



EDCTP NEWSLETTER

European & Developing Countries Clinical Trials Partnership January 2018 • Volume 13 • No. 1

EDCTP

The power of sharing science

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2018 Prizes open to nominations



EDCTP invites nominations for the following prizes: Scientific Leadership, Outstanding Female Scientist, Outstanding Research Team, and the Dr Pascoal Mocumbi Prize. The prizes will be awarded at the Ninth EDCTP Forum (Lisbon, Portugal, 17-21 September 2018).

With the prizes EDCTP aims to promote African-European scientific research collaboration, and will reward outstanding individual researchers and research teams from sub-Saharan Africa and Europe.

Nominations can only be submitted online before 28 February 2018, 17:00 CET. For more information, please go to the Prizes section on the EDCTP website.

Taking stock of progress

Esteemed stakeholders,

Three years into our programme, its contours have become clearly visible and its project portfolio has grown substantially. I am happy and proud to take stock of this progress and highlight the following achievements.



Dr Michael Makanga
Executive Director

We have stepped up our ability to set clear research priorities that address critical unmet medical needs, with an expanded Scientific Advisory Committee, an annually updated Strategic Research Agenda, scientific stakeholder meetings on thematic topics requiring broader input, and participation in international technical forums for the development of medicinal products.

By the end of 2017, EDCTP had launched 31 calls for proposals: three in 2014, eight in 2015, nine in 2016 and eleven calls in 2017, all to result in projects to accelerate the development of medical interventions. The calls launched in 2014, 2015 and 2016 have resulted in 125 grants with a total estimate value of EUR 263.71 million. These include 35 multicentre clinical research grants with a total estimated value of EUR 223 million (84.8% of total calls budget). The 11 calls launched in 2017 have a total value of EUR € 156.54 million.

Sustained investment in clinical research capacity in sub-Saharan Africa remains a central priority including preparedness for (re-)emerging epidemics. To date, we have funded 58 individual fellowships to promote scientific excellence and leadership (for 39 male and 19 female African fellows), launched an Alumni Network and funded 4 regional networks of excellence focused on research capacity development. EDCTP continued to fund projects to strengthen ethics review and the regulatory framework for conducting clinical research with additional 8 grants recently awarded.

Our funding approach has continued to enable European research alignment and coordination both at project and programme level. Through participation in high-level discussions in Europe, Africa and at global level, alignment with national and regional initiatives is becoming more clearly defined. These initiatives include open access to clinical trial results, the fight against antimicrobial resistance, and collaboration in the framework of the EU-AU strategic partnership. Several new partnerships with non-profit organisations and companies are bringing extra resources to the programme.

In concluding, I would like to express my increased expectation – based on this progress – that the EDCTP programme will achieve the desired results. The increase in the membership of the EDCTP-Association – Nigeria and Ethiopia joined as full members and Angola became an Aspirant member – strengthens my confidence in the growing trust in the long-term value of our partnership.

Dr Michael Makanga
Executive Director



Open calls for proposals

EDCTP-TDR Clinical Research and Development Fellowships

Call budget:	€1.5 million
Funding level:	Up to 100% of eligible costs
Procedure:	Single-stage application
Opening date:	30 November 2017
Closing date:	28 February 2018
Call identifier:	TMA2017IF

Senior Fellowships

Call budget:	€3 million
Funding level:	Up to 100% of eligible costs
Procedure:	Single-stage application
Opening date:	3 November 2017
Closing date:	2 February 2018
Call identifier:	TMA2017SF

EDCTP-GSK Senior Fellowships for co-morbidities between poverty-related diseases (PRDs) and non-communicable diseases (NCDs)

Call budget:	€3 million
Maximum funding:	€500,000
Funding level:	Up to 100% of eligible costs
Opening date:	3 November 2017
Closing date:	2 February 2018
Call identifier:	TMA2017GSF

For more information about calls for proposals and how to apply, please go to the 'Calls for proposals' section of the EDCTP website; signed grants are in the section 'Current Projects'.

EDCTP and GHIT in funding partnership

In December 2017, the Global Health Innovative Technology Fund (GHIT) and EDCTP concluded a strategic partnership to support product development research. The partners' first action was to invest in a paediatric formulation for schistosomiasis. They will co-fund the PZQ4PSAC phase III clinical study, which is sponsored by Merck KGaA and conducted by the Pediatric Praziquantel Consortium. This study will provide clinical data and support for registration of a new praziquantel (PZQ) tablet formulation to treat schistosomiasis in preschool-aged children (PSAC). EDCTP will be contributing €1.99 million and GHIT €3.22 million to the study consortium which has a total project value of €12.10 million, including in-kind and cash contributions by all related parties.

“The joint investment in this project reflects the true value of global partnership aiming to create solutions for countries where the disease is endemic.”

*Dr Michael Makanga,
EDCTP Executive Director*

Schistosomiasis is a highly prevalent parasitic disease in sub-Saharan Africa, which may cause disabling conditions such as anaemia, malnutrition, and impaired childhood development. Although an effective treatment – praziquantel – is available, the tablets are difficult for young children to swallow, have an unpleasant bitter taste, and cannot be administered by crushing the tablet. The Pediatric Praziquantel Consortium was established with the aim of developing, registering and making accessible a new paediatric praziquantel formulation in the form of an orally disintegrating tablet.

2018 Priority: co-infections and co-morbidities

The report on the EDCTP Stakeholder meeting on Co-infections and co-morbidities will be published early 2018. Co-infections and co-morbidities are among the priority topics for EDCTP to be addressed in 2018. Within the scope of its programme, EDCTP intends to invest in research, especially in relation to co-existence of neglected infectious diseases with HIV, TB and malaria.

The meeting took place in The Hague, Netherlands on 13 September 2017 and participants included 52 representatives from academic and research institutions, funding agencies, product development partnerships, industry and international organisations, including members of EDCTP's Scientific Advisory Committee. The aim of the meeting was to establish priorities to inform EDCTP's research agenda. The report summarises the key contributions and recommendations.



Co-infections and co-morbidities

EDCTP Stakeholder meeting

The Hague, the Netherlands, 13 September 2017



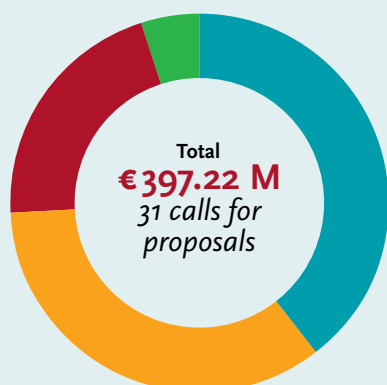
Report

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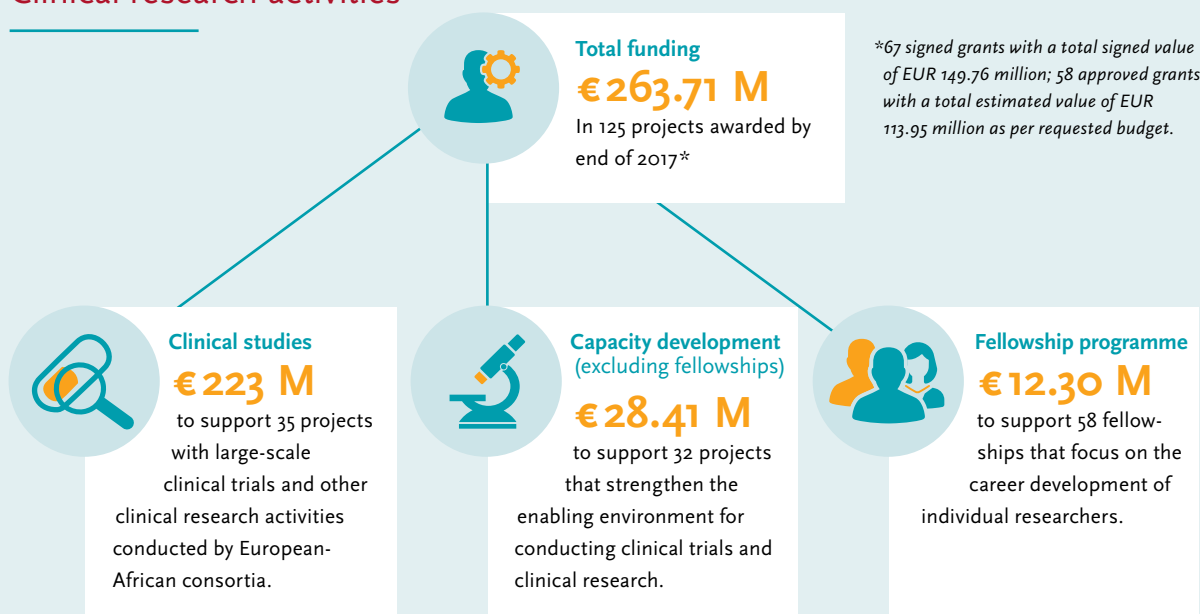
2017 Overview: EDCTP investments in clinical research

Investment in calls for proposals



● 2017	€156.54 M 11 calls	● 2015	€82.54 M 8 calls
● 2016	€138.65 M 9 calls	● 2014	€19.49 M 3 calls

Clinical research activities



Country participation



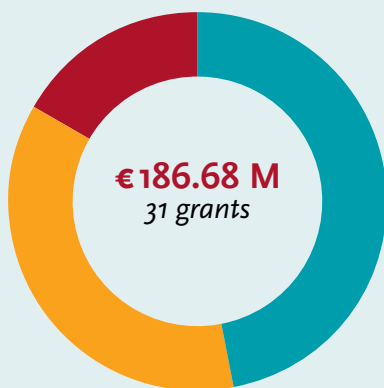
- 125** projects involve 54 countries, including:
- 35** sub-Saharan countries
- 16** European countries
- 3** other countries

Clinical studies: medical interventions against poverty-related infectious diseases

By interventions

Note:

A further € 36.32 M for 4 grants was awarded to projects not related to a particular intervention. All figures include both estimated and actual value of grants.

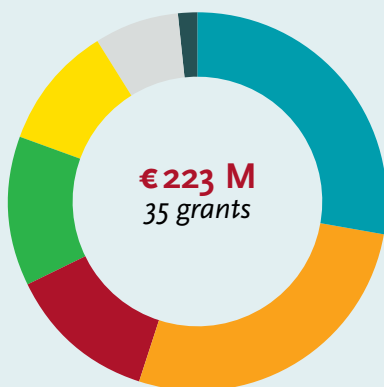


- Vaccines, 9 grants
€87.87 M
- Drugs, 12 grants
€67.94 M
- Diagnostics, 10 grants
€30.87 M

By diseases

Note:

These figures include both estimated and actual value of grants.

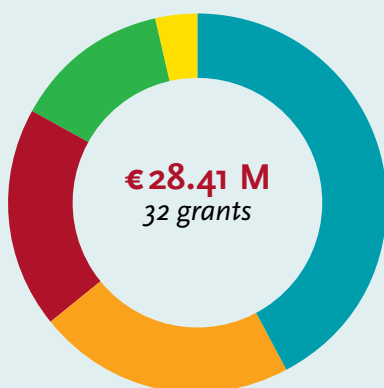


- Tuberculosis, 9 grants
€62.47 M
- HIV & HIV-associated infections (excluding TB), 9 grants
€60.34 M
- Neglected infectious diseases, 6 grants
€28.60 M
- Malaria, 4 grants
€28.57 M
- Emerging diseases, 3 grants
€23.23 M
- HIV/TB, 3 grants
€16.37 M
- Lower respiratory tract infections, 1 grant
€3.42 M

Capacity development: enabling the environment for conducting clinical research

Note:

These figures include both estimated and actual value of grants.

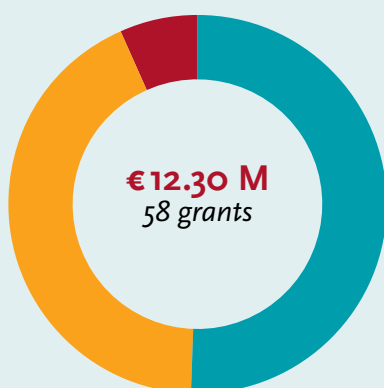


- Regional Networks of Excellence, 4 grants
€11.97 M
- Pharmacovigilance: improving detection, assessment, understanding and prevention of adverse drug effects, 3 grants
€6.31 M
- Enhancing evidence-informed policy making, 6 grants
€5.35 M
- Strengthening ethics and regulatory framework for conducting clinical trials, 13 grants
€3.84 M
- Enhancing preparedness for tackling new epidemics, 6 grants
€0.94 M

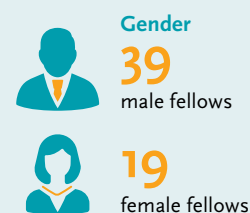
Fellowship programme: supporting individual researchers in sub-Saharan Africa

Note:

These figures include both estimated and actual value of grants.



- Senior Fellowships, 13 grants
€6.25 M
- Career Development Fellowships, 36 grants
€5.25 M
- EDCTP-TDR Clinical Research and Development Fellowships, 9 grants
€0.80 M



Strategic capacity development

Capacity for vaccine R&D: World Bank Task Force

EDCTP's Executive Director, Dr Michael Makanga, was invited to join the World Bank International Task Force on Strengthening Country Capacity for Vaccines Research and Development (IVTF), an initiative set up in response to the urgent need to strengthen research and development capacity in low-income countries (LMICs). Dr Makanga chairs the Work Stream 'Identifying existing capacity that can be built upon in LMICs. EDCTP's commitment to research capacity development in sub-Saharan Africa will contribute to the overall response to this question. The IVTF will propose ways in which national governments and development partners can effectively and sustainably establish and finance vaccine research & development (R&D) capacity at the national level, initially focusing on the WHO R&D Blueprint priority diseases.

EDCTP supports collaborative clinical research for a comprehensive range of medical interventions, including vaccines, for poverty-related infectious diseases affecting sub-Saharan Africa. In 2017, its portfolio of vaccine projects has grown to 9 interventional studies. The vaccine portfolio includes HIV and HIV-associated infections, tuberculosis, malaria, neglected infectious diseases, and emerging and re-emerging infections.

Development and regulation of medical products in Africa

In 2017, EDCTP signed a cooperative agreement with the New Partnership for Africa's Development (NEPAD) to build on progress made by NEPAD and WHO-AFRO for further development capacity for medical product development and regulation in Africa. The main objective of the EDCTP-NEPAD agreement is to strengthen and harmonise the regulatory systems for medical products (medicines and vaccines).

NEPAD, an implementing agency of the African Union (AU), has generated important political support through the Regional Economic Communities and related institutions that are involved in African regulations development and/or harmonisation efforts. For example, the implementation of the African Medicines Regulatory Harmonization (AMRH) Initiative in the East African Community (EAC) has reduced drug approval times for several branded medicines by about 40-60% through joint dossier assessments between the EAC partner states and has contributed to saving already scarce resources.

The AMRH initiative now extends to other regional economic communities, including the Economic Community of West African States (ECOWAS); the Southern African Development Community (SADC); the Economic and Monetary Community of Central Africa (CEMAC); and the Intergovernmental Authority for Development (IGAD) in the Horn of Africa.

In November 2017, EDCTP attended in Accra, Ghana a meeting of the African Vaccine Regulatory Forum (AVAREF) and the 5th African Medicines Regulators' Conference (AMRC) in Accra, Ghana. This meeting aimed to foster the regional regulatory convergence and harmonisation in the context of the global health agenda. EDCTP was represented by Dr Thomas Nyirenda, South-South Networking and Capacity Development Manager.

AVAREF is an entity of the WHO Regional Office for Africa established in 2006, partly through EDCTP support, as a network of National Regulatory Authorities (NRAs) and Ethics Committees (ECs). The aim of AVAREF is to develop regulatory capacity in Africa and to promote harmonisation of practices in support of oversight of clinical trials in Africa.

During the AVAREF's conference the attendees considered policy documents for adoption, including its strategic plan and work plan, the Guidelines for joint review of clinical trial applications and Regulatory timelines for review of clinical trial applications. AVAREF members, including EDCTP and AMRH, were also involved in an exercise based on experience gained in the last Ebola outbreaks to improve interaction between regulators, product developers and public health authorities in order to facilitate quick access to health products as part of the response to a public health emergency.

TESAII Network of Excellence launched

The EDCTP regional network of excellence for Southern Africa, i.e. Trials of Excellence for Southern Africa (TESAII)—was launched in Maputo, Mozambique on 30–31 October 2017. EDCTP will invest almost €3 million in the consortium. TESAII is coordinated by Dr Eusebio Macete of the Manhiça Foundation-Manhiça Health Research Centre (FM-CISM).

The kick-off meeting was attended by several high-level stakeholders, including Dr Zacarias Zindoga (Permanent Secretary, Ministry of Health, Mozambique), Dr Mohsin Sidat (Chair of the Manhiça Foundation), Dr Ilesh Jani (Director, National Institute of Health, Mozambique, and the representative for Mozambique to the EDCTP General Assembly) and Prof. Jorge Ferrao (Rector of the Universidade Pedagógica). EDCTP was represented by Dr Leonardo Simão, the High Representative South, and the Project Officer for TESAII, Ms Michelle Nderu.

Currently, TESAII includes 15 institutions from 8 southern African and 4 European countries, which have come together to strengthen and enhance capacities for clinical research, and increase North-South and South-South collaboration and networking activities.



Photo: The TESAII team and guests at the launch event in Maputo.

Investment in research to end TB in 2030

First WHO Global Ministerial Conference on ending TB

The First WHO Global Ministerial Conference on Ending Tuberculosis in the Sustainable Development Era: A Multisectoral Response' was held in Moscow, Russia on 16-17 November 2017.

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. Main topics were national and global commitments, deliverables and accountability; immediate action to address gaps in access to care; and the multidrug-resistant tuberculosis (MDR TB) crisis.

“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 & development.”

*Michael Makanga,
EDCTP Executive Director*

The conference resulted in a Ministerial declaration that will also inform the first UN General Assembly High-Level Meeting on TB in 2018. The Conference also had several important side meetings, e.g. the 'Africa Health Ministers & Parliamentary Tuberculosis Apex Working Breakfast', and a meeting organised by Aeras, TBVI and hosted by the Ministries of Health of South Africa and Argentina on the topic of 'The Urgent Need for New TB Vaccines to End the Epidemic'.

The conference brought together 1000 participants including Ministers of Health and Ministers from other sectors (79 Ministers, and a total of 117 country delegations), diplomats, representatives of public and private organisations/institutions, civil society and patient communities. Dr Michael Makanga and Dr Ole Olesen, EDCTP Director of North-North Cooperation, participated in the conference.



Tackling TB: achievements of EDCTP1

The EDCTP secretariat analysed the achievements of the first EDCTP programme (EDCTP1) in the field of tuberculosis (TB). An overview of the results was published in the International Journal of Tuberculosis and Lung Disease on 1 December 2017*. The publication 'Tackling tuberculosis in sub-Saharan Africa: EDCTP achievements and the road ahead' – by Dr Monique Surette, Dr Pauline Beattie, Dr Thomas Nyirenda, and Dr Ole Olesen – gives an overview of EDCTP1's contributions to the first three elements of the WHO DOTS TB control strategy**, which mobilised European and African funding for TB-related research and generated important evidence on TB diagnostics and treatment regimens. The programme also significantly enhanced the capacity of countries in sub-Saharan Africa to undertake clinical research.

Of the €208 million in grants awarded under the first EDCTP programme, TB research received the largest share (33.2%), followed by HIV/AIDS (29.5%), malaria (24.1%) and HIV-TB (3.4%). Non-clinical trial activities, such as capacity building and networking, received 9.8%. In all, 29 TB-focused grants and nine HIV-TB grants supporting clinical trials were funded, totalling €65.6 million.

A total of 437 researchers working in 117 institutions in 33 countries participated in EDCTP-funded TB trials. Of the top 20 organisations that received funding under the first EDCTP programme, 15 were in Africa (€93.72 million) and 5 were in Europe (€73.97 million).

An EDCTP-commissioned bibliometric analysis tracked*** the increasing prominence of sub-Saharan Africa in TB and HIV-TB research, showing that output of TB research in sub-Saharan Africa increased by 81% between 2003 and 2011. So far, the 29 TB grants supporting clinical trials have generated 252 journal articles. With the anticipated release of more publications, the high impact of EDCTP-funded research on TB is expected to continue.

* DOI: <https://doi.org/10.5588/ijtld.16.0944>

** World Health Organization. *The five elements of DOTS*. Geneva, Switzerland: WHO, 2017. <http://www.who.int/tb/dots/whatisdots/en/>. (accessed August 2017).

*** See EDCTP website for the analysis: <http://www.edctp.org/publication/european-african-clinical-research-bibliometric-analysis-publications-within-scope-edctp2-2003-2011/>

Photo: Dr Michael Makanga meeting Dr Matshidiso Moeti, Regional Director, WHO Regional Office for Africa (right) and Michèle Boccoz, WHO Assistant Director General for External Relations.

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

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