This study should enable the definition of thresholds for a “transmission alarm” to trigger reactive case finding in order to avoid re-emergence of HAT.

Moreover, the accuracy of neopterin and trypanosomal spliced leader RNA detection as early test-of-cure will be determined in therapeutic trials. Early treatment outcome assessment will not only speed up the development and implementation of new drugs for HAT, but will also improve management of relapsing patients in routine patient care.

In the short term the project is expected to result in validation of cost-effective diagnostic algorithms that will facilitate passive case detection, case management and triggering active case detection. The long term results aimed at are introduction of these diagnostic tools in general health care settings, and a contribution to successful, sustainable HAT elimination.

The project will be conducted in Burkina Faso, Côte d'Ivoire, Guinea, and the Democratic Republic of the Congo, with additional testing in regional HAT reference centres in Burkina Faso and the Democratic Republic of the Congo.

Newly signed grants

Call: Ethics and regulatory activities

Improving ethical review process in Sudan through capacity building of national Regulatory Authorities

University of Khartoum, Sudan with partners from Sudan

Starting date: 1 February 2017

Duration: 24 months

Grant budget: EUR 291,042

Grant agreement: CSA-Ethics-873

Developing LMHRA capacity to effectively exercise its regulatory mandate in clinical trials and health research in Liberia

Liberia Medicines and Health Products Regulatory Authority (LMHRA)

Starting date: 1 February 2017

Duration: 24 months

Grant budget: EUR 300,000

Grant agreement: CSA-Ethics-868

Call: Improved treatment and clinical management of poverty-related diseases

High dose ambisome on a fluconazole backbone for cryptococcal meningitis induction therapy in sub-Saharan Africa: a randomised controlled non-inferiority trial

London School of Hygiene & Tropical Medicine, United Kingdom with partners from Botswana, France, Malawi, South Africa, Uganda, United Kingdom, and Zimbabwe

Acronym: AMBITION

Starting date: 1 January 2017

Duration: 48 months

Grant budget: EUR 9,990,712

Grant agreement: TRIA-2015-1092

IPTp with dihydroartemisinin-piperaquine and azithromycin for malaria, sexually transmitted and reproductive tract infections in pregnancy in high sulphadoxine-pyrimethamine resistance areas in Kenya, Malawi, and Tanzania

Liverpool School of Tropical Medicine, United Kingdom with partners from Denmark, Finland, Kenya, Malawi, Norway, Tanzania and United Kingdom

Acronym: IMPROVE

Starting date: 1 December 2016

Duration: 48 months

Grant budget: EUR 7,389,049

Grant agreement: TRIA-2015-1076

Call: Research capacity development in support of the EVD response

Vaccine trials and deployment towards sustainability of Ebola Virus Diseases control

Centre des recherches médicales de Lambaréné (CERMEL) (Gabon) with partners from Germany and the United Kingdom

Acronym: SECC

Starting date: 1 December 2016

Duration: 24 months

Grant budget: EUR 20,000

Grant agreement: EDCTP-CSA-Ebola-2015-363

Call: Strategic actions supporting large-scale clinical trials

A randomised controlled trial to assess the safety, acceptability and pharmacokinetics of a sustained-release tenofovir-alafenamide sub-dermal implant for HIV prevention in women

Centre for the Aids Programme of Research in South Africa (CAPRISA) (South Africa) with partners from Ireland and France

Acronym: CAPRISA-018

Starting date: 1 January 2017

Duration: 60 months

Grant budget: EUR 9,814,469

Grant agreement: SRIA-2015-1061

Globally relevant AIDS vaccine Europe-Africa trials partnership

University of Oxford (United Kingdom) with partners from Kenya, The Netherlands, Uganda, United Kingdom, United States, and Zambia

Acronym: GREAT

Starting date: 1 January 2017

Duration: 60 months

Grant budget: EUR 7,092,010

Grant agreement: SRIA-2015-1066

Evaluation of host biomarker-based point-of-care tests for targeted screening for active TB

Stellenbosch University (South Africa) with partners from Germany, The Netherlands, South Africa and United Kingdom

Acronym: Predict TB

Starting date: 1 February 2017

Duration: 60 months

Grant budget: EUR 7,722,491

Grant agreement: SRIA-2015-1065

EDCTP funding data in World RePORT

EDCTP funding data for 2012-2015 are available at the World RePORT website. This is a unique web-based information sharing platform that maps biomedical research projects funded by major funding organisations. The project aims to facilitate communication and coordination between funders, to provide more transparency and openness on funding flows, and to allow increased cost-effectiveness of funding.

Dr Gabrielle Breugelmans, EDCTP North-North Networking Manager, participated in the project's steering committee from 2013-2016:

“WORLD REPORT IS A GREAT TOOL FOR INFORMATION ON INVESTMENTS IN GLOBAL HEALTH RESEARCH. WE ENCOURAGE MORE FUNDERS (AND PARTICULARLY FUNDERS IN EDCTP MEMBER COUNTRIES) TO COME ON BOARD. IDENTIFICATION OF FUNDING GAPS OR DUPLICATION WILL BECOME EASIER AND CONTRIBUTE TO A BETTER RETURN ON SCARCE RESEARCH FUNDS.”

Currently, 12 funders contribute data to the World RePORT including the National Institutes of Health (NIH, USA), the Bill & Melinda Gates Foundation, the European Commission, EDCTP, and several funders from EDCTP member countries: France, Germany, Sweden and United Kingdom.

Created as a pilot project in 2011 by the Heads of International Research Organizations (HIRO), including the EC, it is hosted by the NIH of the United States, and maintained and upgraded by the IT service provider of NIH. EDCTP specifically contributed to the upgrade and maintenance of the World RePORT that was officially launched at the HIROs meeting in November 2016. The World RePORT also facilitates the development of common standards for data on publicly released funding, and enables data aggregation. Moreover, it will contribute to the implementation of the G7 strategy for research funding in the area of poverty-related infectious diseases and to the international cooperation in research and innovation.

Currently the tool covers funding of research projects in sub-Saharan Africa but soon it will provide insight in funded research in all low- and middle-income countries. Dr Magda Moutaftsi, North-North Networking Officer, who participates in the steering committee as of 2017:

“IN MAY 2017, WORLD REPORT WILL BE EXPANDED BEYOND SUB_SAHARAN AFRICA WHEN THE 2016 DATA IS EXPECTED TO BE UPLOADED.”

EDCTP funding data for 2016 will be uploaded in the second quarter of this year.

For more information about the World RePORT, please access <https://worldreport.nih.gov>.

Financial and project management training to grantees

As part of the activities of the 2016 work plan, EDCTP organised two financial and project management training workshop for its grantees in Dakar, Senegal, from 11-13 April 2016 and in Nairobi, Kenya, from 6-8 December 2016. The three-day workshops were specifically targeted towards better financial and project management of EDCTP2 projects. The coordinators and the scientific and financial project managers of newly selected and on-going EDCTP2 projects were invited to attend. The workshops were conducted by Mr Abdou Barry, EDCTP Director of Finance and Administration, and Dr Ole Olesen, EDCTP Director of North-North Cooperation.

At the workshops, participants were able to improve their understanding of key financial management terms and principles, understand the internal control and risk management implications of some of the decisions they take, and understand the importance of putting in place sound financial management systems. Moreover, the training equipped participants with skills and knowledge on how to effectively and efficiently manage collaborative projects with multiple international collaborators, and how to deliver the intended objectives of the project on time and within the budget.

“OVERALL, THE TRAINING HAS BEEN VERY IMPORTANT AND IT CLARIFIED MANY OF THE IMPLEMENTATION QUESTIONS. IT WAS REALLY TIMELY. I LOVED IT AND IT WILL BENEFIT BOTH ME AS THE PARTICIPANT AND THE INSTITUTION AT LARGE.”

Participant of the training in Nairobi, Kenya

“THIS TRAINING IS WORTH COMING TO AND I HOPE IT WILL CONTINUE. THE TRAINING HAS PREPARED ME VERY WELL FOR MY NEW PROJECT UNDER EDCTP, IN WHICH I AM RESPONSIBLE TO PREPARE THE FINANCIAL REPORTS.”

Participant of the training in Dakar, Senegal



Participants of the financial and project management training in Nairobi, Kenya



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HAVE A QUESTION OR COMMENT?
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