



EDCTP NEWSLETTER

European & Developing Countries Clinical Trials Partnership

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EDCTP

The power of sharing science

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Ninth EDCTP Forum



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

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

The Forum programme includes plenary sessions, parallel sessions, exhibition of posters, symposia, workshops, and various opportunities for discussion and collaboration.

Visit the Ninth EDCTP Forum website (www.edctpforum.org) for more information about registrations, abstracts and scholarships, and the sponsorship packages.

Investing in the future

Esteemed stakeholders,

Our project portfolio is steadily growing and investments to date are on track with the programme's objectives. Here we highlight our recent investment of a 34 million euro in TB vaccine development. Moreover, I

am happy to pre-announce the 2018 round of 11 calls for proposals. This issue of our quarterly newsletter gives a preview of the topics and character of the planned calls for proposals.

Long-term investment in clinical research capacity in sub-Saharan Africa is an important EDCTP programme priority. This includes preparedness for (re-)emerging epidemics. We have taken concrete action by funding two epidemic research preparedness consortia: the African coalition for Epidemic Research, Response and Training (ALERRT), and the Pan-African Network for Rapid Research, Response, Relief and Preparedness for Infectious Diseases Epidemics (PANDORA-ID-NET). These highly collaborative consortia were presented at the first International Conference on (Re-) Emerging Infectious Diseases in Addis Ababa in March this year.

This newsletter also features our support for training African early-career researchers in grant writing skills while taking into account their lusophone, francophone and anglophone backgrounds.



Dr Michael Makanga
Executive Director

Our fellowship programme with its supporting online Alumni platform is presented briefly while a snapshot of its impact is clearly exemplified in interviews with two fellows in different phases of their careers.

I am encouraged by the fact that EDCTP increasingly captures the attention of African policymakers.

EDCTP's membership has grown with Nigeria and Ethiopia joining as full members and Angola as aspirant member. Closer collaboration with African organisations such as the Africa Research Excellence Fund (AREF), New Economic Partnership for African Development (NEPAD), and WHO Regional Office for Africa among others, is also strengthening. We were also invited to contribute to the 19th Summit of East Africa Community Heads of State and their Joint Retreat on Infrastructure and Health Financing and Development in Kampala, Uganda on 21-23 February 2018.

Currently, the deliberations on the next European Framework programme for Research and Innovation are picking up speed. The way forward on a possible third EDCTP programme is also discussed. I am highly optimistic that the long-term value of our partnership and its unique achievements are recognised. But, foremost, let us maintain focus on the one thing – our mission – and continue to deliver on what is expected from the current programme.

Dr Michael Makanga
Executive Director



EDCTP portfolio: Fellowship programme

Fellowships by type



- Senior Fellowships, 13 grants
€6.25 M
- Career Development Fellowships, 35 grants
€5.10 M
- EDCTP-TDR Clinical Research and Development Fellowships, 10 grants
€0.91 M

Fellowships by disease

Note:

A further €0.90 M for 10 grants was awarded to projects on non-disease specific topics.

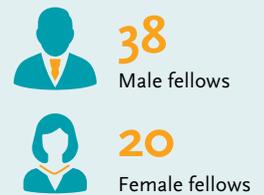


- Tuberculosis, 12 grants
€3.09 M
- HIV & HIV-associated infections, 15 grants
€2.80 M
- Malaria, 8 grants
€2.50 M
- Neglected infectious diseases, 7 grants
€1.74 M
- Diarrhoeal diseases, 2 grants
€0.65 M
- Multiple infections, 2 grants
€0.29 M
- Low respiratory tract infections, 1 grant
€0.15 M
- Emerging diseases, 1 grant
€0.14 M

Fellowships by country



Fellowships by gender



A network for EDCTP fellows

EDCTP launched an Alumni Network and a dedicated online platform to support African researchers funded under its fellowship programmes. The platform makes the professional profiles of all EDCTP fellows easily accessible. Moreover, it facilitates professional networking and collaboration among the more than 100 current and former EDCTP fellows from sub-Saharan Africa.

“The Alumni Network and its interactive platform will enable fellows to learn peer-to-peer from each other without any implied authority regarding position or discipline.”

*Prof. Moses Bockarie,
EDCTP Director of South-South Cooperation and Head of Africa Office*

Visit the Alumni Network platform at <http://edctpalumninetwork.org/>

Fellowships are part of the broader EDCTP funding strategy to support development of African clinical research capacity. The approach includes investments in capacity development integrated in clinical research, the fellowship programme, four regional Networks of Excellence, and ethical, regulatory and legal frameworks.

The Alumni Network and a beta-version of its platform were launched at a workshop held in Johannesburg, South Africa on 3-4 October 2017. The workshop was attended by 74 current and former EDCTP fellows, and by representatives of EDCTP Networks of Excellence and several African organisations working on research, health and development.

A video on the workshop is available on the EDCTP YouTube channel (youtube.com/edctpmedia).

EDCTP Fellows interviewed



**Prof. Collen
Masimirembwa**

*Founder President /
Chief Scientific Officer
AiBST, Zimbabwe*

“The EDCTP Fellowship enabled me to establish a research group with both clinical and laboratory expertise around a research project on clinical efavirenz pharmacogenetics. The work resulted in the publication of four papers in international peer-reviewed journals and the training of one PhD student.

“It also enabled us to attract research grants from other public and private funders, such as the Swedish

International Science Program, Novartis, NEPAD and AstraZeneca. With their support, we trained Master’s and PhD students in the field of pharmacokinetics and pharmacogenetics, established our now world class phase I Clinical Trial Unit, developed for commercialisation the pharmacogenetics testing algorithm from our efavirenz clinical work, and conducted an investigator-initiated clinical study on the pharmacogenetics of rosuvastatin in people of African origin.

“So, the first EDCTP Senior Fellowship was catalytic in my institute’s capacity to conduct clinical pharmacogenetics research and the results are having real impact on clinical guidelines and practice. The pharmacogenetics test and dosing algorithm we developed, GeneDose-Efavirenz, have been recognised with several awards including, most recently, the Human Genome Organisation (HUGO) African award.

“I expect my new EDCTP Fellowship to have a similar impact. Our clinical studies are uncovering clinically relevant genomic diversity of African populations. I expect to train 10 MSc students in genomics and precision medicine and 2 PhD students in clinical pharmacogenetics. The two clinical studies that will be done, will contribute to safe and efficacious use of praziquantel (a schistosomicide) and efavirenz (antiretroviral drug). It will also enable me to establish new international partnerships as well as strengthen old ones, and to attract private and public funding for research in Africa.”



Dr Isidore Traore
*Head Department
Clinical Research Centre
MURAZ, Burkina Faso*

“When I received the EDCTP-TDR Clinical Research and Development Fellowship, I was a junior medical researcher at Centre MURAZ heading the Department of Clinical Research. I had just completed my PhD and had experience as field coordinator of HIV research, and in monitoring several clinical trials conducted in Africa.

“From my field experiences, I had learnt that to move forward more quickly and efficiently with the Centre MURAZ Department of Clinical Research, I needed to acquire advanced knowledge and skills in clinical trials, and to develop training modules in key topics.

“The EDCTP-TDR Fellowship gave me a great opportunity to get first-hand experience of cutting edge aspects of clinical trials at Merck in Germany. After my placement, I started to apply what I had learnt to my work at Centre MURAZ. The skills in project oversight I have gained at Merck are now applied to overseeing two research projects: an international HIV prevention research programme in West Africa funded by the Canadian Institutes of Health Research (CIHR), and a capacity development project funded by the Belgium Institute of Tropical Medicine.

“My placement at Merck also made me more confident and productive in writing research protocols, in planning, conducting and overseeing clinical trial activities. The experience also helps me to develop training modules that I use and share with the other young and junior researchers at Centre MURAZ. And, of course, I am working to build a long-term partnership between Merck and the new Department of Clinical Research of Centre MURAZ.”

Writing grant proposals: workshops for African researchers

Workshop in Portuguese on EDCTP grant proposal writing

On 29-31 January 2018, EDCTP supported the first of a series of workshops on grant proposal writing to strengthen the capacity of researchers from lusophone, francophone and anglophone countries to secure funding. The workshops are based on EDCTP funding mechanisms and grant review processes and consist of practical sessions on grant proposal writing.

The first workshop focused on Portuguese-speaking researchers. Through a call for participation, a total of 24 were selected from Angola, Cape Verde, Guinea Bissau and Mozambique. The workshop was organised by the Barcelona Institute for Global Health (ISGlobal) and the Manhica Health Research Centre - Fundação Manhica (CISM) in Maputo, Mozambique and funded by EDCTP and the Instituto de Salud Carlos III in Spain. EDCTP was represented by Ms Ana Lúcia Weinberg (North-North Networking Officer). Trainers included experts from ISGlobal, CISM, TDR (Special Programme for Research and Training in Tropical Diseases), and the National Bioethics Committee of Mozambique.



Photo: Participants of the EDCTP grant proposal writing workshop in Maputo, Mozambique

EDCTP-AREF Preparatory Fellowships

The Africa Research Excellence Fund (AREF) was established by the UK Medical Research Foundation to invest in talented, emerging researchers in Africa. Based on a shared vision of supporting research capacity in Africa for Africa, EDCTP and AREF launched a 2017 joint call for Preparatory Fellowships. The fellowships aim to enhance the competitiveness of early career post-doctoral African scientists and clinicians who aspire to win fellowships or grant support. The fellowships offer short-term training placements at European or African host organisations.

In this context, AREF hosted 37 post-doctoral research scientists from 12 African countries at an 'Essential Grant-Writing Skills' workshop in Entebbe (Uganda), 12-14 March 2018. The workshop was facilitated by a team from AREF and the UK Medical Research Foundation. EDCTP was represented by Dr Michelle Singh (Project Officer). Post-workshop feedback has been very positive; currently participants work on their stage 2 proposals.



Photo: Seated from left to right: Dr Jane Kengeya-Kayondo (AREF Senior Science Programme Manager and workshop coordinator); Dr Samuel Okware (Uganda National Health Research Organisation & GA representative for Uganda in the EDCTP Association); Prof. Tuman Corrah (Director, AREF); Mayor Kayanja Vincent De Paul (Mayor of Entebbe Town); Prof. Vinand Nantulya (Busiteme University) and Prof. Gibson Kibiki (East African Health Research Commission). Photo credit: Geoffrey Semaganda (Action Wealth Academy)

EDCTP at East Africa Community Summit

The East Africa Community (EAC) convened its 19th Summit of EAC Heads of State and Joint Retreat on Infrastructure and Health Financing and Development on 21-23 February 2018 in Kampala Uganda. The Retreat on 22 February was preceded by the first Round Table on 'investing in health infrastructure, systems, services and research for the accelerated attainment of universal health coverage and sustainable development goals' on 21 February. The Round table programme contributed to the discussions at the Joint EAC Heads of State Retreat the next day. EAC presented its Priority Framework 2018-2028 for investment in the health sector.

Dr Michael Makanga, EDCTP Executive Director, was invited as a speaker at the Round Table with a presentation on the EDCTP strategy and its support of research capacity development for clinical trials of pharmaceutical products in the EAC region.

He also participated in the Retreat together with the EDCTP High Representative for Africa, Dr Leonardo Simão.



Photo: Left to right: Dr Makanga (EDCTP); Hon. Umyy Mwalimu, Minister of Health and Social Welfare (Tanzania); Hon. Sarah Achieng Opendi, Minister of State for Health (Uganda); and Hon. Patrick Ndimubanzi, Minister of State for Health in charge of Public Health and Primary Healthcare (Rwanda)

TB vaccine trials: €34 million investment

Recently, EDCTP committed €34 million in funding for four large clinical trials on candidate TB vaccines. This is the largest European investment into clinical development of TB vaccines to date (with two grants signed and two under preparation). It boosts the joint commitment to combat one of the world's most devastating diseases.

“EDCTP is proud to invest in international collaborative research consortia that conduct clinical research & development on new candidate TB vaccines.”

*Dr Michael Makanga,
EDCTP Executive Director.*

The **POR TB consortium** unites 6 African and 2 European research institutions, clinical trial sites and vaccine developers to conduct an innovative and cost-effective TB vaccine phase IIb trial to determine efficacy of the multistage candidate vaccine H56:IC31* for prevention of recurrent TB disease.

The **POI TB project**, involving 4 African and 3 European partners, will apply an innovative trial design, prevention of established infection (POI), in a phase II efficacy trial to test a lead candidate TB vaccine, H56:IC31. This POI trial aims to establish a new paradigm to facilitate early TB vaccine clinical development decisions, discover potential correlates of protection and/or risk, and building capacity to lay the foundation for phase III TB vaccine trials.

The **priMe consortium**, including 9 African, 5 European, and 1 Indian partner, will conduct a multicenter Phase III double-blind, randomised, controlled trial to evaluate the efficacy and safety of VPM1002 in comparison to BCG in HIV-exposed and HIV-unexposed infants.

The **MTBVAC-Newborns project** will support a phase IIa dose-defining study of MTBVAC, a novel candidate TB vaccine based on live-attenuated *M. tuberculosis*. It will evaluate the safety, reactogenicity, immunogenicity, and potential for IGRA (Interferon Gamma Release Assay) conversion and reversion of MTBVAC in South African newborns.

Epidemic preparedness: ALERRT and PANDORA-ID-NET

At the 1st International Conference on (Re-)Emerging Infectious Diseases (ICREID) in Addis Ababa, Ethiopia on 12-14 March 2018, a symposium presented two EDCTP-funded epidemic research preparedness consortia: the African coalition for Epidemic Research, Response and Training (ALERRT), and the Pan-African Network for Rapid Research, Response, Relief and Preparedness for Infectious Diseases Epidemics (PANDORA-ID-NET).

EDCTP was represented at the conference by its High Representative for Africa, Dr Leonardo Simão, and Jean Marie Vianney Habarugira, the Project Officer responsible for ALERRT and PANDORA-ID-NET. Contributions of the European Union through EDCTP under Horizon 2020, and three EDCTP member countries – Germany, Sweden and the United Kingdom – enabled EDCTP to support these consortia with almost € 10 million each. The ALERRT project began on 1 December 2017 and had its launch meeting in Addis Ababa on 10-11 March 2018. The PANDORA-ID-NET project started on 1 March 2018.

ICREID was organised by the Africa Centres for Disease Control and Prevention (Africa CDC), the continental body responsible for coordinating public health emergency response. ALERRT and PANDORA-ID-NET will contribute to the efforts across the continent, collaborating with emergency response teams that are being set up by Africa CDC in different regions.

Funding the ALERRT and PANDORA-ID-NET consortia resulted from the EDCTP call for proposals 'Research and clinical management of patients in PRD epidemics in sub-Saharan Africa'. The aim was to establish multidisciplinary consortia able to provide accelerated evidence for the optimal clinical management of patients, and for guiding the public health response to severe infectious outbreaks.



Photo: Left to right: Dr Leonardo Simão, EDCTP High Representative for Africa; Prof. Peter Horby, Centre for Tropical Medicine and Global Health; Jean Marie Vianney Habarugira, EDCTP Project Officer

Planned 2018 calls for proposals

The EDCTP calls for proposals are supported through three distinct types of Horizon 2020 'actions':

- **Research & Innovation Actions (RIA)** are multicentre clinical trials conducted by research consortia involving both European and African research teams, with integrated capacity development and networking elements.
- **Coordination & Support Actions (CSA)** support activities that strengthen the enabling environment for conducting clinical trials and clinical research, including ethical review and regulatory capacity.
- **Training & Mobility Actions (TMA)** are fellowships that focus on the career development of individual researchers or research team members.

In 2018, EDCTP intends to launch 11 calls for proposals to support clinical research and related activities on poverty-related diseases (PRDs). Details of the call texts are planned to be published on the website in May 2018, pending approval of the EDCTP work plan for 2018 by the European Commission and the EDCTP General Assembly. **All dates are therefore indicative.**

Diagnostic tools for poverty-related diseases

Type:	Research & Innovation Action (RIA)
Procedure:	Two-stage application
Open to applications:	4 July 2018
Deadline for applications:	11 October 2018

Advances in product development for effective prevention, treatment and management of co-infections and co-morbidities

Type:	Research & Innovation Action (RIA)
Procedure:	Two-stage application
Open to applications:	4 July 2018
Deadline for applications:	18 October 2018

Strategic action for overcoming drug resistance in malaria

Type:	Research & Innovation Action (RIA)
Procedure:	Single-stage application
Open to applications:	4 July 2018
Deadline for applications:	30 October 2018

Vaccines for diarrhoeal diseases or lower respiratory tract infections

Type:	Research & Innovation Action (RIA)
Procedure:	Single-stage application
Open to applications:	4 July 2018
Deadline for applications:	30 October 2018

Strategic action for the comparison, selection and development of malaria vaccine candidates

Type:	Research & Innovation Action (RIA)
Procedure:	Single-stage application
Open to applications:	4 July 2018
Deadline for applications:	1 November 2018

Capacity development to facilitate delivery and uptake of new or improved medical interventions in African health systems

Type:	Coordination & Support Actions (CSA)
Procedure:	Two-stage application
Open to applications:	4 July 2018
Deadline for applications:	18 October 2018

Ethics and regulatory capacities

Type:	Coordination & Support Actions (CSA)
Procedure:	Single-stage application
Open to applications:	2 August 2018
Deadline for applications:	22 November 2018

Career Development Fellowships

Type:	Training & Mobility Actions (TMA)
Procedure:	Single-stage application
Open to applications:	6 August 2018
Deadline for applications:	27 November 2018

EDCTP Clinical Research and Product Development Fellowships

Type:	Training & Mobility Actions (TMA)
Procedure:	Single-stage application
Open to applications:	25 October 2018
Deadline for applications:	1 February 2019

EDCTP-AREF Preparatory Fellowships

Type:	Training & Mobility Actions (TMA)
Procedure:	Two-stage application
Open to applications:	2 November 2018
Deadline for applications:	February 2019

Senior Fellowships

Type:	Training & Mobility Actions (TMA)
Procedure:	Single-stage application
Open to applications:	2 November 2018
Deadline for applications:	28 February 2019

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