EDCTP

The power of sharing science

Annual Report 2017

Maintaining momentum

Supported by the European Union

Photo:
DREAMM project staff member, Malawi

About EDCTP

The European & Developing Countries Clinical Trials Partnership (EDCTP) is a public–public partnership between 14 European and 16 African countries, supported by the European Union.

EDCTP's vision is to reduce the individual, social and economic burden of poverty-related infectious diseases by affecting sub-Saharan Africa.

EDCTP's mission is to accelerate the development of new or improved medicinal products for the identification, treatment and prevention of infectious diseases, including emerging and re-emerging diseases, through pre- and post-registration clinical studies, with emphasis on phase II and III clinical trials. Our approach integrates conduct of research with development of African clinical research capacity and networking.

The second EDCTP programme is implemented by the EDCTP Association supported under Horizon 2020, the European Union's Framework Programme for Research and Innovation.

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Maintaining momentum

Esteemed Stakeholders,

Since the EDCTP2 programme was launched in 2014, we have extended and built upon the achievements of the first EDCTP programme, supporting studies that promise to have a major impact on poverty-related infectious diseases in sub-Saharan Africa and are enhancing the capacity of countries in sub-Saharan Africa to undertake clinical research.

Up until the end of 2017, we have awarded 124 grants with an estimated total value of €255.9 million. This has included funding for 32 multicentre clinical trials, accounting for €195.24 million of our funding. These trials involve researchers from 35 sub-Saharan Africa countries and 16 European countries.

EDCTP-funded trials are fighting the poverty-related infectious diseases responsible for the greatest burden of disease in sub-Saharan Africa – HIV, tuberculosis (TB), malaria, diarrhoeal diseases and lower respiratory infections – as well as emerging and re-merging infections of epidemic potential.

For TB, we support a range of major studies evaluating both novel drug regimens and innovative new vaccine candidates – including the largest European investment into clinical evaluation of TB vaccines to date.

Our HIV projects include an innovative adaptive trial evaluating novel vaccines in combination with pre-exposure prophylaxis. Several studies are examining treatment of TB/HIV co-infections, a major challenge given the drug-drug interactions between antiretrovirals and anti-TB drugs. They are also a reminder that people seldom experience infections in isolation. Therefore, our funding also encompasses co-infections, such as cryptococcal meningitis, responsible for one in five HIV-related deaths in sub-Saharan Africa.

We also have a strong focus on populations often excluded from clinical trials such as pregnant women and children, illustrated by important studies on malaria we have funded. Trials are examining pre-emptive treatment strategies for pregnant women using anti-malarial drugs to reduce the harmful impact of infections on mother and child. We have also provided funding to advance the development of candidate malaria vaccines, which could have a major impact on prevention of a disease that is showing signs of resurgence after many years of retreat.

We recently awarded our first grants for studies on neglected infectious diseases. We are supporting studies evaluating a novel mass drug administration in pre-school children and new diagnostics for schistosomiasis and two treatment trials for leishmaniasis. Diarrhoeal disease and lower respiratory infections are new areas of interest for us. We awarded our first grants in these areas in 2017, for studies addressing issues such as respiratory tract co-infections in children with HIV and additional dosing of rotavirus vaccine to enhance protection in young infants.

> "We have a strong focus on populations often excluded from clinical trials such as pregnant women and children."

Capacity building remains one of our core objectives. Capacity building activities are integrated into our clinical research projects, but we also provide specific funding for capacity-building activities. We have awarded €48.4 million to 34 projects strengthening research infrastructure and the regulatory environment for clinical research, as well as an additional €12.26 million through our fellowship programme, supporting 58 fellows at various stages of their research career.

International networking – North–South and South–South – makes an important contribution to the development of regulatory and ethical review capacity, and to the development of consistent practices that facilitate multicentre trials. A key contribution to this networking is made by our four regional networks of excellence. Networks are also building the capacity of countries to prepare for, respond to and prevent emerging infectious disease outbreaks.

We also recognise that we can achieve more by working in partnership. We have developed productive strategic relationships with bodies such as the WHO Regional Office for Africa, NEPAD Agency of the African Union and the Africa CDC - Centres for Disease Control and Prevention, to identify synergies and align activities. We have also entered into partnerships and issued joint calls with other national and international organisations with like-minded interests, including commercial bodies and non-profit organisations.

With most projects underway or just starting, it is too soon to see progress towards our goal of improving the health and wellbeing of the people of sub-Saharan Africa. Nevertheless, given the excellence of the studies we are supporting and the importance of the issues they are addressing, I am confident that they will deliver evidence that ultimately will make a real difference to the lives of millions on people on the African continent.

All this progress would not be possible without the contributions and cooperation of many people. I wish to sincerely thank the members of the EDCTP Association General Assembly, the Scientific Advisory Committee and the various independent scientific review committees for their great support and input. Special thanks go to the members of the Board, our High Representatives and the Executive Secretariat for the hard work, mission-focus and enduring spirit through a very busy and highly productive year.

Dr Michael Makanga
Executive Director

Message on behalf of the EDCTP General Assembly

Looking back on 2017, I would firstly like to applaud the progress made in the execution of the second EDCTP programme. Many of the activities and outcomes so far have already been highlighted by Michael Makanga.

EDCTP has made great progress towards reaching the programme's targets: through funding of potentially high-impact clinical studies on development and acceleration of medical interventions; product-focused implementation research to facilitate translation of evidence into policy and practice; development of sub-Saharan African research capacities at individual, institutional, national and international levels; impressive research coordination and collaboration at all levels in the various projects; and the demonstrable benefits for the health sector and populations resulting from improved preparedness for diseases with epidemics potential. EDCTP is set on a course to deliver the objectives of the programme.

Secondly, it should not be forgotten that much research underpinning EDCTP is carried out directly by member countries through their own national programmes that lie within the scope of EDCTP. The European Union recognises this effort as a contribution that counts towards the European Union investment in achieving the objectives of EDCTP. EDCTP member countries continue to develop and expand the opportunities to contribute to EDCTP through these so called Participating States' Initiated Activities.

> "EDCTP has made great progress towards reaching the programme's targets."

Thirdly, the external midterm evaluation of the programme led to a very positive assessment, concluding that EDCTP was on target to deliver its objectives and recommending that there should be a third EDCTP programme. The report made a number of recommendations that will help improve the strategic development of EDCTP and help us to prepare for any successor programme.

I would also like to commend the work of the Scientific Advisory Committee during the last few years. The Committee is now fully constituted with seventeen members and has done an excellent job in advising the Secretariat and the General Assembly on the scientific and strategic opportunities and priorities.

Moreover, I would like to highlight that we recently had three more African countries join the EDCTP Association: Ethiopia and Nigeria as members and Angola as an aspirant member taking the number of African partners to 17. Our common task is to involve all member countries fully in the activities of the EDCTP.

In conclusion, I would like to express my belief that EDCTP has established a sound platform on which to build for the coming years. The European Commission has made clear it aims to expand the next European budget for Research & Innovation as part of the European Union's Multiannual Financial Framework 2021-2027. The EDCTP Association has proved its effectiveness and I am convinced that EDCTP is well placed to take on a third programme under Horizon Europe and to help address the burden of infectious diseases in sub-Saharan Africa.

Dr Mark Palmer
Chair of the Board and General Assembly of the EDCTP Association


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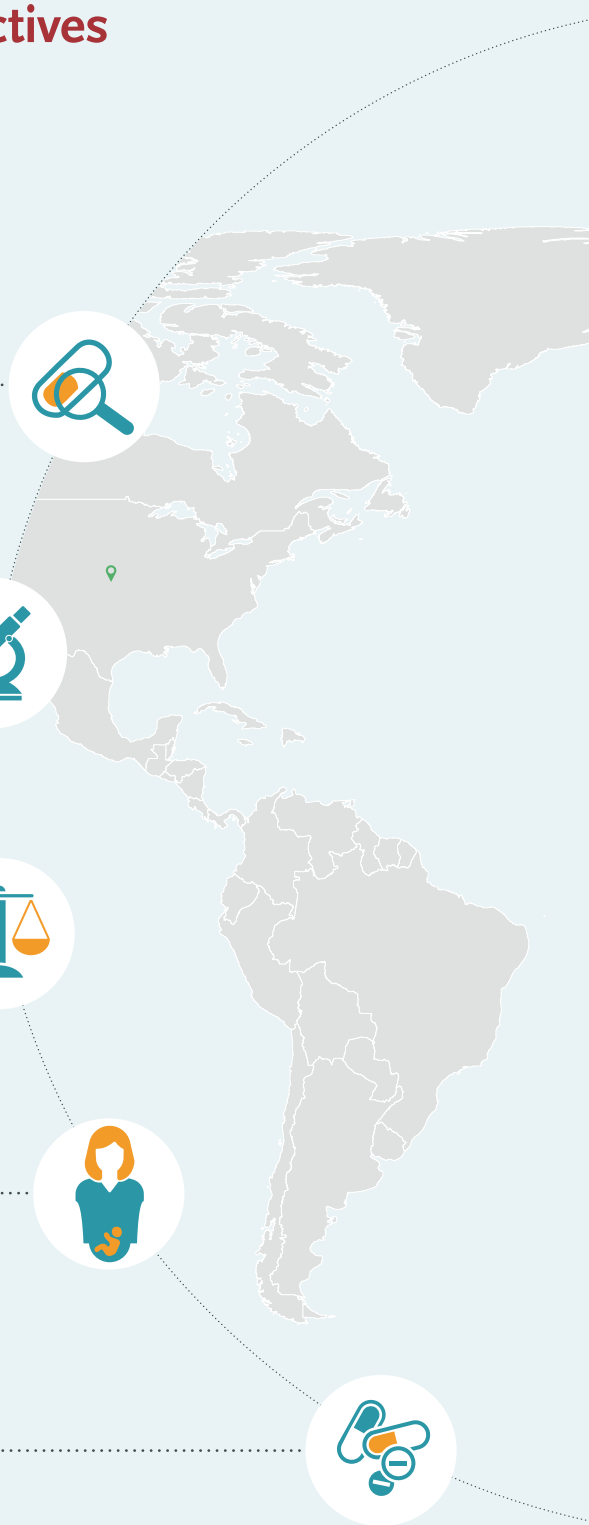
Towards EDCTP's objectives

(2014-2017)



Clinical trials

55 funded clinical studies to conduct research on treatment, vaccines or diagnostics.

Fellowships

58 researchers from sub-Saharan Africa are supported through the EDCTP fellowship scheme.

Ethics and regulatory

13 grants are funded to strengthen the **regulatory framework** and increase capacity for **research ethics review** in sub-Saharan Africa.

Vulnerable populations

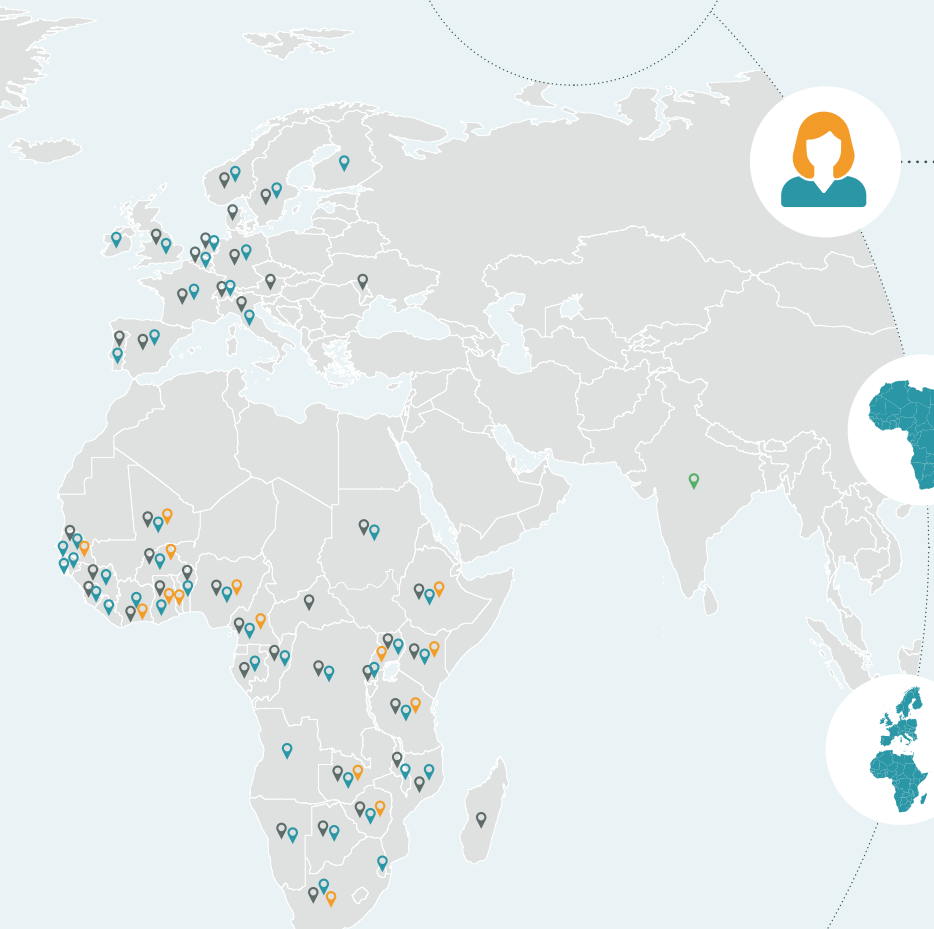
19 grants prioritise treatment for **vulnerable populations** such as children and pregnant women.

Research results into policy

86% of EDCTP's investments towards collaborative clinical trials and clinical studies are expected to **contribute to the development of guidelines for improved or extended use of existing medical interventions.**

€255.90 M

Total funding towards
124 projects awarded
by end of 2017.



Gender

34.4% grants are led by a **female project coordinator.**

Leadership

69% grants are coordinated by a sub-Saharan African institution, including fellowship grants to sub-Saharan African researchers.

Institutions

206 sub-Saharan institutions and 95 European Institutions participate in EDCTP projects.

Third party contributions

€6.67 million in contribution from third-parties to EDCTP programme. These include contributions from charitable foundations, industry, and product development partnerships.

Country involvment in EDCTP

- Collaborative clinical trials and clinical studies
- Capacity development (excluding fellowships)
- Fellowship programme
- Collaborating partners in global clinical trials

Photo:
DREAMM project staff member, Tanzania

4 2017 in a nutshell

January - March

Projects and results

PanACEA2 – the second programme of the Pan-African Consortium for the Evaluation of Antituberculosis Antibiotics – is led by Professor Martin Boeree (University of Nijmegen, The Netherlands). It held its inaugural meeting in Cape Town, South Africa, on 7-8 March 2017. The meeting gathered 80 delegates from all beneficiaries of the grant to discuss the tasks for the next five years.

Building on results from the consortium's first portfolio of clinical trials, PanACEA2 aims to develop at least two promising TB treatment regimens to the point where they can be tested in a phase III clinical study. Its second main objective is to advance one new agent to a phase IIB study. Clinical trial activities will be conducted at eleven research sites in six countries in sub-Saharan Africa – Gabon, Malawi, Mozambique, South Africa, Tanzania and Uganda – with integrated research capacity development. The project received an EDCTP contribution of almost €11.4 million. Additionally, the German and Swiss governments will make contributions directly to PanACEA2 of almost €3 million and €336,000, respectively.

The **Predict-TB project**, led by Professor Gerhard Walzl (Stellenbosch University, South Africa), was launched in Cape Town, South Africa, on 16–17 March 2017. The Predict-TB study is testing the hypothesis that a combination of microbiological and radiographic markers will be able to identify the 80-85% of TB patients likely to be cured by 16 weeks of conventional therapy. Sufficiently accurate prediction of treatment success would allow treatment of most TB patients to be shortened from the current standard duration of 24 weeks. The study will use an array of tools (positron emission tomography/computed tomography imaging, the Xpert/MTB-RIF assay and bacterial load markers) and will also evaluate new biomarkers for predicting treatment outcome.

EDCTP is investing €7.7 million in the project which has also secured substantial (50%) financing from other funders. Together, the Bill & Melinda Gates Foundation, EDCTP, the National Institutes of Health (NIH) and the National Institute of Allergy and Infectious Diseases (NIAID) are funding the South African component of the study, while the Gates Foundation is supporting additional studies in China. The overall project value is more that €25 million.

First findings were published by two EDCTP projects funded under the call 'Maximising the impact of EDCTP research: translation of research results into policy and practice'. For instance, the **IMPP-ACT** team (led by Dr Jenny Hill of the Liverpool School of Tropical Medicine, UK), published the findings of a modelling study. The study examined the potential significance of low use of intermittent preventive treatment of malaria in pregnancy with sulphadoxine-pyrimethamine (IPTp-SP). The results suggest that, even with recent declines in malaria transmission and the spread of SP resistance, a failure to integrate IPTp-SP into antenatal care could be leading to substantial numbers of preventable cases of malaria in pregnancy, with significant implications for the health of mothers and their infants.[1]

1. Walker PG, Floyd J, Ter Kuile F, Cairns M. Estimated impact on birth weight of scaling up intermittent preventive treatment of malaria in pregnancy given sulphadoxine-pyrimethamine resistance in Africa: A mathematical model. PLoS Med. 2017;14(2):e1002243. doi: 10.1371/journal.pmed.1002243.

"First findings were published by two EDCTP projects funded under the call 'Maximising the impact of EDCTP research: translation of research results into policy and practice."

Advocacy and EDCTP

From 1 January 2017, **Switzerland** became fully associated to the Horizon 2020 programme making Swiss participants eligible again for EDCTP funding. However, Switzerland, an aspirant member of the EDCTP Association, did not yet become a full member.

The EDCTP **Scientific Advisory Committee**, its main advisory body, was expanded with new members broadening its expertise. Professor Catherine Hankins (Amsterdam Institute for Global Health, The Netherlands) was appointed as the new Chairperson.

EDCTP published the **highlights of the Eighth EDCTP Forum** (Lusaka, Zambia, 6-9 November 2016). Forum abstracts were published in an online supplement of the *British Medical Journal Global Health* in February 2017 (DOI:10.1136/bmjgh-2016-000260).

The 2016 G-FINDER report on **investments in research and development on poverty-related and neglected infectious diseases** was published by Policy Cures in February 2017 (www.policycuresresearch.org/g-finder-2016). The USA, UK and European Union (EU) were the top three public funders in this area in 2015, contributing more than two-thirds of the total public R&D investment (US$1,378 million). The report noted a significant increase in EU investments, reflecting the EU's expanded contribution to the second EDCTP programme.

> "The 2016 G-FINDER noted a significant increase in EU investments, reflecting the EU's expanded contribution to the second EDCTP programme."

'Friends of Europe', an NGO think tank, hosted a launch event for the report in Brussels, Belgium, on 16 February 2017, with a high-level panel including Bill Gates (Bill & Melinda Gates Foundation), Carlos Moedas (European Commissioner for Research, Science and Innovation) and Luc Debruyne (President of Global Vaccines, GlaxoSmithKline). Dr Michael Makanga, Executive Director, and Dr Ole Olesen, Director of North-North Cooperation, represented EDCTP at the meeting.

On 27 February 2017, the **UK's All-Party Parliamentary Group on Global Health** hosted a meeting at the Houses of Parliament on the value of EDCTP as an 'African-European partnership for global health benefit'. The meeting, chaired by Dr Daniel Poulter MP, involved more than 100 participants including members of the UK Parliament, representatives of UK-based funders, UK researchers, NGOs, private foundations, and participants from the private sector.

To illustrate the impact of the EDCTP programme, a video[2] was shown featuring a young child from Malawi, highlighting the potential impact of paediatric fixed-dose combination therapies for HIV-infected children, which were evaluated in the EDCTP-funded CHAPAS-1 and CHAPAS-3 trials. CHAPAS-1 confirmed the efficacy of the first antiretroviral formula designed specifically for children, leading to their large-scale rollout. CHAPAS-3 provided the first data in African children on paediatric formulations of a new generation of antiretroviral drugs, generating key evidence to support WHO recommendations on antiretroviral use in children.

A workshop on **national research activities within the scope of EDCTP** was organised at the request of several member countries of the EDCTP Association. The workshop for all EDCTP member countries took place in Vienna, Austria, on 21-22 March 2017. Representatives from 11 member countries discussed the role of national research activities that fall within the scope of EDCTP and the dissemination of information on EDCTP funding in member countries. Participants also discussed opportunities and mechanisms for better alignment of national activities, including harmonisation of research capacity development activities.

2. Video credit: produced by Picturing Health and supported by the Medical Research Council – Clinical Trials Uni

April - June

Projects

The **AMBITIONcm** phase III clinical trial was launched at a meeting in Gaborone, Botswana, on 30-31 May 2017, following the signing of the EDCTP grant agreement in January 2017. The €10 million AMBITIONcm trial is coordinated by Dr Joseph Jarvis (London School of Hygiene and Tropical Medicine, UK) and evaluates a shortened and simplified treatment for cryptococcal meningitis, suitable for use in resource-poor settings. The disease is responsible for almost 20% of all HIV- related deaths in Africa.

WANETAM II (the West African Network for TB, AIDS and Malaria) held its inaugural meeting in Dakar, Senegal, on 21 June 2017. This EDCTP-funded was established under the first EDCTP programme. WANETAM II has attracted additional partners and expanded to a network of 19 institutions, including new sites in Togo and Sierra Leone. It plans to extend its research scope to encompass neglected tropical diseases and Ebola.

Advocacy and partnerships

Through a UK-based **malaria awareness campaign**, information on EDCTP investments and an interview with Dr Michael Makanga were published on World Malaria Day. The publication was distributed to UK audiences and subsequently made available online and at international conferences.

In May 2017, considering the importance of **clinical data sharing** for global health, the EDCTP Association Board endorsed the WHO joint statement on clinical trial transparency and agreed to implement WHO standards for reporting of clinical trial results. EDCTP continued to contribute funding data to the World RePort (https://worldreport.nih.gov), a web-based platform for **sharing information on biomedical research funding.**

On 12 May 2017, the **Leprosy Research Initiative** 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 that are co-endemic with leprosy.

On 16 June 2017, the **Fundación Mundo Sano** and EDCTP signed a partnership agreement to leverage research funding for neglected infectious diseases. Mundo Sano will contribute to clinical and product-focused implementation research soil-transmitted helminthiases.

On 19 June 2017, Senegal launched its new **Institute for Health Research, Epidemiological Surveillance, and Training (IRESSEF)**. Dr Michael Makanga was one of the invited speakers at the opening ceremony, attended by the President of Senegal, His Excellency Mr Macky Sall. The Institute aims to become a hub for health research, surveillance and training in Africa. The opening ceremony was part of a scientific symposium on partnerships for public health.

> “In May 2017, the EDCTP Association Board endorsed the WHO joint statement on clinical trial transparency and agreed to implement WHO standards for reporting clinical trial results.”

July - September

Calls for proposals

Eight calls for proposals were launched in July and August 2017:

- Treatment innovations for poverty-related infectious diseases
- Strategic actions supporting large-scale clinical trials
- Clinical trials to reduce health inequities in pregnant women, newborns and children
- Targeting control and elimination of neglected infectious diseases through clinical trials
- Targeting control and elimination of neglected infectious diseases through product-focused implementation research
- EDCTP-AREF Preparatory Fellowships (joint call with the Africa Research Excellence Fund, to enhance the competitiveness of up-and-coming postdoctoral African scientists and clinicians)
- Ethics and regulatory capacities
- Career development fellowships

EDCTP membership and expert consultation

On 11 September 2017, **Nigeria** became the 29th member of the EDCTP Association. As representatives to the EDCTP General Assembly were designated Dr Akin Oyemakinde (Federal Ministry of Health) and Professor S L Salako (Nigerian Institute of Medical Research).

> "On 11 September 2017, Nigeria became the 29th member of the EDCTP Association."

On 13 September 2017, EDCTP held a **stakeholder meeting on co-infections and co-morbidities** in The Hague, The Netherlands. The invited participants included 52 representatives from academic and research institutions, funding agencies, product development partnerships, industry and international organisations, and members of the EDCTP Scientific Advisory Committee.

Photo:
DREAMM project staff members, Tanzania

October - December

Calls for proposals

In November EDCTP launched its remaining 2017 calls for proposals:

- EDCTP-TDR Clinical Research and Development Fellowships, a joint call with TDR (the Special Programme for Research and Training in Tropical Diseases)
- Senior fellowships
- EDCTP-GSK senior fellowships for co-morbidities between poverty-related diseases and non-communicable diseases, a joint call with GlaxoSmithKline (GSK).

Projects

The EDCTP regional network of excellence for Southern Africa — **Trials of Excellence for Southern Africa (TESAII) — was laun**ched in Maputo, Mozambique, on 30–31 October 2017. EDCTP is investing almost €3 million in the consortium, which is coordinated by Dr Eusebio Macete, Director of the Manhiça Foundation-Manhiça Health Research Centre, Mozambique. TESAII aims to develop, strengthen and expand clinical research capacity in southern African, focusing on infectious diseases accounting for the greatest burden of morbidity and mortality in the region.

EDCTP membership and partnerships

EDCTP launched its **research leadership network for EDCTP fellows** (https://edctpalumninetwork.org). More than 70 former and current EDCTP fellows attended a two-day workshop in Johannesburg, South Africa, on 3-4 October 2017 to discuss the development of the network and its interactive online platform, which will facilitate exchange of ideas and collaboration among the growing number of EDCTP fellows.

In October 2017, EDCTP signed an agreement with the University of Oxford's Global Health Network to develop an **online single-entry point toolkit regarding data sharing** for researchers involved in clinical trials.

A new partnership of WHO African Region, TDR and EDCTP was formed in recognition of a common interest in strengthening health research capacity in African countries. In this partnership, EDCTP represents several of its member countries that contribute funding to activities of the partnership: the German Federal Ministry of Education and Research (BMBF), the UK Medical Research Council (MRC) and the Swedish International Development Cooperation Agency (Sida). One concrete output was a 2017 call for proposals: 'Joint WHO-AFRO/TDR/EDCTP small grants scheme for implementation research on infectious diseases of poverty'.

On 1 December 2017, **Ethiopia and Angola joined the EDCTP** Association – Ethiopia as a full member and Angola as an aspirant member country. The Ethiopian Federal Ministry of Health will be represented in the EDCTP General Assembly by Dr Taye Tolera Balcha (Armauer Hansen Research Institute, Addis Ababa) and Dr Tsigereda Kifle (Ethiopian Public Health Institute). The Angolan National Institute of Public Health will be represented by Dr Joana Filipa Machado de Morais Afonso (National Institute of Public Health) and Dr Moisés Francisco (Angolan Health Research Centre).

On 8 December 2017, the **Global Health Innovative Technology Fund** (GHIT, Japan) and EDCTP entered into 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 being carried out by the Pediatric Praziquantel Consortium. EDCTP contributed €1.99 million and GHIT €3.22 million to the study, which has a total project value of €12.10 million, including in-kind and cash contributions from all parties involved.

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On 1 December 2017, Ethiopia and Angola joined the EDCTP Association – Ethiopia as a full member and Angola as an aspirant member country.
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Photo:
DREAMM project staff members, Tanzania


BIOSYNEX
BIOSYNEX

5

Investments in research and innovation

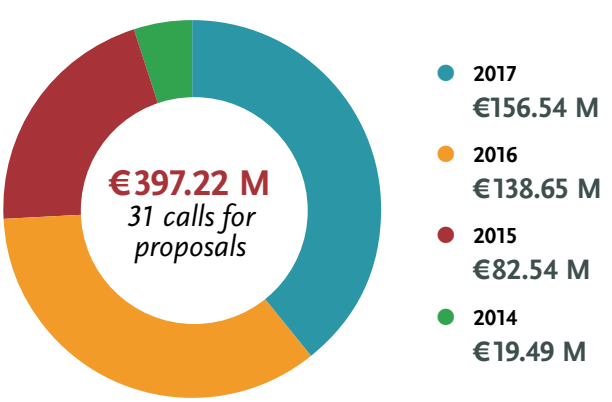
(2014-2017)

The high-level strategy for the EDCTP2 programme is set out in its Strategic Business Plan. The annually updated Strategic Research Agenda states the priorities within this strategy and lists EDCTP's current portfolio of grants. From this framework, with the advice of the EDCTP Scientific Advisory Committee and in consultation with stakeholders, EDCTP produces an annual work plan containing the calls for proposals and other activities.

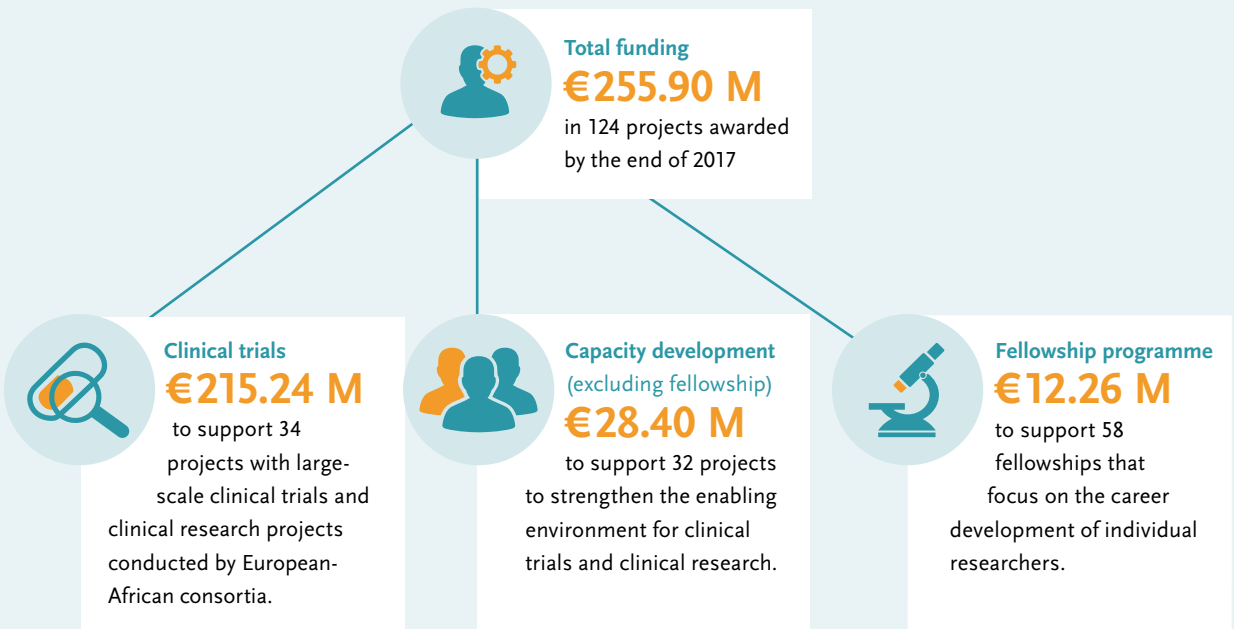
An example of the continuous consultation process was the stakeholder meeting on co-infections and co-morbidities held on 13 September 2017. EDCTP convened 52 representatives from academic and research institutions, funding agencies, product development partnerships, industry and international organisations, including members of EDCTP's Scientific Advisory Committee, to discuss research priorities in this area. The recommendations from the stakeholder meeting informed the drafting of EDCTP's work plan for 2018.

The EDCTP 2017 work plan was approved by the European Commission on 3 July 2017. Eight calls for proposals were immediately launched and advertised widely. Three calls followed in the last quarter of 2017.

Calls launched



Clinical studies by funding mechanism



Support is provided under three funding mechanisms:

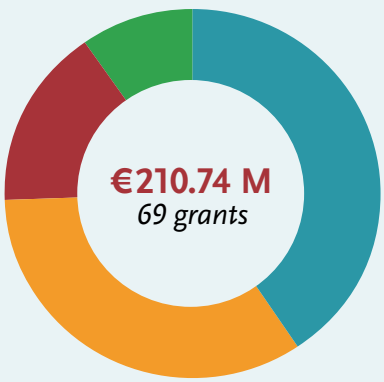
- Research and Innovation Actions (RIAs), supporting clinical trials and clinical research activities
- Coordination and Support Actions (CSAs), supporting capacity strengthening, networking and collaboration
- Training and Mobility Awards/Fellowships (TMAs), supporting researchers and clinical research staff from sub-Saharan Africa to develop their clinical research capacities and skills.

Proposals submitted via EDCTP's online grants management system are checked for eligibility before being referred to independent expert reviewers. Reviewers evaluate proposals against three criteria (excellence, impact and implementation), submitting a score and a summary of their evaluation. For each call, a Scientific Review Committee discusses all proposals and agrees on a consensus summary and score. Proposals are ranked in order of priority, according to their score. Proposals above a quality threshold and within the available budget are funded. All applicants receive the consensus evaluation summary and score of their proposal as feedback. In 2017, 11 review committee meetings were held to evaluate proposals received in response to the 2016 work plan calls.

Clinical studies: medical interventions against poverty-related infectious diseases

By medical intervention

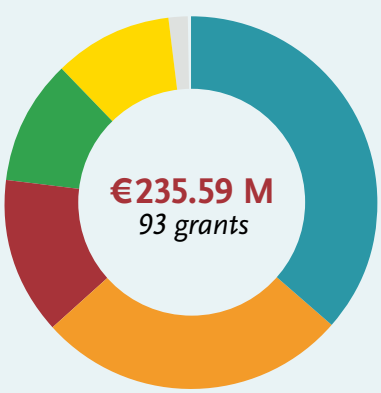
Note:
A further €45.16 M for 44 grants was awarded to projects not related to a particular intervention. All figures include both estimated and actual value of grants.



- Vaccines, *17 grants*
  €85.60 M
- Drugs (treatment and prevention), *26 grants*
  €71.53 M
- Diagnostics, *20 grants*
  €33.57 M
- Product-focused implementation research, *6 grants*
  €20.04 M

By disease

Note:
A further €20.31 M for 31 grants was awarded for projects on non-disease-specific topics such as ethics and regulatory support, networking and fellowship grants. All figures include both estimated and actual value of grants.



- Tuberculosis, *26 grants*
  €85.73 M
- HIV & HIV-associated infections, *26 grants*
  €64.09 M
- Malaria, *14 grants*
  €32.05 M
- Neglected infectious diseases, *13 grants*
  €25.18 M
- Emerging diseases, *10 grants*
  €24.32 M
- Diarrhoeal diseases and lower respiratory tract infections, *4 grants*
  €4.22 M

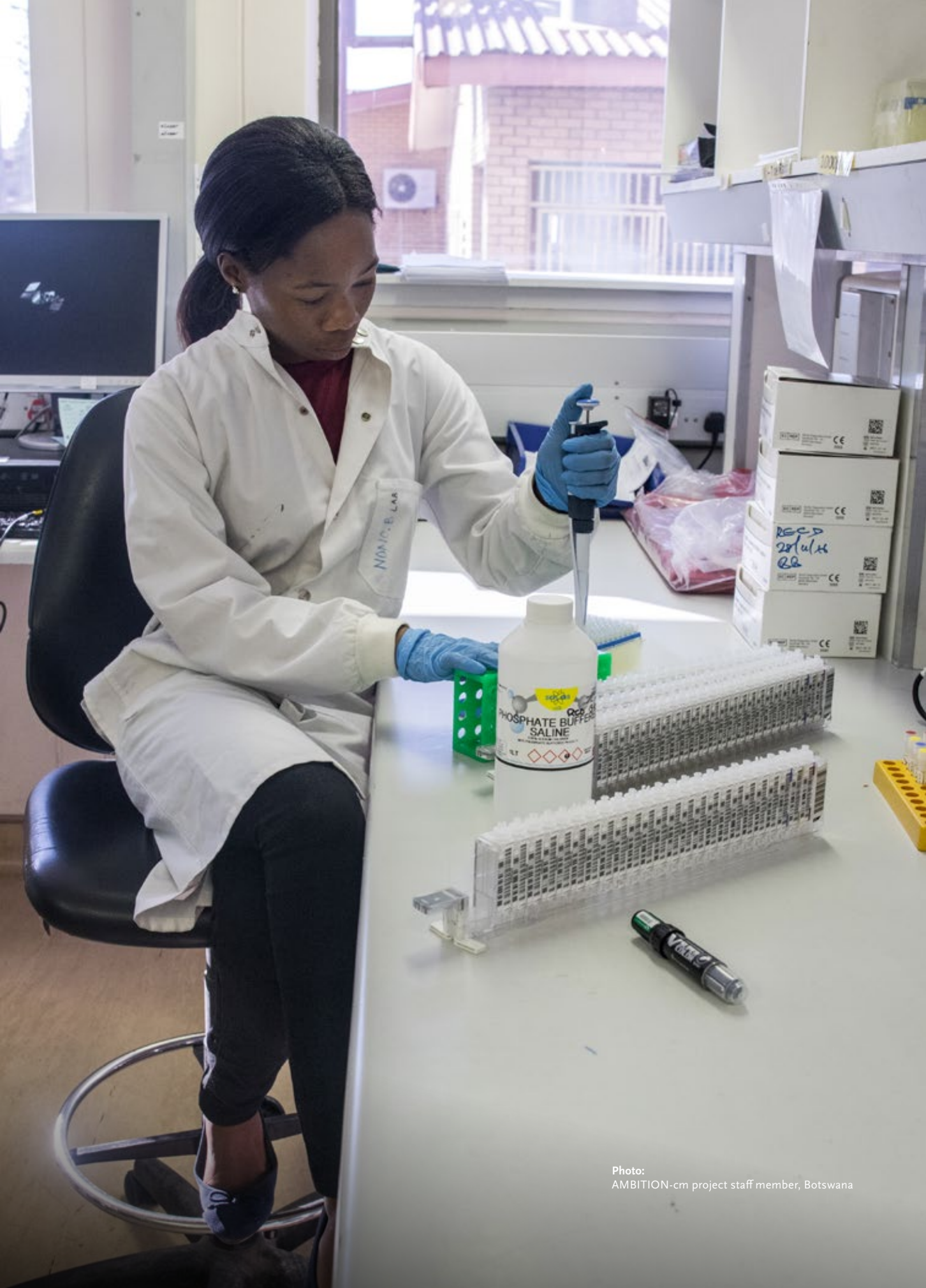


Photo:
AMBITION-cm project staff member, Botswana

5.1

HIV

According to UNAIDS[3], approximately 36.7 million people were living with HIV at the end of 2016. Even though considerable progress has been made to end the AIDS epidemic by 2030, there were still 1.8 million new infections in 2016 and 1 million people died from AIDS-related illnesses.

Current EDCTP research priorities are:

- Innovative prevention methods;
- Product-focused implementation research to increase access to antiretroviral therapy; and
- Optimisation of treatment regimens for vulnerable populations such as pregnant women, children and people with co-infections.

3.UNAIDS Factsheet July 2017

Since 2014, EDCTP has supported 26 HIV projects with a total grant value of €64.12 million. Its HIV portfolio consists of projects on prevention, diagnosis and treatment of HIV and HIV-associated infections.

Although effective antiretroviral therapy (ART) is now available, optimised treatment regimens and formulations are required for key groups, such as children, pregnant women, and adults with co-infections and co-morbidities.

EDCTP portfolio: HIV and HIV-associated infections

Collaborative clinical trials and clinical studies

- DREAMM *United Kingdom*
- GREAT *United Kingdom*
- LIFE Study *Mozambique*
- PrEPVacc *United Kingdom*
- CAPRISA 018 *South Africa*
- CHAPAS 4 *Zimbabwe*
- AMBITION-cm *United Kingdom*
- CHAPS *United Kingdom*
- PROMISE-EPI *France*

Career Development Fellowships

Career Development Fellowships

- Dr Ilse Marion Sumari-de Boer *Tanzania*
- Dr Obinna Ekwunife *Nigeria*
- Dr Jane Frances Namukasa Wanyama *Uganda*
- Dr Tchounga Boris Kevin *Cote d'Ivoire*
- Dr Joseph Fokam *Cameroon*
- Dr Mercy Karoney *Kenya*
- Dr Agnes Kiragga *Uganda*
- Dr Admire Chikandiwa *South Africa*
- Dr Aida Sivro *South Africa*
- Dr Tecla Temu *Kenya*
- Dr Deogratius Ssemwanga *Uganda*
- Asst. Professor Yaya Kassogue *Mali*
- Dr Yunia Mayanja *Uganda*

Senior Fellowships

- Dr Immaculate Nankya *Uganda*
- Professor Collen Masimirembwa *Zimbabwe*

Intervention/study topic

Drugs | *Diagnostics* | *Vaccines* | *Product-focused implementation research* | *Behavioral and social sciences* | *Other*

PrEPVacc study

Vaccines against HIV infection

EDCTP awarded a €15 million grant to the PrEPVacc consortium, led by Professor Jonathan Weber (Imperial College of Science Technology and Medicine, UK), for the evaluation of two candidate HIV vaccines in combination with pre-exposure prophylaxis. The PrEPVacc study will evaluate two prime-boost immunisation strategies in Mozambique, Uganda, South Africa and Tanzania.

The PrEPVacc study is a randomised, blinded, placebo-controlled, three-arm, two-stage, adaptive phase IIb clinical trial. Two intervention arms will test a combination of the candidate vaccines. The design of the study is adaptive. If interim analysis shows no probability of significant protection in an arm of the study, that arm could be abandoned, allowing for expansion of the other arm. During the 40-week vaccination schedule all participants will receive pre-exposure prophylaxis. The acceptability, uptake, adherence and effectiveness of pre-exposure prophylaxis will be assessed in addition to vaccine efficacy.

MRC/UVRI Uganda will be responsible for clinical trial management, the trial database and all blinded statistical analyses, with laboratory and clinical expertise developed at all clinical sites. MRC South Africa and Cape Town University will support the trial statistician in Uganda and conduct the statistical analysis by treatment group.

DREAMM

HIV-associated central nervous system infections

HIV-associated central nervous system (CNS) infections are responsible for up to 25% of HIV-related deaths. Cryptococcal meningitis and tuberculous meningitis are leading causes of HIV-associated meningitis in sub-Saharan Africa. Cryptococcal meningitis alone is estimated to account for up to 20% of HIV-related mortality and its incidence in Africa, unlike in resource-rich settings, has remained largely unchanged despite antiretroviral rollout. In resource-poor settings, mortality due to cryptococcal meningitis ranges from 24% to over 60%, while tuberculous meningitis mortality can be as high as 70%. Delays in diagnosis contribute significantly to high mortality.

The DREAMM project, coordinated by Dr Angela Loyse (St George's University of London, UK), received a €1.9 million grant in 2016. It is evaluating a new semi-quantitative cryptococcal lateral flow antigen test (CrAg LFA; developed by the Pasteur Institute, Paris, France) in Cameroon, Malawi, and Tanzania. The novel CrAg LFA has high clinical potential as it detects patients who are at increased risk of mortality and may benefit from more aggressive or prolonged antifungal therapy.

This study has an additional important component involving the implementation of a diagnostic and therapeutic algorithm designed to reduce delays in the diagnosis of cryptococcal meningitis and initiation of appropriate treatment. This involves integrating the diagnostic into care pathways and engaging with policymakers.

WISH project:
HIV prevention in women in Rwanda

In 2015 EDCTP awarded a €0.5 million grant to the WISH project, coordinated by Professor Janneke van de Wijgert (University of Liverpool, UK), which aims to improve HIV prevention and sexual and reproductive health care in women at high risk of HIV in Rwanda. The project builds on previous studies involving Rinda Ubuzima, an NGO based in Kigali, Rwanda, that specialises in HIV prevention and sexual and reproductive health research in women, particularly those at high risk of HIV. It has operated a research clinic and laboratory in Kigali since 2004 and has successfully implemented three EDCTP1-funded projects.

The purpose of the WISH project was to:

- Formalise the role of Rinda Ubuzima as an HIV prevention/sexual and reproductive health research and training centre in Rwanda;
- Demonstrate to national stakeholders that it is feasible and affordable to improve sexual and reproductive health services in high-risk women; and
- Engage stakeholders in discussions about adaptations of the Rwanda treatment guidelines for STIs, opportunities for better integration of vertical HIV and sexual and reproductive health programmes, and preparations for a rollout of novel vaginal microbicides and multipurpose technologies for HIV and pregnancy prevention as soon as efficacious products become available.

Data collection was completed in March 2017. The investigators found that: prevalence of urogenital infections is high in this study population; participant-reported symptoms and physician-observed signs do not reliably predict the presence of urogenital infections; and point-of-care testing was feasible and acceptable in the Kigali setting. However, some point-of-care tests are prohibitively expensive for resource-poor settings and better tests are needed for bacterial vaginosis and vulvovaginal candidiasis.

Photo:
TRIP project staff member, Tanzania

5.2

Tuberculosis

According to the WHO's 2017 Global Tuberculosis Report, in 2016 an estimated 10.4 million people developed tuberculosis (TB), caused by *Mycobacterium tuberculosis* (Mtb), and approximately 1.3 million HIV-negative people and 374,000 HIV-positive individuals died from the disease. An estimated 25% of cases occurred in Africa, where HIV infection is most prevalent. The spread of drug-resistant strains of Mtb has only aggravated the situation further. On 20 May 2017, the G20 Health Ministers, meeting in Berlin, Germany, recognised drug-resistant TB as an important threat, acknowledging the need to develop new drugs, diagnostics and vaccines.

The Global Plan to End TB 2016-2020, produced by the Stop TB Partnership, provides a roadmap for the fight against TB. The 2017 Treatment Action Group TB R&D Report stated that the US$4.02 billion funders invested in TB R&D between 2011 and 2016 falls well short of the US$9 billion target set forth in the Global Plan. Specific funding gaps were identified in all areas of research, including basic science (outside EDCTP's scope), diagnostics, drugs, vaccines and operational research.

EDCTP's investments in TB research

EDCTP has made significant investments in TB research. During the first EDCTP programme, TB research (including TB/HIV) received the largest share (36.6% or €68.54 million) of the programme's €208 million funding. At the end of 2017, EDCTP2's total investment in TB and TB/HIV research has surpassed that committed in the first programme and stands at €88.38 million, with 27 projects supported. The TB portfolio includes studies on diagnostics, vaccines, drugs, and behavioural and social science.

EDCTP portfolio: tuberculosis

Collaborative clinical trials and clinical studies

- StopTB/HIV at one *United Kingdom*
- Screen TB *South Africa*
- DIAMA *Benin*
- Predict TB *South Africa*
- RaPaed TB *Germany*
- PanACEA *Netherlands*
- VirTUAL *United Kingdom*
- POR TB consortium *Denmark*
- MTBVAC - Newborns *Spain*
- priMe *Germany*
- TREATS *United Kingdom*

Career development Fellowships

- Dr Ali Esmail *South Africa*
- Dr Stephanus Malherbe *South Africa*
- Dr Sean Wasserman South Africa
- Dr Christine Sekaggya-Wiltshire *Uganda*
- Dr Nelita du Plessis *South Africa*
- Dr Sylvie Kwedi *Cameroon*
- Dr Evaezi Okpokoro *Nigeria*
- Dr Marieke van der Zalm *South Africa*

Senior Fellowships

- Professor Grant Theron *South Africa*
- Professor Keertan Dheda *South Africa*
- Dr Stellah George Mpagama *Tanzania*
- Professor Wendy Burgers *South Africa*

Pharmacovigilance

- PAVIA *Netherlands*

Evidence-informed policy

- TWENDE *United Kingdom*
- EXIT-TB *Tanzania*

Intervention/study topic

- *Drugs*
- *Diagnostics*
- *Vaccines*
- *Product-focused implementation research*
- *Behavioral and social sciences*
- *Other*
- *Training*

TB Vaccines

In 2017, EDCTP committed €34 million to four large clinical trials on candidate TB vaccines. The trials will be conducted by 28 research institutions in sub-Saharan Africa, Europe and India.

POR TB:
prevention of recurrent TB

The POR TB consortium, coordinated by Professor Peter Andersen of the Statens Serum Institute, Denmark, received an EDCTP grant of €13.8 million. It unites six African and two European research institutions, clinical trial sites and vaccine developers. It will carry out a phase IIb trial to determine the efficacy of the multistage vaccine H56:IC31, which targets multiple points of the infection process. The trial will specifically assess the efficacy of H56:IC31 at preventing recurrent TB, which happens in 4–8% of patients who receive drug treatment.

priMe
an improved version of BCG

The priMe consortium, including nine African, five European, and one Indian partner, was awarded an EDCTP grant estimated at €12.5 million. The project is coordinated by Dr Leander Grode (Vakzine Projekt Management GmbH, Germany). It will conduct a multicentre phase III double-blind, randomised, controlled trial to evaluate the efficacy and safety of the BCG-derived VPM1002 vaccine in comparison to BCG in HIV-exposed and HIV-unexposed infants. Although it has some benefits, BCG provides little protection against pulmonary TB and is not suitable for immunocompromised individuals. VPM1002 is an engineered version of BCG designed to enhance the destruction of Mycobacterium tuberculosis (Mtb) within macrophages.

MTBVAC-Newborns
attenuated Mtb

MTBVAC is a novel candidate TB vaccine based on a live attenuated human Mtb isolate. The MTBVAC-Newborns project, which is coordinated by Ms Ingrid Murillo (Biofabri S.L. in Spain) and received an EDCTP grant of €5.6 million, will support a phase IIa dose-defining study of MTBVAC in South African newborns to evaluate the safety, reactogenicity and immunogenicity of the vaccine, and its effects on TB diagnostic assays.

TB TREATMENT TREATS
combined HIV/TB prevention

For people living with HIV, TB is the most significant co-infection as 40% of HIV deaths in 2016 were due to TB. The **TREATS project** (Tuberculosis Reduction through Expanded Antiretroviral Treatment and Screening for active TB) was developed in response to this.

The project is led by Professor Helen Ayles (London School of Hygiene and Tropical Medicine (LSHTM), UK). TREATS, which was awarded a grant of €12.9 million in 2017, consists of four connected studies that will provide definitive cluster-randomised evidence of the effect of a household-level combined HIV/TB prevention intervention on the burden of TB at a population level. These studies are nested within the ongoing HPTN071(PopART) clinical trial conducted in Zambia and South Africa, the largest ever trial of a combination HIV/TB prevention intervention.

The HPTN071(PopART) trial is a cluster randomised trial in 21 communities with a population size of approximately 1 million individuals. It offers a unique opportunity to assess the impact on the burden of TB of combination HIV prevention (including universal HIV testing and treatment) combined with population screening for active TB. The recent WHO endorsement of a 'universal treatment' strategy for HIV, which focuses attention on HIV case-finding, will also offer an opportunity to conduct TB screening on a large scale. The results from the TREATS project will provide information on the additional costs and benefits of combined TB and HIV prevention strategies at population level.

TREATS will also assess novel methods to measure the effect of interventions on the burden of TB in trial communities. The latest interferon gamma release assay (QuantiFERON® Gold Plus) will be assessed for measuring impact on the incidence of infection. A combination of Xpert® MTB/RIF and computer-aided digital X-ray (CAD4TB) will be evaluated for measuring prevalence of active TB. These new methods will provide information about the best way to measure TB incidence and prevalence, ultimately informing estimates of global TB burden.

VirTUAL
treatment of TB/HIV co-morbidity

The VirTUAL (Vulnerable population tuberculosis antiretroviral) project, led by Dr Catriona Waitt (University of Liverpool, UK), aims to generate evidence to inform the clinical management of TB patients on second-line antiretroviral therapy in groups such as pregnant women, children and adolescents. The project was awarded a €2 million grant from EDCTP in December 2017 and started in February 2018.

Current WHO-recommended second-line antiretroviral therapy contains boosted protease inhibitors (bPIs). Significant drug–drug interactions between the key anti-TB drug rifampicin and bPIs preclude the use of bPIs at standard doses. A lack of data on dosing of bPI regimens in patients requiring TB treatment is a significant barrier to their use in low-resource settings.

VirTUAL will integrate computational approaches for predicting drug–drug interactions with clinical studies to determine exposure variability in vulnerable populations. The objectives of the project are: a) to improve current understanding of drug disposition in complex clinical scenarios, and b) provide a flexible platform for identifying clinical strategies across multiple disease areas.

Pharmacokinetic models will be developed to characterise interactions between bPIs and rifampicin. Combined with clinical data from dose escalation studies in Uganda, the models will be used to identify suitable bPI dosing strategies for vulnerable populations.


TABLETS

5.3

Malaria

In 2016, according to the WHO World malaria report 2017, there were an estimated 216 million cases of malaria and 445,000 deaths, more than 90% of them in Africa. Some 15 countries – 14 of them in sub-Saharan Africa – account for 80% of the global malaria disease burden. Current treatment of malaria is highly dependent on artemisinin-based combination therapies (ACT).

Recent reports of drug resistance highlight the need to develop new antimalarial drugs, including non-ACT-based treatments that can be used in combination with other antimalarials or that can produce a single, radical cure. In addition, there is a need to develop drugs for pregnant women and children, co-infected individuals, and drugs to support malaria elimination.

By end of 2017, EDCTP2 had committed more than €32 million on 14 malaria research projects addressing malaria epidemiology, prevention and implementation research. These include research on novel drugs and drug combinations, and the assessment of the impact of current medicinal interventions. Importantly, the majority of the supported studies focus on high-risk populations such as children and pregnant women.

EDCTP portfolio: malaria

Collaborative clinical trials and clinical studies	Career Development Fellowships	Senior Fellowships	Evidence-informed policy
IMPROVE *United Kingdom*	Dr Kingsley Badu *Zambia*	Dr Peter Olupot-Olupot *Uganda*	IMPP-ACT *United Kingdom*
IMPROVE-2* *United Kingdom*	Dr Atinuke Olaleye *Ghana*	Professor Faith Osier *Kenya*	IMPACT *United Kingdom*
MAMAH *Spain*	Dr Richard Mwaiswelo *Tanzania*	Prof Dr John Lusingu *Tanzania*	
MMVC *United Kingdom*	Dr Jean-Bertin Bukasa Kabuya *Zambia*	Dr Francis Ndungu *Kenya*	

Intervention/study topic

Drugs | *Diagnostics* | *Vaccines* | *Product-focused implementation research* | *Behavioral and social sciences* | *Other*

Reducing malaria in pregnancy

Pregnant women are particularly vulnerable to infection by Plasmodium falciparum. Because of this, the WHO recommends intermittent preventive therapy in pregnancy (IPTp) with sulphadoxine-pyrimethamine (SP) for pregnant women in malaria-endemic regions. However, SP has adverse effects in HIV-infected women taking cotrimoxazole, a prophylactic antibiotic given in combination with antiretroviral drugs. Therefore, alternative drugs are urgently needed to prevent malaria in this vulnerable group, particularly as an estimated 12 million HIV-infected women live in malaria-endemic regions.

The **MAMAH** project, coordinated by Professor Clara Menéndez Santos (Instituto de Salud Global, Barcelona, Spain), will evaluate the safety and efficacy of dihydroartemisinin-piperaquine (DP) for IPTp in HIV-infected women who are taking cotrimoxazole and antiretroviral drugs daily. The study is a randomised double-blind placebo-controlled superiority clinical trial and conducted in Gabon and Mozambique. The project received an EDCTP grant of almost €3 million.

Targeting malaria at multiple stages

An ideal malaria vaccine would target all stages of the parasite's life-cycle, but no such vaccine has reached clinical trials in Africa. The **MMVC** (Multi-stage Malaria Vaccine Consortium) project, coordinated by Professor Adrian Hill (University of Oxford, UK), aims to progress a promising multi-stage vaccine towards a large phase IIb efficacy trial in young children (5-9 months old) in West and East Africa. MVVC received an EDCTP grant of €15 million.

All four components of the vaccine (targeting sporozoite, liver, blood and sexual stages) have strong validation. The project will implement a series of lead-in trials in 2018-2020 building towards a phase IIb efficacy trial from late 2020 to 2023. First, efficacy of the vaccine and selected components will be evaluated in controlled human malaria infection trials, using new capacity in Kenya and Tanzania. Age de-escalation trials will then be conducted, documenting safety and immunogenicity. This will lead to a phase IIb trial in infants at sites of differing malaria endemicity in Kenya, Sierra Leone and Burkina Faso.

In parallel, new trial capacity will be developed to test the ability of the combination vaccine and/or its transmission-blocking component to prevent human-to-mosquito transmission in African adults, in light of the potential use of the combination vaccine in elimination campaigns.

Photo:
PfSPZ Challenge study, Kenya

> "Alternative drugs are urgently needed to prevent malaria in HIV-infected pregnant women."
>
> *Prof. Clara Menéndez Santos*
> *Spain*

5.4

Neglected infectious diseases

Neglected infectious diseases are a diverse group of diseases that affect an estimated 1.2 billion people worldwide. They disproportionately affect the world's poor, causing significant mortality and morbidity. Global investment in research and development of new products is limited and there is an urgent need to develop new or improved products and to optimise the use of existing products to achieve disease elimination. Neglected infectious diseases are widespread in sub-Saharan Africa and an estimated 500 million people are affected by the most common infections, including soil-transmitted helminths, schistosomiasis, lymphatic filariasis, trachoma and onchocerciasis.

Seventeen of the WHO list of neglected tropical diseases were added to the scope the EDCTP2 programme in 2014. By the end of 2017, six projects had been funded with a total value of €23.4 million. Large projects have been funded in four diseases – human African trypanosomiasis, schistosomiasis, cysticercosis/ taeniasis and leishmaniasis – while fellowships have been awarded for research projects on schistosomiasis, Buruli ulcer, leishmaniasis and lymphatic filariasis. Two calls for proposals were launched in 2017 that will expand the neglected infectious diseases portfolio: at least six more projects will be funded in 2018 with an estimated value of €22.7 million.

Neglected infectious diseases

	Collaborative clinical trials and clinical studies		Career Development of researchers	
Human African trypanosomiasis	DiTECT-HAT *France*			
Schistosomiasis	FREEBILY *Netherlands*	PZQ4PSAC *Netherlands*	Dr Humphrey Kariuki Njaanake *Kenya*	Dr Justin Komguep Nono *Cameroon*
Leishmaniasis	Afri-KA-DIA *Switzerland*	PREV_PKDL *Germany*	Dr Dawit Wolday *Ethiopia*	
Taeniasis/ (neuro) cysticercosis	SOLID *Belgium*			
Lymphatic filariasis			Dr Dziedzom de Souza *Ghana*	Dr Alexander Kwarteng *Ghana*
Buruli ulcer			Dr Michael Frimpong *Ghana*	Dr Richard Phillips *Ghana*

Intervention

Drugs | *Diagnostics* | *Vaccines* | *Other*

Schistosomiasis

Schistosomiasis is a common parasitic disease in sub-Saharan Africa that can cause anaemia, malnutrition and impaired childhood development. Sub-Saharan Africa accounts for 93% of the estimated 207 million cases of schistosomiasis. Two major types of schistosomiasis exist in sub-Saharan Africa, urogenital and intestinal schistosomiasis, caused by *Schistosoma haematobium* and *S. mansoni*, respectively. Control strategies are mainly focused on mass drug administration programmes, with the drug praziquantel administered to school-aged children.

EDCTP awarded funding to two clinical research projects in 2017: the PZQ4PSAC project focused on paediatric drug development, and the FREEBILY project, which is examining improved diagnostics and test-and-treat strategies. Schistosomiasis research is also the focus of two career development fellowships.

The **PZQ4PSAC** project, coordinated by Dr Remco de Vrueh (Lygature, The Netherlands), was awarded an EDCTP grant of €2.0 million in 2017. The project supports a phase III clinical trial in Kenya and Cote d'Ivoire to assess the efficacy and safety of a single dose of orally disintegrating praziquantel tablets in pre-school children. A paediatric formulation for this group is needed as praziquantel tablets are difficult for young children to swallow and have a bitter taste. The Global Health Innovative Technology Fund (GHIT, Japan) and EDCTP are jointly funding this study with co-funding from consortium partners including industry partner Merck and not-for-profit partners.

The **FREEBILY** project, coordinated by Dr Govert van Dam (Leiden University Medical Centre, The Netherlands), aims to address a diagnostics gap for schistosomiasis. Diagnosis of schistosomiasis mainly relies upon microscopic egg detection in stool or urine, methods that are not very sensitive or scalable. Therefore, reliable easy-to-use non-invasive diagnostic tools are needed. The FREEBILY study will evaluate the sensitivity and specificity of antigen tests based on urine and serum samples to detect Schistosoma infections in pregnant women, mothers and young children. It will also assess their potential as tools for test-and-treat schistosomiasis control strategies. Clinical studies will be performed in Madagascar and Gabon, testing a point-of-care diagnostic (the circulating cathodic antigen test) and a laboratory-based lateral flow test (circulating anodic antigen). In addition, the consortium will develop a duplex test combining both antigens in one point-of-care test. FREEBILY was awarded a grant of €3.0 million in 2017.

Leishmaniasis

Leishmaniasis is a vector-borne parasitic disease, transmitted by sand flies. Globally it affects up to a million people, causing 20–30,000 deaths annually. Visceral leishmaniasis (VL), or kala-azar, is fatal if left untreated in 95% of cases. Currently, the highest burden of VL worldwide is in eastern Africa, with most of the cases observed in Ethiopia, Kenya, Somalia, Sudan, South Sudan and Uganda. In this region, there is a lack of appropriate diagnostic tools and treatment options, and no vaccines are available. Even after successful treatment, individuals may develop post-kala-azar dermal leishmaniasis, a severe and chronic condition. Many patients do not receive treatment, which probably contributes to the persistence of visceral leishmaniasis in communities.

In 2017, two clinical research projects on leishmaniasis were awarded funding: Afri-KA-DIA, focused on drugs for treatment, and PREV_PKLD, which will test a candidate vaccine to prevent post-kala-azar dermal leishmaniasis. One senior fellowship was awarded for research on leishmaniasis diagnostics.

The **Afri-KA-DIA** project, coordinated by Dr Jorge Alvar (Drugs for Neglected Diseases Initiative), aims to improve treatment and diagnosis of visceral leishmaniasis in East Africa. A phase III clinical trial is being conducted to assess a new treatment regimen, oral miltefosine and paromomycin, which is more convenient and less toxic than currently used treatments. The trial involves six sites in Kenya, Uganda, Ethiopia and Sudan, and will also evaluate innovative diagnostic tools and biomarkers for managing visceral leishmaniasis cases in routine patient care.

The project was awarded an EDCTP grant of €5.6 million in 2017. Total project funding amounts to €11.6 million, with additional support being provided by the Amsterdam Medical Centre and Nederlands Kanker Instituut (both in The Netherlands), Instituto de Salud Carlos III (Spain), DNDi and FIND (Switzerland), and the London School of Hygiene and Tropical Medicine (UK).

The **PREV_PKDL** consortium, coordinated by Dr Odile Leroy (European Vaccine Initiative, Germany), was awarded an EDCTP grant of €8 million to test the candidate vaccine ChAd63-KH for the prevention of post-kala-azar dermal leishmaniasis (PKDL). In Sudan, nearly a third of cured visceral leishmaniasis patients develop PKDL within 12 months. Two trials with clinically cured visceral leishmaniasis patients will be conducted in Sudan:

- A dose escalation, age de-escalation phase IIa safety study; and
- A phase IIb safety and efficacy study. In addition, consortium members will analyse immune responses in patient cohorts recruited in Ethiopia, Kenya, Sudan and Uganda, to provide insights into the natural history of disease and biomarkers of PKDL development. The activities will also build the capacity for immunology research in the region.

Photo:
TB IRIS study volunteers, South Africa

5.5

Diarrhoeal diseases and lower respiratory tract infections

Diarrhoeal diseases

Diarrhoeal diseases kill more than 500,000 children under the age of five every year[4]; more than 300,000 of these deaths occur in sub-Saharan Africa. Therefore, diarrhoeal diseases were added to the scope of EDCTP2 To the end of 2017, two studies have been funded, including a €0.5 million trial led by Dr Roma Chilengi (Centre for Infectious Disease Research, Zambia) which is examining whether a third dose of rotavirus vaccine can compensate for the reduced response to the vaccine commonly seen in low-income settings.

4.See WHO factsheet May 2017 on diarrhoeal disease: www.who.int/news-room/fact-sheets/detail/diarrhoeal-disease

Lower respiratory tract infections

Globally, lower respiratory tract infections are the leading infectious cause of death, accounting for 2.7 million deaths a year, including 700,000 children under five (340,000 of them in sub-Saharan Africa). Lower respiratory tract infections are another new area of EDCTP interest, and two studies have been funded up to the end of 2017. These include a €3.4 million trial led from Imperial College London and funded in partnership with the UK MRC and the Wellcome Trust, which is evaluating different approaches for the delivery of oxygen therapy to children with pneumonia and whether supplemental feeding improves outcomes[5].

5. The Lancet Infectious diseases, 23 August 2017

Diarrhoeal diseases and lower respiratory tract infections

Collaborative clinical trials and clinical studies	Career Development Fellowships	Senior Fellowships
COAST-Nutrition *United Kingdom*	Dr Caroline Cleopatra Chisenga *Zambia*	Dr Roma Chilengi *Zambia*
	Dr Michael Owusu *Ghana*	

Intervention		
Drugs	*Vaccines*	*Other*
Disease		
Diarrhoeal diseases	*Lower respiratory tract infections*	

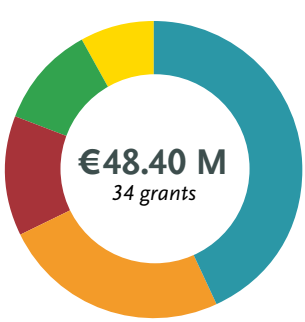
6

Clinical research capacities in sub-Saharan Africa

Projects to benefit underserved populations in Africa cannot be successfully executed without well-trained and equipped research teams making use of efficient clinical trial processes.

EDCTP investment in this area focuses on creating and developing African capacity to design and conduct clinical research on poverty-related infectious diseases. In addition, EDCTP aims to nurture an enabling and sustainable environment for clinical research by strengthening systems for research governance in sub-Saharan Africa, including legal frameworks, research ethics committees and regulatory bodies. This ensures that countries can host clinical studies that are according to international standards and respect local regulations.

Capacity development: enabling the environment for conducting clinical research



- Health system preparedness for outbreak response, *8 grants*
  €20.94 M
- Networks of Excellence, *4 grants*
  €11.98 M
- Pharmacovigillance, *3 grants*
  €0.5 M
- Evidence-informed policy, *6 grants*
  €0.09 M
- Ethics and regulatory framework, *13 grants*
  €3.83 M

Note: *These figures include both estimated and actual value of grants.*

6.1 Research ethics

By the end of 2017, 13 grants with a total value of €3.83 million had been awarded to enable 10 sub-Saharan African countries to establish and develop robust national medicines regulatory systems and capacity for ethical review of research, medicinal products and technologies for use in humans.

West Africa

Strengthening ethics research review

In the past 10 years, there has been a great increase in the number of clinical trials in West Africa. The recent Ebola epidemic and the consequent urgent need for clinical trials brought out challenges in ethical oversight and protection of volunteers in West Africa. Strengthening ethics committees is crucial to provide better protection for study volunteers and patients.

Mali, Ghana and Guinea have common challenges related to the training of members of ethics committees, their governance and sustainability. One of the challenges is lack of formal collaboration between national ethics committees and institutional review boards within and between these countries. Multicentre clinical trials and emergency research during epidemic situations, such as Ebola outbreaks emphasise the need for coordination and the development of a regional ethics network.

The **REECAO** project (Renforcement de l'Éthique des Essais Cliniques en Afrique de l'Ouest [Strengthening clinical research ethics review in West Africa]). Initially, it was led by Professor Ogobara Doumbo (Ministry of Health and Public Hygiene, Mali) who sadly passed away on 9 June 2018. The project received an EDCTP grant of €299,881 to reinforce ethics review of clinical trials in Ghana, Guinea and Mali through establishing joint ethical oversight, involving European and African partners.

Liberia

Strengthening capacity for clinical research during outbreaks

Since 2003, Liberia has been recovering from civil conflict and rebuilding its health sector. The Liberia Medicines and Health Products Regulatory Authority (LMHRA) was established as the national regulatory authority in 2010. LMHRA is responsible for authorising the marketing of medicines and healthcare products as well as for other regulatory activities. The response to the Ebola outbreak in Liberia led to an increasing number of requests for approval of clinical trials for treatment and diagnosis.

In 2016, EDCTP awarded a €300,000 grant to the **Lib-Regul-Trials** project. Led by Dr David Sumo of the LHMRA, it aims to develop the capacity of LMHRA to exercise its mandate as a regulatory body for clinical research in Liberia and to ensure that LMHRA staff have the needed expertise.

"The lack of a regulatory framework and regulations to guide the conduct of clinical trials in Liberia was one of the main difficulties," explains Dr David Sumo of the LHMRA. "The only guideline available was one developed by a small team at LMHRA with limited expertise in clinical trials. Consequently, important aspects of clinical trial guidelines were omitted. Additionally, LMHRA had limited human resources and no platforms to review trial protocols, effectively and appropriately monitor trial sites, or understand and analyse clinical trials outcomes, including serious adverse events.

The project helps us to develop a regulatory framework and other regulations for the conduct of clinical trials in Liberia. The LMHRA is also developing electronic platforms for the receipt, review, and approval of clinical trial protocols, and for monitoring and auditing the enrolment of clinical trial participants and sites." Another important aspect of this project is ensuring that staff at LMHRA has the necessary expertise to conduct regulatory activities.

The **IGORCARDIA** project was designed to further strengthen the LMHRA regulatory mandate and capacity to regulate research on diagnostics for infectious diseases. The project, awarded €299,910 in 2017, is coordinated by Dr Alfredo Mayor Aparicio (Barcelona Institute for Global Health, Spain), with support from the Juan Ciudad Foundation and Saint Joseph's Catholic Hospital in Monrovia, Liberia. The objectives are to strengthen LMHRA's capacity to: regulate the use of diagnostics in research; supervise diagnostics research; and establish inter-agency collaboration.

The IGORCARDIA project draws on the achievements of the **SELeCT** project. In 2016, this project, also led by Dr Alfredo Mayor Aparicio, received a grant of €250,000 to strengthen the institutional capacity at St Joseph's Catholic Hospital to conduct clinical research between and during infectious disease outbreaks. Through this project, completed in 2017, a range of activities were undertaken, from training, research, and laboratory upgrading to community engagement.

6.2 Research preparedness for new epidemics

The Ebola outbreak in West Africa has catalysed activities focused on delivering effective therapeutic, diagnostic and preventive interventions. The testing and implementation of these interventions requires functioning health research infrastructures and increased research capacity in the affected countries, as well as the willingness of affected populations to engage in clinical research activities. A call for proposals was launched in July 2016 to address these capacity challenges.

Six institutions in Africa and Europe received funding to strengthen capacity to conduct high-quality health research during health emergencies and/or epidemic outbreaks. These projects were supported under the 2015 joint call for proposals from EDCTP, TDR (the WHO's Special Programme for Research and Training in Tropical Diseases), and the UK MRC to increase capacity for research during Ebola outbreaks in sub-Saharan Africa. These projects received a total investment of €1.5 million.

Northern Uganda

Capacity to address infectious disease outbreaks

The **ENDORSE** project aimed to develop and transfer knowledge in northern Uganda on serious infectious disease outbreaks by training health care workers, where possible using a train-the-trainers model. Clinical and laboratory personnel was trained to detect and respond to infectious disease epidemics. The project also improved personal protection and biosafety and promoted coordination and networking among different.

healthcare institutions in the region. Moreover, it supported the standardisation of practices and procedures for research and clinical work. Finally, ENDORSE engaged successfully with politicians and state administrators.

Sierra Leone

Building health system capacity

Health research capacity in Sierra Leone is currently weak and there is a need for national multidisciplinary health research. In 2016, the **ReCAP-SL** project received an EDCTP grant of €250,000 to establish a research centre within the College of Medicine and Allied Health Sciences (COMAHS) that can serve as a research coordinating centre and lead on health systems research and capacity strengthening in Sierra Leone. The objective is to deliver reliable, relevant evidence for effective policy-making.

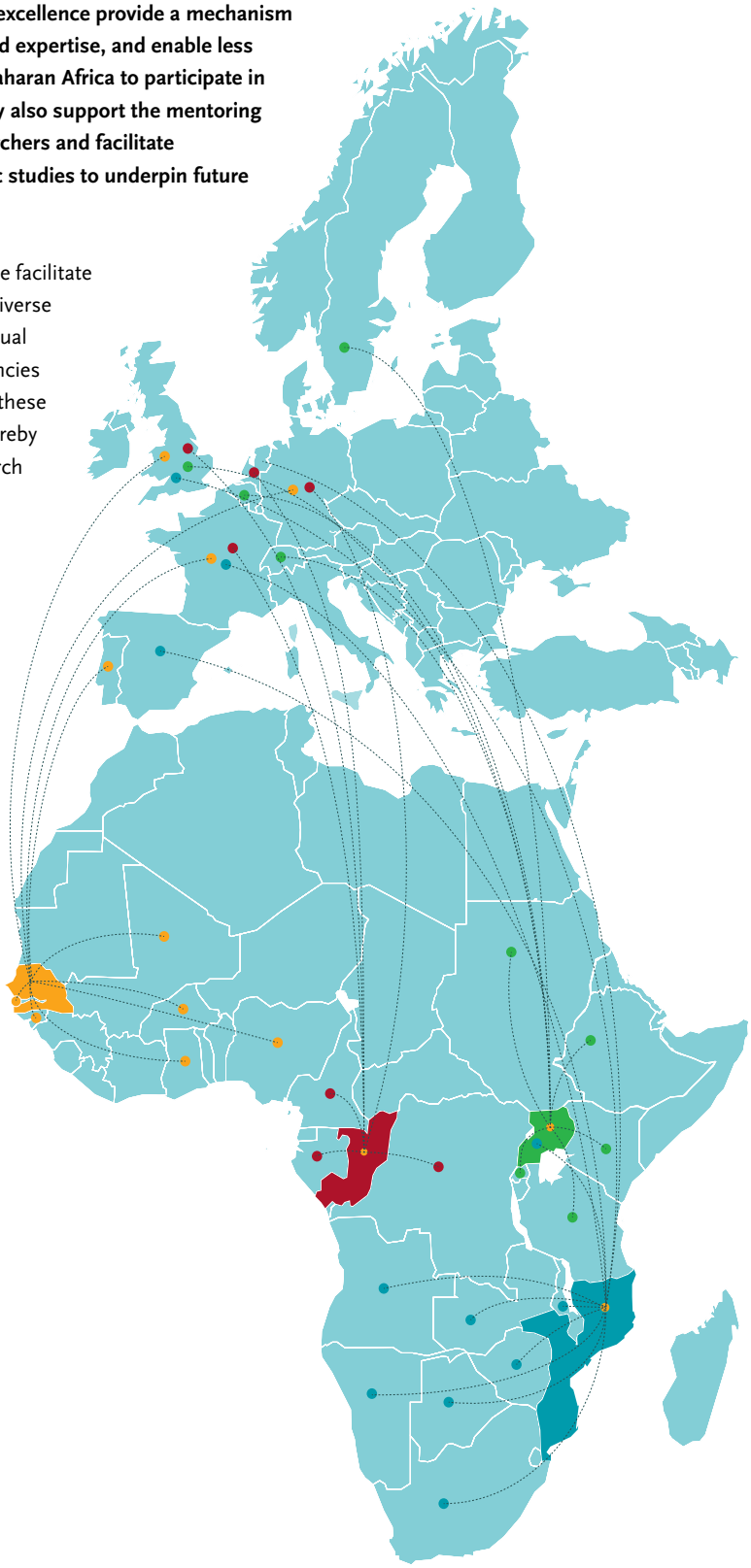
The project is led by Dr Haja Wurie (University of Sierra Leone) and implemented by COMAHS in Freetown, Sierra Leone. It is being carried out in partnership with researchers from the Liverpool School of Tropical Medicine, UK. The project aims to strengthen COMAHS's capacity for multidisciplinary research, and to enable its research centre to ensure coordination between researchers, health practitioners and policy-makers. Four health research fellows will be appointed to conduct research and support the Master of Public Health course offered at COMAHS. They will help to develop modules in health systems research and clinical research tailored to the local context and focused on Ebola, emergency response and responsive health systems. Moreover, ReCAP-SL will support the capacity of the National Ethics Committee to respond to the increased demand for ethical review of multidisciplinary research proposals.

Photo:
DREAMM project staff, Malawi

6.3 Networks of Excellence

The EDCTP regional networks of excellence provide a mechanism to share resources, knowledge and expertise, and enable less experienced institutions in sub-Saharan Africa to participate in multicentre clinical research. They also support the mentoring and training of early-career researchers and facilitate epidemiological and demographic studies to underpin future clinical trials.

The regional networks of excellence facilitate regional collaboration by uniting diverse institutions that bring their individual strengths in skills-based competencies and infrastructure and in this way these institutions learn and develop, thereby raising the quality of clinical research and practice in sub-Saharan Africa. These networks host four ISO15189 accredited laboratories. One of these laboratories is part of the Africa CDC Regional Integrated Surveillance and Laboratory Networks (RISLNET).



Central Africa

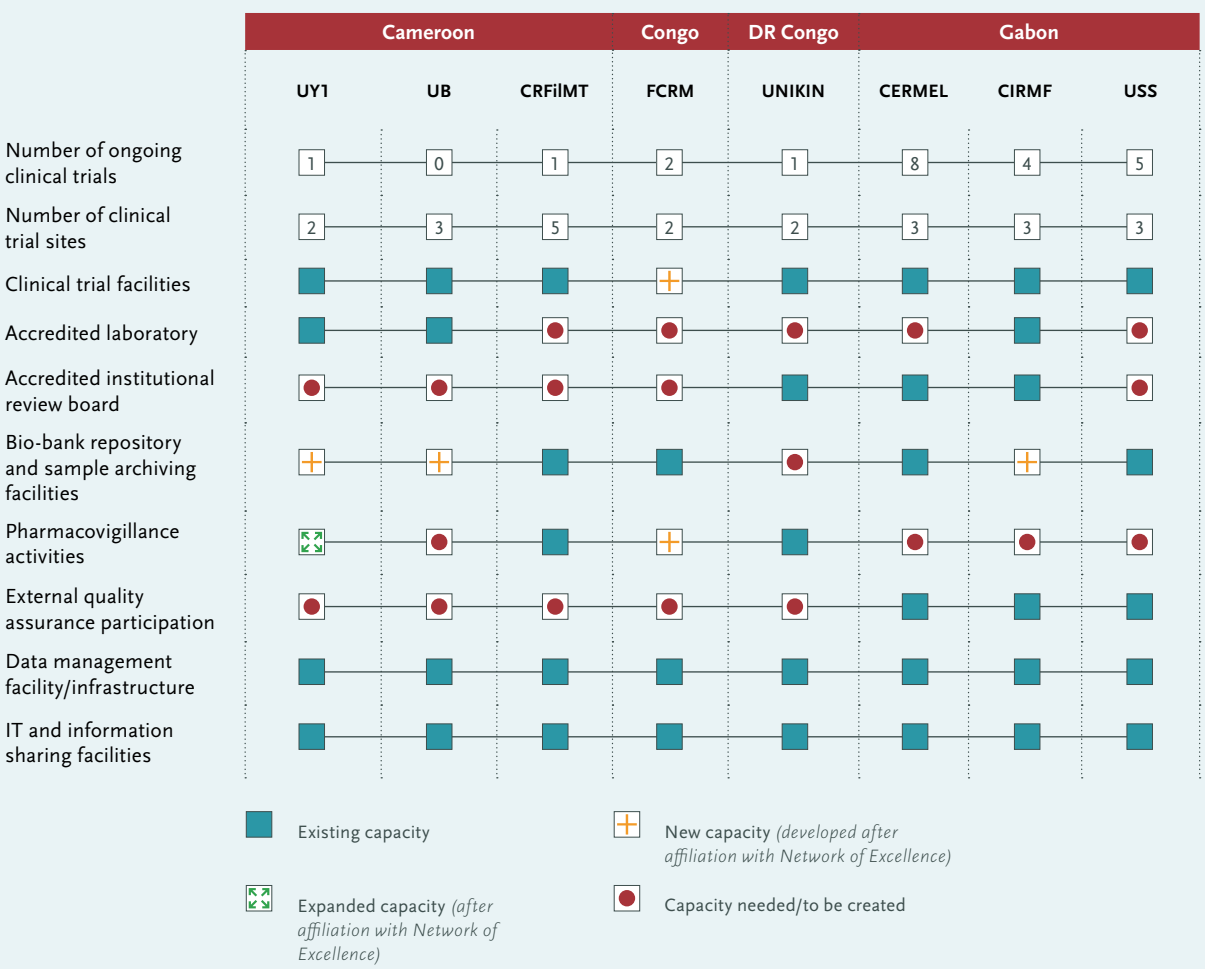
CANTAM2 Venture

The Central African Network on TB, HIV and Malaria (CANTAM) was established in 2008 under the first EDCTP programme. In July 2017, it received a grant to, among other things, include NIDs in its scope. Led by Professor Francine Ntoumi (Congo), the network expanded to include representatives from three to four central African countries, one Southern African country and three European partners. The new African countries that joined CANTAM2 Venture are DRC and Zambia.

Alongside its capacity-building and networking activities, it is involved in projects on epidemiological studies of adverse drug reactions and antimicrobial resistance, antimalarial pharmacovigilance, host-directed therapies for TB, and parasitic worm infections.
In response to the Ebola outbreak, the network will develop a flexible, ready-to-apply methodological framework, including regulatory and ethical aspects. The aim of the framework is to enable the immediate implementation of trials and other clinical studies in the early phase of any infectious outbreak that threatens regional health security.

www.cantam.org

CANTAM2 Venture: Capacities of African institutions



Eastern Africa

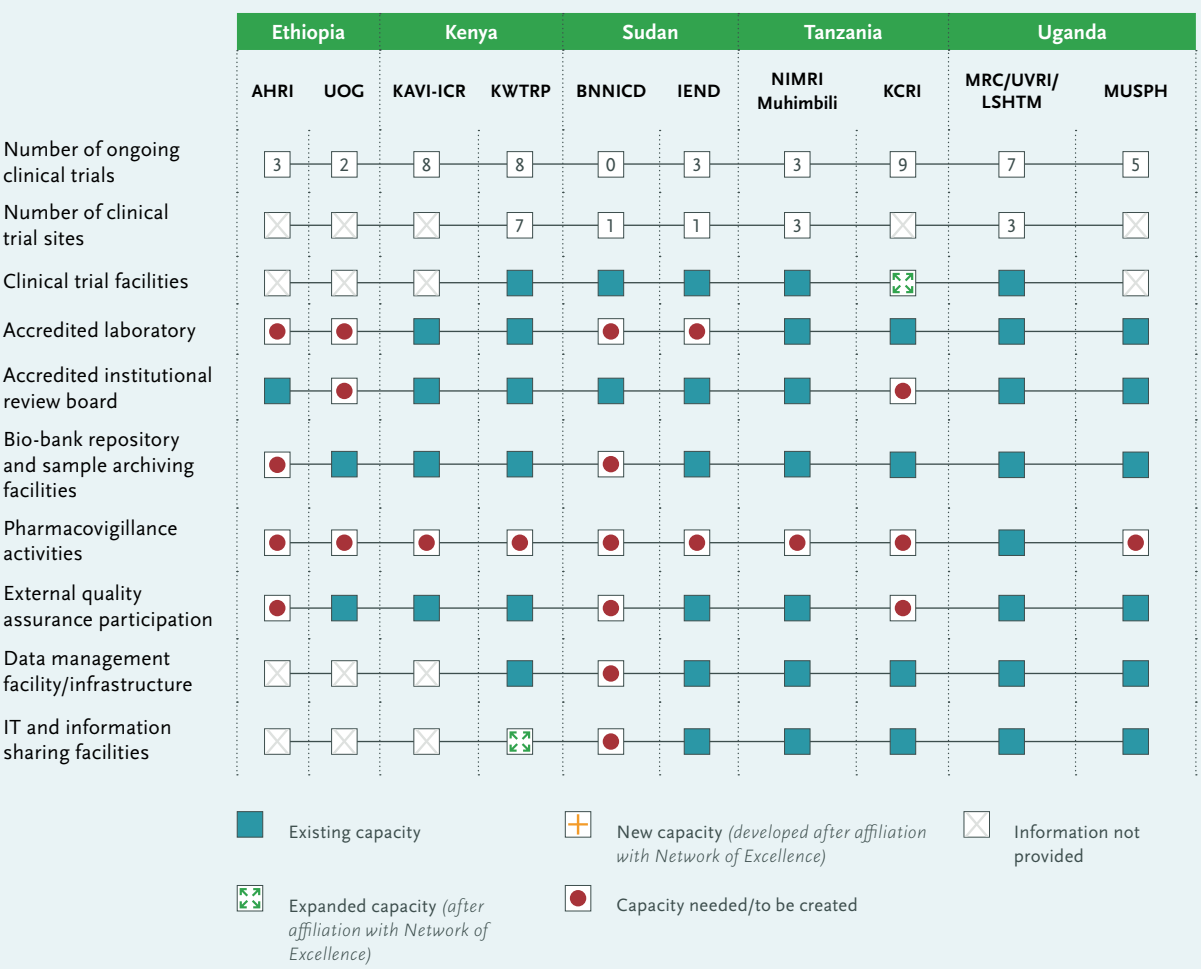
EACCR2

The East African Consortium for Clinical Research was set up in 2009. In September 2017, the network received a grant under EDCTP2. Led by Professor Pontiano Kaleebu (Uganda), it includes representatives from six East African countries and four European partners. Alongside its capacity building and networking activities, it is involved in projects on retention of HIV-infected mothers and babies in HIV care, HIV pharmacovigilance in young people, epidemiological studies of malaria, and trials of ACT efficacy and resistance.

The EACCR2 has expanded its work to include NIDs; the collaboration 'node' will manage and strengthen the needed facilities to conduct clinical trials on neglected, emerging and re-emerging infectious diseases that burden the region. To contribute to clinical research capacity, the network developed an e-learning centre that hosts short courses covering every step, process, and issue that need to be understood, to conduct a high quality clinical study. Every course is written to be globally applicable and is peer reviewed and regularly updated.

www.cantam.org

EACCR2: Capacities of African institutions



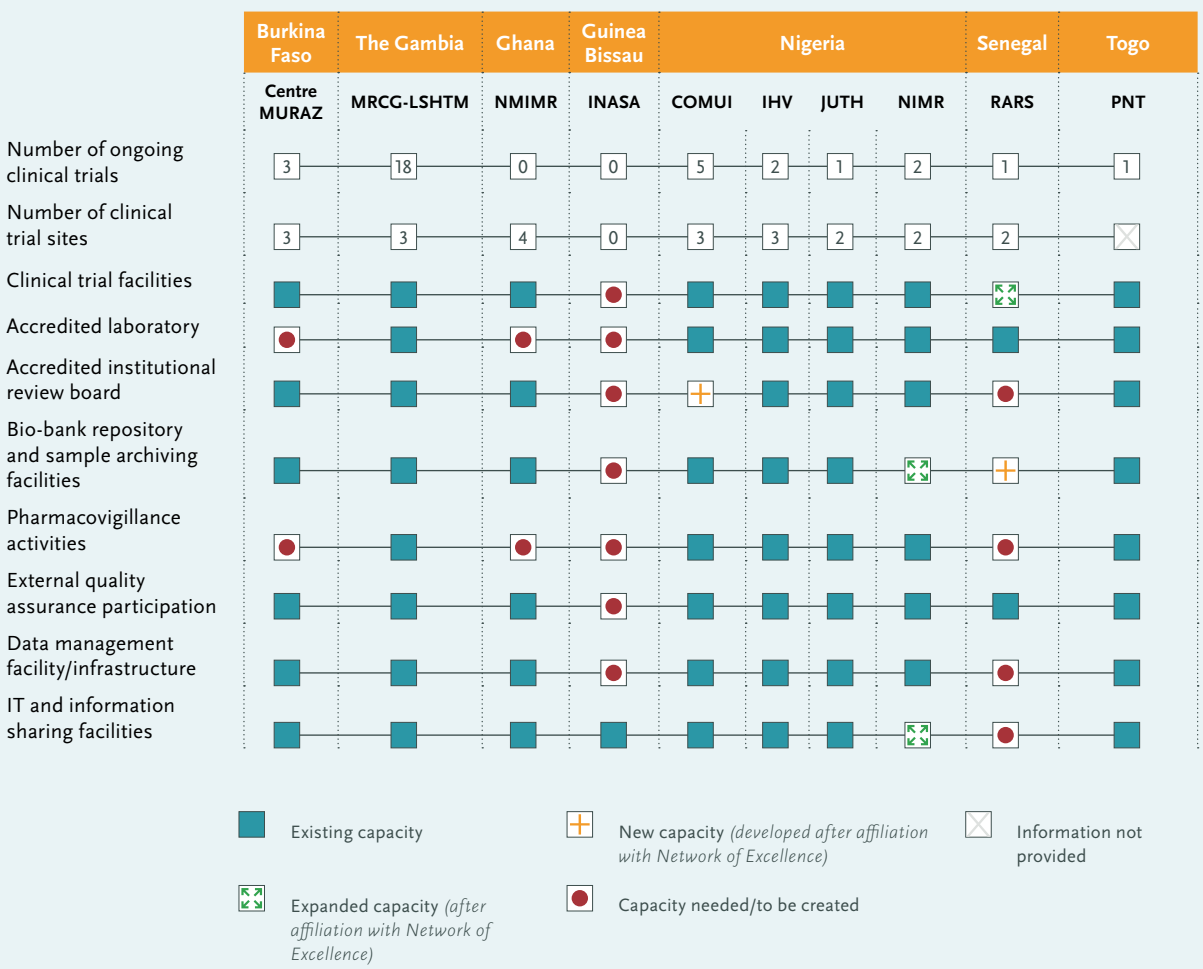
Western Africa

WANETAM

The West African Network for TB, AIDS and Malaria (WANETAM) was established in 2009. In October 2017 it received new EDCTP funding. Led by Professor Souleymane Mboup (Senegal), the network has expanded and includes representatives from seven to ten West African countries and four European partners. It is building capacity and collecting baseline data to facilitate trials on TB diagnosis and treatment, malaria prevention and treatment, HIV drug resistance, and clinical surveillance, diagnosis and preventative management of neglected infectious diseases and emerging infections. The network aims to undertake actions involving governments and sub-regional institutions and diversify its funding to support network activities and strengthen its sustainability.

www.wanetam.com

WANETAM: Capacities of African institutions

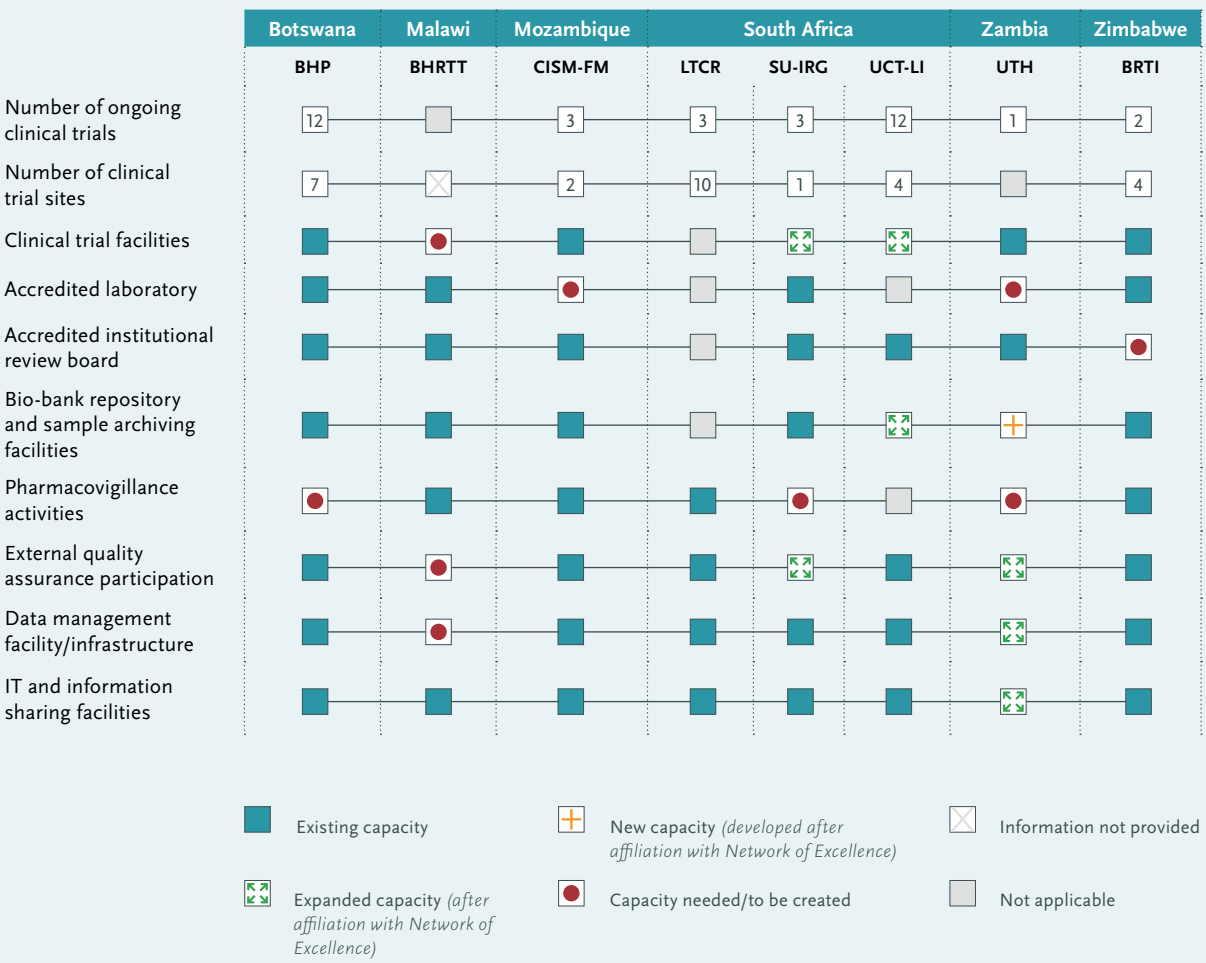


Southern Africa

TESA II

The Trials of Excellence in Southern Africa (TESA) network was set up in 2009 under the first EDCTP programme. EDCTP awarded a new grant in September 2017. Led by Professor Eusebio Macete (Mozambique), the network includes representatives from eight southern African countries, one East African country and four European partners. Alongside its capacity development and networking activities, it invests in the establishment of an accredited referral data management centre and three referral laboratories in different regions within Southern Africa to serve as a training platform for other members. It also develops activities for communication and policy dialogue.

TESA II: Capacities of African institutions



Institutions mentioned in the tables

Cantam2 Venture

UY1	University of Yaounde 1, Cameroon
UB	University of Buea, Cameroon
CRFilMT	Neglected Tropical Diseases Research Centre, Yaounde, Cameroon
FCRM	Congolese Foundation for Medical Research, Brazzaville, Republic of Congo
UNIKIN	University of Kinshasa, Kinshasa, Democratic Republic of Congo
CERMEL	Centre of Medical Research Lambarene, Lambarene, Gabon
CIRMF	International Centre for Medical Research of Franceville, Franceville, Gabon
USSA	University of Health Sciences of Gabon, Libreville, Gabon

EACRR2

AHRI	Armauer Hansen Research Institute, Addis Ababa, Ethiopia
UOG	University of Gondar, Gondar, Ethiopia
KAVI-ICR	KAVI- Institute of Clinical Research, Nairobi, Kenya
KWTRP	KEMRI-Wellcome Trust Research Programme, Kilifi, Kenya
BNNICD	Blue Nile national Institute for Communicable Diseases, Gezira, Sudan
IEND	Institute of Endemic Diseases, Khartoum, Sudan
NIMRI Muhimbili	National Institute for Medical Research, Muhimbili, Tanziania
KCRI	Kilimanjaro Clinical Research Institute, Kilimanjaro, Tanzania
MRC/UVRI/LSHTM	Medical Research Council UK/Uganda Virus Research Institute and London School of Hygiene & Tropical Medicine Uganda Research Unit, Entebbe, Uganda
MUSPH	Makerere University School of Public Health, Kampala, Uganda

WANETAM

Centre Muraz	Centre Muraz, Bobo-Dioulasso, Burkina faso
MRCG-LSHTM	Medical Research Council Unit The Gambia – London School of Hygiene and Tropical Medicine, Banjul, The Gambia
NMIMR	Noguchi Memorial Institute for Medical Research, Accra, Ghana
INASA	National Institute of Public Health of Guinea-Bissau, Bissau, Guinea-Bissau
COMUI	College of Medicine, University of Ibadan, Ibadan, Nigeria
IHV	Institute of Human Virology, Abuja, Nigeria
JUTH	Jos University Teaching Hospital, Jos, Nigeria
NIMR	Nigerian Institute of Medical Research, Yaba, Nigeria
RARS	African AIDS Research Network, Dakar, Senegal
PNT	National Plan for the Fight against Tuberculosis, Togo

TESA II

BHP	Botswana-Harvard AIDS Institute Partnership (BHP), Botswana
BHRTT	Blantyre Health Research and Training Trust, Blantyre, Malawi
CISM-FM	Manhiça Health Research Centre- Manhiça Foundation, Maputo, Mozambique
LCTR	LT Clinical Research (Pty) Ltd., Pretoria, South Africa
SU-IRG	Stellenbosch University – Immunology Research Group, Stellenbosch, South Africa
UTH	University Teaching Hospital, Lusaka, Zambia
BRTI	Biomedical Research and Training Institute, Harare, Zimbabwe

Photo:
DREAMM project staff, Malawi

6.5

Developing research leadership

EDCTP is committed to supporting the careers of African researchers. Training of Master's and PhD students, as well as needs-driven short-term training, mentoring and exchange, is integrated into EDCTP-funded clinical research projects. An extensive fellowship programme provides career opportunities and support to African researchers to develop their research careers and become scientific leaders.

Dr Suzanne Staples
Ethiopia

By the end of 2017, the EDCTP2 programme had awarded 58 grants with a total value of €12.26 million to support African researchers at various stages of their careers. Fellows have been supported in 14 countries, for research in all EDCTP's disease areas.

Currently, the fellowship programme comprises four kinds of fellowships that reflect different career stages of clinical researchers.

EDCTP-AREF Preparatory Fellowships

These fellowships – a joint call with the Africa Research Excellence Fund (AREF), an independent charity, registered under the umbrella of the MRC UK – aims to bridge the critical gap early in the career path from research experience to research leadership. The fellowships are designed to enhance the competitiveness of up-and-coming postdoctoral African scientists and clinicians through 3–9-month placements at a host organisation. The scheme will improve the ability of fellows to design, plan and execute research projects, manage research relationships, and generate competitive research proposals.

Clinical Research and Product Development Fellowships

Through these fellowships, researchers have an opportunity to experience and develop skills in clinical trials research outside an academic or public-sector setting through 12-month placements in partner organisations that adhere to stringent regulatory standards. In addition to increasing the pool of talent and in turn increasing the impact on research and development capacity in sub-Saharan Africa, these fellowships will also contribute to stronger collaboration between research institutions, researchers and clinical staff, pharmaceutical companies, contract research organisations, clinical or academic affiliated research organisations and product development partnerships.

Since 2014, 10 Clinical Research and Product Development Fellows have been supported. Dr Suzanne Staples is a junior researcher based at THINK TB & HIV Investigative Network in South Africa. Through this fellowship, Dr Staples aims to gain experience in areas of tuberculosis research and clinical trials she has not yet been exposed to. This will enable her to improve her knowledge on how to conduct TB research of high quality in order to make a significant contribution to the field and to those affected by disease. Upon her return to her home organisation, Dr Staples aims to be involved in the training and capacity building of other aspiring researchers and research staff to inspire and enable them to conduct quality research as well as assist in setting up other world-class research facilities.

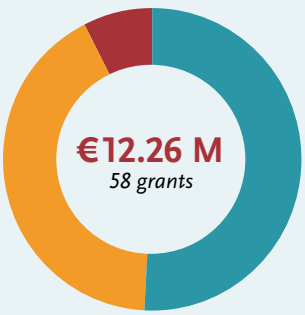
Fellowships by country

Fellowships by gender

38
Male fellows

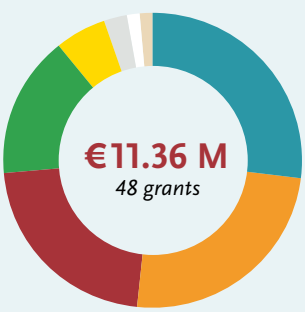
20
Female fellows

Fellowships by type



- **Senior Fellowships,** *13 grants*
  €6.25 M
- **Career Development Fellowships,** *35 grants*
  €5.1 M
- **EDCTP-TDR Clinical R&D Fellowships,** *10 grants*
  €0.91 M

Fellowships by disease



- **Tuberculosis,** *12 grants*
  €3.09 M
- **HIV & HIV-associated infections,** *15 grants*
  €2.8 M
- **Malaria,** *8 grants*
  €2.5 M
- **Neglected infectious diseases,** *7 grants*
  €1.74 M
- **Diarrhoeal diseases ,** *2 grants*
  €0.65 M
- **Multiple infections,** *2 grants*
  €0.29 M
- **Lower respiratory tract infections,** *1 grant*
  €0.15 M
- **Emerging diseases,** *1 grant*
  €0.14 M

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

Dr. Christine Sekaggya-Wiltshire
South Africa

Dr. Richard Phillips
Kenya

Career Development Fellowships

These fellowships enable junior to mid-career researchers to train and develop clinical research skills. Fellows are given the chance to conduct their own research under the guidance of a mentor and to develop into independent researchers able to manage their own research teams. Support for researchers in this phase of their careers will help to establish a critical mass of internationally recognised scientific leaders in sub-Saharan Africa.

A total of 21 Career Development Fellows from 14 different countries were funded under the 2016 call. Among these is **Dr Christine Sekaggya-Wiltshire**, a mid-career medical researcher based at the Infectious Diseases Institute (IDI), Uganda. The current WHO goal of ending the global TB epidemic by 2035 will not be achieved without considerable new advances in TB treatment. A growing body of evidence has indicated that the current dose of rifampicin (10mg/kg) is inadequate. Several studies have suggested that dose escalation (to 20-35mg/kg) is safe, and that higher doses (35mg/kg) may accelerate clearance of TB bacteria from the sputum of infected individuals. However, these studies have almost entirely been completed on HIV negative TB patients, or TB-HIV co-infected patients without severe immunosuppression who are not yet receiving antiretroviral therapy (ART).

Her project, **SAEFRIF**, aims to determine the effect of higher doses of rifampicin (20mg/kg and 35mg/kg) on efavirenz concentrations and the safety of TB regimens containing high doses of rifampicin in TB-HIV-infected patients also receiving efavirenz-based ART. The results of this study will inform Phase III clinical trials which can be performed in a larger group of TB-HIV co-infected patients to determine the utility of higher doses of rifampicin in this population.

Senior Fellowships

These fellowships support the development of African research leaders who are already established in their field. As well as producing high-impact scientific publications that inform policy and practice, fellows will be more competitive and capable of attracting funding and will have the capacity to mentor and train the next generation of researchers.

A total of eight Senior Fellows from 8 countries were funded under the 2016 call. Dr Richard Phillips a Senior Lecturer from Kwame Nkrumah University of Science and Technology (KNUST), Ghana, was awarded under this call. His project **BuruliNox** aims to determine the ability of the nitric oxide releasing (NOx) dressing combined with oral rifampicin and clarithromycin to shorten the time to complete healing of Buruli lesions by comparison with the same antibiotic therapy combined with standard dressings. Buruli ulcer is a neglected infectious disease caused by *Mycobacterium ulcerans* (Mu) which occurs mainly in rural parts of West Africa including Ghana. Treatment with antibiotics, rifampicin with either streptomycin or clarithromycin, has transformed management of Buruli ulcer but it is given for 8 weeks and the rate of healing is highly variable even in patients with seemingly similar lesions. BuruliNox proposes using a novel nitric oxide-generating wound dressing to rapidly kill Mu and enhance healing. If results are positive, treatment will be shortened and made more convenient and efficient for patients.

Photo:
DREAMM project staff, Tanzania

Partnership and cooperation

EDCTP High Representatives

The EDCTP High Representatives act as advocates for EDCTP aiming to increase its high-level visibility and to promote partnerships with both private and public organisations in the fight against poverty-related diseases.

Professor Marcel Tanner, the High Representative for Europe, represented EDCTP in several strategic initiatives in 2017, discussing collaboration with other funders, raising awareness of the EDCTP2 programme and increasing its visibility and impact. Activities included meetings with several pharmaceutical companies, major global health research funders such as the Bill & Melinda Gates Foundation, and key opinion leaders in the European Parliament, as well as participation in bilateral meetings with European EDCTP member countries.

The activities of **Dr Leonardo Simão**, the High Representative for Africa, focused on encouraging African governments to engage more fully with EDCTP or get involved in its activities. By the end of 2017, participation of sub-Saharan African countries in the EDCTP Association had increased from 14 to 16, Nigeria and Ethiopia having joined as full members and Angola having become an aspirant member of EDCTP.

Moreover, the EDCTP Association's strategy to enhance the adherence of African EDCTP member countries to their EDCTP commitments was fully implemented in 2017, targeting Cameroon, Gabon, Niger, Senegal, and Tanzania. The challenges were also discussed with key regional leaders, including the Commissioner of Social Affairs in the African Union and the Regional Director for the WHO Africa Region.

Photo:
From left to right: Dr Line Matthiessen *(Acting Director for Health Research in the Directorate General Research & Innovation at the European Commission)*, Dr Cissy Kityo *(Deputy Executive Director of the Joint Clinical Research Centre, Uganda)*, Dr Daniel Poulter *(MP of the UK All-Party Parliamentary Group on Global Health)*, Dr Leonardo Simão *(EDCTP High Representative for Africa)*, Professor Marcel Tanner *(EDCTP High Representative for Europe)*, and Sir Brian Greenwood *(Professor of Clinical Tropical Medicine at the London School of Hygiene & Tropical Medicine, United Kingdom)* during the panel discussion at the a meeting on EDCTP as an 'African-European partnership for global health benefit' at the Houses of Parliament in London, United Kingdom in February 2017.

7.1 Contributions of the EDCTP member countries

Research activities that are within the scope of the EDCTP programme but are funded and implemented independently from EDCTP by one or more EDCTP member countries, are incorporated into annual EDCTP work plans. These so-called Participating States' Initiated Activities (PSIAs) are important as they demonstrate the commitment of member countries to EDCTP and promote research collaboration in Europe and sub-Saharan Africa. Taken together, the PSIAs also generate an overview of national research activities on poverty-related diseases. This facilitates better coordination, alignment and, where appropriate, integration of relevant national programmes, one of the key objectives of EDCTP. Financially, the European PSIAs count towards the EDCTP funding matched by the European Union.

In 2017, three European EDCTP member countries (Austria, France, Germany) organised a workshop on PSIAs in Vienna, Austria, on 21-22 March 2017. Representatives from Austria, Denmark, France, Germany, Italy, Mozambique, Norway, Portugal, Spain, Switzerland and the UK attended the workshop, while the European Commission and EDCTP were also represented. The meeting discussed opportunities for cooperation between the EDCTP member countries and better alignment of national activities, including harmonisation of capacity-building activities and a joint Participating States funding scheme.

The contributions by European Participating States to the EDCTP programme reached a total of €435.9 million by the end of 2017. This amount includes a cash contribution of €12.5 million to EDCTP and €423.4 million in contributions through PSIAs. By the end of 2017, African member countries had contributed a total of €968,879 through PSIAs, including €70,891 in 2017.

Several EDCTP activities were jointly funded with European member countries, including Germany, Portugal, Sweden and the United Kingdom.

In 2017, EDCTP received funding from the German Federal Ministry of Education and Research (BMBF) in support of the following EDCTP projects: the African coalition for Epidemic Research, Response and Training (ALERRT); a clinical trial under the Pan-African Consortium for the Evaluation of Antituberculosis Antibiotics (PanACEAII), and a combination efficacy study in Africa of two HIV-1 candidate vaccine regimens with pre-exposure prophylaxis (PrEPVacc).

Portugal, through the Foundation for Science and Technology (FCT) co-funded the LusoAfro-BioEthics project, which aims at strengthening bioethics committees in the Lusophone African region.

A partnership with the Swedish International Development Cooperation Agency (Sida) also provided funding for ALERRT and PrEPVacc as well as five projects supporting to establish and develop capacities for ethical review of clinical research in sub-Saharan Africa.

The UK Joint Global Health Trials (JGHT) is a partnership between the UK Medical Research Council (UK MRC), the Department for International Development, the National Institute for Health Research and the Wellcome Trust. In 2017, EDCTP signed a co-funding agreement with JGHT to fund two clinical trials (the IMPROVE and AMBITION projects).

A partnership with the UK Department of Health brought in additional funding for two research areas:

- Clinical trials and operational research to optimise the use of products for poverty-related diseases in mothers, newborns, children and/or adolescents; and
- Research and clinical management of patients in infectious disease epidemics in sub-Saharan Africa.

7.2

Cooperation in Africa

EDCTP represented three of its members – the German Federal Ministry of Education and Research (BMBF), the UK MRC and the Swedish International Development Cooperation Agency – in a new partnership with WHO's Reginal Office for Africa and TDR, the Special Programme for Research and Training in Tropical Diseases. This new WHO AFRO/TDR/EDCTP partnership was formed in recognition of a common interest in strengthening the capacity for health research in African countries. The partnership has been implemented through a joint call for proposals on implementation research on infectious diseases of poverty.

In 2017, a growing interest in EDCTP Association membership among sub-Saharan African countries became noticeable as well as an increase in commitment of current African EDCTP member countries. Moreover, EDCTP strengthened its working relationships with key regional partners in the African health and development sectors, including WHO AFRO, the NEPAD Agency of the African Union, the African Network for Drugs and Innovation, the Alliance for Accelerating Excellence in Science in Africa, and regional economic communities. Through these relationships, EDCTP aims to align and coordinate its activities with other regional stakeholders, to leverage additional support to countries and institutions, and to secure synergies with the work of national governments, the African Union and WHO-AFRO.

In 2017, EDCTP signed a cooperative agreement with the NEPAD Agency to create a strategic partnership to promote greater coordination. The main objective is to accelerate capacity development for regulatory systems optimisation, technical expertise development in clinical trials authorisation, market authorisation and safety surveillance/pharmacovigilance for medicinal products, and ethics review activities in Africa. Ultimately, these efforts will help to shorten product development timelines (from clinical trials to market authorisation). Three recipients of EDCTP funding undertaking pharmacovigilance projects will work closely with NEPAD.

EDCTP continued to be involved in the work of African Vaccine Regulatory Forum (AVAREF), to the establishment of which it contributed funding in 2006 under the first programme. AVAREF is based in the WHO-AFRO office in Brazzaville, Congo. It provided ethics and regulatory oversight for the Ebola-affected countries (Sierra Leone, Liberia and Guinea) that had limited facilities to perform these functions during the 2014 Ebola outbreak. The EDCTP call for proposals specifically for Ebola-affected countries resulted in three projects in Sierra Leone and Liberia for enhancing preparedness for new epidemics. In November 2017, EDCTP participated in the regulatory conference of AVAREF and the 5th African 'Medicines Regulators' Conference in Accra, Ghana.

Photo:
DREAMM project staff members, Malawi

7.3

Private sector cooperation

EDCTP aims to develop partnerships with like-minded organisations, both private companies and non-profit organisations engaged in product development.

Two new partnerships brought in additional resources for clinical and product-focused implementation research on neglected infectious diseases. On 12 May 2017, the **Leprosy Research Initiative** and EDCTP signed a partnership agreement to boost leprosy-related research. The aim is to combine resources to support clinical and implementation research in sub-Saharan Africa on leprosy and neglected infectious diseases co-endemic with leprosy.

> "I am encouraged by our new partnerships towards funding of R&D for neglected infectious diseases."
>
> *Dr Michael Makanga*

The **Fundación Mundo Sano** and EDCTP signed a partnership agreement on 16 June 2017 to combine research funding for neglected infectious diseases. Mundo Sano will contribute to clinical research in soil-transmitted helminthiases. Two EDCTP calls in 2017 were dedicated to neglected infectious diseases, focusing on control and elimination through, firstly, clinical trials and, secondly, product-focused implementation research.

A joint call with the **Africa Research Excellence Fund** (AREF) was launched on 14 July 2017. The EDCTP-AREF Preparatory Fellowships aim to enhance the competitiveness of up-and-coming postdoctoral African scientists and clinicians aspiring to win international, regional or national fellowships or grant support, such as

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

EDCTP Career Development Fellowships. This is achieved through short-term placements at host organisations in EU Member States, in countries associated to Horizon 2020 or in sub-Saharan Africa.

On 3 November 2017, **GlaxoSmithKline** (GSK) and EDCTP launched a joint call for proposals for senior fellowships for research on non-communicable disease co-morbidities associated with poverty-related infectious diseases. The call is in response to the growing challenge of non-communicable diseases in Africa. EDCTP and GSK have committed equal funding to this initiative.

In December 2017, EDCTP and the **Global Health Innovative Technology Fund** (GHIT) established a partnership to support product development research. The partners' first action was to 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 tablet formulation to treat schistosomiasis in preschool-aged children. EDCTP will be contributing €1.99 million and GHIT €3.22 million to the study, which has a total project value of €12.10 million, including in-kind and cash contributions by all related parties.

Photo:
Dr Michael Makanga and Dr Silvia Gold (Fundación Mundo Sano) at the signature of the partnership agreement

Photo:
Members of the General Assembly of the EDCTP Association

EDCTP Governance

The EDCTP programme is governed by the **General Assembly** of the EDCTP Association, the legal structure for the second EDCTP programme (2014-2024).

The Association Board is entrusted by the General Assembly with the management of the Association and the oversight of the Secretariat.

The **Scientific Advisory Committee** is the principal advisory body to EDCTP.

The programme is implemented by the **Secretariat**.

8.1

General Assembly of the EDCTP Association

	GA representative		Deputy GA representative	
Angola (Aspirant member)	Dr Joana Filipa Machado de Morais Afonso	National Institute of Public Health	Dr Moisés Francisco	Angolan Health Research Centre
Austria	Dr Christiane Druml	Medical University of Vienna	Dr Hemma Bauer	Austrian Federal Ministry of Science and Research
Burkina Faso	Dr Sodiomon Bienvenu Sirima	Centre National de Recherche et de Formation sur le Paludisme (CNRFP)	Dr Ali Sie	Centre de Recherche en Santé de Nouma (CNRST)
Cameroon	Prof. Sinata Koulla Shiro	Ministry of Public Health	Prof. Anne-Cécile Zoung Kanyi Bissek	Ministry of Public Health
Congo	Prof. Deby Gassaye *succeeded by* Prof. Francine Ntoumi *Association Board member*	University Marien Ngouabi		
Denmark	Mr Mikkel Lyndrup	Statens Serum Institute		
Ethiopia	Dr Taye Tolera Balcha	Armauer Hansen Research Institute	Dr Tsigereda Kifle	Ethiopian Public Health Institute
Finland	Dr Jarmo Wahlfors	Academy of Finland	Dr Sirpa Nuotio	Academy of Finland
France	Prof. Jean-François Delfraissy *succeeded by* Prof. Yazdan Yazdanpanah *Vice-chair of the Board*	Agence Nationale de Recherches sur le Sida et les Hépatites Virales (ANRS); Institut de microbiologie et des maladies infectieuses (IMMI) Aviesan, Institut thématique multi-organismes: Immunologie, inflammation, infectiologie et microbiologie (Itmo I³M)	Dr Bernadette Murgue *succeeded by* Prof. Yves Lévy Mr Guillaume Fusai	Institut national de la santé et de la recherche médicale (INSERM) Institut national de la santé et de la recherche médicale (Inserm) Ministère de l'éducation nationale, de l'enseignement supérieur et de la recherche
Gabon	Dr Ayola Akim Adegnika	Centre de Recherches Médicales de Lambaréné	Prof. Jean-Bernard Lekana Douki	Université des Sciences de la Santé
The Gambia	Hon. Omar Sey *succeeded by* Hon. Saffie Lowe Ceesay	Ministry of Health and Social Welfare	Mr Ebrima Bah	Ministry of Health and Social Welfare
Germany	Dr Joachim Klein	Bundesministerium für Bildung und Forschung	Dr Detlef Böcking *Association Board member*	Deutsches Zentrum für Luft und Raumfahrt e.V
Ghana	*To be nominated*		Prof. Kwadwo Koram	University of Ghana
Ireland	Mr Vincent Maher	Irish Aid, Department of Foreign Affairs	Mr Patrick Empey	Irish Aid, Department of Foreign Affairs
Italy	Dr Stefano Vella *Association Board Vice-Chair* *succeeded by* Dr Pietro Alano	Istituto Superiore di Sanità (ISS)	Dr Benedetta Mattioli	ISS
Luxembourg	Dr Helena Burg	Fonds National de la Recherche		
Mali	Prof. Agrégé Abdoulaye Djimdé	University of Science, Techniques and Technology of Bamako	Prof. Mahamadou Aly Thera	University of Science, Techniques and Technology of Bamako
Mozambique	Dr Ilesh Jani	Ministry of Health	Dr Eusébio Macete *Association Board Vice-Chair*	Health Research Centre of Manhiça
Netherlands	Dr Gerrie Tuitert	NWO-WOTRO Science for Global Development	Ms Ella de Voogd *succeeded by* Mr Frank van de Looij	Ministry of Foreign Affairs
Niger	Mrs Sakina Habou Ocquet	Ministry of Public health	Ms Halima Boubacar Maïnassara	Centre de Recherche Médicale et Sanitaire CERMES
Nigeria	Dr Akin Oyemakinde	Federal Ministry of Health	Prof. Babatunde L. Salako	Nigerian Institute of Medical Research

	GA representative		Deputy GA representative	
Norway	Dr Sigurd Røtnes	Norwegian Directorate of Health	Dr Wenche Dageid *succeeded by* Mrs Åse-Marit Kristiansen	The Research Council of Norway
Portugal	Dr Ricardo Pereira	Foundation for Science and Technology (FCT)	Dr Ana Quartin	FCT
Senegal	Prof. Alioune Dieye	University Cheikh Anta Diop		
South Africa	Mr Mmboneni Muofhe	Department of Science and Technology (DST)	Mr Daan du Toit	DST
			Prof. Jeffrey Mphahlele	Vice President of Research, South African Medical Research Council
			Ms Vinny Pillay	DST
			Mr Toto Matshediso	DST
Spain	Dr Rafael De Andrés Medina *succeeded by* Dr Tomas López-Peña Ordoñez	Instituto de Salud Carlos III		
Sweden	Prof. Hannah Akuffo	Swedish International Development Agency (Sida)	Assoc. Prof. Maria Teresa Bejarano *succeeded by* Dr Eren Zink	Swedish International Development Cooperation Agency (Sida)
Switzerland (Aspirant member)	Dr Isabella Beretta	State Secretariat for Education and Research		
Tanzania			Dr Flora Tibazarwa *succeeded by* Dr Khadija Malima	COSTECH
Uganda	Dr Sam Okware	Uganda National Health Research Organisation (UNHRO)	Prof. Pontiano Kaleebu	Uganda Virus Research Institute
United Kingdom	Dr Mark Palmer *Association Board Chairperson*	Medical Research Council	Dr Morven Roberts	Medical Research Council
Zambia	Dr Elizabeth Chizema-Kawesha *succeeded by* Dr Francis Bwalya	Ministry of Health	Prof. Nkandu Luo	Minister of Higher Education, Research, Vocational Training, Science and Technology

8.2 Observers to the General Assembly

Observer	Representative		Deputy Representative	
European Commission-DG Research & Innovation	Dr Line Matthiessen	Head of Infectious Diseases and Public Health, Directorate-General (DG) for Research & Innovation	Dr Gianpietro van de Goor *succeeded by* Dr Denise O'Connor	Principal Policy Officer for International Cooperation, DG Research & Innovation
European Commission-DG Devco	Dr Walter Seidel *succeeded by*	Head of Sector 'Health', Unit B4, Directorate-General for International Cooperation and Development (DG DEVCO)	Dr Eric Sattin *succeeded by*	Policy Officer for Development Cooperation on Global Health, Unit B4, DG DEVCO
	Dr Jan Pähler	Head of Sector "Health", DG DEVCO	Mr Kevin McCarthy	Policy Officer for Development Cooperation on Global Health, DG DEVCO
WHO Regional Office for Africa	Dr Joseph Caboré	Director for Programme Management	Dr Delanyo Dovlo	Director of Health Systems and Services
African Union Commission of Social Affairs	Dr Olawale Maiyegun	Director for Social Affairs, Commission of Social Affairs		

8.3

Strategic Advisory Committee

The Scientific Advisory Committee (SAC) is the principal advisory group providing the General Assembly and the Executive Secretariat with strategic and scientific advice. The committee also oversees the scientific integrity of the EDCTP programme to assist EDCTP in achieving its mission and objectives. It acts exclusively in the interest of the mission and objectives of EDCTP. In 2017, EDCTP welcomed new SAC members and chairperson.

Photo: Members of the EDCTP Scientific Advisory Committee

The 2016 Scientific Advisory Committee consisted of:

Prof. Catherine Hankins *(Chair)*	The Netherlands
Prof. Eleni Aklillu *(Vice-Chair)*	Sweden
Dr Maryline Bonnet	France
Prof. Christian Burri	Switzerland
Prof. John Gyapong *(Vice-Chair)*	Ghana
Prof. Stefan Kaufmann	Germany
Dr Maria Fraga Oliveira Martins	Portugal
Prof. Clara Menéndez Santos *(Vice-Chair)*	Spain
Prof. Martin Meremikwu	Nigeria
Prof. Keymanthri Moodley	South Africa
Dr. Juliet Nabyonga-Orem	Zimbabwe
Dr Jutta Reinhard-Rupp	Switzerland
Prof. Philippe Sansonetti	France
Prof. Peter G Smith	United Kingdom
Prof. Marleen Temmerman	Belgium
Prof. Halidou Tinto	Burkina Faso
Prof. Sir Alimuddin Zumla	United Kingdom

External observers to the Scientific Advisory Committee

Dr Line Matthiessen	European Commission, DG Research & Innovation
Dr Gianpietro van de Goor	European Commission, DG Research & Innovation
Dr Vasee Moorthy	World Health Organisation, Geneva
Dr Martin O.C. Ota	World Health Organisation African Region, Brazzaville

8.4

EDCTP Secretariat

Dr Michael Makanga	Executive Director
Dr Leonardo Simão	High Representative South
Prof. Marcel Tanner	High Representative North
Abdoulie Barry	Director of Finance and Administration
Dr Ole F. Olesen	Director of North-North Cooperation
Prof. Moses Bockarie	Director of South-South Cooperation and Head of Africa Office
Dr Pauline Beattie	Operations Manager
Dr Gabrielle Breugelmans	North-North Networking Manager
Dr Anne-Laure Knellwolf	Programme Portfolio Manager
Dr Thomas Nyirenda	South-South Networking and Capacity Development Manager
Dr Montserrat Blázquez Domingo	Senior Project Officer
Chris Bruinings	Financial Officer
Andreia Coelho	Administrative Support Officer (as of August 2017)
Mary Jane Coloma-Egelink	Grants Financial Officer
Dr Christy Comeaux	Project Officer (left in December 2017)
Lucien de Corte	Information Technology (IT) Officer
Christopher Dixon	Financial Assistant
Nuraan Fakier	Project Officer
Neodia Flores-Mensing	Grants Finance Assistant
Jean Marie Vianney Habarugira	Project Officer
Dr Michelle Helinski	Project Officer
Suzanne Hoogervorst	Travel and Events Officer
Dominika Jajkowicz	Monitoring & Evaluation Officer (as of October 2016)
Nancy Kensmil	Administrative Officer & HR Assistant (left in July 2017)
Dr Louwrens Kiestra	Legal Officer
Gert Onne van de Klashorst	Communications Officer
Neli Krautsova	Grants Financial Assistant
Mariska Louw	Senior Administrative Officer
Shingai Machingaidze	Project Officer
Dr Magda Moutaftsi	North-North Networking Officer (as of October 2016)
Pete Murphy	Grants Management System Administrator (left as of September 2017)
Michelle Nderu	Project Officer
Lara Pandya	North-North Networking Officer
Daniela Pereira	Communications Officer
Dr Monique Rijks-Surette	Senior Project Officer
Sayma Siddiqui	Grants Financial Assistant
Dr Michelle Singh	Project Officer
Jennifer Stamatelos	Administrative Officer
Ana Lúcia Weinberg	North-North Networking Officer

Photo:
DREAMM project volunteers, Tanzania

9 Summary financial statements 2017

Statement of profit or loss and other comprehensive income

for the year ended 31 December 2017. Expressed in thousands ('000) of euro

	EC 2017	Donor 2017	Total 2017	Total 2016
Calls (grants)				
Contributions	82,413	15,300	97,713	50,159
Grants	(82,413)	(15,300)	(97,713)	(50,159)
Results for the year	-	-	-	-
Others				
Contributions	6,700	362	7,062	6,846
Other	(6,700)	(362)	(7,062)	(6,846)
Results for the year	-	-	-	-
Total results for the year	-	-	-	-

The EDCTP Association has no other comprehensive income.

All income and expenditure relates to continuing activities.
For the full statements and the accompanying notes see **www.edctp.org**

Statement of financial position

as at 31 December 2017 (after appropriation of result). Expressed in thousands ('000) of euro

	31 December 2017	31 December 2016
Current assets		
Debtors and other receivables	50,478	14,684
Cash and cash equivalents	78,110	38,308
Total current assets	**128,588**	**52,992**
Total assets	**128,588**	**52,992**
Non-current liabilities		
Grants and other payables	72,218	25,009
Deferred income EC	-	-
Deferred income donor	12,180	6,224
Total non-current liabilities	**84,398**	**31,233**
Current liabilities		
Grants and other payables	15,121	6,247
Deferred income EC	-	-
Deferred income donor	29,069	15,512
Total current liabilities	**44,190**	**21,759**
Total liabilities	**128,588**	**52,992**

The financial statements were approved by the Executive Director on behalf of the Board:

Dr Michael Makanga
Dated: 15 March 2018

Statement of changes in EC and donor's equity

Expressed in thousands ('000) of euro

	Reserve: EC	Reserve: Donor	Total
Balance as at 31 December 2016	**-**	**-**	**-**
Total comprehensive income for the year	-	-	-
Balance as at 31 December 2017	**-**	**-**	**-**

EDCTP has no unrestricted reserves.

Statement of cash flows

for the year ended 31 December 2017. Expressed in thousands ('000) of euro

	2017	2016
Cash flows from operating activities		
Result for the year	**-**	**-**
Adjustment for:		
(Increase) decrease in debtors and other receivables	22	1,470
Increase (decrease) in grants and other payables	56,083	30,749
Increase (decrease) in deferred income	(16,370)	(36,245)
Net cash flows from operating activities	39,735	(4,026)
Cash flows from investing activities		
Interest received	67	64
Net cash flows from investing activities	**67**	**64**
Net increase (decrease) in cash and cash equivalents	**39,802**	**(3,962)**
Cash and cash equivalents at 1 January	38,308	42,270
Exchange rate effects	-	-
Cash and cash equivalents at 31 December 2017	**78,110**	**38,308**

Colophon

The Hague, the Netherlands, September 2018
European & Developing Countries Clinical Trials Partnership

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

Europe Office
Postal address
P.O. Box 93015
2509 AA The Hague
The Netherlands

Visiting address
Anna van Saksenlaan 51
2593 HW The Hague
The Netherlands

Phone: +31 70 344 0880/0897
Fax: +31 70 344 0899

Africa Office
Postal address
P.O. Box 19070
Tygerberg 7505, Cape Town
South Africa

Visiting address
Francie van Zijl Drive,
Parowvallei 7505, Cape Town
South Africa

Phone: +27 21 938 0690
Fax: +27 21 938 0569

www.edctp.org
info@edctp.org

edctpmedia

@EDCTP

Editors: Daniela Pereira, Gert Onne van de Klashorst, Michael Makanga

Photography: Africa Interactive, Makmende Media
Coverphoto : Clinical Capacity project staff member, Sierra Leone

Design: Studio Duel, The Hague
Printing: Kapsenberg van Waesberge, The Hague

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