

**Update** is a monthly newsletter from the European & Developing Countries Clinical Trials Partnership.



**E D C T P**

## **EDCTP** End of Year Message 2019

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### Our best wishes for a happy festive season and a healthy and successful 2020!

Dear colleagues and friends,

You are kindly invited to read our 2019 end of year message below which offers you a brief summary of EDCTP's achievements to date.

Since 2014, EDCTP invested more than €600 million of funding in European-African research & development partnerships engaged in developing new and improved interventions for the poverty-related infectious diseases affecting sub-Saharan Africa.

I am proud of our achievements so far and truly grateful to all our EDCTP constituencies and staff, advisers, partner organisations and companies, research teams, health care and community workers, and especially the patients and healthy volunteers, who make sure these investments are put to good use so as to ultimately bring better health for all.

On behalf of EDCTP, I wish you a happy festive season, restful holidays, and a healthy and successful 2020.

Michael Makanga  
*Executive Director*



**The EDCTP2 programme**

Since 2014, the EDCTP2 programme has provided €607.9 million of funding to European-African research partnerships advancing new interventions for key infectious diseases affecting sub-Saharan Africa, while also strengthening clinical research capacity in 37 African countries.

EDCTP has grown as an important funder of clinical research in Africa, aligning national activities and creating a critical mass of funding, making possible initiatives beyond the scope of individual national programmes. Its global profile facilitates partnerships with major global players, including the World Health Organization (WHO), global philanthropic foundations, public-private product development partnerships, pharmaceutical companies as well as with countries.

EDCTP2 focuses on the key poverty-related infectious diseases affecting sub-Saharan Africa: tuberculosis (TB), HIV, malaria, diarrhoeal diseases, lower respiratory tract infections, neglected infectious diseases, and emerging and re-emerging infections. It has a particular focus on vulnerable populations who are often excluded from clinical trials and are therefore slow to gain access to innovations, including pregnant women, infants, children and adolescents, and people with additional health conditions (co-infections and co-morbidities). It supports all stages of clinical trials, as well as product-focused implementation research.

## The EDCTP2 portfolio 2014-2019 - new publications



EDCTP Collaborative R&D projects 2014-2019  
(RIA grants)



EDCTP fellowships 2014-2019  
(TMA grants)

## The investments we made

Since its launch in 2014, the EDCTP2 programme has committed €607.9 million of funding (as at November 2019) to 265 projects. Total funding is projected to rise to €792 million by the end of 2020. Most of this funding has been for clinical trials and associated studies:

- Clinical trials and studies: €526.0 million (87%)
- Clinical research capacity building: €51.3 million (8%)
- Fellowship programme: €30.6 million (5%)

The clinical trials and studies encompass 84 projects and 211 clinical studies:

- 70 studies are phase II and III trials of drugs and vaccines delivering key evidence on safety and efficacy.
- 20 studies are phase IV post-licensing studies providing evidence of particular relevance to local policymakers.

EDCTP2 funding has been well spread across priority disease areas. The greatest number of grants and amount of funding has been committed to projects on TB (25 grants, €146.7 million funding), the infection responsible for the greatest global burden of disease. Significant sums have also been committed to malaria (12 grants, €118.5 million) and HIV and HIV-related infections (16 grants, €96.7 million). Funding is beginning to increase for infections added to the EDCTP2 portfolio, including emerging infections (9 grants, €41.6 million) and neglected infectious diseases (13 grants, €48.9 million).

EDCTP2 support has also focused on priority vulnerable populations: 29 studies have involved pregnant women and newborn babies, 74 studies have involved children and 90 studies have included adolescents.

The number of countries participating in EDCTP-funded activities has risen to 65 - of which 37 are situated in Africa, 20 in Europe and 8 elsewhere. Based on signed grant agreements, €278.2 million (59.6%) has been allocated to 198 institutions in sub-Saharan Africa. Eight (8) sub-Saharan African countries received each more than €10 million of EDCTP2 funding.

## The impact we anticipate

As projects take time to start up and typically run for several years, it is too soon for EDCTP2-funded work to have impact on policy and practice already. Nevertheless, several EDCTP2 projects are addressing key gaps in knowledge and promise to deliver the evidence required to guide global and national decision-making. Examples include:

- **Schistosomiasis control in young children:** The PZQ4PSAC trial is evaluating a new more palatable formulation of praziquantel to treat schistosomiasis in pre-school-age children. The new formulation will enable younger children to benefit from a highly effective drug for treatment and mass prevention. (Trial co-funded by the Global Health Innovative Technology Fund and sponsored by Merck.)
- **Better tools for control of parasitic worm infections:** The STOP study is developing a convenient fixed-dose pill that combines ivermectin and albendazole to improve control of parasitic worm infections in Africa.
- **Better detection of sleeping sickness:** The DiTECT-HAT study is evaluating a range of tools that will make it easier to detect, treat and ultimately eradicate sleeping sickness. By evaluating different tools and pathways of analysis, DiTECT-HAT will identify how diagnostic tools could be deployed most effectively to treat infection in routine care, to support eradication campaigns, and to facilitate the development of new drugs.
- **Better treatment of fungal infections:** The AMBITION-cm project is evaluating a novel liposome-based formulation of amphotericin B, which could transform treatment of cryptococcal meningitis, responsible for up to one in five HIV-related deaths in Africa.

- **Novel vaccines:** The THECA study will provide additional data on Typbar-TCV, a typhoid conjugate vaccine that has been recommended for use despite limited data on its efficacy. The PREVAC-UP project will enable an additional four years' data to be collected on the safety and efficacy of the two leading Ebola vaccines, rVSV-ZEBOV-GP and Ad26.ZEBOV, including data on vaccine use in children.
- **Treatment of pneumonia in children:** The PediCAP project is aiming to identify an optimal treatment for severe pneumonia in children, including an earlier switch from injected to oral antibiotics.
- **Prevention of river blindness:** The MoxiMultiDoseMod project is evaluating repeat administration in children of moxidectin, the first new treatment for river blindness (onchocerciasis) approved in 20 years. This is necessary in view of its use in mass drug administration campaigns.

## Groups with unmet medical needs we give priority to

Several projects have the potential to benefit populations with unmet needs we give priority to:

- **Malaria prevention in pregnant women:** The IMPROVE and MAMAH studies are testing the use of new antimalarial drugs to prevent malaria infections in pregnant women, which are particularly harmful to both mothers and newborns. The trials could see preventive drug use extended to a highly vulnerable group, pregnant women living with HIV.
- **HIV treatment in pregnant women:** The PREGART study will determine whether a highly effective new antiretroviral drug is safe to use in pregnant women.
- **Antiretroviral use in children:** Building on highly influential previous work, the CHAPAS-4 study is evaluating potential second-line treatments for children with drug-resistant HIV infections.
- **HIV prevention and treatment in adolescents:** The CHAPS study is investigating variants of pre-exposure prophylaxis that may be more effective in adolescents, while the BREATHER Plus trial is exploring novel delivery of antiretroviral drugs that may lessen the treatment burden on adolescents.

## Through the lens of our programme objectives

### I. Innovative interventions

The EDCTP2 programme is generating important clinical data on a range of innovative interventions for infectious diseases - products that could have a transformative impact on global health.

- **Malaria vaccines:** The Multi-Stage Malaria Vaccine Consortium is testing an innovative combination vaccine targeting multiple points in the malaria parasite life cycle. The PftBV study is evaluating a transmission-blocking vaccine that could prevent spread of infection.
- **TB vaccines:** The prevention of relapse (POR) TB consortium is assessing the safety and efficacy of H56:IC31 using a novel 'prevention of recurrence' approach. The MTBVAC-newborns trial is evaluating better TB protection for newborns to determine whether a weakened form of the TB bacterium offers a better alternative to BCG. The priMe phase III trial is evaluating whether a recombinant form of BCG, VPM1002, a promising alternative to BCG, is safe and effective for use in newborn infants.

- **Broadly neutralising antibodies:** The CAP012 SAMBA project is testing use of this exciting novel technology for HIV prevention specifically in women, while the Neo bnAb study is evaluating its ability to prevent mother-to-child transmission of HIV.
- **Vaccines for diarrhoeal disease:** Diarrhoeal diseases still account for one in ten deaths of young children in sub-Saharan Africa. EDCTP2 trials are evaluating highly promising vaccines designed to prevent infections with enterotoxigenic E. coli (ETEC Vaccine Efficacy study) and Shigella (ShigOraVax trial).

EDCTP is also working in partnership with product development partnerships and drug developers to advance individual therapeutics and collections of compounds:

- **A portfolio of novel antimalarial drugs:** The WANECAM II study is accelerating development of a new class of antimalarial drug developed by Medicines for Malaria Venture (MMV) and Novartis that may have significant advantages over existing treatments. The PAMAFRICA portfolio grant is advancing a suite of novel drugs developed by MMV to address unmet needs in malaria treatment, including single-dose treatments and formulations for young children.
- **New options for TB:** The PanACEA consortium is bringing a hopefully promising novel anti-TB drug, BTZ-043, into Phase II clinical trial. As part of a wider global trial coordinated by the TB Alliance, the SIMPLICI-TB study is evaluating a novel and potentially shorter treatment for drug-sensitive and drug-resistant TB. In the CLICK-TB study, an innovative trial design is being used to compare a suite of anti-TB compounds developed by GSK.

Demonstration of efficacy and safety may not be enough to drive uptake of new interventions. Effectiveness and product-focused implementation studies are important for overcoming practical barriers to the introduction of health care innovations.

- **Cryptococcal diagnosis:** The DREAMM project aims to demonstrate the benefit of introducing early screening for cryptococcal fungal infections, responsible for approximately a quarter of HIV-related deaths.
- **TB diagnosis:** The CAP-TB project is evaluating new TB diagnostic technologies in realistic field settings to determine health impacts and implementation enablers/barriers.

## II. Capacity development impact

Through EDCTP funding, more than 6000 researchers have benefited from training opportunities. Through its fellowships, EDCTP2 has supported 126 aspiring and current African scientific leaders from 20 countries.

Ethics and regulatory projects have been funded in 27 African countries. Sub-Saharan African institutions in 28 countries participate in four sub-regional EDCTP-supported Networks of Excellence, which promote South-South collaboration, sharing of expertise, and capacity building in countries with limited clinical research infrastructure.

Two major partnerships - ALERRT and PANDORA-ID-NET - are developing the capacity of countries in sub-Saharan Africa to detect, prevent and respond to infectious disease outbreaks, and to carry out research in emergency situations. EDCTP2 has also provided several grants to enhance preparedness in countries at risk of Ebola outbreaks.

In collaboration with WHO AFRO, EDCTP has been engaging African governments to strengthen their national health research systems with complementary international

cooperation. The EDCTP Participating States (i.e. member countries of the EDCTP Association) in Africa have been prioritised in this effort.

### **III. European coordination**

European Participating States have provided €158.8 million in cash contributions to EDCTP. In addition, Participating States-Initiated Activities (PSIAs) represent an important component of the EDCTP portfolio. PSIAs are activities that fall within EDCTP2's scope but are implemented or funded by one or more Participating States independently. Inclusion of PSIAs in the EDCTP portfolio helps to align national activities and avoids duplication of efforts.

By the end of 2018, the total value of PSIAs amounted to €556.3 million. Sixty-one (61) countries have participated in PSIAs, 20 from Europe and 41 from Africa. EDCTP2 PSIAs include more than 140 clinical studies as well as other activities that fall within the scope of EDCTP2, including support for capacity development, ethics and regulatory activities, operational and implementation research, and health systems strengthening.

### **IV. External partnerships**

EDCTP2 has so far leveraged an additional €300 million from third parties, including global funders such as the US National Institutes of Health (NIH), philanthropic donors such as the President's Emergency Fund for AIDS Relief (PEPFAR) and the US Agency for International Development (USAID), global funders such as the Bill and Melinda Gates Foundation, product development partnerships such as the TB Alliance and MMV, and pharmaceutical companies.

Joint initiatives have been launched with WHO/TDR, Fundacion Mundo Sano-España, the Calouste Gulbenkian Foundation, the African Research Excellence Fund and GSK, and are being planned with the Coalition for Epidemic Preparedness Innovations (CEPI), Fondation Botnar, Novartis International, and the Africa Centres for Disease Control and Prevention.

In all, 147 private sector entities have been involved in EDCTP2 projects, receiving support of €68 million in funding while contributing matching in-kind co-funding through product development services and supply of investigational products.

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