



EDCTP

The power of sharing science

Annual Report 2016



Supported by the EU



The power of sharing science



Photo:
Clinical staff and study volunteers
at the Amana Hospital in Dar es Salaam, Tanzania
part of the TRIP project led by Dr Sayoki Godfrey Mfinanga

About EDCTP

The European & Developing Countries Clinical Trials Partnership (EDCTP) is a public–public partnership funding collaborative clinical research against poverty-related infectious diseases affecting sub-Saharan Africa.

EDCTP's vision is to reduce the individual, social and economic burden of poverty-related infectious diseases in sub-Saharan Africa, by supporting the clinical development of accessible, suitable and affordable medical interventions.

EDCTP's mission is to accelerate - while enhancing African clinical research capacity - the development of new or improved medical interventions for the identification, treatment and prevention of poverty-related infectious diseases, including emerging and re-emerging diseases in sub-Saharan Africa, through all phases of clinical trials, with emphasis on phase II and III trials.

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Bridging research gaps

Dear friends and colleagues,

It is my privilege to introduce the 2016 Annual Report, the year in which I had the honour of taking the helm of EDCTP to serve as Executive Director. The second EDCTP programme (EDCTP2) is a highly ambitious programme and 2016 was a transformational year for consolidating the organisation itself and accelerating focussed implementation of the programme. We are expected to fund large clinical trials, develop African research capacity, and align national research efforts. In 2016 we clearly began to satisfy these expectations.



As an organisation, we began the implementation of a results-based management approach. We further worked on ensuring coherence of the EDCTP programme through a focused Strategic Business Plan. Guided by our Scientific Advisory Committee, we developed an annual strategic research agenda which identifies specific research gaps and opportunities, and sets specific funding priorities within our extended programme scope. The research agenda also drew on the results of the two stakeholder meetings on diarrhoeal diseases and lower respiratory tract infections held in July 2016. To balance the broad scope, we need to prioritise and focus on bridging research and capacity gaps.

In 2016, we launched nine new calls for proposals while proceeding with the selection and grant agreement processes for the eleven calls for proposals from 2014-2015. By the end of 2016, EDCTP2 had a portfolio of 60 grants with a total value of €97.09 million; €75.11 million of this amount was invested in large-scale clinical trials and clinical research projects. An overview is given in chapter 3 of this report, 'Progress so far'.

“
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”

The chapters on the disease areas summarise the priorities and expand on selected projects that illustrate our investments so far. The development of clinical research capacity, including research enabling ethics review and regulatory capacities, is reported on in chapter 5 of this report. Chapter 6 is dedicated to our advocacy and networking efforts to strengthen international research collaboration. The Annual Report also touches briefly on the research activities funded and implemented directly by the member countries of the EDCTP Association. Our 2016 work plan provides an excellent overview of these so-called Participating States' Initiated Projects (PSIAs) which constitute an integral part of the second programme and contribute directly to achieving our overall objectives.

In November 2016, the eighth EDCTP Forum in Lusaka, Zambia, demonstrated again that international cooperation and coordination are vital for achieving our objectives and are at the heart of the EDCTP approach. We can only expect the best results through alignment and coordination of national research programmes in partnership with the private sector and other stakeholders including international development partners.

Ultimately, it is the commitment and efforts of our many partners that make the progress of the programme possible. Let me mention first the many African and European researchers as well as the volunteers participating in the studies we fund. The role and advice of the experts involved in our stakeholder meetings and the scientific review process for our calls for proposals is highly appreciated. Moreover, I extend my gratitude to the members of the General Assembly who have kept the EDCTP participating states engaged despite the challenging political and economic times. Special thanks go to the EDCTP Board, the Scientific Advisory Committee, the European Commission Officers responsible for EDCTP matters, and the members of the Executive Secretariat who have worked tirelessly to make 2016 successful.

Dr Michael Makanga

Executive Director



Photo:
Clinical staff at the Regional Hospital
of Banfora, Burkina Faso
*part of the WANECA project led by Prof. Abdoulaye
Djimé, funded under the first EDCTP programme*

2 Prioritisation of research funding

To maximise its impact, EDCTP has identified important areas of unmet medical needs and the related gaps in research and capacity development. Its annual calls for proposals reflect its priorities in addressing these needs and gaps for each disease area as well as for research capacity development.

EDCTP's overall programme of work is set out in its **Strategic Business Plan for 2014–2024**, a concise version of which was published in December 2016. It was based on the updated extended version of the EDCTP Strategic Business Plan approved by the member countries in June 2016. This strategy was developed based on extensive input from EDCTP member countries, EDCTP's Scientific Advisory Committee, the Executive Secretariat, and on consultations with the global scientific community, like-minded partner organisations and other stakeholders.

The EDCTP Executive Secretariat – with scientific and strategic advice from the EDCTP Scientific Advisory Committee (SAC) – also prepared the **Strategic Research Agenda**. It outlines the key research gaps for diseases within the scope of EDCTP, and ranks them in terms of priorities. This document, published in December 2016, will be updated annually to adjust its prioritisation in tandem with the global developments on EDCTP target diseases.

The prioritisation takes into account the following criteria:

- state of the product development landscape
- priority infections
- disease burden and treatment/prevention priorities
- emerging opportunities
- balance in the portfolio (i.e. disease areas, types of intervention, types of study, and short-term and long-term priorities).

The overall aim of priority setting is to maximise the impact of the programme by avoiding duplication, and balancing the needs with available resources. The agenda should offer a coherent guiding framework and the flexibility to respond to emerging opportunities and challenges.

The Annual Work Plan for 2017 submitted to the European Commission and EDCTP member countries in September 2016, was developed on the basis of the Strategic Research Agenda by the Executive Secretariat with scientific and strategic advice from the SAC, as well as from the broader scientific community for new areas. To that end experts in the fields of lower respiratory tract infections and diarrhoeal diseases were consulted in two stakeholder meetings on 5 and 6 July 2016, respectively. EDCTP's Scientific Advisory Committee ensures in particular that activities included in the work plan are aligned with the strategic scope and objectives of EDCTP. The European Commission approved the work plan in 2017 after which it was formally endorsed by EDCTP's General Assembly.

The Strategic Business Plan for 2014-2024, the Strategic Research Agenda, and the EDCTP annual work plans are available at www.edctp.org.



Progress so far

(2014-2016)

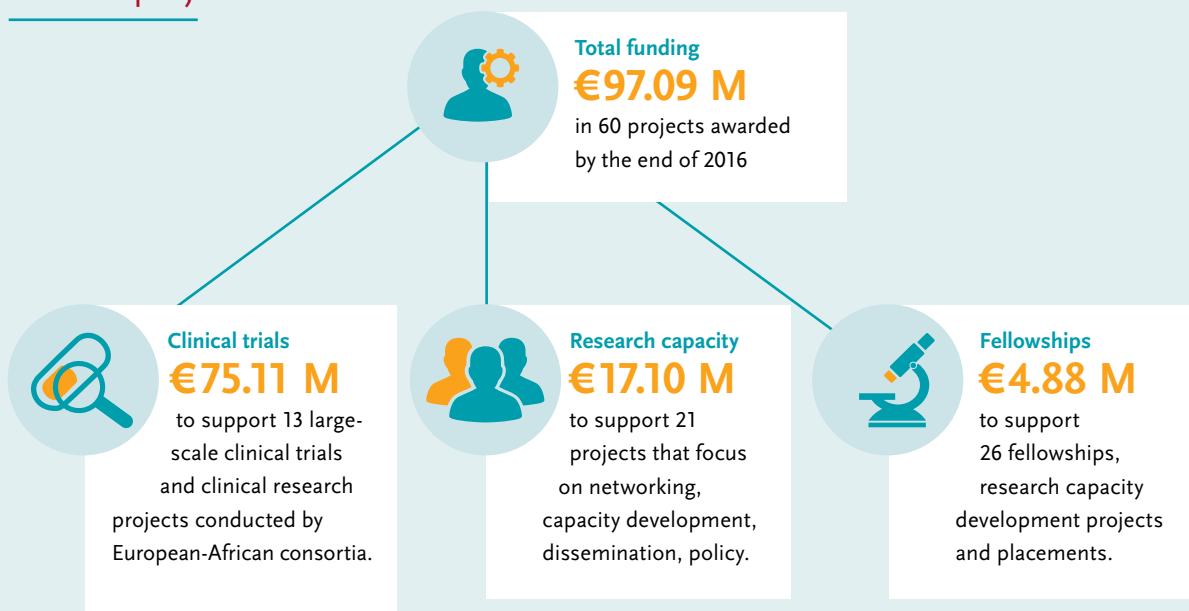
Investment in calls for proposals



- 2016
€138.65 M
- 2015
€82.54 M
- 2014
€19.49 M

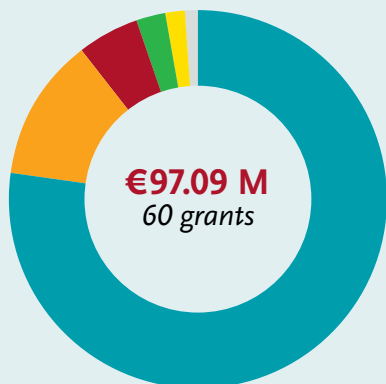
€240.68 million is the total indicative budget for the 20 calls for proposals launched since the start of the second EDCTP programme.

Funded projects



Portfolio of projects

By activity

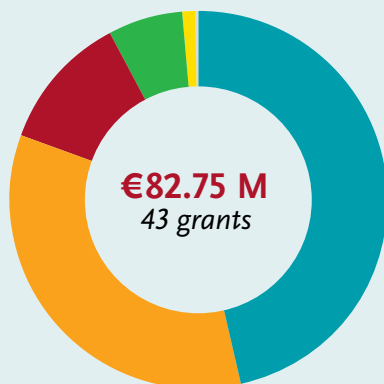


- Clinical research, 13 grants
€75.11 M
- Networks of Excellence, 4 grants
€11.98 M
- Fellowships, 26 grants
€4.88 M
- Translation of research results into policy, 5 grants
€2.43 M
- Ethics capacity and regulatory framework, 6 grants
€1.75 M
- Health system preparedness, 6 grants
€0.94 M

By disease

Note:

A further €14.34M for 17 grants was awarded for projects on non-disease-specific topics such as ethics and regulatory support, networking and fellowship grants.

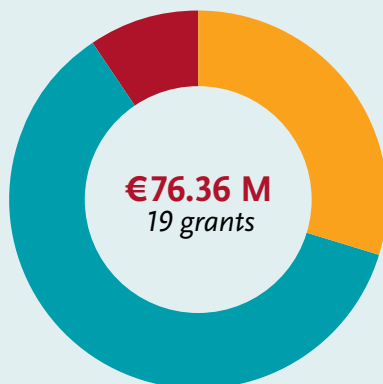


- HIV & HIV-associated infections, 14 grants
€38.58 M
- Tuberculosis, 11 grants
€28.28 M
- Malaria, 6 grants
€9.46 M
- Neglected infectious diseases, 5 grants
€5.34 M
- Emerging diseases, 6 grants
€0.94 M
- Diarrhoeal diseases and lower respiratory tract infections, 1 grant
€0.15 M

By medical intervention

Note:

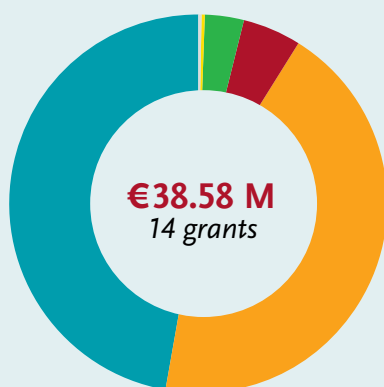
A further €20.73M for 41 grants was awarded to cross-cutting research activities, ethics and regulatory support, networking and fellowships not related to a particular medical intervention.



- Drugs (treatment and prevention), 7 grants
€46.45 M
- Diagnostics, 11 grants
€22.82 M
- Vaccines, 1 grant
€7.09 M

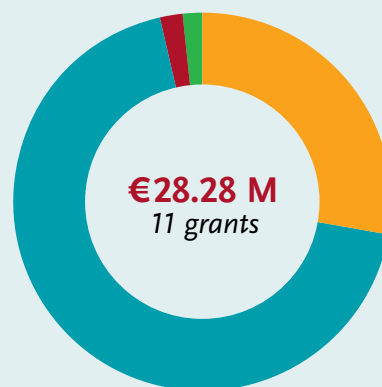
Portfolio of projects by priority areas per disease

HIV



- Treatment, 5 grants
€18.19 M
- Prevention, 2 grants
€16.9 M
- Product-focused implementation research, 4 grants
€1.29 M
- Diagnosis and tracking, 1 grant
€1.19 M
- Epidemiology, 1 grant
€0.15 M
- Pathogenesis/host response/immune response, 1 grant
€0.15 M

Tuberculosis



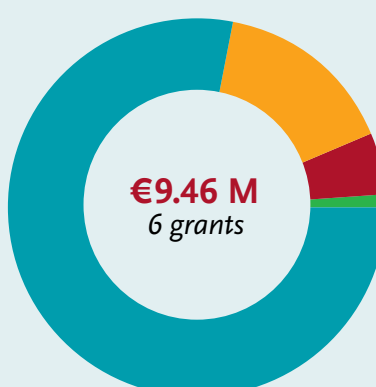
- Treatment, 4 grants
€19.42 M
- Diagnosis and tracking, 4 grants
€7.87 M
- Pathogenesis/host response/immune response, 2 grants
€0.55 M
- Product-focused implementation research, 1 grant
€0.44 M
- Epidemiology, 1 grant
€0.15 M

Neglected infectious diseases



- Diagnosis and tracking, 4 grants
€5.19 M
- Product-focused implementation research, 1 grant
€0.15 M

Malaria



- Prevention, 1 grant
€7.39 M
- Product-focused implementation research, 3 grants
€1.48 M
- Vaccines, 1 grant
€0.5 M
- Treatment, 1 grant
€0.09 M
- Epidemiology, 1 grant
€0.15 M

Participation in EDCTP projects



Leadership

70% grants are coordinated by a sub-Saharan African institution.



Region

15 European countries and **30** sub-Saharan Africa countries are participating in EDCTP grants.



Gender

33% grants are led by a female project coordinator.

Towards EDCTP's objectives



>10 planned clinical trials to be conducted in sub-Saharan Africa.



10 novel treatments and formulations are being investigated.



26 research fellows from sub-Saharan Africa are being supported.



8 grants prioritise treatment for vulnerable populations, such as children and pregnant women.



6 grants were awarded to strengthen regulatory frameworks and to increase capacity for research ethics review in sub-Saharan Africa.





Photo:
Clinical staff and study volunteer at the Amana Hospital
in Dar es Salaam, Tanzania
part of the TRIP project led by Dr Sayoki Godfrey Mfinanga





Photo:
Laboratory staff at the Kilimanjaro Clinical Research
Institute(KCRI)-Kilimanjaro Christian Medical Centre (KCMC)
part of the PanACEA-MAMS project (led by Prof. Martin
Boeree, Prof. Michael Hoelscher and Prof. Stephen Gillespie,
funded under the first EDCTP programme

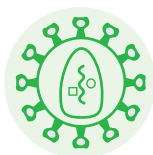
Priorities and clinical research

EDCTP supports collaborative clinical research to accelerate the development of new or improved medical interventions for poverty-related diseases affecting sub-Saharan Africa. Research on the full range of medical interventions, i.e. diagnostics, drugs, vaccines, and other preventive measures such as microbicides, is funded.

The portfolio comprises the following disease areas: HIV, tuberculosis, malaria, neglected infectious diseases, diarrhoeal diseases, lower respiratory tract infections, and emerging and re-emerging infections relevant to sub-Saharan Africa, including Ebola and yellow fever.

Interventional clinical studies make up most of the EDCTP's portfolio. It supports phase I–III safety and efficacy studies, with a particular emphasis on phase II and III trials. Phase IV pharmacovigilance and post-licensing effectiveness studies (pragmatic trials), and product-focused implementation studies are also supported.

HIV



The 2016 report *AIDS by numbers* from UNAIDS makes clear that substantial progress has been made in tackling the AIDS epidemic. However, significant challenges are still to be faced in order to end the epidemic by 2030. In 2015 there were 2.1 million new HIV infections; a total of 36.7 million people were living with HIV.

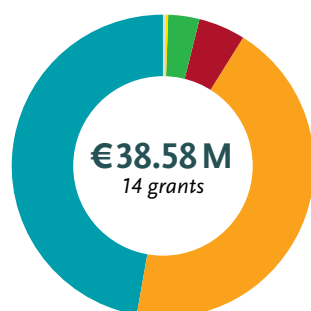
Although effective antiretroviral therapy (ART) is now available, optimised treatment regimens and formulations are required for key groups, such as children, pregnant women, and adults with co-infections and co-morbidities.

Multiple challenges in HIV management need to be addressed, from timely diagnosis and initiation of ART to retention in care. Given the availability of therapeutic options, high priority is given to product-focused implementation research to increase access to evidence-based interventions.

As the number of new HIV cases remains stubbornly high, there is also an urgent need to assess innovative methods of prevention, including microbicides, ARV-based interventions and, ultimately, HIV vaccines.

Since the start of the second programme in December 2014, EDCTP has supported 14 projects for HIV research amounting to €38.58 million in grants. The portfolio includes projects that focus on the treatment and diagnosis of patients with HIV, including those with HIV-associated infections.

EDCTP Strategic research agenda: addressing priority areas for HIV



- Treatment, 5 grants
€18.19 M
- Prevention, 2 grants
€16.9 M
- Product-focused implementation research, 4 grants
€1.29 M
- Diagnosis and tracking, 1 grant
€1.19 M
- Epidemiology, 1 grant
€0.15 M
- Pathogenesis/host response/
immune response, 1 grant
€0.15 M

CHAPAS-4

Second-line antiretroviral treatment for children

In 2014, the World Health Organization (WHO) estimated that approximately 823,000 HIV-infected children and adolescents younger than 15 years of age were receiving antiretroviral treatment (ART) in low- and middle-income countries, the vast majority on first-line regimens. Since 2015, WHO guidelines recommend that all HIV-infected adults and children initiate ART, irrespective of CD4 count or clinical status.

The growing number of children on first-line ART coupled with widening coverage of viral load monitoring leads to the increased detection of first-line virological failure (estimated at up to 20% by 2020). Therefore, the number of children needing to switch to second-line treatment will increase.

In 2016, EDCTP awarded a €7.6 million grant to CHAPAS-4 (Children with HIV in Africa – Pharmacokinetics and Acceptability of Simple antiretroviral regimens). The study focuses on children starting second-line treatment of HIV. “The lack of adherence is a major cause of failure of first-line treatment,” explains Dr Mutsa Bwakura-Dangarembizi, of the University of Zimbabwe College of Health Sciences in Zimbabwe, the coordinator of the CHAPAS-4 project. “We investigate how to optimise second-line treatment in these slightly older children (typically over 6 years of age).”

The 2013 WHO guidelines recommend abacavir+lamivudine+efavirenz as the preferred first-line regimen for children over 3 years old. However, abacavir has only recently become more widely adopted and zidovudine remains a WHO-recommended alternative in children younger than 3 years of age. In 2014, more than 50% of children were receiving zidovudine-based first-line ART. The alternative nucleoside reverse transcriptase inhibitor is then used in second-line treatment (i.e. zidovudine second-line if abacavir used first-line or vice versa).

CHAPAS-4 also builds on some of the lessons learnt from the CHAPAS-1 and CHAPAS-3 trials, funded under the first EDCTP programme. CHAPAS-3 trial showed that children failing either zidovudine- or abacavir-based first-line ART retain high susceptibility to tenofovir-alafenamid. This shows that tenofovir-alafenamid could potentially be used safely and effectively in first-line treatment, but also, in second-line treatment in children who received abacavir- or zidovudine-based first-line ART.

“Moreover, CHAPAS-4 aims to evaluate how regimens with new drugs planned for adult use, can be aligned for older children,” says Dr Bwakura-Dangarembizi. The goal is to optimise the use of specific new antiretroviral drugs/formulations (including dolutegravir, tenofovir-alafenamide and co-formulated atazanavir/ritonavir) in second-line treatment for children to maximise their long-term health gains.

“HIV-infected children face a lifetime of ART. To give them the best chance of a long survival we have to optimise both their first-line treatment and their second-line treatment,” says Dr Bwakura-Dangarembizi. “Ultimately, if we can improve outcomes from second-line treatment in children, we will help them lead healthy longer lives and achieve their full potential.”



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”

*Dr Mutsa
Bwakura-Dangarembizi
Zimbabwe*

CAPRISA 018

Developing a new HIV prevention device for young women in Africa

High rates of HIV infection in young women in Africa remain one of the biggest obstacles to reaching the UNAIDS goal of controlling the global HIV epidemic by 2030. In eastern and southern Africa, women account for 59% of all people living with HIV. Adolescent girls and young women are particularly vulnerable. In 2014, an estimated 3.9 million young people between 15 and 24 years of age were living with HIV, of whom 2.3 million (58%) were young women.

Professor Salim S. Abdool Karim of the Centre for the Aids Programme of Research in South Africa (CAPRISA) and coordinator of the EDCTP-cofunded CAPRISA 018 project, stresses the need to help young women: "Throughout sub-Saharan Africa, HIV prevalence among adolescent girls and young women exceeds that of their male peers, with HIV prevalence up to six times higher in young women in South Africa. Despite their vulnerability, young women have few prevention tools to protect themselves against HIV."

Although the antiretroviral drug tenofovir is effective in preventing HIV infection, clinical trials had disappointing results. Trials of oral and topical tenofovir-containing pre-exposure prophylaxis (PrEP) showed inconsistent results in women, mainly due to varying levels of adherence. The monthly dapivirine vaginal ring, designed to improve PrEP adherence, demonstrated only 27% and 31% HIV protection in two recent CAPRISA clinical trials. New sustained-release formulations are needed to overcome these adherence challenges.

Therefore, the goal of the CAPRISA 018 project is to develop a new, safe and effective prevention tool for young women through assessing a novel sustained-release device containing tenofovir-alafenamide (TAF). Prof. Karim: "Studies of daily, on-demand and monthly regimens have all shown poor adherence in the high-risk population of young women in Africa. We try to overcome this with an implant under

the skin which is to be inserted once a year. This technology is not user dependant and might overcome the adherence challenges of previously tested shorter-term oral and topical formulations."

The project aims to assess this medical device in order to advance it to phase III and finally registration within five years. Prof Karim: "This study will generate essential data on the safety and pharmacokinetics of the TAF implant. It is expected to also generate an estimate of the efficacy of the implant in preventing HIV infection, laying the foundation for a larger phase III efficacy trial."

The project was awarded a €9.8 million grant from EDCTP in 2016 and brings together a consortium of researchers from the Jean Monnet University in St. Etienne (France), Gilead Sciences (Ireland), the Amsterdam Institute for Global Health and Development (The Netherlands), CAPRISA (South Africa), and the Oak Crest Institute of Sciences (USA). "Each consortium member makes its particular skills and capabilities available in order to achieve success. For example, the Oak Crest Institute has extensive experience in implant technologies and the Jean Monnet University has one of a few laboratories in the world capable of measuring blood TAF concentrations," says Prof. Karim. "These strengths combined with CAPRISA's clinical trial capabilities are the perfect combination to achieve the goals of the project."



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against HIV.
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*Prof. Salim S.
Abdool Karim
South Africa*

GREAT project

Evaluating a promising vaccine to end HIV

Even with the remarkable progress in fighting the HIV epidemic, the available means of prevention and treatment remain out of reach or are challenging to adhere to for many. This is particularly true for communities that are mobile or live in remote regions, and for people who fear stigma and discrimination. An effective vaccine could prevent the majority of new HIV infections. An effective, prophylactic HIV-1 vaccine will be the key for any strategy to halt the AIDS epidemic.

The GREAT (Globally Relevant AIDS Vaccine Europe-Africa Trials Partnership) project is led by Professor Tomáš Hanke of the Jenner Institute at Oxford University, United Kingdom (UK). Its main objective is to evaluate a promising vaccine candidate called tHIVconsvX. This candidate is designed to overcome one of the main obstacles to developing a vaccine: HIV's frequent mutations. Targeting highly "conserved" (less variable) regions of the virus, tHIVconsvX triggers production of specialised immune cells called killer T cells that can destroy HIV-infected cells in the body. A previous phase I clinical study found the first-generation candidate to be safe and immunogenic. A new generation has subsequently been adapted with the aim to expand its breadth of protection.

Prof. Hanke: "This second generation of conserved mosaic tHIVconsvX vaccines tested under the GREAT trials has a number of design improvements over the first generation. This results in a better match to global HIV-1 variants than in previous similar vaccines. Vaccine induction of highly effective killer cells could significantly contribute to reducing acquisition of HIV-1 by complementing broadly neutralising antibodies. It also may be central to HIV cure by limiting or even eliminating rebound viraemia. Due to its pan-clade nature, the second-generation vaccines, if successful, could be deployed in any region of the world, they would be 'universal'."

In 2016, EDCTP awarded the project a grant of €7.1 million. The value of the overall project is

almost €19 million. Co-funding is provided by the International AIDS Vaccine Initiative (IAVI), the University of Oxford (UK), and Imperial College, University of London (UK).

The GREAT project also aims to strengthen vaccine trial capacity in Kenya, Uganda and Zambia through conducting a phase IIa trial. The trial will develop infrastructure and prepare research teams, communities and regulatory agencies for a large HIV vaccine efficacy trial. Populations at risk of HIV infection will be enrolled in this trial. These comprise fishing communities around Lake Victoria in Uganda, male and female sex workers and men-who-have-sex-with-men in Kenya, as well as female sex workers, in Zambia. "GREAT aims to work closely with the most vulnerable populations. They are at high risk of HIV-1 infection and need an effective vaccine the most," explains Prof. Hanke. "We want to make sure that safety and immune responses in relevant populations are good, because there is evidence that environments can modify the response to a vaccine."

The project is a collaboration between institutions in Africa, Europe and the United States: IAVI in the USA; Oxford University and Imperial College London in the UK, and in Africa: the Kenya AIDS Vaccine Initiative - Institute for Clinical Research (Kenya), The Kenya Medical Research Institute - Wellcome Trust Research Programme (Kenya), the Medical Research Council at the Uganda Virus Research Institute (Uganda), UVRI-IAVI (Uganda), and the Zambia Emory HIV Research Program (Zambia).

"All partners of this consortium play absolutely key roles in achieving the goals of the GREAT project," says Prof. Hanke. "Oxford designed the vaccine and assays and manages the manufacturing. African clinical research centres engage with communities that ultimately need this vaccine and conduct research into their health and especially immunity. IAVI provides technical support for manufacturing."



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An effective vaccine could prevent the majority of new HIV infections.
”

*Prof. Tomáš Hanke
United Kingdom*

AMBITION-cm

HIV-associated infection with cryptococcal meningitis



“
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mortality of
HIV-associated
cryptococcal
meningitis.
”

*Dr Joseph Jarvis
United Kingdom*

Early mortality in HIV programmes in Africa is considerably higher than in high-income countries. Almost 20% of these deaths are directly attributable to cryptococcal meningitis (CM). The current recommended treatment is a two-week course of amphotericin B. This is a very old and toxic drug, which requires a daily intravenous infusion, frequent blood tests to monitor for side effects, and a prolonged hospital stay. This makes standard courses of amphotericin B very difficult to give in most African hospitals. The only current alternative treatment available is a tablet of fluconazole. Unfortunately, even high doses of this tablet are not able to decrease the mortality due to the disease. New treatments are urgently needed.

Recent data suggest highly effective and much safer therapy for HIV-associated CM is possible with a novel short-course of high-dose liposomal amphotericin (L-AmB, Ambisome), a newer formulation of amphotericin B. An ongoing phase II study in Tanzania and Botswana examines the early fungicidal activity (EFA) of three short-course high-dose L-AmB schedules for the treatment of HIV-associated CM and has already showed promising results. A single 10mg/kg dose of L-AmB is safe, and leads to rapid clearance of infection.

The AMBITION-cm project received an EDCTP contribution of almost €10 million for a multi-centre phase-III randomised non-inferiority trial. The aim of the study is to determine whether the short-course high-dose L-AmB is as effective as a 14-day amphotericin B-based therapy in averting all-cause mortality in HIV-associated cryptococcal meningitis.

“An effective short-course treatment, such as the single high dose of liposomal amphotericin B we are evaluating in this project, would provide for the first time a safe and practical treatment for cryptococcal meningitis in low-resource settings,” says Dr Joseph Jarvis of the London School of Hygiene & Tropical Medicine, UK.

“Giving a single intravenous dose of liposomal amphotericin would be feasible in nearly all hospital settings, and the anticipated excellent safety profile of the short course treatment would mean that routine monitoring blood tests will not be required and patients would not need to stay long in a hospital.”

A total of 850 patients will be recruited in 6 sites in Botswana, Malawi, South Africa, Uganda and Zimbabwe, making this the largest trial ever conducted of HIV-associated cryptococcal meningitis.

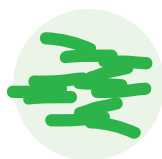
“The trial partnership brings together leading European and African HIV and cryptococcal research groups. It will establish a strong clinical network of African centres for future meningitis trials led by African investigators, and build research capacity and African leadership at these centres,” says Dr Jarvis.

The expected impact of this trial will make effective treatment for HIV-associated cryptococcal meningitis feasible and accessible in the regions where the disease is prevalent. Dr Jarvis: “If successful, the short-course treatment regimens would lead to changes in regional and international treatment guidelines, and provide an effective and practical first-line treatment option. They would have the potential to halve the mortality of HIV-associated cryptococcal meningitis from around 60% seen with fluconazole therapy to 30%. This would transform the management of late-stage HIV infection in Africa and prevent thousands of deaths.”



Photo:
Researchers at the Amana Hospital in Dar es Salaam, Tanzania
part of the TRIP project led by Dr Sayoki Godfrey Mfinanga

Tuberculosis



Ending the tuberculosis (TB) epidemic by 2030 is one of the health targets of the Sustainable Development Goals. Although TB incidence has fallen by an average of 1.5% per year since 2000, TB is still one of the top 10 causes of death worldwide. Over 95% of TB deaths occur in low- and middle-income countries. In 2015, an estimated 480,000 people globally developed multidrug-resistant TB (MDR-TB).

EDCTP's funding priorities are aligned with important research goals for tuberculosis:

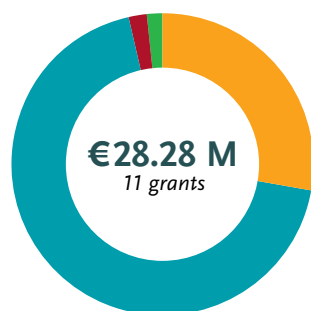
- New approaches to early diagnosis of active TB
- Shortened duration of therapy, where appropriate
- Improved treatment for both drug-sensitive and drug-resistant TB, which will prevent relapse, long-term lung damage, latent TB infection progressing to active TB, and reduce the emergence of drug resistance.

Ultimately, TB control will require affordable, short, and well-tolerated treatments for all forms of TB (i.e., latent TB infection, drug-susceptible and drug-resistant TB disease), point-of-care diagnostic tests able to characterise drug resistance, and an effective vaccine.

EDCTP's current priority is to support the evaluation of new TB diagnostics and treatment regimens for both drug-sensitive and drug-resistant TB, as well as adjunct host-directed therapies. Product-focused implementation research will be required to support the introduction of evidence-based interventions into policy and practice. Strategies for integrated delivery of TB and HIV care will be an important focus.

Under its second programme, EDCTP's investment in TB research has amounted to €28.28 million for 11 projects thus far. The portfolio shows a significant investment in TB treatment. Moreover, several diagnostics projects have been supported, including projects that build on results from the first programme.

EDCTP Strategic research agenda: addressing priority areas for TB



- Treatment, 4 grants
€19.42 M
- Diagnosis and tracking, 4 grants
€7.87 M
- Pathogenesis/host response/
immune response, 2 grants
€0.55 M
- Product-focused implementation research, 1 grant
€0.44 M

PanACEA2

Shortening TB treatment

The ongoing tuberculosis pandemic and a growing number of patients infected with *M. tuberculosis* strains which are resistant to multiple or almost all drugs, is a massive challenge for healthcare systems. WHO reports show that control of the disease cannot be achieved with the available tools. In the *Global Plan to End TB* shorter more effective treatment regimens are identified as critical to progress towards global eradication.

“Current treatment is lengthy, complex and associated with severe side effects,” explains Professor Martin Boeree of the University of Nijmegen in the Netherlands. “The duration of current therapies causes many challenges and fuels patient non-adherence, which plays a significant role in the emergence of drug-resistant TB.”

Prof. Boeree coordinates the PanACEA2 project, which aims to develop at least two promising TB-treatment regimens to the point where they can be tested in a phase III clinical trial. It also aims to advance one new agent to a phase IIb trial. The project will make use of innovative trial designs, new microbiological markers of treatment response, pharmacokinetic-pharmacodynamic analyses and modelling techniques. This approach could accelerate drug development processes by several years.

“Evaluating new and optimised existing drugs could result in a short, safe and all oral regimen. New and improved trial methodologies will accelerate the evaluation of new compounds and regimes and possibly the registration of new drugs. In this way, new and optimised existing drugs that show promise early in the programme could be efficiently incorporated into a new TB regimen,” says Prof. Boeree.

“This flexible approach may even lead to the development of a universal regimen: an all oral short treatment for drug sensitive TB and MDR-TB. It would be a game-changer.”

PanACEA2 builds on results from the consortium’s initial portfolio of clinical trials funded under the first EDCTP programme. The PanACEA consortium consists of a network involving African and European partners. “In this programme, leadership of all trials will be shared between a European and an African investigator, putting African scientists at the forefront of TB therapy development and enhancing national TB expertise,” says Prof Boeree. “There will be a focus on mutual support for quality in trials through co-monitoring by African sites. This will continue to strengthen the network and will provide African researchers with the opportunity, skills and infrastructure to evaluate promising new compounds.”



“
The duration of current therapies fuels patient's non-adherence and thus plays a significant role in the emergence of drug-resistant TB.
”

Prof. Martin Boeree
The Netherlands

Predict-TB

Biomarkers to predict TB treatment duration



“
Ultimately,
we want
to impact
point-of-care
decision-
making on
treatment
duration.
”

*Prof. Gerhard Walzl
South Africa*

Shortening of tuberculosis (TB) treatment is a key element in addressing the global threat of the disease. Shortening treatment to 16 weeks or less will reduce treatment costs, improve treatment adherence and decrease the development of drug resistance. Clinical trials for treatment shortening failed until now but consistently found high (80-85%) treatment success at 16 weeks. If individuals likely cured at 16 weeks could be reliably identified, treatment shortening could be achieved for large number of patients. This is the point of departure for the Predict-TB project.

“The current standard of care, therefore, results in over-treating all patients for a total of 6-months to avoid relapse in a small subset of patients at higher risk for incompletely understood reasons,” says Professor Gerhard Walzl of Stellenbosch University in South Africa and coordinator of the Predict-TB project. “It is generally accepted that the extent of disease in the lungs of TB patients dictates a need for longer treatment duration. But we have been unable to accurately define this extent of disease. In Predict-TB, we are not trying to shorten treatment in all patients but are trying to identify the approximately 80% of patients who can be successfully treated with shorter antibiotic courses. However, we will build in a safety margin and aim to reduce treatment duration in 50% of patients.”

Predict-TB hypothesises that a combination of microbiological and radiographic markers – positron emission tomography (PET)/computed tomography (CT), the Xpert/MTB-RIF assay and bacterial load markers – will identify TB patients who are cured with 16 weeks of conventional therapy. As PET/CT scan technology is both expensive and not readily available, part of this study will be testing new biomarkers for predicting TB treatment outcome.

“These interventions are not intended for a point-of-care setting yet,” explains Prof. Walzl. “This is a proof-of-concept study to evaluate the approach that is based on risk stratification according to

extent of disease. However, we are also working on blood-based markers that can serve as eventual replacements of PET/CT imaging. These markers are based on protein signatures in the blood of patients, are correlated with the extent of disease, and can be measured with simple, point-of-care tests, similar to blood glucose strip tests. So ultimately, we want to impact point-of-care decision making on treatment duration.”

Predict-TB is a prospective, randomised, non-inferiority phase IIb clinical trial. Approximately 620 pulmonary drug-sensitive TB patients will be recruited, 420 of which in South Africa and approximately 200 in China. All subjects will be followed for 72 weeks. The primary objective is to demonstrate that the 72-week (18 month) treatment success rate of standard treatment stopped early at week 16 is not inferior to treatment stopped at week 24, in subjects classified as low risk by PET/CT and bacterial load markers.

If successful, the study has the potential to contribute to a change of WHO guidelines for TB treatment. Prof. Walzl: “Easily measurable blood markers for extent of disease or risk for poor outcome could indeed be implemented on a wide scale in TB monitoring and treatment. If a finger prick test were able to indicate the risk for poor treatment outcome, patients could be stratified into different treatment duration arms and treatment could be shortened in 50-80% of patients. And it would constitute a significant cost saving for treatment programs.”

In 2016, EDCTP awarded the project a grant of €7.7 million. Together, the Bill & Melinda Gates Foundation, EDCTP, the National Institutes of Health (NIH), and NIAID fund the South African component of the study, while the Gates Foundation funds the Chinese component of the larger trial. The overall project value is more than €25 million.

ScreenTB

Streamlining diagnostic approaches of active TB

Tuberculosis (TB) places severe pressure on health care services in low- and middle-income countries. In a setting with a high prevalence of poor lung health and where the presence of other lung infections complicates the detection of active TB, a large financial and logistical commitment from the health care services is needed. Despite the roll-out of the highly sensitive and specific Xpert MTB/RIF (GeneXpert®) sputum test with a potential turn-around time of two hours, many people in high-TB-burden areas still do not have access to efficient TB diagnostic services due to logistical constraints. Undiagnosed TB fuels the transmission of the disease and negatively impacts treatment outcomes.

The African European Tuberculosis Consortium (AE-TBC), funded under the first EDCTP programme, identified a seven-marker serum protein biosignature for the diagnosis of TB irrespective of HIV status and ethnicity in Africa. The ScreenTB project, funded under the second EDCTP programme, will use some of the biomarkers of the AE-TBC project to develop a point-of-care, field-friendly device which is based on finger-prick blood testing. The device's accuracy (sensitivity and specificity) will be tested against gold standard diagnostic tools (such as Xpert MTB/RIF, MGIT culture, TB sputum smear, and chest x-ray).

"The screening test that is being developed in the ScreenTB project is directly based on the findings of the AE-TBC study," says Professor Gerhard Walzl of Stellenbosch University in South Africa and coordinator of the ScreenTB project. "In the latter study, we discovered a 7-protein blood signature that appears to be very promising. This signature will be optimised in ScreenTB for the development of a strip test that can be conducted outside the laboratory by minimally trained health care workers. The test will be similar to a pregnancy or blood glucose strip test."

ScreenTB received a €3 million grant from EDCTP in 2016. The study will recruit 800 patients with symptoms of active TB, regardless of their HIV infection status, in five African countries: Ethiopia, The Gambia, Namibia, South Africa and Uganda.

The successful implementation of a sensitive, cost-effective screening test would streamline diagnostic programmes in resource-limited settings and could decrease unnecessary referrals for expensive GeneXpert® testing by 75%.

Prof. Walzl: "In the longer term, the study needs to move into the implementation phase. This would require large-scale testing in health care settings where people report with symptoms of possible TB. The impact of such a screening test would then have to be evaluated. Ultimately, we are aiming to contribute to a test that will identify those patients in whom further testing for active TB by the highly sensitive and specific, but often centralised and more expensive, gold standard tests is most warranted. This will in turn help the health care services to channel resources more effectively."

**“
A strip test
that can be
conducted
outside the
laboratory
by health
care workers
without much
training.
”**

*Prof. Gerhard Walzl
South Africa*

TWENDE

Effective implementation of TB diagnostics



“We also aim to create a culture and environment in which health care interventions are systematically reviewed.”

*Dr Wilber Sabiiti
United Kingdom*

As approximately 40% of the world's TB cases go without a laboratory test, the TWENDE project – a Swahili word for 'Let's go!' – received an EDCTP grant of €0.4 million to identify barriers to and opportunities for the introduction of TB diagnostics. It aims to create a platform for the translation of research innovations into policy and practice. Its focus is on three East African countries: Kenya, Tanzania, and Uganda.

“Our argument was that it would be very difficult to translate the research innovations into policy and practice without first understanding and removing barriers to implementation,” explains TWENDE's coordinator, Dr Wilber Sabiiti of the University of St. Andrews, United Kingdom. Among these challenges are for example irregular supply of electricity and water for the laboratories, difficulties of procuring laboratory supplies and getting them cleared by the countries' customs authorities, high staff turnover.

Dr Sabiiti: “These practical experiences served as a wake-up call. We understood that the success of a diagnostic is not only about its accuracy to detect the disease but also about the clinical utility and how it could be implemented in the actual settings of a health care system.”

Using TB diagnostics implementation as a model, TWENDE will use a 'go-beyond the laboratory' approach to explore the challenges to and opportunities for removing barriers, from community level up to national policy making.

“Our engagement with policy-makers will include discussing the views from the community. Together, we need to work out the effective means of translating health research innovations into policy and practice and make sure they reach the people who need them most,” says Dr Sabiiti.

The project will draw strength and experiences from three studies funded under the first EDCTP programme: PanACEA, REMox-TB and MAMS-PANBIOME. Dr Sabiiti: “From these projects arose the questions that led to the TWENDE project proposal. They also provided the network of researchers who now form the TWENDE consortium. Part of the consortium is the East African Health Research Commission (EAHRC), a statutory organ of the East African community (EAC) that advises on and oversees all matters of health policy in the EAC. Going forward, the EAHRC will lead efforts of integrating TWENDE and its findings into the policy framework of the EAC”.

TWENDE aims to contribute to streamlining the channels of translating health research innovations into policy and practice in East Africa. Dr Sabiiti: “We also aim to create a culture and environment in which health care interventions are systematically reviewed and the lessons of success are ploughed back into policy-making to improve service delivery in the healthcare system. An effective health care system will in turn lead to effective research and evidence-based policy making and most importantly, better health care delivery to the citizens.”



Photo:
Medical staff and volunteer at the Ubuntu Clinic in
Khayelitsha, South Africa
*part of the PredART project led by Dr Graeme Meintjes,
funded under the first EDCTP programme*

Malaria



Malaria control has made remarkable progress in the last decade. It remains, however, a threat to half of the world's population with more than 200 million new cases of malaria in 2015 and still claims the life of almost half a million people every year, the majority of whom are children under five years of age. According to the WHO 2016 *World Malaria Report*, 92 per cent of malaria deaths occur in sub-Saharan Africa. To end this massive suffering, more needs to be done in research and development to improve diagnostics, develop new treatment drugs and combination regimens, as well as novel vaccines.

For its malaria funding strategy, EDCTP prioritised the following research areas:

- Evaluation of new drugs and drug combinations, with a particular focus on children and pregnant women and uncomplicated malaria. As the majority of individuals living in malaria-endemic areas are exposed to multiple infections, it is increasingly important to understand interactions between antimalarials and drugs used in the treatment of other diseases such as HIV, TB and neglected infectious diseases.
- Field-testing of diagnostics for identifying infection and resistance mutations.
- Evaluation of novel and second generation malaria vaccines effective against both *Plasmodium falciparum* and *vivax* infections.
- Evaluation of the effectiveness of intervention strategies for drugs, vaccines and diagnostics, in the context of malaria elimination.

By the end of 2016, EDCTP2 had invested €9.46 million in malaria research through six projects. 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 Strategic research agenda: addressing priority areas for malaria



- Prevention, 1 grant
€7.39 M
- Product-focused implementation research, 3 grants
€1.48 M
- Vaccines, 1 grant
€0.5 M
- Treatment, 1 grant
€0.09 M

IMPROVE

Malaria prevention in pregnancy

Each year over 30 million pregnancies occur in malaria endemic areas of sub-Saharan Africa. Malaria during pregnancy has devastating consequences for mother and unborn child. Pregnant women are more susceptible to malaria. When compared with non-pregnant women living in malaria-endemic areas, pregnant women have an up to 50% higher risk of infection, which places both mother and foetus at risk of adverse events.

“Pregnant women are often infected with malaria without showing any outward signs or symptoms. If left undetected and untreated, malaria can cause anaemia and interfere with the development of the foetus. This can lead to loss of the pregnancy or premature birth, and low birth weight, which in turn increases the risk of early infant death,” says Professor Feiko ter Kuile of the Liverpool School of Tropical Medicine, United Kingdom.

The World Health Organization (WHO) recommends sulphadoxine-pyrimethamine (SP) as preventive treatment in pregnancy (IPTp) for women without malaria symptoms. However, its efficacy is threatened by increasing resistance to SP, while there are no acceptable alternative antimalarials. Over the last decade, several IPTp trials showed that neither amodiaquine, nor mefloquine, nor chloroquine-azithromycin are a suitable replacement for SP because of their poor tolerability for pregnant women. Furthermore, intermittent screening for malaria and treatment with artemisinin-based combination therapies has shown to be non-superior to IPTp-SP, even in areas with very high SP resistance.

Prof. ter Kuile leads the IMPROVE project which aims to address this clear and urgent need for alternative drugs for malaria prevention in pregnancy. Two earlier exploratory trials from Kenya and Uganda showed that dihydroartemisinin-piperaquine (DP) has the potential to replace SP for malaria prevention in pregnancy. It was more effective than SP in reducing malaria infection and clinical malaria. Prof. ter Kuile: “These trials were not powered to evaluate the impact on adverse pregnancy

outcomes. WHO reviewed the evidence in July 2015 and concluded that DP is a promising alternative to SP but that a larger confirmatory trial is needed before implementation of IPTp-DP could be recommended for health care use.”

IMPROVE will determine the efficacy, safety and cost-effectiveness of IPTp-DP, alone or combined with azithromycin (a broad-spectrum antibiotic active against sexually transmitted infections/reproductive tract infections). The trial aims to provide definitive data to determine whether DP is a suitable alternative in endemic areas with high SP resistance. “A positive result may contribute to a change in WHO policy for countries with these levels of parasite resistance, including most countries in east and southern Africa. It may result in healthier pregnancies and healthier newborns for many women,” explains Prof. ter Kuile.

The project received a €7.4 million, composed of funding from the European Union and the Joint Global Health Trials scheme, which is a partnership between the UK Department for International Development, the UK Medical Research Council, the National Institute for Health Research, and the Wellcome Trust. Additional funding of £2.7 million has been provided by the Joint Global Health Trials to include a trial with HIV-infected pregnant women alongside the main study with HIV-uninfected participants.

IMPROVE is a collaboration of institutions under the umbrella of the Malaria in Pregnancy (MiP) Consortium. The network consists of ten research groups, of which six are in Europe: Liverpool School of Tropical Medicine, London School of Hygiene and Tropical Medicine, and University College, London in the United Kingdom; the Centre for Medical Parasitology, University of Copenhagen, Denmark; University of Bergen, Norway; and University of Tampere, School of Medicine, Finland. Four centres are in Africa: Kenya Medical Research Institute, Kenya; College of Medicine, Malawi; the National Institute of Medical Research and the Kilimanjaro Christian Medical Centre, both in Tanzania.



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WHO
recommends
a preventive
treatment in
pregnancy.
However,
efficacy is
threatened
by increasing
drug
resistance.
”

Prof. Feiko ter Kuile
United Kingdom



“
**IMPACT
aims to
determine DP
cardiotoxicity
and its
correlation
with dose
and drug
concentration.**
”

*Dr Anja Terlouw
United Kingdom*

IMPACT project *Optimising a dosing regimen*

The antimalarial dihydroartemisinin-piperaquine (DHA-PPQ) is highly efficacious against uncomplicated malaria. It is considered the most promising antimalarial for drug-based efforts to reduce malaria transmission. However, widespread use of an antimalarial among unselected populations (as in mass drug administration campaigns) requires a drug with a wide therapeutic range and an excellent safety profile. This poses a challenge for DHA-PPQ as it has a relatively narrow therapeutic range. Safety concerns regard especially children who are possibly under-dosed and certain groups at risk for cardiac problems, for which the safe concentration threshold is uncertain.

On the basis of an initial consultation of the Malaria Policy Advisory Committee in 2016, WHO decided to review the evidence on the cardiac safety of antimalarials, with a particular interest in piperaquine. “This resulted in a WHO Evidence Review Group meeting in October 2016. The ADAPT and IMPACT projects contributed to this process and provided opportunities for more in-depth pooled individual-level analyses,” says Dr Anja Terlouw of the Liverpool School of Tropical Medicine (LSTM) in the United Kingdom, the coordinator of the IMPACT project.

The ADAPT study, led by Dr Victor Mwapasa (Malawi-Liverpool-Wellcome Trust Research Programme, Malawi) and funded under the first EDCTP programme, will deliver an important contribution to the IMPACT project. “The ADAPT studies contribute safety data from three clinical studies to the current project as part of a series of literature reviews and pooled individual-level analyses. These studies explore the frequency and magnitude of PPQ cardiotoxicity and potential drug-drug interactions with ARVs, affecting PPQ levels,” says Dr Terlouw.

The IMPACT project received an EDCTP grant of €0.5 million. It aims to determine the frequency and severity of DP cardio-toxicity, and its correlation with dose and drug concentration. The analyses will make use of two pioneering data sharing platforms on antimalarial efficacy and safety, developed by Worldwide Antimalarial Resistance Network (WWARN) and LSTM. Findings will be used to determine the upper PPQ dose thresholds (according to key risk groups) and identify remaining research priorities. The project will also be useful to raise awareness of the need for dose optimisation research among researchers, funders and control programmes.

Dr Terlouw: “IMPACT will help guide policy recommendation around DHA-PPQ safety. Beyond DHA-PPQ, it will demonstrate the importance of identifying global research priorities for antimalarial safety studies and, secondly, of integrating their safety data analyses into WWARN’s global efficacy data platform. The combination of these two steps offers a powerful approach for dose optimisation applicable across a range of drugs.”



Photo:
Medical staff and volunteer at the Regional Hospital
of Banfora, Burkina Faso
part of the WANEAM project led by Prof. Abdoulaye
Djimé, funded under the first EDCTP programme

Neglected infectious diseases



Eighteen neglected infectious diseases (NIDs) were part of the scope of the second EDCTP programme in 2016 (Box 1). The London Declaration on Neglected Tropical Diseases targets 10 of these NIDs for control or elimination. This is to be achieved mainly through (mass) drug administration programs, supplemented by vector control efforts for some NIDs. For some of the NIDs diagnostic tools are needed to identify infections and reservoirs.

Based on the current situation in NID research and control, EDCTP has several funding priorities. Where effective treatment already exists, it prioritises clinical trials of combination therapies and implementation research, i.e. to identify the most effective delivery of treatment in particular settings. Where treatment is inadequate or lacking entirely, it will support

early-phase clinical trials. For key NIDs, it aims to invest in new diagnostics, including products to characterise host responses.

So far EDCTP2 has supported five projects on NIDs with a total value of €5.34 million. Most supported projects are studies to evaluate diagnostic tools.

* Based on the WHO list of neglected tropical diseases; Chagas disease is not in the EDCTP scope.

Box 1: Neglected infectious diseases in the scope of EDCTP*

- | | |
|--|---|
| • Buruli ulcer | • Lymphatic filariasis |
| • Chikungunya | • Mycetoma |
| • Dengue | • Onchocerciasis (<i>river blindness</i>) |
| • Dracunculiasis (<i>guinea-worm disease</i>) | • Rabies |
| • Echinococcosis | • Schistosomiasis |
| • Foodborne trematodiasis | • Soil-transmitted helminthiasis |
| • Human African trypanosomiasis (<i>sleeping sickness</i>) | • Taeniasis/Cysticercosis |
| • Leishmaniasis | • Trachoma |
| • Leprosy (Hansen's disease) | • Yaws (<i>Endemic treponematoses</i>) |

EDCTP Strategic research agenda: addressing priority areas for NIDs



- Diagnosis and tracking, 4 grants
€5.19 M
- Product-focused implementation research, 1 grant
€0.15 M



Photo:
Researchers at the Amana Hospital in Dar es Salaam, Tanzania
part of the TRIP project led by Dr Sayoki Godfrey Mfinanga

DiTECT-HAT

Diagnostic tools to eliminate sleeping sickness



“
We expect
to propose
suitable
diagnostic test
algorithms
and an early
test of cure.
”

Dr Veerle Lejon
France

Human African trypanosomiasis (HAT), also known as sleeping sickness, is caused by infection with the parasites *Trypanosoma brucei gambiense* (Tbg) or *Tb rhodesiense*, and transmitted by tsetse flies. In the last decade, the prevalence of Tbg HAT has dramatically decreased and HAT has been targeted for elimination by 2020. However, integration of diagnosis and case management into the general health system, monitoring of eliminated foci and development of safe and efficacious drugs, remain important challenges to achieve sustainable elimination of sleeping sickness.

“Diagnosis of sleeping sickness has to be taken over by non-specialised hospitals and health centres, as specialised structures become too expensive,” explains Dr Veerle Lejon of the Institut de Recherche pour le Développement (IRD) in France. “Diagnostic tests and algorithms have to be adapted to this new working environment. Furthermore, easy to administer drugs should be developed. There are new drugs in the pipeline but drug trials are slowed down by the need to follow up treated patients for 18 months to confirm cure. An earlier test of cure is really needed. Moreover, it is important to avoid that the disease re-emerges and becomes again epidemic, as has happened in the past. A suitable monitoring system has to be set up.”

Dr Veerle Lejon is the coordinator of the DiTECT-HAT project, the first grant funded under EDCTP2 on one of the NIDs. The project received an EDCTP contribution of almost €3 million to determine the diagnostic performance and cost-effectiveness of diagnostic tools and algorithms for early and rapid diagnosis of Tbg HAT. The tools will be evaluated in peripheral health centres, for passive case detection, therapeutic response, and post-elimination monitoring. The project will be conducted in Burkina Faso, Côte d'Ivoire, Guinea, and the Democratic Republic of the Congo (DRC), with additional testing in regional HAT reference centres in Burkina Faso and the DRC.

Dr Lejon: “The last decade has seen big progress in the development of rapid diagnostic tests for sleeping sickness. These tests do not need special equipment or reagents, are easy to perform and the result is known in 15 minutes.”

Different tests are already available. However, they have hardly been compared or combined. “We also want to know if it is worth to combine rapid tests, a strategy already used for diagnosis of HIV. Furthermore, the less experienced health structures might benefit from supporting the rapid tests with more reliable reference tests. Such tests can be done in national or regional reference laboratories, on dry blood samples on filter paper. Reference testing on dry blood samples is probably also well suited for elimination monitoring,” says Dr Lejon.

For the early test of cure, DiTECT-HAT collaborates with an ongoing drug trial (DNDi-OXA-02-HAT) where patients are followed up rigorously and samples of blood and cerebrospinal fluid are already taken. The project uses the available samples to evaluate several new promising tests in order to identify the best algorithms for diagnosis, follow-up, and monitoring of sleeping sickness.

If successful, the project expects to propose suitable diagnostic test algorithms, and a post-elimination monitoring system that detects sleeping sickness outbreaks early and reliably. Moreover, DiTECT-HAT expects to identify an early test of cure, possibly as a blood test. This will simplify new drug trials, but will also contribute to routine care of patients in which treatment failure is suspected. Lejon: “In the long term, we hope to extrapolate our findings to other endemic countries and contribute to sustainable elimination of sleeping sickness.”

SOLID

Point-of-care diagnosis for taeniasis and (neuro)cysticercosis

Taeniasis is the intestinal infection caused by adult tapeworm. When left untreated, a more serious condition known as cysticercosis develops as *Taenia solium* larvae invade body tissues. When larvae build up in the central nervous system, muscles, skin and eyes, it leads to (neuro)cysticercosis – the most severe form of the disease and a common cause of seizures worldwide. (Neuro)cysticercosis is estimated to be responsible for 30% of all epilepsy in countries where the parasite is endemic. Currently, there are no cheap, easy to apply, sensitive and specific diagnostic tools available for the detection of this parasite.

A point-of-care lateral flow test developed by the US Centers for Disease Control and Prevention (CDC), is a very promising candidate. The test combines the diagnosis of both (neuro) cysticercosis and taeniasis. This point-of-care test would be a major breakthrough. Its value for early neurocysticercosis case and tapeworm carrier detection and management would contribute much to improving health outcomes as well as reducing the risk of transmission.

The SOLID project received €1.9 million in funding from EDCTP to contribute to the implementation of this rapid, cheap and simple point-of-care test both at the community and primary health facility levels. The project takes place in Tanzania and Zambia. It also aims to improve the capacity in these countries in *T. solium* disease diagnosis and clinical case management as well as their capacity to conduct diagnostic and clinical studies.

“One of the main challenges of (neuro) cysticercosis in Africa at point-of-care level is that the medical sector is very little aware of the *T. solium* (neuro)cysticercosis/taeniasis zoonotic disease complex,” explains Professor Pierre Dorny of the Institute of Tropical Medicine (ITM) Belgium, who leads the SOLID project. “This means that a comprehensive training will be required, firstly on the disease itself, the applicability and use of the test, the

interpretation of the test results, followed by an extensive training in patient management and how the test can be applied for this condition.”

Prof. Dorny: “If successful, the project may support a detailed WHO endorsement and implementation plan, and facilitate commercialisation. The aim is to bring down the total cost per assay and to make it affordable and available to all for routine testing, including in laboratories in countries with limited resources. Wider availability of the point-of-care test will enable researchers to obtain better data on the disease burden which will improve the design of control programmes and their cost effectiveness.”



“
SOLID may support a detailed WHO endorsement and implementation plan, and facilitate commercialisation.
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Prof. Pierre Dorny
Belgium

Emerging and re-emerging infectious diseases



Emerging and re-emerging infectious diseases with epidemic potential are a persistent threat to public health in many African countries and potentially to global health security. Ebola and yellow fever are endemic to sub-Saharan Africa, but infectious diseases with epidemic potential can also be imported from other continents.

The outbreak of Ebola virus disease (EVD) in West Africa has catalysed a number of R&D activities in order to deliver effective diagnostic, therapeutic, and preventive interventions. However, the successful testing and implementation of these interventions requires the availability of functioning health research infrastructures and increased research capacity in the affected countries. Moreover, affected populations need to be willing to participate in research and development activities.

EDCTP's key priorities for emerging and re-emerging infectious diseases include:

- Surveillance and response strategies for newly detected outbreaks.
- Early phase clinical trials for diseases where treatments are inadequate or lacking entirely.

Increasing capacity for Ebola outbreak research

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, the Special Programme for Research and Training in Tropical Diseases (TDR), and the UK Medical Research Council (MRC) to increase capacity for Ebola outbreak research in sub-Saharan Africa. These projects have received a total investment of €1.5 million.

From 10-11 February 2016, these grantees met in Ghana for a workshop on Ebola Virus Disease in order to share and finalise their study plans and identify opportunities for collaboration. The grantees presented project plans and case studies. Lessons learnt from the Ebola crisis, mainly in West Africa, were also summarised. The Noguchi Memorial Institute of Medical Research at the University of Ghana hosted the workshop which was chaired by representatives of EDCTP and the Canadian Institutes of Health Research.



Photo:
Medical staff at the Connaught Hospital in Sierra Leone part of ID-CLINICAL CAPACITY led by Mr Andy Leather

SELeCT

Strengthening capacity in Liberia for clinical research during outbreaks

The 2013–2016 West African Ebola outbreak which resulted in more than 11,300 deaths, highlighted the need for a vaccine against the disease. In 2016, a major trial in Guinea confirmed that an experimental Ebola vaccine was highly protective against EVD. However, further evaluations of treatments for Ebola can only take place as long as the virus circulates. It is important that clinical studies will be resumed when and where the next Ebola outbreak occurs. Therefore, investments must be made to ensure that vaccine trials can be rolled out during outbreaks. Institutional and individual capacities to conduct high quality health research during outbreaks need to be established or strengthened.

In 2016, the SELeCT project, led by Dr Alfredo Mayor Aparicio of the Barcelona Institute for Global Health (ISGlobal), Spain, received from EDCTP €250,000 in funding to strengthen the institutional capacity at St. Joseph's Catholic Hospital (SJCH) in Monrovia, Liberia, to conduct clinical trials between and during future infectious disease outbreaks.

Liberia suffered major losses during the last Ebola outbreak. Its health system was seriously damaged. "In 2014, the SJCH closed down for three months during the Ebola outbreak," says Dr Aparicio. "Nine members of the SJCH staff, including the hospital director, had died of Ebola. In 2015, the Juan Ciudad Foundation (FJC) in Spain invited ISGlobal to visit the SJCH and assess the impact of the crisis on the provision of health services. The hospital's willingness to rebuild its capacities and conduct research on infectious diseases with epidemic potential offered ISGlobal the opportunity to establish a consortium with SJCH and FJC."

Prof. Aparicio: "A training programme on good clinical and laboratory practice targeted SJCH laboratory, clinical, pharmacy, and administrative staff. Five staff members from local health authorities and ten community leaders also participated in this training. As a result, the first mixed-methods research at the SJCH has been launched, and trainees are preparing the standard operating procedures to support six clinical trial units at the SJCH."

Another important aspect of the project is to ensure community engagement. Trust must be built within the study populations. Lack of trust is a major challenge for the affected countries and international groups working to eliminate the transmission of Ebola. "Engagement of local communities cannot be improvised in the midst of an outbreak," explains Dr Aparicio. "Therefore, within SELeCT, we aim at creating discussion platforms where community leaders can collaborate with the St Joseph's Catholic Hospital in planning future research activity."

The SELeCT team expects that the training, networking and community engagement strategies will not only build new capacities for the implementation of clinical trials but will also strengthen existing diagnostic and treatment capacities at the SJCH. This will also contribute to sustainable improvements of the region's community health care.



“Engagement of local communities cannot be improvised in the midst of an outbreak.”

*Dr Alfredo Mayor Aparicio
Spain*

Diarrhoeal diseases and lower respiratory tract infections



The diarrhoeal diseases and lower respiratory tract infections were added to the scope of EDCTP2 as both disease groups are major contributors to global mortality among children under five years of age.

The majority of diarrhoeal diseases can be attributed to unsafe water supplies and inadequate sanitation and hygiene. Global mortality from diarrhoeal diseases has declined in recent years due to the implementation of oral rehydration therapy and improvements in education and socio-economic conditions alongside other interventions. However, in developing countries, it remains the second leading cause of death in children under five.

Lower respiratory tract infections are also a significant contributor to mortality of newborns and children under five years of age, immunocompromised individuals, and the elderly. HIV-infected adults and children acquire lower respiratory tract infections as opportunistic infections which increase their risk of hospitalisation and death.

These disease groups were first included in the portfolio in the 2016 work plan. Two stakeholder meetings to inform EDCTP's funding strategy were held in Amsterdam, The Netherlands on 5 and 6 July 2016. The objectives of the meetings were to review the research landscape, available interventions and products in development, and to identify short- and medium-term priorities for EDCTP in terms of disease, research and intervention. Representatives from academic and research institutions, funding agencies, product development partnerships, among others, participated in the discussions. The reports of these meetings are available at www.edctp.org.

Regarding **diarrhoeal diseases**, EDCTP has prioritised the following pathogens: rotavirus, *Shigella*, enterotoxigenic *E. coli*, *Cryptosporidium* and norovirus. EDCTP's funding priority is the evaluation of vaccines, as they are likely to offer cost-effective ways to manage diarrhoeal diseases. Rotavirus vaccines are beginning to have a major impact globally, but their effectiveness is significantly affected by enteropathy. Vaccines against other viral and bacterial pathogens are entering early clinical phases of development.

For the **lower respiratory tract infections**, the target populations for interventions include children, the elderly and people hospitalised with lower respiratory tract infections, as well as immunocompromised HIV-infected individuals.

Priority pathogens that affect particular population groups are:

- Group B streptococci, respiratory syncytial virus (RSV) and pneumococcus in neonates
- RSV, pneumococcus and cytomegalovirus in children
- Pneumococcus in adults.

Important priorities for lower respiratory tract infections include:

- Simple methods to identify patients who need antibiotics, on the basis of clinical signs;
- Identification and evaluation of the most appropriate antibiotic regimens;
- Low-cost methods for oxygen delivery to treat children with hypoxaemia (low blood oxygen levels).

A first study of lower respiratory tract infections was awarded a grant of €150,000. The epidemiological study will be conducted in Ghana through a Career Development Fellowship.



Photo:
Medical staff at the Connaught Hospital in Sierra Leone
part of ID-CLINICAL CAPACITY led by Mr Andy Leather



Photo:
Medical staff at the Connaught Hospital in Sierra Leone
part of ID-CLINICAL CAPACITY led by Mr Andy Leather

Clinical research capacities in sub-Saharan Africa

EDCTP aims to develop the capacity of sub-Saharan African countries to conduct high-quality clinical trials and product-focused implementation research consistent with fundamental ethical principles and recognised international regulatory standards and good practice.

To achieve this objective, EDCTP is mainly investing in training and mentorship programmes in sub-Saharan Africa, and promoting networking through the exchange of ideas, information and people between institutions in Europe and those in Africa.

It is also supporting activities strengthening the ethical, regulatory and legal framework for conducting clinical trials within the EDCTP scope in sub-Saharan Africa.

Ethics and regulatory capacities

EDCTP aims to establish an enabling environment for clinical research, particularly by helping sub-Saharan Africa countries to strengthen their ethical, regulatory and legal frameworks. They must be able to host clinical studies consistent with international standards and respecting local regulations. In 2016, grants with a total value of €1.75 million were awarded to support six sub-Saharan African countries to establish and develop robust national medicines regulatory systems and capacities for ethical review of clinical research as well as medicinal products and technologies for use in humans.



“
The establishment of a robust ethics review process will ensure efficient and timely review of applications for clinical research.
”

*Dr Shaza Abass
Sudan*

Enhancing ethics in Sudan *Health research ethics review and regulatory capacity in Sudan*

Health research ethics in Sudan is governed by two national regulatory authorities: the National Health Research Ethics Committee (NHREC) and the National Medicine and Poisons Board (NMPB). Both bodies have the legal authority and the responsibility to develop guidelines, and to regulate and oversee the ethical review process and the conduct of research. These regulatory authorities face many challenges in fulfilling their roles.

“The main challenge is the lack of coordination between the two national bodies dealing with ethics and medicinal products regulation respectively,” says Dr Shaza Abass of the University of Khartoum in Sudan. “Other challenges in research ethics in Sudan are attributed to suboptimal functioning of the other state and institutional research ethics committees. This is caused by inadequate budgets, limited competence and the diversity of their membership. Furthermore, there is a lack of legislative framework endorsed by the government that guides medical products regulations.”

Dr Abass coordinates the project ‘Enhancing ethics in Sudan’, funded by EDCTP in 2016. The project received €300,000 in funding to build and strengthen the capacity of the NHREC and the NMPB. “Developing sustainable strategies and guidelines for the NHREC and the NMPB will improve their functionality by reducing redundant operations between these bodies and improve collaboration,” says Dr Abass.

Dr Abass: “National regulatory authorities (NRAs) and ethics committees need to work in close cooperation, with open communication and clarity of roles and responsibilities in areas such as review and approval of clinical trials applications involving investigational medical products. Training of NRAs and research ethics committee members, support the recognition and accreditation process for institutional and national ethics committees, and networking these bodies will improve the overall regulatory and ethics review process.”

“The establishment of a robust ethics review process will on one hand ensure efficient and timely review of applications for clinical research and, on the other hand, ensure the scientific integrity of research and the protection of the rights and welfare of the highly vulnerable patients who often participate in this research.”

TRUST *Project on fair and ethical research*

EDCTP participates in the TRUST project, which aims to support high ethical research standards, equitable research partnerships, and fair research. TRUST is a three-year project funded under the European Union’s Horizon 2020 programme. The project will run from October 2015 to September 2018. It created an international network on global research ethics governance to identify generic risks of exporting non-ethical practices. It also aims to develop, in collaboration with vulnerable populations, tools and mechanisms for the improvement of research governance structures.

From 19-20 October 2016, the European partners and advisors of the TRUST consortium convened at the ANRS headquarters in Paris, France. All partners' provided activity updates and discussed policy briefs. COHRED presented the online version of the Fair Research Contracting web tool. EDCTP contributed to the analysis of ethical principles contained in local, national and international research ethics codes. This analysis will support the working group responsible for one of the main deliverables of TRUST, a Global Code of Conduct.

The attending partners included ACF (Action contre la faim), COHRED, EDCTP, FGVA (Foundation Global Values Alliance), Inserm, UNESCO, Signosis Spri, and UCLan (Centre for Professional Ethics, University of Central Lancaster).

Lib-Regul-Trials *Developing regulatory capacity in Liberia*

The Liberia Medicines and Health Products Regulatory Authority (LMHRA) was established as the national regulatory authority in 2010. It is an autonomous government agency that reports to the National Legislature and the office of the President of the Republic of Liberia. LMHRA is responsible for authorising the marketing of medicines and healthcare products as well as for other regulatory activities: registration, inspection, import control, licensing, market and quality control, advertisement and promotion control, and pharmacovigilance in Liberia. The response to the Ebola outbreak in Liberia led to an increasing number of requests for approval

of clinical trials for treatment and diagnosis, which created many challenges for LMHRA to effectively regulate these trials. "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 LMHRA. "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."

Dr Sumo is the coordinator of the Lib-Regul-Trials project. In 2016, EDCTP awarded a €300,000 grant to the LMHRA in order to develop capacity to effectively exercise its mandate as a regulatory body for clinical research in Liberia. Dr Sumo:

"The project helps the LMHRA 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.



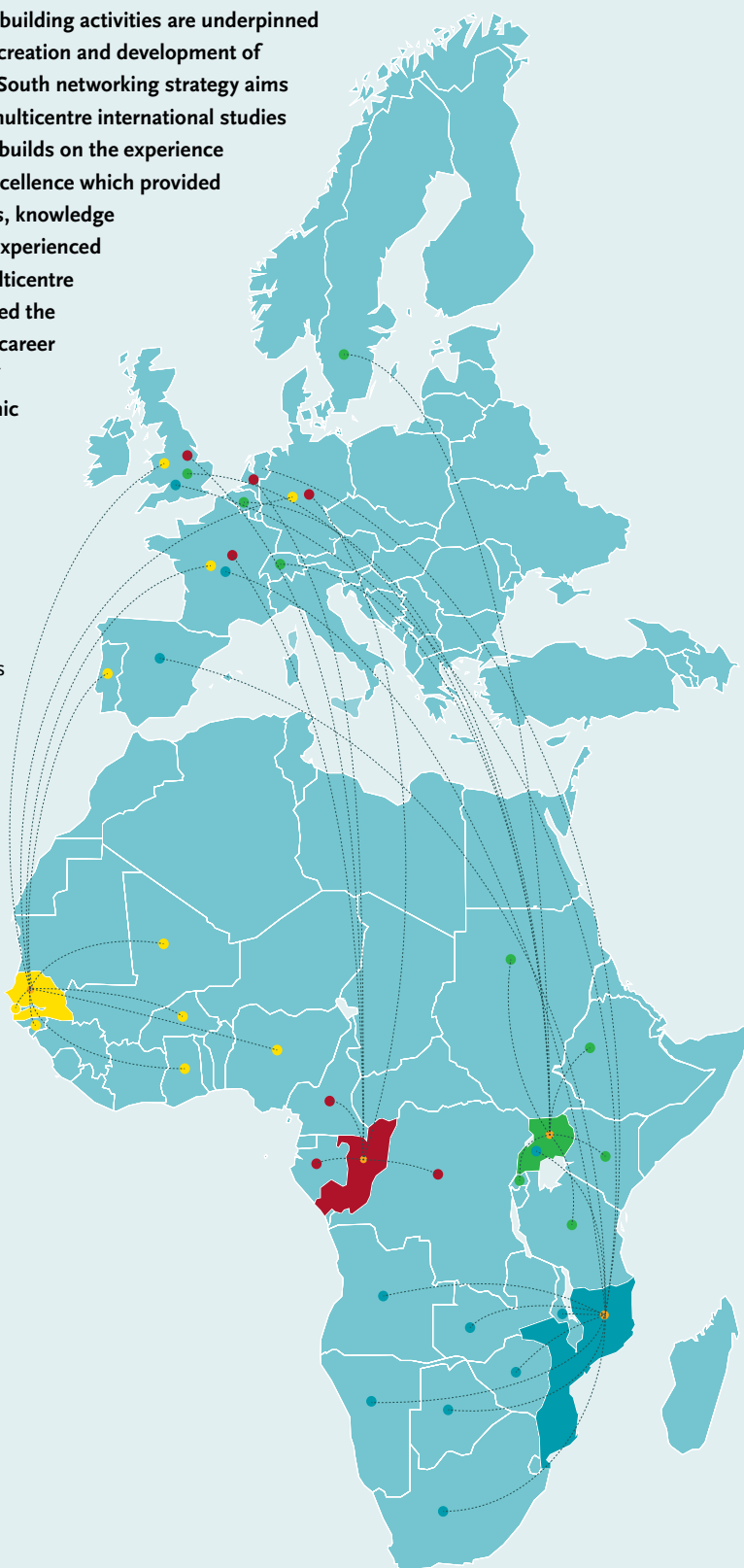
“
The project helps the LMHRA to develop a regulatory framework and other regulations for the conduct of clinical trials in Liberia.
”

Dr David Sumo
Liberia

Networks of Excellence

EDCTP's research and capacity-building activities are underpinned by a strong commitment to the creation and development of research networks. Our South–South networking strategy aims to expand African capacity for multicentre international studies through sharing of expertise. It builds on the experience with the EDCTP Networks of Excellence which provided a mechanism to share resources, knowledge and expertise, and enable less experienced institutions to participate in multicentre clinical trials. They also supported the mentoring and training of early-career researchers, and the conduct of epidemiological and demographic studies in order to facilitate the preparation of future trials.

Four Networks of Excellence were established under the first EDCTP programme. Now under the second programme, these networks will build on the results of their first grants to increase South-South and North-South research collaborations, competences and capacity to conduct clinical trials. In 2016, grants were again approved for the Networks of Excellence to a total of approximately €12 million.



CANTAM2 venture Central Africa Clinical Research Network

Congo	• Fondation Congolaise pour la Recherche Médicale.
Cameroon	• Central African Network for Tuberculosis, HIV/AIDS and Malaria (CANTAM) • University of Yaoundé • Organisation de Coordination pour la lutte contre les Endémies en Afrique Centrale (OCEAC) • University of Buea • Centre for Research on Filariasis and other Tropical Diseases
DR Congo	• University of Kinshasa (UNIKIN)
Gabon	• Faculté de Médecine, Université des Sciences de la Santé Libreville • Centre de Recherches Médicales de Lambaréné (CERMEL) • Centre international de recherches médicales de Franceville (CIRMF)
France	• Institut de Recherche pour le Développement (IRD)
Germany	• University of Tübingen • Eberhard Karls Universität Tübingen
Netherlands	• University of Amsterdam (UVA) • Academisch Medisch Centrum – Amsterdam
United Kingdom	• University College London (UCL) • St. George's University of London

WANETAM II West African Network for TB AIDS and Malaria

Senegal	• Université Cheikh Anta Diop
Burkina Faso	• Centre Muraz
The Gambia	• Medical Research Council (MRC) Unit • National Public Health Laboratory (NPHL)
Ghana	• University of Ghana • Noguchi Memorial Institute for Medical Research (NMIMR)
Guinea-Bissau	• Bandim Health Project
Mali	• Malaria Research and Training Center (MRTC) • University of Bamako
Nigeria	• Nigerian Institute of Medical Research (NIMR) • University of Ibadan
France	• Institut de Recherche pour le Développement (IRD)
Germany	• Research Center Borstel
Portugal	• Instituto de Higiene e Medicina Tropical, Universidade Nova de Lisboa
United Kingdom	• London School of Hygiene and Tropical Medicine (LSHTM)

EACCR II Eastern Africa Consortium for Clinical Research II

Uganda	• Uganda National Health Research Organisation
Ethiopia	• Addis Ababa University (AAU)
Kenya	• Kenya Medical Research Institute (KEMRI)-Center for Global Health Research (CGHR) • KEMRI–Wellcome Trust Research Programme
Rwanda	• University of Rwanda (UR)
Sudan	• University of Khartoum (IEND)
Tanzania	• National Institute for Medical Research (NIMR) • Kilimanjaro Clinical Research Institute (KCRI) • Kilimanjaro Christian Medical Centre (KCMC)
Uganda	• Ministry of Health • MRC/UVRI Uganda Research Institute on AIDS
Belgium	• Prins Leopold Instituut voor Tropische Geneeskunde
Netherlands	• Stichting Katholieke Universiteit • Amsterdam Institute for Global Health and Development (AIGHD)
Sweden	• Karolinska Institute
Switzerland	• Centre Hospitalier Universitaire Vaudois (CHUV)
United Kingdom	• University of Oxford • University College London (UCL)

TESA II Trials of Excellence in Southern Africa II

Mozambique	• Centro de Investigação em Saúde de Manhiça (CISM)
Angola	• Centro de Investigação em Saúde de Angola
Botswana	• Botswana-Harvard AIDS Institute Partnership (BHP)
Malawi	• Blantyre Health Research and Training Trust
Namibia	• University of Namibia
South Africa	• Stellenbosch University • University of Cape Town (UCT) • LT Clinical Research
Uganda	• Uganda National Health Research Organisation
Zambia	• University Teaching Hospital
Zimbabwe	• Biomedical Research and Training Institute (BRTI) • University of Zimbabwe
France	• European Clinical Research Infrastructure Network (ECRIN-ERIC)
Netherlands	• Amsterdam Institute for Global Health and Development (AIGHD)
Spain	• Barcelona Institute for Global Health (ISGlobal)
United Kingdom	• University College London (UCL)

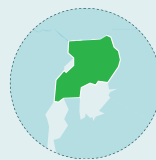


Congo

CANTAM2 venture

“The initial phase of CANTAM, funded under the first EDCTP programme, was the start of the network. There were limited collaborations among the institutions. Moreover, many of the institutions that were part of the network had limited human and infrastructure resources. Now with CANTAM2, all participating institutions have the requirements to conduct clinical research according to international standards. To achieve its goals, CANTAM2 expanded and new partners bringing additional expertise have joined the network. In brief, CANTAM1 represented the birth of the research coalition against infectious diseases in Central Africa; CANTAM2 is about the growth and maturity of the coalition.”

Professor Francine Ntoumi
CANTAM2 coordinator



Uganda

EACCR II

“In EACCR II, we will expand our activities to include neglected infectious diseases and emerging and re-emerging infections, in addition to HIV, TB and malaria – the diseases we were working on EACCR I, funded under the first EDCTP programme.

Now we need to harness local resources and to ensure that our institutions and researchers are able to apply for additional funding to implement joint activities including clinical trials. This is one of our objectives. We plan to continue sharing information on funding opportunities and also meet regularly to think of and implement new ideas.

There are also new territories we want to explore such as sharing of resources and guidelines in diverse areas including shared bio-banks or repositories accessible to students, researchers and funders. Here we need to take an inventory of what exists but also try to change the mind set to show the benefit of sharing such resources.”

Professor Pontiano Kaleebu
EACCR II coordinator



Senegal

WANETAM II

“WANETAM II will build on the achievements in capacity building for clinical studies and interventions of the network funded under the first EDCTP programme. The new network will structure training and collaboration through thematic networks of excellence in TB, HIV/AIDS and malaria and a new capacity strengthening in neglected tropical diseases (NTD) and Ebola.

The strategy of training and collaboration will focus on project-based training to build research leadership; hands-on clinical studies; resource and platform infrastructure development for data sharing and collaborative research; surveillance to build the evidence-base needed for designing clinical trials; diagnostics to support interventions; and building quality assurance management to support the steps for laboratory accreditation.

There will be cross-cutting training courses to enhance professional development and scientific competency in clinical trials and research support.”

Professor Souleymane Mboup
WANETAM II coordinator



Mozambique

TESA II

“In 2010, a group of nine institutions from six different countries established the Trials of Excellence in Southern Africa (TESA) consortium, under the first EDCTP programme. The network aimed to build capacity and strengthen research sites for the conduct of clinical trials in the fields of HIV/AIDS, TB and malaria. It provided upgrades or accreditation for infrastructures, training and mentorship programmes for researchers (mainly focused on MSc and PhD programs) and implemented baseline studies for the diseases mentioned.

Building on these successes and experiences, TESA II is more ambitious. Currently, it brings together 11 African institutions from 8 different countries: 3 European institutions from 3 countries plus a European Research Infrastructure Consortium (ECRIN) which provides support for institutions and researchers with the preparation and implementation of multinational trials. The 15 institutions collaborate to strengthen the capacities for clinical research in Southern Africa built during TESA I by increasing the collaboration and networking activities of the consortium. TESA II will not only focus on capacity development, training and mentorship programmes, but will also focus on stronger collaboration and dialogue between the institutions for greater impact.”

Dr Eusebio Macete
TESA II coordinator

Developing scientific leadership

EDCTP is committed to supporting the careers of African researchers. Research training for Master's and PhD students has to be integrated in EDCTP-funded clinical research as well as needs-driven short-term training, mentoring and exchange. An extensive fellowship scheme aims to provide career opportunities and support African researchers to achieve scientific leadership. By end of 2016, EDCTP2 had awarded 26 grants to a total value of €4.88 million to support African researchers at various stages of their careers.



Prof. Grant Theron
South Africa

Senior Fellowships

"In terms of global health, I hope this fellowship will contribute to improving the way TB – the single biggest cause of death in Africa – is diagnosed in populations at risk, such as people living with HIV. If new tests are available close to patients and optimally configured so that they can have an immediate impact on patient management, they may result in the earlier initiation of TB treatment and long-term improvements in patient health. This fellowship will also support three trainees – a PhD and a MSc student, and a post-doctoral fellow – each of whom will train to become independent researchers. The creation of a biobank of well-characterised samples will serve as a foundation for future research."

Professor Grant Theron, South Africa



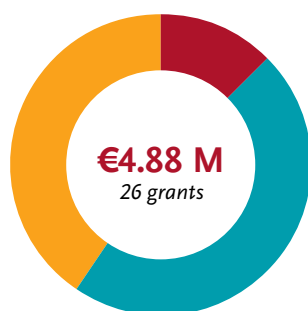
Prof. Faith Osier
Kenya

Senior Fellowships

"This fellowship has already given me greater visibility and credibility as an African Research Leader. I have been able to substantially expand my group through the recruitment of additional PhD students. Together we will address some of the scientific challenges of malaria vaccine development in Africa and contribute high quality data towards this goal. I will strengthen South-South partnerships and collaborations within the SMART network. I will also build strong links between Northern and Southern institutions through the shared supervision of PhD students by Northern and Southern collaborators. The project also provides research material for the training of Masters and post-graduate diploma students in Africa. This fellowship has also enabled me to leverage additional funding for specific scientific projects related to our main project and training activities. Thus, I envisage that my career will continue to grow substantially in terms of additional research funding raised, publication outputs and the building of research training capacity."

Professor Faith Osier, Kenya

Fellowships by type



- **Senior Fellowships, 5 grants**
€ 2.3 M
- **Career Development Fellowships, 14 grants**
€ 1.97 M
- **EDCTP-TDR Clinical R&D Fellowships 7 grants**
€ 0.61 M

EDCTP-TDR Fellowships

“Research establishments in low- and middle-income countries do not make a significant contribution yet to global drug development, including the tools that are needed most in our respective regions, e.g. drugs for poverty-related diseases. With this in mind, I developed an interest in getting hands-on training at a pharmaceutical industry and acquire transferrable skills on clinical trials. The EDCTP-TDR clinical research and development fellowship enabled me to work with a team at Novartis Institute of Biomedical Research on early phase trials. The fellowship gave me the opportunity to understand the sponsor functions, from set-up to reporting, of phase I, including first-in-human studies, and phase II trials. I hope my career in drug development will move to the next level by improving my capacity to manage a clinical trial, handle ethics review processes and the role of regulatory authorities, and strengthen clinical trial teams in Ethiopia and in the region at large.”

Dr Solomon Abay, Ethiopia

Career Development Fellowships

“As a young researcher working in a developing country, it is quite challenging to become an established independent researcher and team leader. It is even more difficult to conduct research on neglected tropical diseases (NTDs), since this field is usually underfunded compared to other tropical diseases. I have had much field and lab experience, and this fellowship will contribute to the enhancement of my clinical and operational research skills. Despite the challenges, NTDs also present opportunities for drug discovery and the development of treatment strategies and better diagnostics. This work will position me to take advantage of future opportunities to evaluate new interventions and diagnostics for NTDs.”

Dr Dziedzom K. de Souza, Ghana

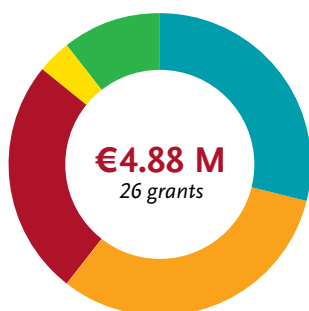


Dr Solomon Abay
Ethiopia



Dr Dziedzom K. de Souza
Ghana

Fellowships by disease



Note: A further €0.61 million was awarded to 7 non-disease-specific fellowship grants.

- **Tuberculosis**, 5 grants
€ 1.35 M
- **HIV & HIV-associated infections**, 7 grants
€ 1.24 M
- **Malaria**, 3 grants
€ 1.08 M
- **Neglected infectious diseases**, 3 grants
€ 0.45 M
- **Diarrhoeal diseases and lower respiratory tract infections**, 1 grants
€ 0.15 M



Photo:
Researchers at the Connaught Hospital in Sierra Leone
part of ID-CLINICAL CAPACITY led by Mr Andy Leather

Collaboration to achieve more

EDCTP aims to build relationships and broker sustainable partnerships. It promotes North–South, South–South and North–North networking and develops relationships with multiple private and public sector organisations.

We support networking activities which pursue the following objectives:

- Foster productive research relationships between European and African researchers and research organisations.
- Align European and African funders, institutions and authorities in order to concentrate efforts, promote efficiency and avoid duplication.
- Attract investments from partners in the business, governmental and charitable sectors.

Through its calls for proposals and funding principles, EDCTP helps to establish new North-South collaborations for the conduct of collaborative clinical research in sub-Saharan Africa.

“
We need
more African
countries in
EDCTP.
”



**Dr Leonardo
Santos Simão**

*High Representative
South*

EDCTP High Representatives: Goodwill Ambassadors

In October 2016, EDCTP appointed two High Representatives. The High Representatives play an important role in increasing the high-level visibility of the programme and promoting partnerships with both private and public partners in the fight against poverty-related diseases. Dr Leonardo Santos Simão, a former Minister of Health and Minister of Foreign Affairs and Cooperation of Mozambique, was appointed High Representative South, with special focus on sub-Saharan Africa, and Professor Marcel Tanner, former Director of the Swiss Tropical and Public Health Institute, became the High Representative North, with special focus on Europe.

Dr Leonardo Santos Simão is a medical doctor by training. After his graduation from the Eduardo Mondlane University, Mozambique in 1980, he worked in rural areas of Mozambique as medical officer at district and provincial levels. He holds a Master's degree in Public Health (Community Health in Developing Countries) from the London School of Hygiene & Tropical Medicine (United Kingdom). He also taught in the Faculty of Medicine of the Eduardo Mondlane University, Mozambique. Dr Simão was the Executive Director of the Joaquim Chissano Foundation, which is dedicated to the social, economic and cultural development of Mozambique. He is the Chairman of the Mediation Reference Group of the Southern African Development Community, and Chairman of the steering committee of the Business Environment Support Fund in Mozambique, a development initiative funded under Denmark's development cooperation activities.



**Prof. Marcel
Tanner**

*High Representative
North*

Professor Marcel Tanner was Director of the Swiss Tropical and Public Health Institute from 1997 to 2015 and currently President of the Swiss Academy of Sciences. He holds a PhD in medical biology from the University of Basel and a MPH from the University of London. He received global recognition for his expertise in research and control of infectious diseases. He lived and worked in Africa and Asia, trained more than 200 African PhD and Master's students, and has published extensively in many fields of health research (>650 original papers). He was co-investigator and coordinator of the first African malaria vaccine trial in 1992 and participated as co-principal investigator in several major intervention trials on malaria and schistosomiasis. From 1981-1985, he transformed a Swiss field laboratory into what is now the Ifakara Health Institute in Tanzania and continued as its programme director from 1987-1997 while working in Europe.

“
International
initiatives cannot
work without
national roots.
”

Coordination of European national funding and collaboration with partners

EDCTP promotes the coordination and pooling of national resources by encouraging its European member countries to develop collaborative research together and with countries in sub-Saharan Africa and/or other partners using the EDCTP funding framework. These studies can be financed and managed by EDCTP through its calls for proposals or run by Participating States themselves as so-called Participating States' Initiated Activities (PSIAs).

PSIAs are research activities within the scope of the EDCTP programme that are funded and implemented independently from EDCTP by one or more member countries. PSIAs are an important means for member countries to demonstrate their commitment to the EDCTP objectives. The incorporation of the PSIAs in the EDCTP annual work plans facilitates the achievement of one of EDCTP's key objectives: better coordination, alignment, and, where appropriate integration of relevant national programmes to increase the cost-effectiveness of European public investments. When funded by European member countries they also count towards matching the EU funding of EDCTP (up to €683 million).

An analysis based on the PSIAs in the EDCTP work plans 2014, 2015 and 2016 shows that on average a PSIA involves four countries. Approximately one fourth involve a single country and 50% of PSIAs involve up to 4 countries. Approximately 10% of PSIAs are performed by at least 10 countries.

EDCTP's objectives include developing partnerships with like-minded organisations, both private companies as non-profit organisations engaged in product development. Moreover, we seek to work with other funders and international organisations towards common goals. An example is the EDCTP–TDR Clinical R&D Fellowship, a funding scheme that is run in partnership with the WHO's Special Programme for Research and Training in Tropical Diseases (TDR).

In 2016 the Calouste Gulbenkian Foundation and EDCTP renewed their collaboration agreement in order to develop research capacity in Portuguese-speaking African countries. The foundation, a Portuguese private institution of public utility that supports both individuals and organisations, will contribute up to €265,000 to EDCTP's fellowship programmes provided through EDCTP grants to successful applicants from Portuguese-speaking African countries.

6.3 Networking and advocacy activities in Africa

EDCTP engages with African governments to promote a better alignment of research and development agendas within our areas of interest. For advocacy and outreach activities, EDCTP engages with key African stakeholders in strategic initiatives for collaboration. Awareness and visibility of the EDCTP programme were raised at many occasions.

In August 2016, the EDCTP participated in the sixty-sixth session of the WHO/AFRO Regional Committee meeting in Addis Ababa and held consultative discussions with the Director General of WHO and Health Ministers from the Ebola affected countries about EDCTP projects in the Mano River Union countries.

In 2016, EDCTP continued to coordinate with its African member countries in recording their national programme activities. As a result of the high level engagements in Addis Ababa, Ethiopia, Angola and Nigeria expressed their interest in becoming members of EDCTP.

EDCTP organised two financial and project management training workshops for its grantees in Dakar, Senegal, from 11-13 April 2016 and in Nairobi, Kenya, from 6-8 December 2016. The three-day workshops were specifically intended to facilitate better financial and project management of EDCTP projects. The coordinators and the scientific and financial project managers of newly selected and on-going EDCTP projects were invited to attend.

The training provides networking opportunities for grantees and managers from different African countries.



Photo:
His Excellency the President of the Republic
of Zambia, Mr Edgar Chagwa Lungu, participates in the
opening ceremony of the eighth EDCTP Forum on
6 November 2016



6-9 November 20

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EDCTP Forum

The EDCTP Forum, held every two years, provides a platform for scientists from Europe and Africa to share findings and ideas, and to establish new collaborative connections.

The eighth EDCTP Forum took place in Lusaka, Zambia, from 6-9 November 2016. The Eighth Forum was the first to be opened by a head of state. This was both an indication of the commitment of the Zambian Government to health research and a sign of the increasing political recognition of the value of EDCTP's contribution to health research in Africa.

His Excellency the President of the Republic of Zambia, Mr Edgar Chagwa Lungu said that his Government would continue to 'pursue a vigorous agenda' on health research. Speakers from EDCTP and the European Community congratulated Zambia on its commitment to health and health research and thanked it for the support it has given to EDCTP since the programme was first launched. Speakers at the Forum's opening session stressed that Africa and Europe are equal partners in EDCTP and called upon African countries to engage fully with the programme and make their voices heard in deciding on the priorities for health research. EDCTP aims not simply to discover new treatments but to support the entire 'pipeline' in which a new product is clinically tested and finally brought to the point where it can be used in routine health care.

The Forum presented a comprehensive scientific programme with a total of 39 sessions for more than 400 participants. The programme consisted of 123 oral presentations in plenary, parallel and collaborative sessions, panel discussions and educational workshops, as well as 133 poster presentations. Moreover, research groups and other organisations contributed a total of nine scientific symposia. Alongside the main programme were four satellite meetings.

Participants from 48 countries attended the Forum with almost 70% coming from African countries. A report with highlights from the Forum is available at www.edctp.org.

As part of the Forum, a closed high-level meeting took place on 7 November 2016. It brought together invited representatives and policy makers from existing and aspiring EDCTP member countries in Africa and Europe, African regional bodies, health and research councils, and funding agencies. The first part of the meeting focused on EDCTP's value to African countries through the facilitation of research uptake and the rapid translation of results into policy on poverty-related infectious diseases. The second part was dedicated to the Ebola virus disease outbreak in West Africa.

6.5 EDCTP prizes

The award ceremonies of the 2016 EDCTP prizes took place at the eighth EDCTP Forum. Four prizes were awarded to recognise outstanding individual researchers and research teams. These prizes also aim to further research-related activities of the laureates in sub-Saharan Africa.



Award for
**Outstanding
Female Scientist**

Professor Marleen Temmerman

Professor Marleen Temmerman received the EDCTP 2016 Award for Outstanding Female Scientist on 8 November 2016. The award consisted of a trophy and 20,000 euro. The award was presented by Professor Nkando Luo, the Honourable Minister of Higher Education, Research, Vocational Training, Science and Technology of Zambia. The award recognises an excellent world-class female scientist residing in sub-Saharan Africa and working in research activities within the scope of the second EDCTP programme.



Award for
**Dr Pascoal
Mocumbi Prize**

Professor Fred Binka

The EDCTP 2016 Dr Pascoal Mocumbi Prize was given to Professor Fred Binka in recognition of his outstanding achievements in advancing health research and capacity development in Africa. The ceremony took place at the closing session of the eighth EDCTP Forum on 9 November 2016. The award consisted of a trophy and 50,000 euro. Professor Charles Mgone, former Executive Director of EDCTP, presented the award to Prof. Fred Binka. The Dr Pascoal Mocumbi Prize rewards an individual in recognition of his or her outstanding achievements in advancing health research and capacity development in Africa with significant impact on the wellbeing of the African population.



Award for
**Scientific
Leadership**

Professor Shabir A. Mahdi

On 7 November 2016, Professor Shabir A. Mahdi received the EDCTP 2016 Award for Scientific Leadership. The award consisted of a trophy and 10,000 euro and was presented by Dr Michael Makanga, EDCTP Executive Director. This award recognises an excellent world-class scientist up to 50 years of age residing in Africa and working in research activities within the scope of the second EDCTP programme.

Award for
Outstanding Research Team



University of Zambia – University College London Medical School (UNZA-UCLMS)

The EDCTP 2016 Award for Outstanding Research Team was given to the UNZA-UCLMS Research & Training Program on 6 November 2016. The award consisted of a trophy and 50,000 euro. At the opening session of the eighth EDCTP Forum, Dr Peter Mwaba, on behalf of his team, received the award from His Excellency, the President of the Republic of Zambia, Mr Edgar Chagwa Lungu. The award is given to an outstanding research team in Africa or Europe working on poverty-related infectious diseases within the scope of the second EDCTP programme.





Photo:
Dr Sodiomon Sirima and research team
at the Regional Hospital of Banfora, Burkina Faso
part of the WANEAM project led by Prof. Abdoulaye
Djimé, funded under the first EDCTP programme



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**.

General Assembly of the EDCTP Association

	GA representative		Deputy GA representative	
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	CNRFP
Cameroon	Prof. Sinata Koulla Shiro	Ministry of Public Health	Prof. Anne-Cécile Zoung Kanyi Bissek	Ministry of Public Health
Congo	Prof. Deby Gassaye	University Marien Ngouabi	Prof. Francine Ntoumi <i>Association Board member</i>	University Marien Ngouabi
Denmark	Mr Mikkel Lyndrup	Statens Serum Institute		
Finland	Dr Jarmo Wahlfors	Academy of Finland	Dr Sirpa Nuotio	Academy of Finland
France	Prof. Jean-François Delfraissy	Agence Nationale de Recherches sur le Sida et les Hépatites Virales (ANRS); Institut de microbiologie et des maladies infectieuses (IMMI)	Dr Bernadette Murgue	Institut national de la santé et de la recherche médicale (INSERM)
			Mr Guillaume Fusai	Ministère de l'éducation nationale, de l'enseignement supérieur et de la recherche
			Prof. Patrice Debré	INSERM
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	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 <i>Association Board member</i>	Deutsches Zentrum für Luft und Raumfahrt e.V
Ghana	Prof. John Gyapong	University of Ghana	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 <i>Association Board Vice-Chair</i>	Istituto Superiore di Sanità (ISS)	Dr Benedetta Mattioli	ISS
Luxembourg	Dr Carlo Duprel <i>succeeded by</i>	Fonds National de la Recherche,		
	Dr Helena Burg	Fonds National de la Recherche		
Mali	Prof. Agrégé Abdoulaye Djimé	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 Eusebio Macete <i>Association Board Vice-Chair</i>	Health Research Centre of Manhica
Netherlands	Dr Gerrie Tuitert	NWO-WOTRO Science for Global Development	Dr Marcel de Kort	Ministry of Foreign Affairs, succeeded by
			Ms Ella de Voogd	Ministry of Foreign Affairs
Niger	Mrs Sakina Habou Ocquet	Ministry of Public health	Dr Odile Ouwe Missi Oukem <i>succeeded by</i>	Centre de Recherche Médicale et Sanitaire (CERMES),
			Ms Halima Boubacar Maïnassara	CERMES
Norway	Dr Sigurd Røtnes	Norwegian Directorate of Health	Dr Wenche Dageid	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		

GA representative			Deputy GA representative	
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
			Mrs Mamohlosing Tlhagale <i>succeeded by:</i>	DST
			Mr Toto Matshediso	DST
Spain	Dr Rafael De Andrés Medina	Instituto de Salud Carlos III	Dr Tomas López-Peña Ordoñez	Instituto de Salud Carlos III
Sweden	Prof. Hannah Akuffo	Swedish International Development Agency (Sida)	Assoc. Prof. Maria Teresa Bejarano	Sida
Switzerland (Aspirant member)	Dr Isabella Beretta	State Secretariat for Education and Research		
Tanzania	Dr Hassan Mshinda	Tanzania Commission for Science and Technology (COSTECH)	Dr Flora Tibazarwa	COSTECH
Uganda	Dr Sam Okware	Uganda National Health Research Organisation (UNHRO)	Prof. Pontiano Kaleebu	Uganda Virus Research Institute
United Kingdom	Dr Mark Palmer <i>Association Board Chairperson</i>	Medical Research Council	Dr Morven Roberts	Medical Research Council
Zambia	Dr Elizabeth Chizema-Kawesha	Ministry of Health	Prof. Nkandu Luo	Ministry of Gender and Child Development; after September 2016, Minister of Higher Education, Research, Vocational Training, Science and Technology

7.2 Observers to the General Assembly

Observer	Representative		Deputy Representative	
European Commission	Dr Line Matthiessen	Head of Infectious Diseases and Public Health, Directorate-General (DG) for Research & Innovation	Dr Gianpietro van de Goor	Principal Policy Officer for International Cooperation, DG Research & Innovation
European Commission	Dr Walter Seidel <i>succeeded by</i>	Head of Sector 'Health', Unit B4, Directorate-General for International Cooperation and Development (DG DEVCO)	Dr Eric Sattin <i>succeeded by</i>	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 Cabor	Director for Programme Management	Dr Delanyo Dovlo	Director of Health Systems and Services
African Union	Dr Olawale Maiyegun	Director for Social Affairs, Commission of Social Affairs		

The Scientific Advisory Committee

The Scientific Advisory Committee 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, in order to assist EDCTP in achieving its mission and objectives. It acts exclusively in the interest of the mission and objectives of EDCTP.



Photo: Members of the EDCTP Scientific Advisory Committee

The 2016 Scientific Advisory Committee consisted of:

Prof. Tumani Corrah (<i>Chair</i>)	The Gambia
Dr Salim Abdulla	Tanzania
Prof. Eleni Aklillu (<i>Vice-Chair</i>)	Sweden
Prof. Moses Bockarie	United Kingdom (left as of July 2016)
Dr Marilyn Bonnet	France
Prof. Simon Croft	United Kingdom
Prof. Knut Fylkesness	Norway
Prof. Stefan Kaufmann	Germany
Dr Maria Fraga Oliveira Martins	Portugal
Prof. Clara Menéndez Santos	Spain
Prof. Marie-Louise Newell	United Kingdom
Prof Gita Ramjee	South Africa
Prof. Philippe Sansonetti	France
Mr Jean Marie Talom	Cameroon
Prof. Ali Zumla (<i>Vice-Chair</i>)	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

Dr Michael Makanga	Executive Director (as of January 2016)
Dr Leonardo Simão	High Representative South (as of October 2016)
Prof. Marcel Tanner	High Representative North (as of October 2016)
Abdoulie Barry	Director of Finance and Administration
Prof. Moses Bockarie	Director of South-South Cooperation and Head of Africa Office (as of July 2016)
Dr Ole F. Olesen	Director of North-North Cooperation
Dr Pauline Beattie	Operations Manager
Dr Gabrielle Breugelmans	North-North Networking Manager
Dr Anne-Laure Knellwolf	Programme Portfolio Manager (as of April 2016)
Dr Thomas Nyirenda	South-South Networking and Capacity Development Manager
Hager Bassyouni	North-North Networking Officer (left in January 2016)
Dr Montserrat Blázquez Domingo	Senior Project Officer
Chris Bruinings	Financial Officer
Ana Lúcia Cardoso	North-North Networking Officer
Mary Jane Coloma-Egelink	Grants Financial Officer
Dr Christy Comeaux	Project Officer
Lucien de Corte	Information Technology (IT) Officer
Christopher Dixon	Financial Assistant
Nuraan Fakier	Project Officer
Neodia Flores-Mensing	Grants Finance Assistant (as of May 2016)
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
Dr Louwrens Kiestra	Legal Officer (as of June 2016)
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)
Dr Perry Mohammed	Special Advisor (left in March 2016)
Pete Murphy	Grants Management System Administrator
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
Jing Zhao	Grants Financial Officer (left in January 2016)



Photo:
Study volunteer at the Amana Hospital
in Dar es Salaam, Tanzania
part of the TRIP project led by Dr Sayoki Godfrey Mfinanga

8 Summary financial statements 2016

Statement of profit or loss and other comprehensive income

for the year ended 31 December 2016. Expressed in thousands ('000) of euro

	EC 2016	Donor 2016	Total 2016	Total 2015
Calls (granst)				
Contributions	43,175	6,984	50,159	1,925
Grants	(43,175)	(6,984)	(50,159)	(1,925)
Results for the year	-	-	-	-
Others				
Contributions	6,356	490	6,846	2,365
Other	(6,356)	(490)	(6,846)	(2,365)
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.

Statement of financial position

as at 31 December 2016 (after appropriation of result). Expressed in thousands ('000) of euro

	31 December 2016	31 December 2015
Current assets		
Debtors and other receivables	14,684	1,599
Cash and cash equivalents	38,308	42,270
Total current assets	52,992	43,869
Non-current liabilities		
Grants and other payables	25,009	
Deferred income EC	-	2,365
Deferred income donor	6,224	472
Total non-current liabilities	31,233	12,695
Current liabilities		
Grants and other payables	6,247	35
Deferred income EC	-	15,423
Deferred income donor	15,512	15,716
Total current liabilities	21,759	31,174
Total liabilities	52,992	43,869

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

Dr Michael Makanga

Dated: 13 April 2017

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 2015	-	-	-
Total comprehensive income for the year	-	-	-
Balance as at 31 December 2016	-	-	-

EDCTP has no unrestricted reserves.

Statement of cash flows

for the year ended 31 December 2016. Expressed in thousands ('000) of euro

	2016	2015
Cash flows from operating activities		
Result for the year	-	-
Adjustment for:		
(Increase) decrease in debtors and other receivables	1,470	(1,581)
Increase (decrease) in grants and other payables	30,749	507
Increase (decrease) in deferred income	(36,245)	43,304
Net cash flows from operating activities	(4,026)	42,230
Cash flows from investing activities		
Interest received	64	40
Net cash flows from investing activities	64	40
Net increase (decrease) in cash and cash equivalents	(3,962)	42,270
Cash and cash equivalents at 1 January	42,270	-
Exchange rate effects	-	-
Cash and cash equivalents at 31 December 2016	38,308	42,270

Colophon

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