

Update is a monthly newsletter from the European & Developing Countries Clinical Trials Partnership.



EDCTP

The Power of Sharing Science

EDCTP Update

November 2017



Supported by the EU

WHO Global Ministerial Conference on Ending TB

WHO organised the first **Global Ministerial Conference on Ending Tuberculosis in the Sustainable Development Era: a Multisectoral Response** in Moscow, Russian Federation, from 16-17 November 2017. The conference brought together Ministers of Health and Ministers from other sectors, diplomats, representatives of public and private organisations and institutions, civil society, and affected people and communities. EDCTP was represented by its Executive Director, Dr [Michael Makanga](#), and Dr [Ole F. Olese](#), Director of North-North Cooperation.

The aim of the conference was to accelerate implementation of the United Nations (UN) Sustainable Development Goals (SDGs) and the WHO End TB Strategy to end the global TB epidemic by 2030 through national and global commitments, deliverables and accountability, and immediate action addressing gaps in access to care and the multidrug-resistant tuberculosis (MDR TB) crisis. The conference resulted in a Ministerial declaration that will also inform the first UN General Assembly High-Level Meeting on TB in 2018.

Speaking at the first plenary of the conference, Minister of Health of South Africa and Chair of the Stop TB Partnership, Dr Aaron Motsoaledi emphasized the need bring the discussion to end TB at the level of heads of state and government and UN leaders.



Dr Aaron Motsoaledi, Minister of Health of South Africa and Dr Makanga



EU Commissioner for Health and Food Safety, Vytenis Andriukaitis and Dr Makanga

The Conference also had several important side meetings [Africa Health Ministers & Parliamentary Tuberculosis Apex Working Breakfast; and "The Urgent Need for New TB Vaccines to End the Epidemic, organised by Aeras, TBVI and hosted by the Ministries of Health of South Africa and Argentina, among others). The Conference presented a great opportunity to explore opportunities for cooperation.

Michael Makanga: "We need to join forces and call upon governments around the world to commit and tangibly contribute towards ending the suffering caused by TB through a major and sustained investment in TB research and development (R&D). The EDCTP Programme is scaling up its investments in the fight against TB. By early 2018, the partnership, supported by the European Union, expects to have committed already 72.6 million euros to TB research."



Dr Michael Makanga (EDCTP Executive Director) meeting Dr Matshidiso Moeti, Regional Director WHO regional office for Africa (right) and Michèle Bocoz, WHO Assistant Director General for External Relations.

EDCTP at ASTMH, 5-9 November 2017

In partnership with the Wellcome Trust, EDCTP contributed a symposium to the programme of the annual conference of the American Society for Tropical Medicine and Hygiene (ASTMH 2017, Baltimore, USA, 5-9 November).



The sponsored symposium (session 130) under the title 'Challenges and opportunities of conducting clinical trials in pregnant women and future infants in resource-limited settings' took place on 8 November 2017.

Conducting clinical trials in low- and middle-income countries (LMICs) is essential to deliver new and improved medical interventions that are safe, effective, appropriate and accessible for the affected population. Pregnant women and their unborn children in LMICs are particularly vulnerable to a range of infections that can lead to significant mortality and morbidity to mother and baby. There is a need to develop medical products to prevent and treat infection in pregnancy and that can be implemented effectively in LMICs.

However, the systematic exclusion of pregnant women from clinical trials conducted by product developers, as well as the challenges (scientific, ethical, social, cultural) of conducting research in pregnant women limit the development, testing and approval of safe, affordable and

effective products for pregnant women. There is a need to maximise the impact of research through collaboration and data sharing from individual trials conducted in pregnant women.

The symposium focused on the practical challenges faced and lessons learned by researchers conducting clinical trials in pregnant women in LMICs with presentations on malaria, HIV and Zika infection in pregnant women. The studies presented are conducted in sub-Saharan Africa (Malawi and Mozambique), Asia (Thailand) and South America (Brazil).

- **Ruth Faden** (Berman Institute of Biomedical Ethics, Johns Hopkins University, USA): 'Social, ethical and legal implications of research in pregnant women during the Zika outbreak';
- **Khátia Munguambe** (University Eduardo Mondlane & Centre for Health Research of Mozambique (CISM), Mozambique): 'Community engagement in the context of clinical trials on reproductive health' and child health'.
- **Victor Mwapasa** (College of Medicine-University of Malawi, Malawi): 'Practical challenges with implementing studies involving pregnant women in an African setting with high HIV and malaria prevalence';
- **Rose McGready** (University of Oxford and Shoklo Malaria Research Unit, Thailand): 'Effects of malaria and other tropical infections on maternal and child health'.

EDCTP country visit to Tanzania

An EDCTP team comprising Mr [Abdoulie Barry](#), Director of Finance and Administration, Dr [Thomas Nyirenda](#), South-South Networking and Capacity Development Manager, and Dr [Michelle Helinski](#), Project Officer, visited EDCTP project sites in Moshi and Dar es Salaam, Tanzania, between 13 and 17 November 2017. Tanzania is currently participating in 11 EDCTP2-funded projects. It is one of the most successful countries in sub-Saharan Africa in attracting EDCTP funding.

Three organisations were visited, namely the Kilimanjaro Christian Medical Centre (KCMC)/ Kilimanjaro Clinical Research Institute (KCRI) in Moshi and the National Institute of Medical Research (NIMR) and Ifakara Health Institute (IHI) in Dar es Salaam. Due to the early stage of most projects, for most projects only technical preparedness and financial and operational capacities were assessed.

EDCTP regularly conducts visits in countries where substantial financial investments have been made. The visits create opportunities to exchange views and offer support and guidance to meet the required standards in project implementation, documentation, reporting and financial controls.



In front of the Kilimanjaro Clinical Research Institute

Recent events

November 2017 | This annual meeting of EU policy makers involved in Public-Public-Partnerships, is organised by ERA-LEARN (DG RTD, European Commission). Ms. [D. Jajkovicz](#), EDCTP Monitoring & Evaluation Officer, attended the meeting which focused on Horizon 2020 interim evaluation and the ex-ante impact assessment by the European Commission in the context of the EU policy cycle towards Framework Programme 9 (FP9). This policy context provides good opportunities for EDCTP Participating States to express their political commitment towards continuation of EDCTP under FP9.

CRISPR | Paris, France | 13 November 2017 | The meeting 'Fostering responsible research with genome editing technologies (CRISPR)' was organised by the French institute INSERM (biomedical research and human health). Dr [Anne-Laure Knellwolf](#), EDCTP Project Portfolio Manager, attended as an observer on behalf of Dr Michael Makanga, EDCTP Executive Director. The meeting aimed to raise awareness of the ethical implications of the use of these new technologies and discuss recommendations which would enable Europe and European researchers to advance a responsible science effort in this area.

Further reading: Heidi C. Howard et alii: 'One small edit for humans, one giant edit for humankind? Points and questions to consider for a responsible way forward for gene editing in humans'. [European Journal of Human Genetics](#), September 2017

INTER TB | London, UK | 17 November 2017 | The International Consortium for Trials



of Chemotherapeutic Agents in Tuberculosis (INTERTB), coordinated by Prof. Amina Jindani at St George's, University of London, held its annual meeting. Dr [Monique Surette](#), (EDCTP Senior Project Officer) represented EDCTP. Dr Corinne Merle (London School of Tropical Medicine & Hygiene) presented the results of the EDCTP-funded RAFA trial. 'A randomised controlled trial of 3 strategies for the treatment of ARV-naive HIV-infected patients with

tuberculosis'. The RAFA project received co-funding from the French National Agency for Research on AIDS and Viral Hepatitis (ANRS), the Research Council of Norway, and the Swedish International Development Cooperation Agency (SIDA).

EDCTP training for grantees | Johannesburg, South Africa, 29 November - 01 December 2017 | EDCTP organised for grantees the last Financial and Project Management Training of this year. The objective of this two-day training workshop is to provide trainees with the knowledge and financial management skills required to enable them to improve financial accountability and transparency in their respective institutions. The training is conducted by [Abdoulie Barry](#) (Director of Finance and Administration), Dr Ole Olesen (Director of North-North cooperation), and [Dr Pauline Beattie](#) (Operations Manager) with support from [Jane Coloma-Egelink](#) (Grants Finance Officer).

Recent publications

AMRH, NEPAD & EDCTP | The latest [quarterly newsletter \(July-September 2017\)](#) of the African Medicines Regulatory Harmonization (AMRH) initiative, a programme of the African Union implemented as part of the Pharmaceutical Manufacturing Plan for Africa (PMPA), has an item on the collaboration between the NEPAD Agency and EDCTP: 'EDCTP partnering with NEPAD to enhance medicines regulatory systems in Africa'. Prof. [Moses Bockarie](#), EDCTP Director of South-South Cooperation is quoted as saying: "EDCTP has identified the NEPAD Agency as a key strategic partner in advancing the work of the organisation especially in Africa".

EDCTP and vaccines | Ole Olesen, 'European & Developing Countries Clinical Trials Partnership (EDCTP)', profile of the organisation with a focus on vaccine/immunotherapeutics development in the field of poverty-related infectious diseases. [Journal of Human Vaccines and Immunotherapeutics](#) 14 November 2017. [Dr Ole F. Olesen](#) is EDCTP Director of North-North Cooperation.

TB treatment | PanACEA II | Interesting video by Euronews© on the PanACEA II clinical trial 'Finding better and quicker ways to tackle TB'. The video shows interviews with patients and researchers in Malawi, The Netherlands, and Tanzania. EDCTP is the main funder of the [PanACEA II project](#) with a grant of EUR 11.4 million. [Watch the video.](#)

EDCTP and TB | [Surette M.A.](#), [Beattie P.](#), [Nyirenda T.](#), [Olesen, O.F.](#) : [Tackling tuberculosis in sub-Saharan Africa: EDCTP achievements and the road ahead](#) | International Journal of Tuberculosis and Lung Disease, Vol. 21, nr. 12, 1 December 2017.



Malaria vaccine study MVVC2 | Victorine A. Mensah, et alii: 'Safety and Immunogenicity of Malaria Vected Vaccines Given with Routine Expanded Program on Immunization Vaccines in Gambian Infants and Neonates: A Randomized Controlled Trial', [Frontiers of Immunology](#), 20 November 2017.

The study was funded by EDCTP through a Strategic Primer grant award (Grant nr. SP.2011.41304.025) with co-funding from the Swedish International Development Cooperation Agency (Sida); the UK Medical Research Council; Irish Aid, Department of Foreign Affairs and Trade, Ireland; and the Bundesministerium für Bildung und Forschung (BMBF), Germany. The European Vaccine Initiative (EVI) coordinated the project under phase two of the Malaria Vected Vaccines Consortium (MVVC 2).

Clinical trial data sharing | Robert Kiley et alii: Data Sharing from Clinical Trials - A Research Funder's Perspective. [New England Journal of Medecine 2017](#); 377:1990-1992, 16 November 2017

World Malaria Report 2017 | WHO | 29 November 2017 | Global response to malaria at crossroads: WHO report shows gains are levelling. Read [WHO press release](#).

Latest EDCTP news | November 2017 |

- [EDCTP Network of Excellence for Southern Africa launched](#) 29 November 2017
- [EU action against antimicrobial resistance: EDCTP's contribution](#) 15 November 2017
- [GSK and EDCTP launch joint call for Senior Fellowship proposal](#) 3 November 2017

Open Calls for Proposals

Currently, EDCTP has three calls for proposals that are open to applications.

- [Senior Fellowships](#) - opens on 3 November
- [EDCTP-GSK Senior Fellowships for co-morbidities between poverty-related diseases \(PRDs\) and non-communicable diseases \(NCDs\)](#) - opens on 3 November
- [EDCTP-TDR Clinical Research and Development Fellowships](#) - opens on 30 November.

More funding opportunities:

- **TRANSVAC | Open call for applications for vaccine development support** | Transvac is a collaborative infrastructure project funded by the European Commission, currently under Horizon 2020. The project is a joint effort of leading European groups working in the field of vaccine development, and is coordinated by the [European Vaccine Initiative](#) (EVI). TRANSVAC is designed to accelerate vaccine development by enhancing European vaccine research and training, and increase sustainability of EC vaccine projects by implementing a permanent research infrastructure for early vaccine development. The current [call for applications](#) was launched on 15 October 2017.
- **McGill Summer Institute in Infectious Diseases and Global Health** | Montreal, Canada, 11-22 June 2018 | [Accepting applications now](#) | Deadline (in case visa is needed) 28 Feb 2018.

Recently signed projects

Grant agreements have been signed for the following projects:

Call for proposals on Strategic actions supporting large-scale clinical trials (2016)

Afri-KA-DIA | Towards an adopted, safe, effective combination treatment for African visceral leishmaniasis (Kala Azar) and improved diagnostic tools. Project coordinator: Dr Jorge Alvar (DNDi, Geneva, Switzerland)

Call for proposals on Ethics and regulatory capacities (2016)

IGORCADIA | Improved governance and research capacities in diagnostics for infectious diseases of the Liberian Medicines and Health Products Authority. Project coordinator: Dr Alfredo Mayor

Aparicio (ISGlobal, Barcelona, Spain).

SMERT | Streamlining ethics review process and regulatory framework in Tanzania. Project coordinator: Dr Nyanda Elias Ntinginya (NIMR, Mbeya, Tanzania).

Call for proposals on EDCTP Regional Networks (2015)

EACCR2 | Eastern Africa Consortium for Clinical Research 2. Project coordinator: Prof. Pontiano Kaleebu (UNHRO), Entebbe, Uganda)

The EDCTP Regional Network **Trials of excellence for Southern Africa (TESA II)** held the launch meeting of its second programme in Maputo, Mozambique from 30-31 October 2017. The coordinating institution is the Manhiça Foundation (FM-CISM), Maputo, Mozambique and has partner institutions in Angola, Botswana, France, Malawi, Namibia, Netherlands, South Africa, Spain, Uganda, United Kingdom, Zambia, and Zimbabwe. The coordinator of the network is Dr. Eusebio Macete (FM-CISM). [Read the news item.](#)

Dr Michael Makanga, EDCTP Executive Director: "The launch of TESAI is very pleasing news. We are very hopeful that this reinvigorated regional network of excellence will further contribute to a measurable increase in collaborative research (South-South and North-South collaborations) and offer clinical trials training opportunities that will improve competences and capacity to conduct high quality clinical research/trials in Africa."



[Left to right:] Dr Ilesh Jani (Director National Institute of Health INS, Mozambique), Dr Leonardo Simão (EDCTP High Representative), Dr Zacarias Zindoga (Permanent Secretary Ministry of Health, Mozambique), Ms. Michelle Nderu (EDCTP Project Officer for TESAI).

upcoming events

GHIT Fund | R&D Forum | 8 December 2017 | The Japanese [Global Health Innovative Technology Fund](#) is a public-private partnership dedicated to facilitating international partnerships that bring Japanese innovation, investment and leadership to the global fight against infectious diseases and poverty in the developing world. The GHIT Fund will hold its R&D Forum in Tokyo, Japan, on 8 December. Partnership between EDCTP and GHIT is expected to be strengthened during the meeting.

The Science Forum South Africa | Pretoria, South Africa | 7-8 December 2017 | The [SFSA](#) aims to start "igniting conversations about science". Eager to build on the success of 2015 and 2016, SFSA2017 will again serve as a large, open, public platform for debating the science and society interface. Information in French [here](#).

2018 Events | EDCTP will contribute to:

- the 7th Pan African Conference on Malaria of the [Multilateral Initiative on Malaria](#) (MIM), Dakar, Senegal, from 15-20 April 2018;
- the [22nd International AIDS Conference \(AIDS 2018\)](#) in Amsterdam, The Netherlands from 23-27 July 2018; and
- the 49th Union World Conference on Lung Health (with a focus on human rights), in The Hague, The Netherlands, from 24-27 October 2018.

9th World Health Summit 2017 Regional Meeting | Coimbra, Portugal | 19-20 April 2018 Click [here](#) for preliminary information. Brochure [here](#).

Ninth EDCTP Forum | Lisbon, Portugal | 17-21 September 2018 | The theme of the Forum will be 'Clinical research and sustainable development in sub-Saharan Africa: the impact of North-South partnerships'. The [Ninth EDCTP Forum 2018](#) is held in partnership with the [Portuguese Foundation for Science and Technology](#) and the [Calouste Gulbenkian Foundation](#).



EDCTP
The power of sharing science

Supported by the EU



Save the date!

Ninth EDCTP Forum 2018

*Clinical research and sustainable
development in sub-Saharan Africa:
the impact of North-South partnerships*

When: 17-21 September 2018

Where: Lisbon, Portugal

Who: Scientists, policy makers, funders and global health partners in the field of clinical research and development for poverty-related diseases

The Ninth EDCTP Forum 2018 is held in partnership with the Portuguese Foundation for Science and Technology and the Calouste Gulbenkian Foundation.

Stay up to date and visit www.edctp.org to subscribe to our newsletter.

FCT Fundação
para a Ciência
e a Tecnologia

 CALOUSTE
GULBENKIAN
FOUNDATION

European & Developing Countries Clinical Trials Partnership (EDCTP)

EDCTP | +31 70 344 0880 | info@edctp.org | www.edctp.org

The EDCTP2 programme is supported under Horizon 2020,
the European Union's Framework Programme for Research and Innovation

STAY CONNECTED:

