

EDCTPNEWSLETTER European & Developing Countries Clinical Trials Partnership July 2017 • Volume 12 • No. 3

The power of sharing science

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2016 Annual Report

The EDCTP Annual Report for 2016 covers the activities and achievements of the programme from 2014-2016. The second EDCTP programme is a highly ambitious programme and 2016 was a transformational year for consolidating the organisation itself and accelerating focussed implementation of the programme.

In 2016, we launched nine new calls for proposals while proceeding with the selection and grant agreement processes for the eleven calls for proposals from 2014-2015. By end of 2016, EDCTP had a portfolio of 60 grants with a total value of €97.09 million; €75.11 million of this amount was invested in large-scale clinical trials and clinical research projects.

The EDCTP Annual Report 2016 will be available at *www.edctp.org* in August 2017.



A growing portfolio

Our esteemed Stakeholders,

It is very heartening to witness the steady growth of the EDCTP portfolio of projects funded under our second programme. This development is reflected in the Annual Report 2016 to be released in

August. Its chapter 'Progress so far' provides a snapshot of the nine calls for proposal worth over €138.6 M that we launched in 2016, and the collective state of play from earlier calls for proposals. By the end of 2016, EDCTP2 had finalised agreements for 60 grants with a total value of €97.09 million. Of this amount, €75.11 million was invested in large-scale clinical trials and clinical research projects. Since then, the selection and approval of all remaining grants from the calls for proposals issued in 2016 has formally been concluded and preparation of the respective grant agreements is in full force.

Further expansion of the programme portfolio is expected with the eleven new calls for proposals for 2017 we recently published with a total investment of greater than €156.5M. Calls for proposals on treatment improvement, large strategic clinical trials, and trials for improving maternal and child health are already open. In partnership with the Africa Research Excellence Fund, we opened a call for proposals for researchers at the beginning of their career. The fellows will receive a placement at a strong institution in Europe or Africa to enhance their competitiveness for international, regional and national fellowships or grant support. Additionally, two calls for proposals were launched with the specific aim to support research targeting neglected infectious diseases.



Dr Michael Makanga Executive Director

This newsletter also features policy events in Europe, the start of large clinical trials and developments in Africa where established partners take initiative and new partners are coming on board. Senegal which has a long history of involvement in EDCTP,

officially launched its new Institute for Health Research, Epidemiological Surveillance, and Training (IRESSEF) with solid support from international partners and the Senegalese government. In Angola, EDCTP's High Representative for Africa, Dr Leonardo Simão discussed the possibilities to involve the country's research effort in EDCTP projects in alignment with its priorities. Malawi was visited by a senior EDCTP team to discuss the large studies that will take place in Malawi. Finally, Ethiopia, Kenya and Nigeria expressed a clear interest to join EDCTP as member countries when they fulfil admittance requirements of the EDCTP-Association.

In concluding, I am particularly happy to mention the new partnership agreements, both in the field of neglected infectious diseases. The Leprosy Research Initiative (The Netherlands) agreed to support leprosy-related research via EDCTP. The Mundo Sano Foundation (Spain) will contribute to clinical and product-focused implementation research in neglected diseases and soil-transmitted helminthiases. We greatly appreciate these new collaborations and the growing support from all our esteemed partners.

Dr Michael Makanga Executive Director

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Open calls for proposals

Treatment innovations for poverty-related diseases

Call budget:	€30 M
Expected number of grants	s: 3-5
Funding level:	Up to 100% of eligible costs
Procedure:	Two-stage application procedure
Opening date:	3 July 2017
Deadline:	19 September 2017

Strategic actions supporting large-scale clinical trials

Call budget:	€43 M
Expected number of grant	s: 2-4
Funding level:	Up to 100% of eligible costs
Procedure:	Two-stage application procedure
Opening date:	3 July 2017
Deadline:	19 September 2017

Clinical trials to reduce health inequities in pregnant women, newborns and children

Call budget:	€38.23 M
Expected number of grant	s: 5-10
Funding level:	Up to 100% of eligible costs
Procedure:	Two-stage application procedure
Opening date:	4 July 2017
Deadline:	13 October 2017

Targeting control and elimination of NIDs through clinical trials

Call budget:	€18.8 M
Expected number of grants:	4-6
Funding level:	Up to 100% of eligible costs
Procedure:	Single-stage application
Opening date:	4 July 2017
Deadline:	31 October 2017

Targeting control and elimination of NIDs through product-focused implementation research

Call budget:	€11.2 M
Expected number of grants	: 3-5
Funding level:	Up to 100% of eligible costs
Procedure:	Single-stage application
Opening date:	4 July 2017
Deadline:	2 November 2017

EDCTP-AREF Preparatory Fellowships

Call budget:	€800,000
Maximum funding:	€70,000
Funding level:	Up to 100% of eligible costs
Procedure:	Two-stage application procedure
Opening date:	14 July 2017
Deadline:	13 October 2017

More information about calls for proposals is available at *www.edctp.org*.

EDCTP signs new partnership agreements

On 12 May 2017, the **Leprosy Research Initiative** (LRI) and EDCTP signed a partnership agreement to boost leprosy-related research. The aim is to leverage resources and pool funds to support clinical and implementation research in sub-Saharan Africa on leprosy, and neglected infectious diseases (NIDs) that are co-endemic with leprosy.

The funding agreement was signed by LRI Director Mr Jan van Berkel and for EDCTP by Dr Michael Makanga, Executive Director, and Mr Abdoulie Barry, Director of Finance & Administration.



Mr Jan van Berkel and Dr Michael Makanga signing the partnership agreement

" Partnerships lie at the heart of our work, and I am encouraged by our new partnerships which will bolster our funding towards neglected infectious diseases R&D."

Michael Makanga, EDCTP Executive Director

The **Mundo Sano Foundation** and EDCTP signed a partnership agreement on 16 June 2017 to leverage research funding for NIDs. Mundo Sano will contribute to clinical and product-focused implementation research in neglected diseases and soil-transmitted helminthiases. The agreement was signed by Dr Silvia Gold, Mundo Sano Chairperson, and Dr Michael Makanga, EDCTP Executive Director.



The collaboration is envisaged in the context of two EDCTP calls for proposals in 2017: 'Targeting control and elimination of NIDs through clinical trials' and 'Targeting control and elimination of NIDs through product-focused implementation research'. Please visit *www.edctp.org* for more information on these calls for proposals.

Launch of EDCTP-funded projects

IMPROVE

The **IMPROVE** project led by Professor Feiko ter Kuile from the Liverpool School of Tropical Medicine (LSTM), held a kick-off meeting in Blantyre, Malawi on 23 and 24 May 2017. The meeting gathered about 30 delegates from all beneficiaries of the project to discuss the tasks and priorities for the next four years. The project received an EDCTP contribution of almost \notin 7.4 million, composed of funding from the European Union and the Joint Global Health Trials scheme, which is a partnership between the UK Departmeant for International Development, the UK Medical Research Council, the National Institute for Health Research, and the Wellcome Trust. Additional funding of slightly over \notin 3.1 million has been provided by the Joint Global Health Trials, to include a trial with HIV-infected pregnant women alongside the main study with HIV-uninfected participants. The consortium consists of a network of 11 institutions from Africa, Europe and the EDCTP scientific officer following the IMPROVE project.

Intermittent preventive treatment in pregnancy (IPTp) with sulphadoxine-pyrimethamine (SP) for asymptomatic women is the only malaria prophylaxis in pregnancy recommended by the World Health Organization (WHO). However, the high-level of SP resistance in certain malaria-endemic areas threatens its efficacy. There is thus an urgent need to find alternative chemoprophylactics for IPTp. The IMPROVE project builds on previous findings from the IPTp-SP, ISTp-SP (intermittent screening and treatment with sulphadoxine-pyrimethamine) and DP (dihydroartemisinin-piperaquine) studies carried out by the global Malaria in Pregnancy (MiP) research consortium which was cofunded by EDCTP during its first programme. Exploratory studies conducted in Kenya and Uganda showed that DP has the potential to replace SP for malaria prevention in pregnancy. However, both these trials were small and not powered to assess birth outcomes. In July 2015, the MiP consortium presented the final data to WHO, with the recommendation that a multicentre clinical trial using IPTp-DP as an alternative to SP (in IPTp-SP) should be conducted before DP could be considered for health care use.

The IMPROVE study is a multinational superiority trial comparing the efficacy, safety and tolerance of IPTp-SP (control) versus IPTp-DP, alone or combined with azithromycin to reduce the adverse effects of malaria and curable sexually-transmitted and reproductive tract infections (STIs/RTIs) in pregnant women in Kenya, Malawi and Tanzania living in areas with high resistance to SP. Positive findings of this study may contribute to a policy change in the WHO guidelines for IPTp.

AMBITION-cm

The **AMBITION**-cm project coordinated by Dr Joseph Jarvis of the London School of Hygiene & Tropical Medicine, United Kingdom, was launched at a kick-off meeting in Gaborone, Botswana on 30 and 31 May 2017. EDCTP Project Officer Dr Christy Comeaux follows the project and participated at the meeting.

Almost 20 per cent of HIV-related deaths are directly attributable to cryptococcal meningitis (CM). The AMBITION-cm project was developed to evaluate a new treatment course for CM in a phase III clinical trial. In January 2017, the EDCTP grant agreement awarding almost €10 million to the study consortium was signed.

The current recommended treatment for CM in HIV-infected patients is a two-week course of amphotericin B, an old and toxic drug. Treatment requires a daily intravenous infusion, frequent blood tests to monitor side effects, and a prolonged hospital stay. This makes the standard course of amphotericin B difficult to administer in most African hospitals. Patient mortality is approximately sixty percent.

The AMBITION-cm project aims to determine whether a short treatment course of a single intravenous high-dose liposomal amphotericin (L-AmB, Ambisome), a newer formulation of amphotericin B, is as effective as the 14-day amphotericin B-based therapy in averting all-cause mortality in patients with cryptococcal meningitis. A total of 850 patients will be recruited at six sites in Botswana, Malawi, South Africa, Uganda, and Zimbabwe, making this the largest trial ever conducted for this HIV-associated co-infection.

If successful, the study would provide for the first time a safe and shortened treatment for cryptococcal meningitis in low-resource settings. Administering a single intravenous dose of liposomal amphotericin B would be feasible in nearly all hospital settings. Routine monitoring is expected to be easier in view of the anticipated safety profile of the treatment course, which could also result in a shorter hospital stay. Ultimately, this could lead to improved patient access to a better treatment, and reduced treatment costs.

For an overview of all current projects, go to www.edctp.org > Our Projects > Current Projects.

Senegal: IRESSEF launched

On 19 June 2017, Senegal launched IRESSEF, its new Institute for Health Research, Epidemiological Surveillance, and Training [Institut de la recherche en santé, surveillance épidémiologique et de formation]. The institute has the ambition to become a hub for health research, surveillance and training in Africa. Dr Michael Makanga was one of the invited speakers at the opening ceremony which was presided over by the president of Senegal, His Excellency Mr Macky Sall.

"This new institute with its ambition to be a power house for research and training in West Africa is part of the rise of African research ownership."

Dr Michael Makanga

The opening ceremony was part of a scientific symposium on partnerships for public health: 'Building partnerships to advance surveillance responses to disease threats, laboratory quality management systems and access to quality diagnostics, and public health research in Africa'. WANETAM II (the West African Network for TB, AIDS and Malaria) held a first meeting on 21 June 2017, as part of the event. This Network of Excellence was established under the first EDCTP programme on 31 July 2009. WANETAM II has successfully managed to attract additional partners and expanded to a network of 19 institutions with new institutions from Togo and Sierra Leone. It has plans to improve collaborative research by using the acquired skills and capacities built in the first phase to support multi-site clinical trials and vaccine discovery research. In addition, it plans to extend its research scope to encompass Neglected Tropical Diseases (NTD) and Ebola.

The meeting reunited WANETAM II partners and enabled them to have a better understanding of each other's strengths regarding the planned activities of the network, and how they fit together. Ms Michelle Nderu (EDCTP Project Officer) attended on behalf of EDCTP.

Africa Pavilion at BIO 2017

The BIO Ventures for Global Health (BVGH) organised its third Africa Pavilion at the BIO International Convention 2017 (BIO 2017) in San Diego, CA (USA), from 19 to 22 June 2017. The Pavilion showcased the innovation and life science capabilities of African research organisations and provided networking opportunities for African country delegations. The Pavilion featured exhibitors from 24 countries: Angola, Botswana, Burkina Faso, Burundi, Cameroon, Ethiopia, The Gambia, Ghana, Guinea Bissau, Kenya, Malawi, Mali, Mozambique, Namibia, Nigeria, Rwanda, Sierra Leone, Senegal, South Africa, South Sudan, Tanzania, Uganda, Zambia, and Zimbabwe.

The EDCTP Networks of Excellence TESA (Trials of Excellence for Southern Africa) and CANTAM (Central Africa clinical research Network) were present at the Pavilion. TESA's participation at the Africa Pavilion was supported by two EDCTP member countries, Spain and UK.

Dr Leonardo Simão, High Representative South, represented EDCTP at meetings and at the Pavilion.



EDCTP at First Africa Health Forum

The World Health Organisation in the African Region convened the first Africa Health Forum in Kigali, Rwanda on 27 and 28 June 2017 under the theme "Putting People First: The Road to Universal Health Coverage in Africa". The aim of the meeting was to provide a forum for high-level engagement on the topics of health security, equity and Universal Health Coverage, communicable diseases, social and economic determinants of health, and the Sustainable Development Goals.

Dr Michael Makanga, EDCTP Executive Director, gave the keynote speech at the session: "Health research, innovation and data for sustainable development" on Day 1 of the forum. He was joined in the discussion by Dr Joseph B. Babigumira, Professor Pontiano Kaleebu, and Dr Mary Amuyunzu-Nyamongo which addressed the importance of integrated systems and processes to collect, analyse, disseminate and utilise health data in setting the African health research agenda.

The unaddressed burden of disease in many African countries will hinder achievement of the Sustainable Development Goals (SDGs). The meeting resulted in a Call to Action to further health research and innovation.

Malawi country visit

EDCTP makes regular visits to countries in sub-Saharan Africa, where strategically important projects are implemented or substantial financial investments have been made. On 16-19 May 2017, an EDCTP team, comprising Dr Ole Olesen (North-North Cooperation Director), Dr Gabrielle Breugelmans (North-North Networking Manager), and Dr Thomas Nyirenda (South-South Networking and Capacity Development Manager), visited three institutions in Malawi that participate in projects under the second EDCTP programme (EDCTP2).

The three institutions that were visited were the College of Medicine (CoM) in Blantyre, the Malawi-Liverpool-Wellcome Trust (MLW) Collaboration, and the University of North Carolina (UNC) project site in Lilongwe. Both CoM and MLW are based in Blantyre and have participated in EDCTP-funded projects during the first EDCTP programme. In the second programme, the CoM is a key partner in two newly initiated Research and Innovation Actions (RIA), namely the IMPROVE project for treatment of malaria in pregnancy and the PanACEA project for development of improved treatment for tuberculosis. CoM is also a partner in two Coordination and Support Actions (CSA), namely the IMPP-ACT and the IMPACT projects, in the latter of which MLW is also participating. The UNC Project-Malawi is based in Lilongwe and was awarded its first two grants as partner in the DREAMM and AMBITION EDCTP2 projects.

The EDCTP team met with several people from the three institutions that are involved in the implementation of the various projects. This provided opportunities to discuss the different projects, review any unexpected obstacles and possibilities for moving promising results forward. During the visit to Malawi, the EDCTP team also contributed to a public information session at CoM about the EDCTP2 programme. This session was attended by approximately 100 people, and therefore also provided a valuable opportunity to discuss the opportunities and priorities of EDCTP2 in a direct dialogue with active scientists in Malawi.

New SAC members

Two new members have jointed the EDCTP Strategic Advisory Committee (SAC) as of 1 July 2017.



Dr Juliet Nabyonga-Orem Zimbabwe

Dr Juliet Nabyonga-Orem currently works for the World Health Organisation (WHO) as a Medical Officer in charge of health policies, strategies and governance. She also heads the health systems and services cluster of the WHO Inter-country support team for East and Southern Africa. Her core experience in health system development spans over 16 years within Africa focusing mainly on building countries' capacity in policy development; health financing; designing, implementing and evaluating health sector reforms; and health system performance assessment.

Dr Nabyonga-Orem was Regional advisor on health systems partnerships, monitoring and evaluation, based at the WHO Regional office for Africa in Congo Brazzaville. Prior to moving to the Regional office for Africa, she worked at the WHO Uganda office as a Health Economics advisor and head of the health systems and services cluster. Before joining WHO, she worked at various levels of the health care system in Uganda.

Juliet Nabyonga-Orem received her Bachelor of Medicine and Bachelor of Surgery from Makerere University in Uganda. She later obtained an MSc in Health Economics from University of York in the United Kingdom, and a PhD in Public Health from Catholic University of Leuven, Belgium.



Professor Keymanthri Moodley South Africa

She is a Professor in the Department of Medicine and Director of the Centre for Medical Ethics and Law, Department of Medicine, Faculty of Health Sciences, Stellenbosch University. In 2017, she was also appointed Adjunct Professor, Department of Social Medicine, University of North Carolina-Chapel Hill, USA. She is a family physician and a bioethicist. She has worked as principal investigator on clinical trials since 1999, and served on the University Research Ethics Committee. Since 2011, Prof. Moodley has co-hosted an NIH Fogarty program to develop capacity in Health Research Ethics in Africa in collaboration with the Bioethics Center, University of North Carolina-Chapel Hill, USA. The program has graduated 40 postgraduate scholars from 10 African countries over the past 4 years. She is currently Chair of the Research Ethics Committee of the South African Medical Research Council. In 2017 she was awarded her fourth NIH grant to develop a doctoral program in Clinical and Research Ethics - the first NIH funded program of its kind in Africa.

EDCTP Association

The General Assembly (GA) of the EDCTP Association met on 22-23 May 2017 for its regular meeting. The members approved the financial statements and the EDCTP Annual Report 2016, and the EDCTP work plan for 2017. Further, the GA discussed plans for the EDCTP Forums in 2018 and 2020, and the EDCTP work plan for 2018.

Additionally, the GA selected new members for the Board of the EDCTP Association. Dr Mark Palmer (United Kingdom, Chairperson), Prof. Francine Ntoumi (Congo), Dr Detlef Böcking (Germany) and Dr Eusébio Macete (Mozambique, Vice-Chair) were re-elected for an additional two-year term as EDCTP Association Board members. Dr Yazdan Yazdanpanah (France, Vice-Chair) was elected for his first two-year term as an EDCTP Association Board member.







Prof. Yazdan Yazdanpanah

France

Dr Mark Palmer United Kingdom

Prof. Francine Ntoumi

Congo





Dr Detlef Böcking Germany

Dr Eusébio Macete Mozambique

European Open Science Cloud Summit

The European Open Science Cloud (EOSC) summit took place in Brussels, Belgium on 12 June 2017. The summit gathered, from all over Europe, 80 high-level decision-makers, representing all categories and scientific fields, including representatives of 15 national scientific infrastructures, 13 research funders and 20 officials from ministries of EU Member States and Associated Countries. Dr Ole Olesen, Director of North-North Cooperation, represented EDCTP at the meeting. The Summit was convened to demonstrate commitment to the European Open Science Cloud as an open commons for Europe's research and innovation, and to mobilise concrete support to open datasharing practices and platforms.

In his opening speech, Commissioner Carlos Moedas (European Commissioner for Research, Science and Innovation), outlined his vision for a structure where "researchers should be able to access all publicly funded research data in a single click". The meeting resulted in the drafting of an EOSC declaration, which will later be made available to the wider public by the European Commission in order to allow additional stakeholders to pledge their support.

EDCTP is currently establishing a portal, or single entry point, that will allow researchers in EDCTP projects to easily deposit, share and retrieve clinical trial data. Dr Ole Olesen: "EDCTP is already taking an active and pioneering role in implementing the EOSC by requiring all research data from our clinical trials to be openly available and shared". EDCTP is also taking steps towards the establishment of a new platform that will allow clinical researchers to share and develop clinical trial protocols with feedback from the wider scientific community



Reaching out to potential members of the EDCTP Association

Angola has recently expressed interest in participating in the EDCTP programme and even in becoming a member of the EDCTP Association. In 2017, Dr Leonardo Simão, EDCTP High Representative South, honoured the invitation of the Minister of Health of Angola, Dr Luis Gomes Sambo, to visit the country for high-level consultative discussions with scientists, heads of research institutions, and senior government officials in the Ministry of Health and Ministry of Science and Technology.

Meetings were held with the Minister of Health, Dr Sambo, and the National Director for Scientific Research in the Ministry of Science and Technology, Dr Domingos da Silva Neto. Dr Simão was accompanied by Dr Joana Filipa M. M. Afonso, Director General of the National Institute of Public Health, and proposed future EDCTP contact person.

Dr Sambo expressed particular interest in development of national capacity for research (especially clinical trials) in line with current priorities in Angola given its epidemiological profile and vulnerability to epidemic outbreaks. Moreover, it was explained that the national institutional framework for research in Angola was under review, following directives issued by the Ministry of Science and Technology.

Dr Leonardo Simão: "EDCTP has received several recent grant applications from Lusophone African countries. I greatly support such actions and networking, which will hopefully lead to an increase in research funding and activities in Angola."

Dr Simão visited the Angola National Health Research Centre (CISA) and the National Institute of Public Health. Dr Simão explained that EDCTP offers several capacity development options that would be of interest to Angolan research and policy-making communities. At CISA, Dr Simão learned more about the current cooperation between CISA and the Calouste Gulbenkian Foundation in Portugal, and the Manhiça Health Research Center (CISM) in Mozambique.

French information event on EDCTP

The French Ministry of Higher Education, Research and Innovation (MESRI) and Aviesan Sud (part of the National Alliance for Life and Health Sciences dedicated to research and partnership with countries in the South) held an information event on the second EDCTP programme in Paris, France on 30 June 2017.

EDCTP was represented by Dr Michael Makanga (Executive Director) who held a presentation on EDCTP's research strategies and the role of French research in the programme, and Dr Ole Olesen (Director of North-North Cooperation). The meeting also included presentations by Dr Line Matthiessen (Acting Director of the Health Directorate, DG Research and Innovation, European Commission), as well as testimonials about the opportunities and benefits of participating in EDCTP projects. The first presentation was given by Professor Philippe van de Perre (INSERM, Montpellier) who coordinated the PROMISE-PEP project. Dr Veerle Lejon (IRD, Montpellier), who coordinates the DiTECT-HAT project (http://www. ditect-hat.eu/) for better diagnostic tools for human African trypanosomiasis, gave the second presentation. The meeting attracted approximately 100 participants from the scientific community in France, many of whom actively asked questions about the possibilities for submitting applications to EDCTP.

EDCTPnewsletter

This is a guarterly newsletter from the EDCTP secretariat.

EDCTPnewsletter online To view this newsletter online, please visit www.edctp.org

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Have a question or comment?

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