EDCTP

The power of sharing science

Annual Report 2019

Steering the portfolio for impact

Supported by the European Union

Photo: IMPROVE project staff members, Kenya

About EDCTP

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

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

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

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

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Stronger partnerships for the common good

EDCTP has catalysed partnerships and collaborations that are better preparing sub-Saharan African countries for the health challenges that they face – including the COVID-19 pandemic.

This is my first Annual Report as Chair of the EDCTP General Assembly, and I must start by paying tribute to my predecessor, Dr Mark Palmer, who has made an excellent job of steering the EDCTP2 programme since its inception. I would also like to thank the Board members who recently completed their terms of office for their tireless efforts, and to welcome our four new Board members from Europe and sub-Saharan Africa.

This is a very exciting time to be taking up the role of Chair. Over recent years, EDCTP has consolidated its position as the focal point for collaboration in health research between Europe and sub-Saharan Africa. Many innovative projects have been funded, and promise to accelerate the development of much-needed new vaccines, drug treatments and other interventions, particularly for vulnerable and disadvantaged groups such as children and pregnant women.

Equally importantly, EDCTP's commitment to capacity building – embedded in its clinical trial support and through specific grants – is laying the foundation for the research of the future in sub-Saharan Africa. Through its fellowship schemes, EDCTP is building human capacity for research, while capacity-building support is helping to develop essential infrastructure for clinical research. Collaborations with European laboratories are enabling sub-Saharan Africa researchers and institutions to absorb the latest scientific thinking and adopt emerging scientific methodologies and techniques.

One important consequence has been the creation of platforms that can be repurposed to address the threat posed by COVID-19 in sub-Saharan Africa. Our epidemic preparedness networks are playing important roles in the response to COVID-19 and our research collaborations have created the capacity for studies of the SARS-CoV-2 virus, its spread, its impact on people and its control.

We should also not forget that Europe benefits significantly from these partnerships. European researchers gain from access to patient populations and local expertise and experience of disease, and have much greater opportunity for their research to make a difference to people's lives. Europe as a whole benefits because control of infectious disease in low-resource settings is central to global health security.

The past year has seen existing partnerships and collaborations strengthened and new ones created. We have reached out to potential partners in the public and private sector, and organisations such as product-development partnerships that span the two. While our main axis of collaboration remains between Europe and sub-Saharan Africa, we have increasingly been forging productive relationships further afield, in regions such as Asia, Latin America and North America.

These achievements have all been dependent on financial contributions from the EU and from EDCTP member countries in Europe and sub-Saharan Africa, through direct contributions and submission of Participating States' Initiated Activities (PSIAs) to the EDCTP portfolio. PSIAs provide an important mechanism for aligning activities within Europe. We also appreciate the contributions made by third-party organisations for joint activities in areas of common interest.

One important point we must always bear in mind is that we cannot 'boil the ocean'. Our resources are limited, and spread too thinly would achieve too little. By focusing on specific priority areas, we can ensure that we achieve true impact, and can be more strategic in the kind of support we provide. By recognising our niche, we can also better identify potential partners and ensure our activities align and complement those of others.

A further reason why this is an exciting time to be taking up the reins as Chair is that we are planning for the next iteration of the EDCTP programme. Research and development can be a long and difficult process, beset by challenges and uncertainty. We need to maintain the momentum to propel promising interventions down the 'pathway to impact' – to ensure their introduction into health systems to meet the needs of communities. We need to consolidate our position and recognise where we have developed areas of strength, and coordinate with others to ensure that we are not duplicating efforts or overlooking major priorities.

But we also need to be aware of some of the major emerging challenges in sub-Saharan Africa. Antimicrobial resistance is undermining the effectiveness of treatments for some of the most common infections in the region, and threatens the very future of medicine by compromising our ability to control infection. As COVID-19 has illustrated, emerging infections can have a devastating impact on health and countries' economies. Climate change is having many consequences, including impacts on the epidemiology of infectious disease and human population movements that increase exposure to infectious agents. Research will be an essential component of the public health response to these challenges.

No country can tackle these challenges alone. Success will depend on collaborative and focused efforts through regional partnerships and North–South collaborations, including a wider range of global partners. More than ever, global health is truly global.

Professor Yazdan Yazdanpanah
Chair, EDCTP General Assembly

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From project to portfolio – steering for impact

EDCTP2 funding has entered a new, more strategic phase as we aim to maximise the impact of our investments.

EDCTP must choose carefully who, where and what it funds. Scientific excellence is, of course, essential – poor-quality research wastes resources and is potentially dangerous if it gives a misleading picture of the efficacy, effectiveness and safety of medical interventions. Open calls for proposals, competitive application processes and peer review are well-established mechanisms to ensure excellence, and central to EDCTP's ways of working.

But excellence is not the only criterion we care about. A second key factor is potential impact, the contribution a project or initiative could make to the achievement of EDCTP objectives. We also consider the quality and efficiency of the implementation plans proposed, as we need to be sure that grantees can deliver what they promise.

These criteria have served us well, but as the number of projects in the EDCTP2 portfolio continues to grow, we must increasingly look not just at individual proposals but also at our portfolio as a whole. And we need to ask ourselves some searching questions. Are we truly tackling the questions that matter to sub-Saharan Africa? What can funding agencies like EDCTP do to strengthen links between projects to avoid duplication and promote synergies? How can we ensure that scientific findings influence policy and practice, so that people in the region actually benefit?

We also have to take a step back and consider the wider context in which research takes place. Are all countries equally placed to carry out high-quality clinical research? What obstacles are compromising the competitiveness of individuals, institutions and countries? Are countries' health systems in a position to take advantage of emerging new evidence from research?

Questions such as these require us to think more strategically about our funding. In terms of relevance, the consultative development of our annual strategic research agenda highlighted key evidence gaps and priority areas for research, which feed into our annual workplans and calls for proposals. An analysis of our funding to date suggests that we are effectively focusing support on the questions that matter (p.12).

However, after six years of funding in the current programme, we have established an extensive portfolio of projects in our priority areas. Rather than just adding further to this portfolio, we also need to examine how best to ensure the success of projects, their lasting legacy, and the use of research findings within health systems – to ensure that people in need reap the rewards of research. In particular, we need to consider how some of the core principles that underlie our work – such as collaborative international partnerships and a commitment to capacity development – can be mobilised to address these challenges.

Evidence of this new mindset can be seen in areas where EDCTP has developed particular strengths, such as TB vaccine development (p. 18) and malaria drug development (p. 21). Here, we are supporting activities to build connections between projects, to create an environment that focuses time and resources on the most promising interventions, and to align stakeholders to accelerate the 'pathway to impact'.

This approach also requires us to consider our niche in a much larger ecosystem, and how we can align and coordinate our work with others. We have developed highly constructive partnerships with academic research institutions, product development partnerships, and industry partners.

Indeed, recent years have seen us extend our range of partners, in Europe, sub-Saharan Africa and beyond. Much of this reflects the unstinting efforts of our High Representatives. For example, we now have strong relationships with the WHO Regional Office for Africa (WHO-AFRO) and with the Africa Centres for Disease Control and Prevention (Africa CDC), as well as with bodies

such as the African Vaccine Regulatory Forum (AVAREF) and the African Medicines Quality Forum (AMQF), under the umbrella of NEPAD's African Medicines Regulatory Harmonisation initiative. In Europe and further afield, we have also explored opportunities for collaboration with various industry partners, foundations, national development cooperation partners, as well as the EU development agency, DEVCO.

The desire to achieve a lasting legacy has fuelled our approach to capacity development, which is integrated into our clinical trial funding and also supported through specific grants schemes. Our extensive fellowship programme, for example, which has so far funded 130 researchers, is supporting regional research leaders as well as the next generation of up-and-coming leaders. These researchers are addressing key local health challenges, but are also globally networked – providing opportunities to absorb new scientific thinking and to adopt innovative new research methodologies.

Recent years have seen significant investments in developing national ethics review and regulatory capacity, with EDCTP-funded activities in 27 countries in sub-Saharan Africa (p. 28). These projects are essential for developing an environment for research that protects the interests of participants in clinical studies but also facilitates the trials that are needed to evaluate new interventions with the potential to improve people's health.

In 2019, a specific focus has been the 'digital divide'. Digital technologies are revolutionising clinical data collection but also offer opportunities to increase the efficiency of the submission, review and oversight of clinical research proposals. The EDCTP ethics call in 2019 included opportunities for funding to digitalise these critical processes.

This kind of funding recognises that certain countries, and groups of individuals such as women, are disadvantaged and are less able to compete for funding. The risk is that individuals are unable to achieve their potential because of their sex or location, and that funding becomes ever more concentrated in countries and institutions that have a head start.

We are taking a range of steps to ensure that all can compete on a level playing field (p. 36). We are paying special attention to the obstacles that women face in science (generally and in sub-Saharan Africa specifically), monitoring gender representation, and wherever possible taking steps to avoid unconscious bias.

For countries, we are attempting to address the language barriers that disadvantage French-speaking and Portuguese-speaking countries, for example through grant-writing, project and financial management workshops in French and Portuguese. Developing the capacity of countries with less mature health research systems is a key aim of our four regional Networks of Excellence (p. 34). We have also piloted an extension of our senior fellowship scheme, 'senior fellowship-plus', through which senior fellows are paired with researchers from countries with less well-developed health research systems, who benefit from mentoring, support and networking opportunities.

We have also sought to leverage the critical mass of EDCTP funding by encouraging the development of links between research networks and consortia. We now support multiple networks, including international research collaborations, regional Networks of Excellence, the EDCTP fellows alumni network, and two pandemic preparedness networks (ALERRT and PANDORA-ID-NET). Importantly, these provide a platform that can be repurposed to address emerging health threats – such as the COVID-19 pandemic.

The long-term aim of EDCTP is not just to save lives through the accelerated development of new medical interventions, but also to ensure that sub-Saharan Africa has the capability to identify and address its own health challenges through research. We have worked with WHO-AFRO to map the capabilities of national health research systems using its 'barometer' tool (p. 33). The last survey in 2018 revealed encouraging progress in several areas. The next survey in 2020 will hopefully show that this momentum has been maintained and accelerated.

More than six years after the launch of EDCTP2, we can therefore say with confidence that we are on track to meet our objectives. In some areas, we have already surpassed our targets – including the numbers of countries in sub-Saharan Africa participating in EDCTP studies. Health gains inevitably take many years to achieve, but clearly the ground is being laid not just for the introduction of new or improved medical interventions but also for fully functioning and sustainable national health research systems. EDCTP is both promoting and facilitating national ownership of health challenges and the capacity to address them – not least emerging threats such as COVID-19.

On behalf of the entire partnership I extend our sincere appreciation to all of you who have contributed to the success of EDCTP through the years.

Dr Michael Makanga
Executive Director

Calls launched

(2014-2019)

- **2019** €127.17 M
- **2018** €163.51 M
- **2017** €188.37 M
- **2016** €155.63 M
- **2015** €80.22 M
- **2014** €16.85 M

Towards EDCTP's objectives

(2014-2019)

Medical interventions

New or improved medical interventions against poverty-related infectious diseases.

217
the total number of clinical studies supported by EDCTP2 since 2014. Of these, 59% (130) are interventional (clinical trials) and 41% (87) are non-interventional studies.

Collaboration and capacity development

Increase cooperation with sub-Saharan Africa through capacity building for conducting clinical trials according to ethical principles and regulatory standards.

37
sub-Saharan African countries participate in EDCTP projects involving 208 sub-Saharan African organisations. These account for 57.6% of total EDCTP funding.

European coordination

Improve coordination, alignment and integration of European National Programmes.

14
European countries are members of the EDCTP Association.

External partnerships

Increase international cooperation with public and private partners.

52
countries participate in EDCTP-funded activities: 36 sub-Saharan African countries and 16 European countries.

EU cooperation

Increase interaction with other EU initiatives, including those linked to development assistance.

3
grant consortia were established through an EDCTP call to support health systems/service optimisation research capacities in cooperation with development assistance. Two of these consortia received funding from international development cooperation partners (SIDA and USAID).

57% (71)
are phase II and III trials of drugs and vaccines which aim to deliver key evidence on safety and efficacy, as well as provide data to support product registration.

15% (18)
of the large-scale clinical studies involve post-licensing (phase IV) studies with a view to influencing health policies and practice and optimising the delivery of medical interventions for the wide range of sub-Saharan African health systems and diverse populations.

10% (21)
of all studies target pregnant women and their children. Other key populations are also involved in the studies, such as newborns and infants (35; 17%), children (64, 31%) and adolescents (60; 29%).

32
sub-Saharan Africa countries host recruitment sites of EDCTP-funded collaborative clinical studies.

27
sub-Saharan African countries have received EDCTP support for the establishment of functional regulatory systems and capacities for ethical review of clinical research.

€23.43 M
has been invested to support preparedness of six sub-Saharan African countries in the fight against Ebola outbreaks and other (re)emerging health security concerns.

130
fellowships that focus on the career development of researchers from 18 sub-Saharan African countries.

7,488
people have participated in EDCTP project-related training and workshops on topics such as study protocol development, specimen collection, research and administration, Good Clinical Practice and epidemic preparedness.

16
sub-Saharan African countries are members of the EDCTP Association. By end of 2019, these members have submitted 120 Participating States' Initiated Activities (PSIAs) of total committed value of €67 million.

€158.8 M
total cash received from the European Participating States to the EDCTP programme.

€995 M
total amount committed in 280 Participating States' Initiated Activities (PSIAs) submitted by the European Participating States by end of 2019.

371
institutions are involved in EDCTP projects, including 208 sub-Saharan African institutions, 150 European institutions, and 13 institutions from other countries.

60%
of the total EDCTP grant value is allocated to sub-Saharan African institutions (€186 million).

162
private sector entities are involved in EDCTP projects. By end of 2019, these organisations have received €89.26 million in grant value.

17
EDCTP African member countries participated in a survey to inform the development of a strategic policy plan for strengthening health research system capacities of countries in sub-Saharan Africa. This project is a joint initiative between EDCTP and WHO AFRO.

3

EDCTP in 2019

The number of projects funded through the EDCTP2 programme jumped to 271 in 2019, supporting activities at more than 200 institutions in 37 countries in sub-Saharan Africa, as well as at 150 institutions in 16 countries in Europe.

Ten new calls for proposals were launched in 2019 and awards were agreed for the 11 calls opened in 2018. EDCTP2 has now developed an extensive portfolio, balanced across its focus disease areas:

- 84 collaborative clinical research grants
- 217 clinical studies in progress or planning stages
- 37 countries and 208 organisations in sub-Saharan Africa participating in EDCTP projects, alongside 16 countries and 150 institutions in Europe
- 27 countries in sub-Saharan Africa benefiting from ethics review and regulatory strengthening projects.

EDCTP2 is seeing substantial sums invested in the sub-Saharan Africa science base:

- €526.04 million invested in grant funding, 87% for large collaborative clinical trials
- €1.06 billion committed by European and African EDCTP Participating States Member States through cash and in-kind contributions
- €323.90 million likely to be leveraged through collaborative activities with third parties
- 57.6% of EDCTP funding going to sub-Saharan Africa partners.

EDCTP2 is also making important contributions to the development of human capital in the African region:

- 130 fellowship grants awarded (37.3% to women)
- 172 long-term trainees supported (including 85 PhDs) from 26 countries; 47% of trainees are women
- 318 clinical trials-related training courses organised for 7,488 participants

The EDCTP portfolio is well-balanced, with 63.1% of projects being focused on the three major poverty-related infectious diseases (HIV and HIV-associated infections, tuberculosis and malaria), 15.5% on neglected infectious diseases, 10.7% on emerging and re-emerging infections, and 10.7% on diarrhoeal diseases and lower respiratory tract infections.

Support is currently being provided for 217 clinical studies, 60% of them interventional trials. Most trials are phase II and III trials of drugs and vaccines (57.3%), although 11.3% are phase IV and implementation studies. Of key populations, pregnant and breastfeeding women are involved in 10% of studies, newborns and infants in 17%, children in 31% and adolescents in 29%.

New initiatives

EDCTP continued to explore opportunities for partnerships and cooperation with other global bodies. It developed new agreements with **Novartis International** and **Fondation Botnar** for a component of the career development fellowship scheme focused on maternal, child and adolescent health and wellbeing, and also launched a joint call with the **Coalition for Epidemic Preparedness Innovations (CEPI)** to support the clinical development of Lassa fever vaccines.

EDCTP has also been consulting with the European Commission's Directorate-General for International Cooperation and Development (**DEVCO**) to explore opportunities for collaboration. A strategic call is being devised requiring projects to receive co-funding from development cooperation agencies.

Other important activities have included a **workshop on gender and regional disparities in research funding**, held in November 2019, and a consultative meeting on strengthening national health research systems in Africa, held in October 2019. The latter, jointly organised with the WHO Africa Region and the Republic of Congo, brought together senior government officials, representatives from the African Union and Regional Economic Committees, and other key stakeholders to agree a roadmap to improve take-up of health research findings and knowledge translation. EDCTP agreed to contribute to support further development of the WHO Africa Region's Africa Health Observatory.

EDCTP's investment in research & development

(2014-2019)

Total funding
€608.41 M
In 271 projects awarded by end of 2019.

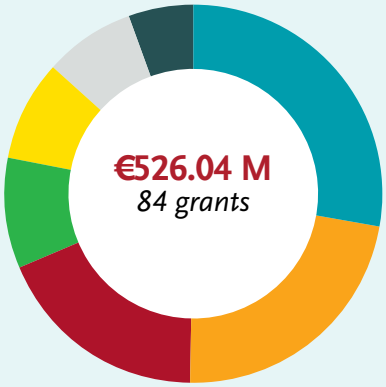
Collaborative clinical trials and clinical studies
€526.04 M
to support **84 projects** with large-scale clinical trials and other clinical research activities conducted by European-African consortia.

Clinical research capacity
€51.27 M
to support **57 projects** that strengthen the enabling environment for conducting clinical trials and clinical research.

Fellowship programme
€31.10 M
to support **130 fellowships** that focus on the career development of individual researchers.

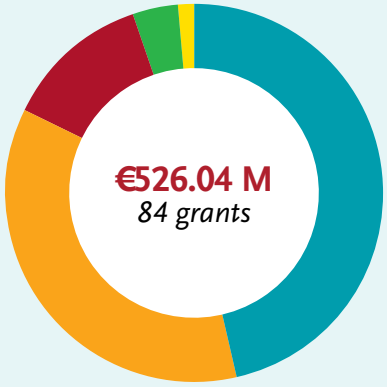
Collaborative clinical trials and clinical studies

By disease



- Tuberculosis, *25 grants* **€146.73 M**
- Malaria, *12 grants* **€118.51 M**
- HIV & HIV-associated infections, *16 grants* **€96.74 M**
- Neglected infectious diseases, *13 grants* **€48.85 M**
- Diarrhoeal diseases, *5 grants* **€45.50 M**
- Emerging infectious diseases, *9 grants* **€41.61 M**
- Lower respiratory tract infections, *4 grants* **€28.09 M**

By intervention



- Drugs, *39 grants* **€244.85 M**
- Vaccines, *18 grants* **€189.26 M**
- Diagnostics, *22 grants* **€65.75 M**
- Combined interventions, *4 grants* **€21 M**
- Product-focused implementation research, *1 grant* **€5.98 M**

EDCTP portfolio: medical interventions against poverty-related infectious diseases

(2014-2019)

Phase Ia/b

VirTUAL
Uganda, South Africa

MoxiMultiDoseMod
DR Congo, Ghana

PEAU-EBOV-RDC

CAP012 SAMBA Trial
South Africa, Zambia

MMVC
The Gambia, Kenya

PfTBV
Burkina Faso, Guinea, Liberia, Mali

MIMVac-Africa
Burkina Faso, Gabon, Mozambique, Tanzania

ETEC Vaccine Efficacy
The Gambia, Zambia

ShigOraVax
Burkina Faso, Zambia

Phase IIa/b

CAPRISA 018
South Africa

PROMISE-EPI
Burkina Faso, Zimbabwe

PanACEA
Ethiopia, Malawi, Mali, Mozambique, Nigeria, Rwanda, South Africa, Senegal, Tanzania

CLICK-TB
South Africa

StatinTB
South Africa

Simplici-TB
Gabon, Malawi, Mozambique, South Africa, Tanzania, Uganda

DATURA
Cameroon, Guinea, Tanzania, Uganda

WANECAM II
Burkina Faso, Gabon, Mali, Niger

PAMAFRICA
Burkina Faso, Gabon, Mozambique, Uganda

SINDOFO
Burkina Faso, Kenya, Mozambique

HAT-r-ACC
Malawi, Uganda, Zambia

EMPIRICAL
Code d'Ivoire, Malawi, Mozambique, Uganda, Zambia, Zimbabwe

GREAT
Kenya, Uganda, Zambia

Neo bnAb
Mozambique, Tanzania

PrEPVacc
Mozambique, Tanzania, Uganda

MTBVAC-Newborns
South Africa

POR TB
South Africa, Tanzania

MMVC
Burkina Faso, Kenya, Sierra Leone, Tanzania

PfTBV
Burkina Faso, Guinea, Liberia, Mali

MIMVac-Africa
Burkina Faso, Gabon, Mozambique, Tanzania

PREV-PKDL
Ethiopia, Kenya, Sudan, Uganda

ShigOraVax
Burkina Faso, Zambia

PREPARE
South Africa, Uganda

PREVAC-UP
Guinea, Liberia, Mali, Sierra Leone

Phase III

CHAPS
South Africa, Uganda

AMBITION-cm
Botswana, Malawi, South Africa, Uganda, Zimbabwe

CHAPAS-4
Uganda, Zambia, Zimbabwe

BREATHER Plus
Kenya, South Africa, Uganda, Zimbabwe

VITALITY
Zambia, Zimbabwe

META TRIAL
Tanzania

INTENSE-TBM
Cote d'Ivoire, Madagascar, South Africa, Uganda

PROTID
Tanzania, Uganda

WANECAM II
Burkina Faso, Gabon, Mali, Niger

IMPROVE
Kenya, Malawi, Tanzania

IMPROVE-2
Kenya, Malawi

MAMAH
Gabon, Mozambique

ASAAP
Benin, Burkina Faso, Gabon, Ghana, Mali

PYRAPREG
Burkina Faso, DR Congo, The Gambia, Mali, Mozambique

MoxiMultiDoseMod
DR Congo, Ghana

HAT-r-ACC
Malawi, Uganda, Zambia

Phase IV

STOP
Ethiopia, Kenya, Mozambique

PZQ4PSAC
Cote d'Ivoire, Kenya

AfriKADIA
Ethiopia, Kenya, Sudan, Uganda

COAST-Nutrition
Kenya, Uganda

priMe
Gabon, Kenya, South Africa, Tanzania, Uganda

THECA
Burkina Faso, DR Congo, Ghana, Madagascar

BabyGel

ETEC, ETVAX
Zambia

DIAGMAL
Burkina Faso, Ethiopia, Kenya, Namibia, Sudan

PREGART
Ethiopia, Uganda

5FC HIV-Crypto
Ethiopia, Uganda

TREATS
South Africa, Zambia

PEOPLE
Comoros, Madagascar

FibroScHot
Uganda

PEP4LEP
Ethiopia, Mozambique, Tanzania

PediCAP
South Africa, Uganda, Zambia, Zimbabwe

NIFTY
Senegal, Uganda

LIFE Study
Mozambique, Tanzania

Non-phase diagnostic trial

CAP-TB
Tanzania, Mozambique

Predict TB
South Africa

RaPaed TB
Malawi, South Africa, Tanzania

PreFIT
Mozambique, South Africa, Uganda

XACT III
Mozambique, South Africa, Zimbabwe

SeroSelectTB
Ethiopia, Tanzania, South Africa

STool4TB
Eswatini, Mozambique, Uganda

ERASE-TB
Mozambique, Tanzania, Zimbabwe

TB TRIAGE+
Lesotho, South Africa

AfriKADIA
Ethiopia, Kenya, Sudan, Uganda

DiTECT-HAT
Cote d'Ivoire, Burkina Faso, DR Congo, Guinea

FREEBILY
Madagascar, Gabon

SOLID
Tanzania, Zambia

LAMP4Yaws
Cameroon, Cote d'Ivoire, Ghana

AdjustEBOVGP-Dx
DR Congo

MobEBO-DRC
DR Congo

Observational study

DREAMM
Cameroon, Malawi, Tanzania

DIAMA
Benin, Cameroon, DR Congo, Ethiopia, Guinea, Mali, Nigeria, Rwanda, Senegal

Stop TB/HIV at one
Ethiopia, Nigeria

Screen TB
Ethiopia, The Gambia, Namibia, South Africa, Uganda

DIAMA
Benin, Cameroon, DR Congo, Ethiopia, Guinea, Mali, Nigeria, Rwanda, Senegal

TriageTB
The Gambia, South Africa, Uganda

Intervention
- Drugs
- Vaccines
- Diagnostics

Other
- Product-focused implementation research

Disease
- HIV and HIV associated infections
- Tuberculosis
- Malaria
- Neglected infectious diseases
- Emerging diseases
- Lower respiratory tract infections
- Diarrhoeal diseases

Population
- Adults (18yr and above)
- Adolescents (10yr-17yr)
- Children (2yr-9yr)
- Infants (above 1mo-1yr)
- Pregnant women and/or newborns (birth to 1mo)

3.1

Participating States' contributions

Projects directly funded by Participating States are making an important contribution to the EDCTP2 portfolio.

As well as EDCTP-managed projects, the EDCTP2 portfolio includes projects that are directly funded and managed by Participating States but fall within the remit of EDCTP2. Submission of such 'Participating States-initiated activities' (PSIAs) provides an important mechanism for coordinating activities across European and African partners, avoiding duplication of efforts and helping to identify neglected priorities and evidence gaps.

An in-depth analysis in 2019 found that 400 PSIAs have been submitted to 2014–2020 work plans, 280 from European countries and 120 from sub-Saharan African countries. Collectively, these amount to a financial commitment of €1.06 billion.

Of the 184 completed projects to date, PSIAs are well-balanced across disease areas, type of intervention, and stage of clinical evaluation. They include at least 117 clinical studies, as well as projects focused on capacity building and strengthening of ethics oversight and regulatory infrastructure for clinical research.

As with EDCTP-managed projects, PSIAs are highly collaborative. Notably, one-fifth of PSIA funding has been committed to international product development partnerships. Several of these partnerships are leading or involved in major EDCTP2 trials, emphasising important complementarity between the two funding streams. PSIAs have also provided a mechanism to further advance successful research carried out in the first EDCTP programme.

PSIAs have made many important contributions to the clinical evaluation of new interventions, including those targeted at vulnerable populations such as pregnant women, young children and people with co-morbidities. Examples include work on Ebola vaccines, clinical trials on antiretroviral drugs, and novel diagnostics for TB.

Projects have also examined implementation issues, including innovative methods to improve retention in HIV care, as well as a widely used smartphone app on HIV drug interactions to guide clinical decision-making. Evidence on long-lasting insecticidal bed nets impregnated with PBO (piperonyl butoxide) led WHO to revise its guidelines and endorse use of pyrethroid–PBO nets.

The interim analysis of completed projects has also revealed that PSIAs map closely to EDCTP's priority research questions in each disease area. Where priority topics are not covered by EDCTP projects or PSIAs, this provides insight into remaining areas where evidence is needed, to guide future funding activities.

Overview of PSIAs

PSIAs

€1.06 BN

Total amount committed to 400 PSIAs submitted between 2014-2020.

European PSIAs

€995 M

Total amount committed to **280 PSIAs** submitted by EDCTP European Participating States.

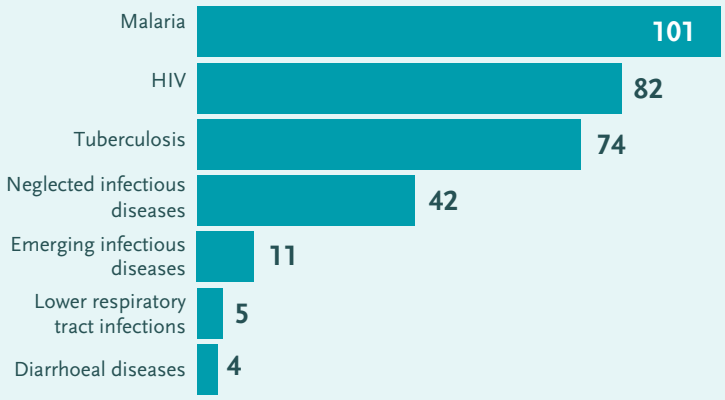
African PSIAs

€67 M

Total amount committed to **120 PSIAs** submitted by EDCTP African Participating States.

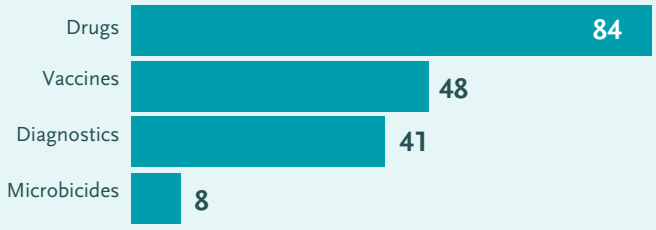
Number of PSIAs

By disease



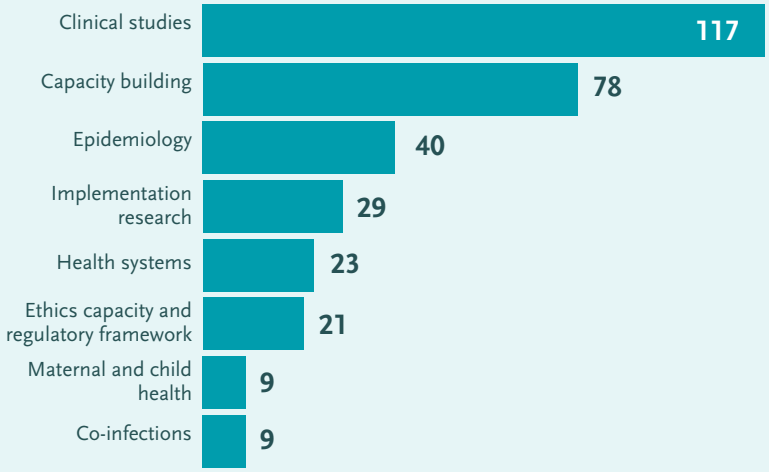
Note: *Including PSIAs from work plans 2014-2019; excluding withdrawn PSIAs. Values are non-unique; PSIAs may be counted multiple times across categories owing to their cross-cutting nature. Excluding PSIAs where the disease area has not yet been reported.*

By intervention



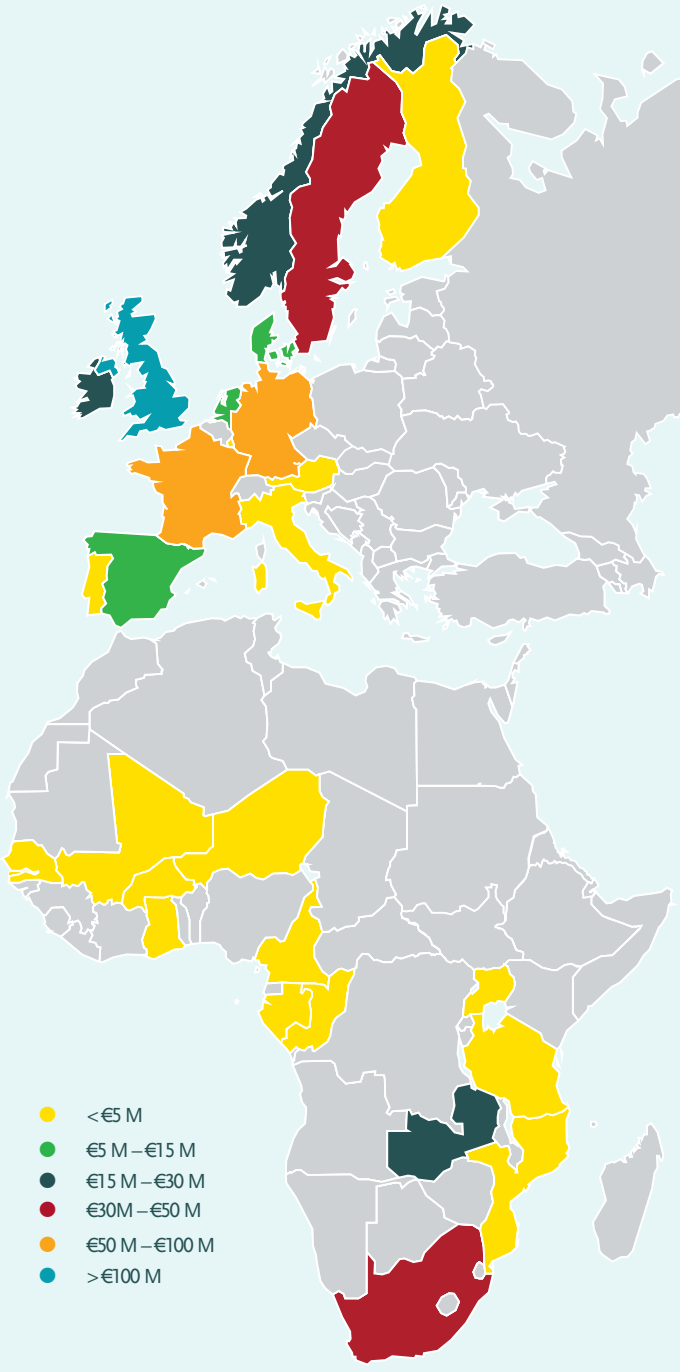
Note: *Including PSIAs from work plans 2014-2019; excluding withdrawn PSIAs. Values are non-unique; PSIAs may be counted multiple times across categories owing to their cross-cutting nature. Excluding PSIAs where the type of intervention has not yet been reported.*

By topic



Note: *Including PSIAs from work plans 2014-2019; excluding withdrawn PSIAs. Values are non-unique; PSIAs may be counted multiple times across categories owing to their cross-cutting nature. Excluding PSIAs where the topic has not yet been reported.*

Funding to PSIAs by country



Note: *Indicative PSIA commitments as specified in work plans 2014-2019; excluding withdrawn PSIAs.*

3.2

TB vaccines take flight

Encouraging progress is being made in the battle against TB.

Tuberculosis (TB) is responsible for more deaths than any other single organism – an estimated 1.5 million people died from TB in 2018 and 10 million people fell ill. More than a quarter of TB deaths occur in sub-Saharan Africa.

For many decades, prevention of infection has relied on the BCG vaccine, which is only partially effective and has multiple drawbacks. Now, however, innovative new approaches are being used to create more powerful vaccines with much greater potential to prevent infection with *Mycobacterium tuberculosis* (Mtb) and the spread of disease.

EDCTP is funding three TB vaccine trials. The **MTBVAC-Newborns** and **priMe** projects are focusing on alternatives to BCG to prevent infection in infants – precisely engineered vaccines based, respectively, on Mtb and *M. bovis* (from which BCG was originally derived). By contrast, the **POR-TB** project is aiming to prevent recurrence of disease in patients supposedly cured of Mtb by antibiotic treatment – typically, one in ten patients will relapse.

TB vaccine pipeline

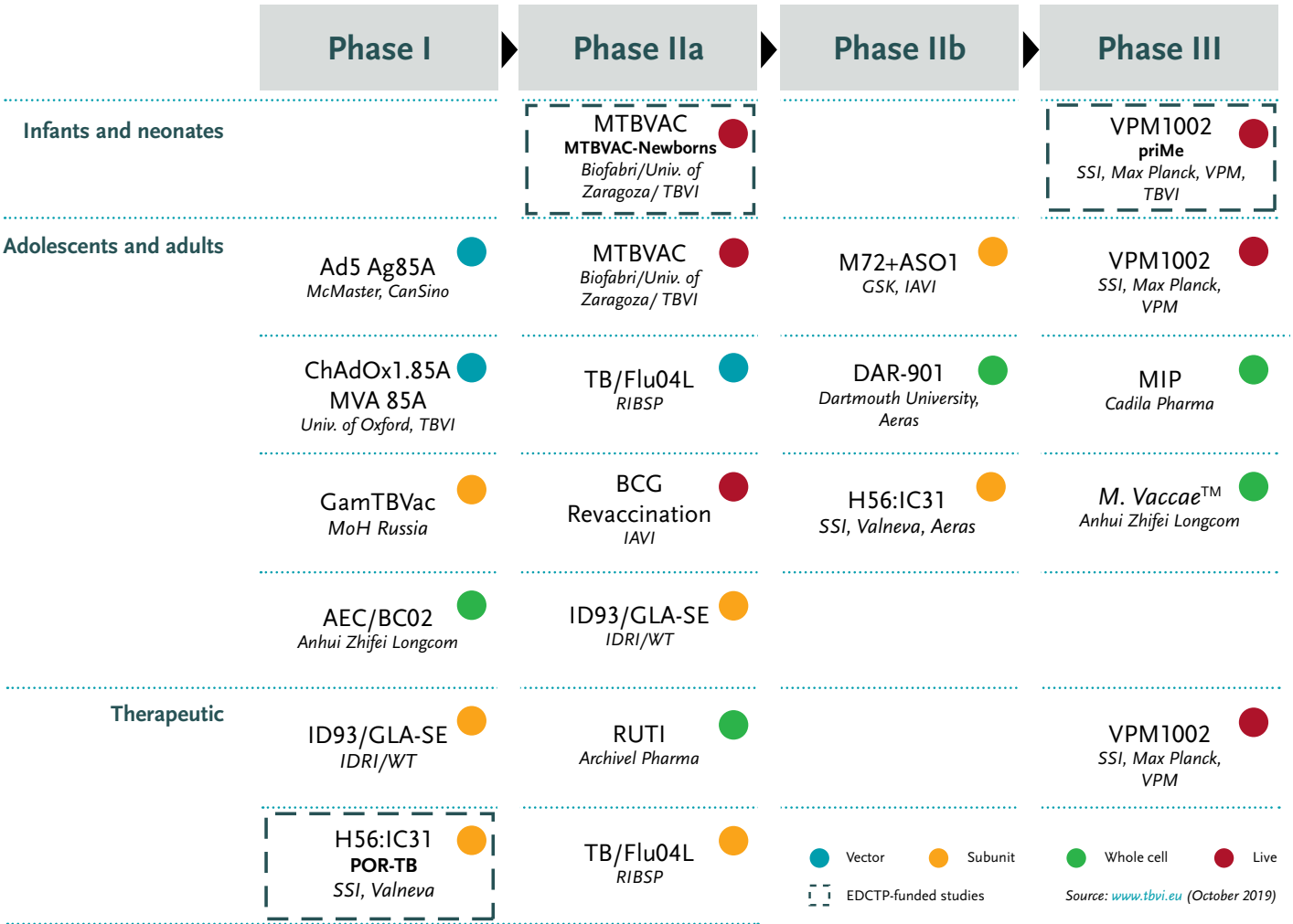


Photo: MTBVAC-Newborns project staff members, South Africa

Enhancing collaboration

Although the projects are focused on different kinds of vaccine, there is great potential to improve efficiencies and impact by strengthening the links between them and with other global TB vaccine endeavours. To achieve this, in 2019 EDCTP provided dedicated funding to the **Tuberculosis Vaccine Initiative (TBVI)**, a non-profit foundation set up to accelerate the development of TB vaccines. The project will provide additional resources and coordination to the three EDCTP projects, helping them to draw on further technical support and expertise, and to share experience, in order to achieve their goals.

Given these exciting developments, it is important that the pathway to impact is as smooth as possible – so that people rapidly benefit from effective new vaccines. To achieve this, early and coordinated attention needs to be given to the clinical evaluation of candidate vaccines and the pathways of licensing and implementation.

In 2019, EDCTP therefore awarded a one-year grant to the Amsterdam Institute of Global Health and Development (AIGHD) to support a global consultation and drafting of a **new global TB vaccine R&D roadmap**. Working in close collaboration with the World Health Organisation (WHO), AIGHD will consult with TB vaccine stakeholders globally, to map out the current state of play, key obstacles and enablers, and priority areas for R&D. It will cover the entire R&D chain, including TB vaccine research, product development, and product licensing and implementation.

The project will ensure that the interests and perspectives of all key groups – including researchers, product developers, funders, regulatory agencies, and national and global bodies focused on TB control – have a shared understanding of challenges at each stage and how they can be collaboratively addressed. The final roadmap will therefore be a vital strategic tool to guide their decision-making and activities, and ultimately accelerate the delivery of new TB vaccines to populations in need

3.3

TB drug development

A key phase II trial, being run under the PanACEA umbrella, has begun testing a highly promising new TB drug.

The international **PanACEA consortium** was set up to accelerate development of new TB drugs, by coordinating activities across multiple groups, promoting use of novel laboratory techniques, and using innovative trial designs (such as the innovative 'multi-arm, multi-study' MAMS trial, an adaptive trial comparing ways to shorten TB treatment).

A further priority in TB control is the development of additional agents for multidrug-resistant (MDR) and extremely drug-resistant (XDR) TB. These require more intensive treatment, and survival rates are very poor, especially for XDR-TB.

In its latest project, the PanACEA consortium is evaluating a highly promising new drug known as BTZ-043, an inhibitor of cell wall synthesis in *Mycobacterium tuberculosis* (Mtb). BTZ-043 is highly selective for mycobacteria and is active on all Mtb isolates tested, including MDR and XDR strains.

Following a successful phase I trial, the PanACEA trial, launched in November 2019, is the first time BTZ-043 has been given to patients in Africa. The drug is being given to 80 patients in Cape Town, South Africa, initially to identify the most appropriate dose. The efficacy of the optimised dose will then be compared with standard TB treatment.

Identified in 2014, BTZ-043 has moved rapidly from discovery through to clinical trials. The existing PanACEA infrastructure has meant that sites could be rapidly mobilised to test this exciting new agent, from an entirely new chemical family and with activity against hard-to-treat drug-resistant TB.

3.4

Keeping malaria options open

For malaria, no single treatment or vaccine can meet every therapeutic need – a portfolio approach is essential.

Following years of reducing mortality, progress in malaria control has stalled. Around 400,000 people still die of malaria each year, most of them young children in sub-Saharan Africa.

Effective drugs exist for malaria, and a vaccine is undergoing pilot implementation studies in three countries. However, this is no time for complacency. The threat of drug resistance is very real, and vaccines offering greater efficacy are urgently required.

A portfolio approach is therefore essential. Progressing a range of products allows for the inevitability that some will not end up suitable for use, because of lack of efficacy or safety concerns. In addition, drugs and vaccines have to perform a range of functions in different populations, so products with different properties may be required.

The **PAMAFRICA portfolio grant** is progressing a portfolio of drug products managed by the Medicines for Malaria Venture (MMV). It is aiming to develop a single-dose cure for malaria, testing two compounds in development as well as a new formulation of existing drugs for young infants. It is also evaluating a new injectable form of cipargamin for severe malaria caused by drug-resistant parasites. Other emerging promising antimalarials will also be evaluated under this portfolio grant.

Novartis and MMV are partners in the **WANECAM II project**, a global collaboration coordinated from Mali, which is testing an antimalarial from an entirely new class, known as KAF156 or ganaplacide, to be used in combination with lumefantrine.

For vaccines, the **MMVC project** has the ambitious goal of developing a vaccine targeting all key stages of the malaria parasite life-cycle – pre-liver, liver, bloodstream and mosquito. A vaccine against the parasite forms found in the mosquito is also the goal of the **PfTBV portfolio grant.** The major advantage of this type of vaccine is that it would prevent completion of the parasite life-cycle in mosquitoes, blocking transmission.

Finally, the **MIMVaC-Africa portfolio grant** is bringing together a global consortium to assess five vaccine candidates in controlled human infection studies. The most promising will then be evaluated in a field efficacy trial.

3.5

Deadly combinations

Poverty-related infectious diseases are seldom experienced in isolation – a better understanding of interactions between them and with non-communicable diseases is essential.

Although infectious diseases are often studied individually, in reality patients with infections often have other health conditions. One obvious example is HIV and TB, often found together, as HIV increases the risk of TB disease. Co-infections can interact with one another and also impact on treatment – drugs for one condition can interfere with those used to treat another.

For example, initiation of treatment of HIV/AIDS with antiretroviral drugs can lead to a sudden flare up of TB as a patient's immune system recovers (known as immune reconstitution inflammatory syndrome, IRIS). The **PredART trial**, funded under the first EDCTP programme (2003-2015), showed that treatment with a widely available steroid, prednisone, significantly reduced morbidity in IRIS patients[1]. A follow-up trial is assessing whether prednisone can prevent IRIS developing in high-risk patients.

TB is a particular risk for people at an advanced stage of HIV infection, who account for up to a quarter of HIV patients in sub-Saharan Africa. The **DATURA trial**, awarded in 2019, is assessing whether intensified treatment of TB in this group can reduce high levels of mortality.

As well as other infections, poverty-related infectious diseases also interact with non-communicable diseases. TB, for example, increases the risk of type II diabetes, while diabetes increases the severity of TB disease. Furthermore, as more people with HIV infections survive to middle age, they are increasingly at risk of cardiovascular and other non-communicable diseases. As well as understanding implications for treatment when patients have multiple conditions, there is also a growing need to consider how patient care should best be organised and integrated to maximise the benefits to patients.

One in four people globally have inactive (latent) TB infections, and around 10% go on to develop active TB disease. This risk is substantially greater in certain groups, including those with type 2 diabetes. The **PROTID trial**, funded in 2019, is assessing whether preventive treatment of TB in diabetes patients with latent TB is practical, clinically worthwhile and cost-effective.

Awarded in 2019, the **META TRIAL study** will include a large-scale phase III trial to determine whether metformin, an affordable drug widely used to treat diabetes, is also effective at preventing the development of diabetes in people living with HIV at increased risk of the condition. Also funded in 2019, the **VITALITY project** is evaluating the potential of vitamin D and calcium carbonate supplementation to counter the weakening of bone commonly seen in children with HIV infections.

In 2019, EDCTP also funded studies of co-morbidities through a fellowship scheme organised in partnership with GlaxoSmithKline. Through this scheme, **Dr Barbara Castelnuovo** is setting up a cohort of older people with HIV in Uganda, to determine the health risks they face in later life. **Professor Andre Kengne** is aiming to identify the key risk factors for cardiometabolic disease in people living with HIV in sub-Saharan Africa, in a project spanning Cameroon, Nigeria and South Africa. A clearer understanding of the most important risk factors could underpin the design of integrated services for people living with HIV that address both infectious and non-communicable co-morbidities.

In addition, **Dr George PrayGod** is investigating whether impaired gut function, due to infection, is linked to the increased risk of diabetes in people living with HIV. **Professor Marielle Bouyou-Akotet** is exploring whether common parasitic infections affect the risk of cardiometabolic disease in urban and rural populations in a Central African country. Finally, **Professor Dorothy Yeboah-Manu** is assessing how diabetes affects TB disease and responses to treatment.

1 Meintjes G *et al.* Prednisone for the prevention of paradoxical tuberculosis-associated IRIS. *N Engl J Med.* 2018;379(20):1915–1925.

Photo: PredART project staff member and clinical trial volunteer, South Africa

Tackling a hidden killer

The annual G-FINDER report of global health research funding has highlighted EDCTP's major contribution to combating cryptococcal infections, a leading cause of death in people with HIV.

Cryptococcus is an opportunistic fungal infection that poses a serious risk to people with advanced HIV disease. It is responsible for the deaths of up to 20% of people with HIV infections, principally because of brain infections leading to cryptococcal meningitis.

Over several years, EDCTP has developed a suite of projects having a major impact on *Cryptococcus* diagnosis and treatment. Of particular note, the EDCTP-funded **REMSTART trial** showed that a relatively low-cost intervention, based on screening for *Cryptococcus* infections and providing home support to encourage adherence to treatment, reduced mortality by 28%. The follow-up **TRIP project** is testing whether a simplified version implemented in clinics, but using mobile messaging rather than home visits, is similarly effective.

Also focusing on implementation, the **DREAMM study** is piloting the introduction into routine care of screening for central nervous system infections such as cryptococcal meningitis in Cameroon, Malawi and Tanzania. The project will generate important data on cost-effectiveness in routine settings, as well as on factors affecting implementation of new clinical tools and diagnostic algorithms. The activities in Cameroon are co-funded by ANRS, the French Agency for Research on AIDS and Viral Hepatitis.

Better treatments are also required for *Cryptococcus* infections. The **AMBITION-cm trial** is a major phase III trial testing the efficacy of an improved single-dose liposomal formulation of amphotericin B (AmBisome®). Standard amphotericin B is not widely used in resource-poor settings in part because it requires hospitalisation for at least 14 days and its toxicity profile requires costly monitoring. Liposomal amphotericin B has a much better safety profile and, if proven to be equally effective, could provide a more practical first-line treatment option.

In addition, the **5FC HIV-Crypto study**, awarded in 2019, is focusing on an alternative treatment, flucytosine, which also has a challenging dosing schedule. An EDCTP-funded team is developing a new formulation of flucytosine that is easier to administer, including a sustained-release formulation, and will compare its efficacy with the current formulation.

Despite its major burden in sub-Saharan Africa, cryptococcal meningitis remains under-studied and under-funded. The 2019 G-FINDER annual report[2] highlighted the fact that the bulk of non-US funding was routed through EDCTP, and accounted for 85% of global funding on clinical development.

2 Chapman N *et al*. G-FINDER 2019. Neglected Diseases Research and Development: Uneven Progress. 2019. Policy Cures Research. Available at *https://www.policycuresresearch.org/analysis*

3.6

Rolling back sleeping sickness

EDCTP-funded projects are helping to maintain progress towards elimination of a key neglected infectious disease, human African trypanosomiasis (HAT or sleeping sickness).

Control of HAT has been one of the region's great success stories. Infection with trypanosomes – principally *Trypanosoma brucei gambiense*, a single-celled parasite transmitted by the tsetse fly – can lead to lethargy and potentially death. In recent decades, however, cases have been reduced by more than 90% through more effective treatments and vector control.

A major advance has been the development of a new drug for HAT, fexinidazole, by the Drugs for Neglected Diseases initiative (DNDi) and its partners. Fexinidazole is an oral drug, so much easier to administer than current treatments for severe disease, which require use of intravenous drug infusions. The **FEX-g-HAT project**, awarded in 2019, aims to accelerate the introduction of fexinidazole by engaging with health systems and health workers in affected countries to raise awareness of the drug and WHO recommendations on its use, to train health workers on its administration, and to support the development of national health policies.

Launched in 2019, the **HAT-R-ACC study** is assessing whether fexinidazole is also effective against *Trypanosoma brucei rhodesiense*, which causes a more acute form of HAT and is found mainly in East Africa. Fexinidazole is being assessed as an alternative to a toxic arsenic-based drug (melarsopol) and a less toxic but difficult-to-administer drug (suramin).

EDCTP portfolio: neglected infectious diseases

	Drugs	Vaccines	Diagnostics
Human African trypanosomiasis	**HAT-r-ACC** *Malawi, Uganda, Zambia*		**DiTECT-HAT** *Cote d'Ivoire, Burkina Faso, DR Congo, Guinea*
Schistosomiasis	**PZQ4PSAC** *Cote d'Ivoire, Kenya*		**FREEBILY** *Madagascar, Gabon*
	FibroScHot *Uganda*		
Leishmaniasis	**AfriKADIA** *Ethiopia, Kenya, Sudan, Uganda*	**PREV-PKDL** *Ethiopia, Kenya, Sudan, Uganda*	**AfriKADIA** *Ethiopia, Kenya, Sudan, Uganda*
Taeniasis/ (neuro) cysticercosis			**SOLID** *Tanzania, Zambia*
Leprosy	**PEP4LEP** *Ethiopia, Mozambique, Tanzania*		
	PEOPLE *Comoros, Madagascar*		
Onchocerciasis	**MoxiMultiDoseMod** *DR Congo, Ghana*		
Soil-transmitted helminths	**STOP** *Ethiopia, Kenya, Mozambique*		
Yaws			**LAMP4Yaws** *Cameroon, Cote d'Ivoire, Ghana*

Caption	Study phase	Population
Project name *Site(s) in sub-Saharan Africa*	Phase I, Phase II, Phase III, Phase IV	Adults (18yr and above), Adolescents (10yr-17yr), Children (2yr-9yr), Infants (above 1mo-1yr), Pregnant women and/or newborns (birth to 1mo)

A further study, **DiTECT-HAT**, is focusing on diagnostics. Eradication of HAT will ultimately depend on use of a range of tools to detect *T. brucei* infections in different situations. The DiTECT-HAT study is evaluating three tools, to identify cases in clinics so treatment can be started immediately, to support mass population screening, and to evaluate responses to drugs in clinical trials.

For mass population screening, health workers carrying out house-to-house visits can easily collect blood on filter paper and send it to regional HAT reference centres for analysis. This will determine the feasibility and cost of diagnostic algorithms based on rapid diagnostic tests, serological and/or molecular high-throughput tests for post-elimination monitoring. House-to-house visits and testing started in 2019 in the Democratic Republic of the Congo, Côte d'Ivoire and Burkina Faso, and will be completed in 2020. Based on the results, the DiTECT-HAT team will establish an appropriate threshold to trigger active case finding to avoid re-emergence of HAT. The results will also inform the development of algorithms for validation of HAT elimination.

These projects will make an important contribution to the elimination of HAT as a public health threat and then, ideally, its eradication.

Photo: DiTECT-HAT project staff member, Cote d'Ivoire

3.7

Diarrhoeal disease and respiratory infections

EDCTP2 projects are accelerating the development of interventions against diarrhoeal diseases and lower respiratory tract infections – still major killers of young children.

Pneumonia and diarrhoeal diseases are, respectively, the first and third leading causes of death in children under the age of five years. These diseases were added to the scope of the EDCTP2 programme, and recent funding has established a portfolio of projects in this area, with a strong focus on vaccines – generally the most cost-effective way to control infection and minimise the long-term impact of disease on individuals.

Enterotoxigenic *E. coli* (ETEC) is an important cause of diarrhoeal disease in sub-Saharan Africa. A promising vaccine against ETEC has been developed, known as ETVAX, and EDCTP has funded studies to accelerate its introduction in the region.

The **ETEC Vaccine Efficacy study** is conducting a series of safety studies on ETVAX in adults and progressively younger children in Zambia. Assuming no safety issues arise, the project will then progress to a phase IIb study in infants in The Gambia. The related **ETEC ETVAX study**, awarded in 2019, is developing a new formulation better suited to young children, as well as a user-friendly tool for administering the vaccine. The new all-in-one formulation will then be tested in a phase III trial in Zambian infants.

Funded in 2019, the **ShigOraVax** study is evaluating a vaccine against the most common forms of *Shigella*, *S. flexneri* strains 2a, 3a and 6 and *S. sonnei*, all of which are associated with severe diarrhoeal disease. The project aims to develop a whole-cell inactivated vaccine that is protective against all these strains, can be administered orally, and is cheap and easy to manufacture. After safety studies in adults, it will then be tested in children.

Typhoid fever, caused by infections with *Salmonella* Typhi, causes more than 200,000 deaths every year. A typhoid conjugate vaccine, Typbar-TCV®, has been licensed despite limited data on its efficacy. In the **THECA study**, a trial in Ghana will generate data on safety and efficacy and population-level protection, adding to the pool of African data provided by other ongoing trials. In addition, a complementary study in the Democratic Republic of the Congo will be embedded within a mass vaccination campaign, providing additional data on protection when the vaccine is used within routine public health systems, as well as insight into feasibility, programmatic challenges, and cost-effectiveness.

Group B streptococci can be transmitted to babies in the womb or during childbirth and can cause stillbirths and invasive disease in young infants. The **PREPARE study**, funded in 2019, is testing two vaccines that, when given to pregnant women, are designed to prevent the transmission of group B streptococci to their offspring.

Three ongoing trials are focusing on treatment of pneumonia in children. The **PediCAP study** is testing new treatment regimens, to optimise antibiotic use in young children. The **COAST-Nutrition study** is building on an existing major trial of oxygen therapy to determine whether greater use of nutritional supplements improves survival. The **EMPIRICAL trial** is evaluating whether treatment for TB and cytomegalovirus, a common and usually harmless virus, improves survival of HIV-infected infants with severe pneumonia; these infections are turning out to be an unexpectedly common cause of disease in such infants, so presumptive treatment even without formal diagnosis may enhance survival.

Finally, the **BabyGel study** is exploring a simple intervention to reduce infant infections – giving pregnant women alcohol-based hand rub for household use, alongside educational guidance, after they have given birth.

Importantly, the pneumonia studies are also building regional capacity in research on respiratory tract infections, of potential importance in the battle against COVID-19.

Photo: MONOD project staff member and young patient enrolled in the trial, Burkina Faso

3.8

Building capacity for ethics and regulatory review

EDCTP funding has been strengthening the capacity of multiple countries in sub-Saharan Africa to provide effective oversight of clinical research.

Strong ethics and regulatory oversight of clinical trials is essential to protect the interests and health of participants and to maintain public confidence in research. National regulatory authorities (NRAs) need to approve clinical studies involving investigational products and use of registered products for potential label extension or different disease indications. Moreover, NRAs need to coordinate with the institutional and national ethics review committees that evaluate the ethical aspects of research studies.

Despite significant progress made in these areas, many countries in sub-Saharan Africa have critical capacity gaps in their ethics and regulatory bodies. This is an issue of ever-growing importance, as the number of clinical trials in the region increases and trials become even more complex, including studies on vulnerable populations and innovative new trial designs. Inadequate national regulatory capacity can deter sponsors of clinical trials and delay the start of clinical studies.

By the end of 2019, EDCTP had awarded 31 grants to support the development of regulatory and ethics review capacity in 27 countries in sub-Saharan Africa. Projects have focused on training and skills development of regulatory agency staff and members of ethics review committees, enhancing coordination between national agencies, and improving processes, including the introduction of electronic systems for managing clinical research proposals.

Several projects have promoted regional collaborations to share experience and coordinate development, or taken advantage of European links to learn from systems with more mature regulatory environments. Projects have also focused on specific topical issues, such as gender representation in clinical research (**BCA-WA-ETHICS project**), oversight of diagnostics research (**IGORCADIA**) and community engagement in research oversight (**SCINE-U project**).

Collectively, these projects will help to create an enabling environment for clinical research, with more efficient processing of applications and better safeguarding of participants' interests. As well as attracting more clinical studies, they will also ultimately accelerate the introduction of new medical interventions into the region.

EDCTP's contribution towards ethics and regulatory activities in Africa

Photo: TRIP project staff member, Tanzania

3.9

Applying known tools

Implementation studies can ensure that proven interventions are better used to control infectious disease.

Although new drugs, vaccines and other interventions are always needed, many excellent tools and disease-control strategies already exist. More extensive use of these strategies could have a major impact on the burden of poverty-related infectious diseases in sub-Saharan Africa.

EDCTP funds product-focused implementation studies, which provide opportunities to explore and overcome barriers to the use of proven interventions, promoting their take up within health systems.

Three recent studies have focused on malaria control which, after encouraging progress over the past decade, has stalled in the past few years.

Pregnant women are particularly vulnerable to the effects of malaria, which affects their own health and increases the risk of birth complications. One approach known to be effective, and recommended by WHO, is preventive use of antimalarial drugs, known as 'intermittent preventive treatment of malaria in pregnancy' (IPTp), which can be integrated into antenatal care. However, in countries such as Kenya, only 25% of pregnant women receive three or more doses of IPTp. To address this shortcoming, the **Revive IPTp project**, awarded in 2019, is working with communities, health workers and health authorities at a devolved level in Kenya to reinvigorate malaria control in this vulnerable population.

Another proven strategy that is not fully implemented is seasonal malaria chemoprevention (SMC). In settings where malaria is highly seasonal, preventive drug treatment of children during high-risk periods can protect children directly and also reduce the reservoir of parasites able to cause disease. Although recommended by WHO, only 50% of eligible children had access to SMC in 2017. Building on an existing partnership of 14 countries, and with input from WHO and the Medicines for Malaria Venture (MMV), as well as academic support from partners in Senegal and the UK, the **OPT-SMC project** aims to both widen and strengthen implementation of SMC in sub-Saharan Africa.

Finally, the **ADAM project**, awarded in 2019, is aiming to advance malaria elimination in Mozambique, building on earlier successful programmes that reduced the number of cases in southern Mozambique by nearly 80%. The project is working with the National Malaria Control Programme to support a population-wide and follow-up targeted mass drug administration programme to drive down the number of cases in low-transmission areas, as a stepping stone to disease elimination in the country.

3.10

Enhancing drug-safety monitoring

Increasing access to new medications in sub-Saharan Africa is highlighting the need for effective national drug-monitoring systems.

Protecting participants in clinical trials, and the general public once new medicines are introduced, requires effective systems to monitor for potential adverse reactions (pharmacovigilance). Comprehensive systems need to be in place to identify reactions when they occur, to investigate them to determine whether they are truly related to a new intervention, and to take action if public health is threatened.

Many countries in sub-Saharan Africa have weak infrastructure for pharmacovigilance. Building pharmacovigilance capacity is part of several EDCTP-funded projects building national regulatory capacity in clinical research. For example, the **Africlinique project**, funded in 2019, is building pharmacovigilance capacity in countries in Central Africa, starting with Cameroon and the Republic of the Congo, in collaboration with EU institutions and regional bodies such as the African Vaccine Regulatory Forum (AVAREF) and the EDCTP-funded Central African Network on Tuberculosis, HIV/AIDS and Malaria (CANTAM).

In addition, the newly awarded **SPaRCS project** is supporting coordinated development of pharmacovigilance capacity in four southern African states – Eswatini, Namibia, South Africa and Zimbabwe – helping to build a sub-regional community of practice to promote coordinated capacity development.

Two major international projects are also focused on pharmacovigilance. The **PAVIA project** is building pharmacovigilance capacity in Eswatini, Ethiopia, Nigeria and Tanzania. It has established links between key national stakeholders and undertaken baseline studies of national pharmacovigilance capabilities, to inform the development of national capacity-building plans. It is also engaging with the African Union Development Agency (AUDA-NEPAD), to coordinate activities, particularly regarding the African Union Model Law for Medical Products Regulation. The project is initially focusing on TB treatment, with the potential to expand into other disease areas.

The **PROFORMA project** has brought together Ethiopia, Tanzania, Kenya and Rwanda. It has also undertaken baseline national assessments and begun to develop country-specific pharmacovigilance improvement plans. It has also assessed current pharmacovigilance teaching in East Africa in order to inform curriculum development. The project is initially focusing on mass drug administration campaigns and vaccine introductions.

In addition, the **EAPI project** is addressing the shortage of capacity within national regulatory agencies to conduct pharmacovigilance activities. EAPI is a partnership between the Pharmacy and Poisons Board – the national regulatory agency in Kenya – and the University of Nairobi. The partners are jointly developing e-learning materials to enable academic staff to contribute to practical national pharmacovigilance activities. The virtual training tools could also be used to develop capacity across other countries in East Africa.

3.11

Boosting outbreak preparedness

EDCTP-funded consortia have been helping to coordinate efforts to prevent and respond effectively to infectious disease outbreaks.

In 2019, global support was mobilised to tackle a major Ebola outbreak in the Democratic Republic of the Congo (DRC). Towards the end of the year, people in China began to fall ill from an unusual form of pneumonia, later shown to be caused by a novel coronavirus (SARS-CoV-2) and destined to become a devastating global pandemic (COVID-19). These two examples vividly illustrate the hugely damaging health and economic impact of infectious disease outbreaks.

The 2014–16 West Africa Ebola epidemic, which claimed the lives of more than 11,000 people directly and at least as many indirectly through its impact on health systems, highlighted the threat posed by emerging and re-emerging infections in sub-Saharan Africa. As well as struggling to meet clinical challenges, the countries affected were poorly prepared to carry out research that could have improved responses to the epidemic and to future outbreaks.

As infectious disease outbreaks are not bound by country borders, international collaboration is essential. EDCTP has funded two major consortia – the African coalition for epidemic research, response and training (**ALERRT**) and the Pan-African Network for Rapid Research, Response, Relief and Preparedness for Infectious Diseases Epidemics (**PANDORA-ID-NET**) – to build capacity in outbreak detection and responses in sub-Saharan Africa, linking institutions in the region with European centres of excellence in infectious disease.

ALERRT is a multidisciplinary consortium building a patient-centred clinical research network to respond to epidemics across nine countries sub-Saharan Africa, supported by institutions in four European countries. It is creating platforms to build capacity for laboratory and clinical research and for data sharing, able to respond rapidly to new regional threats.

PANDORA-ID-NET, spanning 22 institutions in nine African and four European countries, is strengthening outbreak response capabilities across Africa, in partnership with national governments and other key stakeholders in Africa and Europe. It has adopted a 'one health' perspective, recognising the importance of animal-to-human transmission of novel infectious agents.

The two consortia have also established collaborative links, for example working jointly to develop a set of principles to guide data-sharing practice. Importantly, the presence of these networks has enabled them to take a lead in regional responses to COVID-19, as well as responses to other emerging and re-emerging threats, such as Lassa fever, chikungunya, plague and monkeypox.

EDCTP has also funded a range of smaller projects through a special emergency call for proposals in 2018 triggered by the DRC Ebola outbreak and to boost outbreak response capacity. These Ebola-specific projects have included work on a sensitive new diagnostic for Ebola and related viruses (**AdjustEBOVGP-Dx**), surveillance in Republic of Congo (**EPIRISK-Ebov**), drug testing and surveillance in Uganda (**Capa-CT 2**, which built on a related earlier grant, see below), Ebola patient care in the DRC (**PEAU-EBOV-RDC**) and introduction of a mobile 'laboratory in a suitcase' into the DRC for rapid diagnosis (**MobEBO-DRC**).

These projects complemented other Ebola-specific projects awarded in 2016, which have helped to build research capacity in countries affected by the 2014–16 West Africa Ebola epidemic, such as Sierra Leone (**RECAP-SL**, **ID-CLINICAL-CAPACITY**) and Liberia (**SELeCT**), countries neighbouring the DRC, such as Uganda (**Capa-CT**), and countries and regions at risk of outbreaks, including Gabon (**SECC**) and northern Uganda (**ENDORSE**).

3.12

Health research systems strengthening

In partnership with the WHO Regional Office for Africa, EDCTP is supporting efforts to develop national health research systems in sub-Saharan Africa.

There is a mutually beneficial relationship between national health care systems and national health research systems. A strong health system is better able to support clinical and health-related research, while a strong research system generates evidence to improve the effectiveness and efficiency of health care delivery.

Consistent with the Sustainable Development Goals, sub-Saharan Africa has adopted universal health coverage (UHC) as a key objective. Due to differences in local context, each country will need to forge its own path to UHC. Health research will provide the key evidence to guide countries on this journey.

Unfortunately, sub-Saharan African countries have traditionally had weak health and research systems. To address this issue, in 2016 the region adopted a new 'research for health' strategy. To benchmark national health research systems, the WHO Regional Office for Africa (WHO-AFRO) developed a 'barometer' as a tool to assess capabilities across four domains – governance, developing and sustaining resources, producing and using research, and financing.

In 2018, EDCTP and WHO-AFRO partnered to explore use of the barometer to create a roadmap for the development of national health research systems in the region. EDCTP and WHO-AFRO jointly hosted a kick-off meeting in Accra, Ghana, in July 2018, including 50 representatives from 17 EDCTP Participating States. Results of national surveys of health research systems were presented at a high-level side event at the African Ministers of Health meeting in Dakar, Senegal, in August 2018.

WHO-AFRO, in partnership with EDCTP and Tackling Infection to Benefit Africa (TIBA), an African-led organisation supported by the UK's National Institute for Health Research (NIHR), also published a report mapping the current status of national health research systems in 39 out of the 47 countries in the region. These findings identified significant improvements in many areas since a similar survey in 2014[3].

To maintain momentum, in October 2019, EDCTP and WHO-AFRO organised a follow-up consultative meeting, held in Brazzaville, Republic of Congo, to discuss the development of a roadmap to further strengthen national health research systems. The meeting brought together more than 50 delegates from 17 Participating States and other stakeholders. It was agreed that the barometer was a valuable tool for assessing national health research capabilities, and delegates suggested that some additional components, such as public health emergencies, should be added to it. The 2018 results were discussed and used to develop a roadmap for further strengthening of national health research systems, including the roles of additional stakeholders, in advance of a further national survey in 2020.

Among the outcomes of the meeting was the agreement that EDCTP regional Networks of Excellence would work with Regional Economic Communities to enhance national capacities in EDCTP Participating States. EDCTP also committed to provide funding for the WHO-AFRO Africa Health Observatory to support data collection for calculating barometer scores.

The project is part of a wider partnership with WHO-AFRO, which also includes co-funding for 30 implementation research projects.

3 Rusakaniko S *et al*. Strengthening national health research systems in the WHO African Region - progress towards universal health coverage. *Global Health*. 2019;15(1):50.

3.13

Strengthening regional networking

An independent mid-term evaluation has highlighted some of the achievements of the EDCTP's regional Networks of Excellence, as well as areas for further development.

In 2016, EDCTP awarded funding to four regional Networks of Excellence, to strengthen South–South and South–North collaboration. The key aims of the Networks were to enhance clinical research capacity, for example through coordinated development of research infrastructure, as well as training and mentoring of researchers. Each Network linked together existing centres of excellence but also weaker institutions in the same countries and others with less developed health research systems in the respective sub-regions.

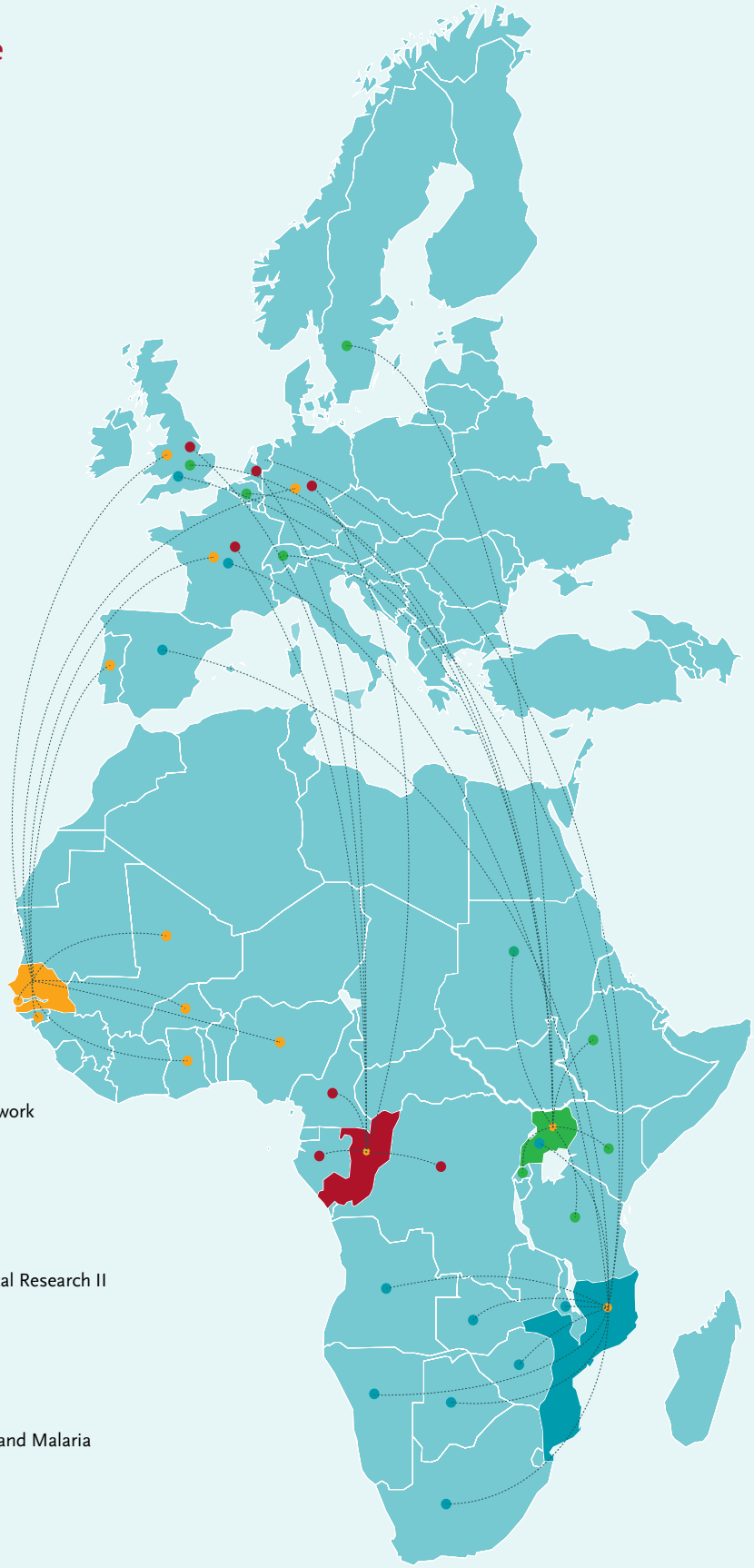
Collectively, the four Networks of Excellence – the **Central African Clinical Research Network (CANTAM2)**, the **East African Consortium for Clinical Research (EACCR2)**, **Trials of Excellence in Southern Africa (TESA2)** and the **West African Network for TB, AIDS and Malaria (WANETAM)** – involve 42 institutions in 25 African countries. Complementarities between sites in each Network can ensure that they are more than the sum of their parts, and offer an attractive platform for multicentre clinical studies.

The independent mid-term evaluation of the Networks in 2019 highlighted a number of successes. The Networks have provided an excellent platform to support training and professional development, through fellowships, PhD, master's and short-term training. Multiple research facilities have been upgraded, including in countries with relatively underdeveloped health systems. Baseline studies have been carried to support future trials, and some progress has been made in development of joint projects, for example the **EXIT-TB project**, which is promoting the uptake of a range of approaches to improve identification of TB cases.

Networks have made active efforts to engage with local policymakers to encourage take up of research findings. They have also established links with other research networks in sub-Saharan Africa, including the EDCTP-funded ALERRT and PANDORA-ID-NET epidemic preparedness networks.

The evaluation panel noted that it takes time to develop effective systems and relationships, and Networks are at an early stage of their development. There were opportunities to build on the foundation established, to develop more extensive North–South collaborations, and to raise awareness of the opportunities for multicentre research studies offered by the Networks.

EDCTP Networks of Excellence



CANTAM2
Central Africa Clinical Research Network
Congo
www.cantam.org

EACCR II
Eastern Africa Consortium for Clinical Research II
Uganda
www.eaccr.org

WANETAM II
West African Network for TB, AIDS and Malaria
Senegal
www.wanetam.org

TESA II
Trials of Excellence in Southern Africa II
Mozambique
www.tesanoe.org

3.14

Ensuring equity in research funding

EDCTP is considering how best to achieve gender and regional equity in its activities and funding.

To ensure the excellence of the research it funds, EDCTP awards funding through competitive calls for proposals. However, this approach tends to favour those already in receipt of funding as well as senior academics, where women are markedly under-represented. As a result, individuals and institutions in countries with less well-developed health research systems, as well as female researchers, are often significantly disadvantaged.

An interim review of the EDCTP2 programme recommended that the organisation find ways to address geographic and gender-related imbalances in funding. A **stakeholder meeting** held in November 2019 in Addis Ababa, Ethiopia, in partnership with the Africa Centres for Disease Control and Prevention (Africa CDC), proposed a range of measures that EDCTP, other funders and regional stakeholders could take to create a more level playing field. In addition, three EDCTP grant-writing workshops were held in Gabon, Côte d'Ivoire and Mozambique in 2018 and 2019, mainly targeting French and Portuguese-speaking aspiring and mid-career African scientists. A total of 96 African scientists participated.

EDCTP has also examined how gender-balanced its processes are. Across all its schemes, 63.7% of grant reviewers were male and 36.3% were female, numbers that have remained broadly stable over EDCTP2's lifetime (2014–19). Women make up 37.7% of participants of scientific review committee meetings. Women also carried out 44.1% of ethics evaluations and made up 42.7% of ethics review panels.

EDCTP strives to achieve gender balance in its evaluation procedures, and gender (and geographic location) is considered when reviewers are selected. However, reviewers typically work in academia, where women hold just 24% of senior positions in the EU (equivalent figures are not available for sub-Saharan Africa but the region's gender imbalance is likely to be at least as great).

Nevertheless, there are numerous examples of women who are playing leading roles in EDCTP projects. **Dr Oumou Maïga-Ascofaré**, for example, began her research career in Mali, before undertaking postgraduate training in Germany. Through a collaboration with a German institute, she was able to establish a research base in Ghana, and was the successful lead applicant on the **ASAAP study**, a collaboration involving five African and two EU countries that is investigating a new antimalarial combination treatment for children.

Other notable female researchers with EDCTP support include **Professor Francine Ntoumi**, coordinator of the CANTAM EDCTP regional Network of Excellence and the PANDORA-ID-NET epidemic preparedness network (and also a member of the EDCTP General Assembly), and **Dr Cissy Kityo Mutuluza**, Executive Director of the Joint Clinical Research Centre, Uganda. EDCTP funding has also provided opportunities for female researchers in Europe to lead major programmes of work, including **Dr Julie Fox** (coordinator of the **CHAPS HIV prevention project**) and **Dr Kirsty Le Doare** (coordinator of the **PREPARE group B streptococcus vaccine study**).

In addition, 37.7% of EDCTP fellows are women, including many who have achieved significant scientific recognition.

Photo: AfriKADIA project staff members, Ethiopia

Equity in research

In November 2019, EDCTP organised a joint meeting with the Africa Centres for Disease Control and Prevention (Africa CDC) to explore gender and regional equity in research.

Scientific excellence is essential to research – unreliable research wastes resources and is potentially dangerous. Competitive calls for proposals and peer review are well-established mechanisms to assure scientific excellence.

However, one drawback of this approach is that disadvantaged groups may struggle to compete, and funding can become concentrated in centres that have been well funded in the past. This can lead to a potentially harmful lack of diversity, and missed opportunities for individuals and institutions with potential but limited experience to contribute to the research enterprise.

In November 2019, EDCTP and the Africa CDC organised a joint meeting at the African Union headquarters in Addis Ababa, Ethiopia, to discuss two specific aspects of equity in research – gender and regional.

Globally, women are under-represented in science, particularly at senior levels. With some notable exceptions, this is also true in sub-Saharan Africa. The workshop included presentations from senior and mid-career female researchers from sub-Saharan Africa, and discussed ways in which EDCTP and other stakeholders could level the playing field so that women are able to compete on an equal footing with men.

It was also suggested that gender should be considered in the design of research studies. A gender perspective could be an important influence on the design of an intervention, or how a trial is organised (for example, how participants are recruited or informed consent is obtained). By way of example, EDCTP's **BCA-WA-ETHICS project** has been working to build capacity to consider gender-related issues in clinical research in countries in West Africa. BCA-WA-ETHICS developed a framework for the ethical evaluation of research protocols from a sex and gender perspective during the COVID-19 pandemic and other epidemics[4].

Discussions also focused on regional equity. Some countries in sub-Saharan Africa have received relatively little funding from EDCTP and participated in few studies. Furthermore, researchers from French- and Portuguese-speaking countries suggested that language barriers made it difficult to compete.

The two-day meeting generated a range of practical recommendations for EDCTP and other stakeholders on ways to address gender-related and regional inequities in research funding.

4 Nkoum N *et al*. Framework for the ethical evaluation of research protocols from a sex and gender perspective during the COVID-19 pandemic and other epidemics. 2020 BCA-WA-ETHICS Policy Brief #1. Available at *https://bit.ly/2D98fqO*

3.15

Rising stars

EDCTP fellowships have supported leading African researchers, as well as up-and-coming future leaders.

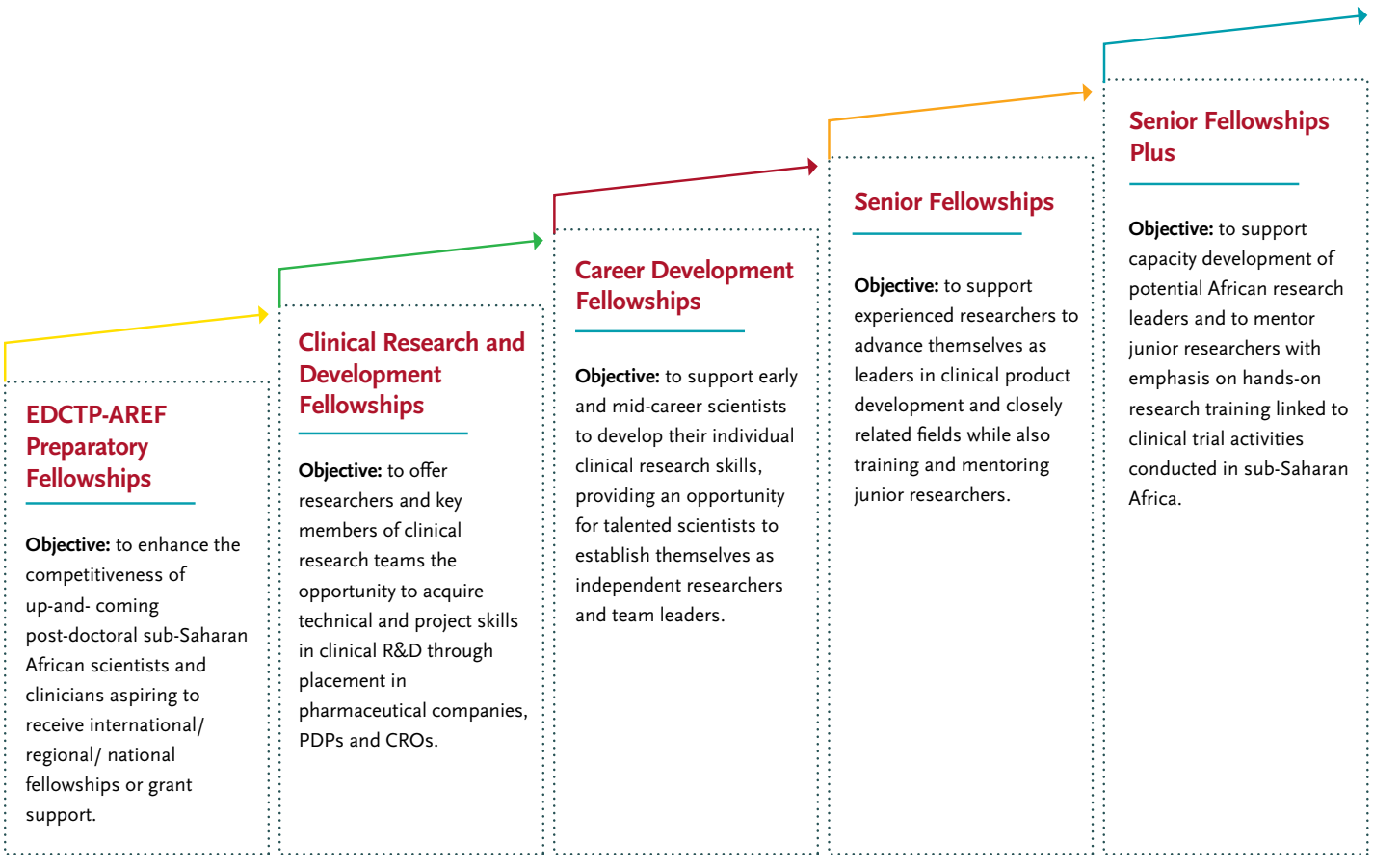
The future of African science will depend on its 'home-grown' talent – research for Africa, led by Africans. **EDCTP Senior Fellowships** provide opportunities for leading researchers to consolidate and develop their research programmes and leadership skills while also contributing to the development of the next generation of researchers as supervisors and mentors. **EDCTP Career Development Fellowships** enable researchers showing outstanding early-career promise to establish their scientific independence within sub-Saharan Africa.

There are many signs that EDCTP fellowships are contributing to the career development of talented researchers. Among Senior Fellows, for example, **Professor Faith Osier (Kenya)** was appointed President of the International Union of Immunological Societies in October 2019. **Dr Stellah Mpagama (Tanzania)** was invited to give a plenary presentation during the Ending TB Emergency session at the 2019 Union Conference held in Hyderabad, India. Dr Mpagama has been a key member of the PanACEA Consortium, which has been testing alternative treatments for TB. In addition, **Dr Stephanus Malherbe (South Africa)** was one of the winners of a 2019 Young Investigator Prize awarded by the International Union Against Tuberculosis and Lung Disease.

Professor Collen Masimirembwa (Zimbabwe) is one of Africa's leading experts in pharmacogenomics. Following his scientific training, he spent 10 years working in industry in Europe before returning to Africa. He set up the African Institute of Biomedical Science and Technology to promote drug discovery and drug development in Africa. In 2018, Professor Masimirembwa was awarded the HUGO African Prize for his contribution to genetics in Africa. He was appointed as a member of the EDCTP Scientific Advisory Committee in January 2019.

Professor Dorothy Yeboah-Manu (Ghana) has developed a wide-ranging programme of research on mycobacterial infections affecting Ghana and other African countries. These include landmark studies on a TB-causing bacterium, *Mycobacterium africanum*, restricted to parts of

EDCTP fellowship programme



West Africa. Professor Yeboah-Manu was awarded the Royal Society's Africa Prize in 2018.

EDCTP's Clinical Research and Product Development Fellowships have also demonstrated significant impact. The fellowships provided researchers with experience within pharmaceutical companies followed by a period of support within host institutions in sub-Saharan Africa. Following his fellowship, **Dr Isidore Traore (Burkina Faso)** was promoted to Assistant Professor at the University of Bobo-Dioulasso and took up the role of Technical Director at his home institution, the Centre Muraz, in Burkina Faso. **Dr Stephen Ian Walimbwa (Uganda)** was appointed Clinical Trials Manager and Clinical Trial Quality Manager and subsequently promoted to Clinical Trials Manager at the Infectious Diseases Institute of Makerere University in Uganda.

After completing her EDCTP-TDR Clinical Research and Product Development Fellowship, **Dr Atinuke Olaleye (Nigeria)** was appointed as Director of the Centre for Advanced Medical Research and Biotechnology (CAMRAB) at Babcock University in Nigeria. Dr Olaleye was subsequently awarded an EDCTP Career Development Fellowship to conduct an observational study on parasite resistance in the context of intermittent preventive treatment of pregnant women. A second EDCTP-TDR Clinical Research and Product Development Fellow, **Dr Solomon Abay**, has also been successful in his application for an EDCTP Career Development Fellowship.

Career Development Fellow **Dr Justin Komguep Nono (South Africa)** was awarded a Future Leaders – African Independent Research (FLAIR) Fellowship through a partnership between the African Academy of Sciences and the Royal Society. Dr Nono has also been appointed a Co-Chair of the Global Schistosomiasis Alliance Research Working Group as well as a WHO Regional Expert for the control of schistosomiasis.

Dr Misaki Wayengera (Uganda) developed a rapid diagnostic test for Ebola virus disease, and was successful in an application to EDCTP to develop his diagnostic test further (**AdjustEBOVGP-Dx project**). In 2019, his product received first prize in the WHO Innovation Challenge (product development category). For this achievement, he also received special recognition in person from the President of Uganda.

Career Development Fellow **Dr Marion Sumari-de Boer** recently published data on adherence to antiretroviral therapy among people living with HIV in the Kilimanjaro region of Tanzania[5]. Her work identified a range of reasons why participants were reporting very high levels of adherence even though two mHealth interventions (text messaging and real-time medication monitoring) were suggesting much lower adherence.

Private sector partnering for maternal and child health

A new partnership with Novartis and Fondation Botnar will provide career development fellowship support in maternal, child and adolescent health and wellbeing.

EDCTP is committed to working with like-minded partners from the public and private sector, to align activities and to leverage additional funding for research into poverty-related infectious diseases.

In 2019, it established a new partnership with Novartis and Fondation Botnar, which is providing €750,000 to support five Career Development Fellowships. The fellowships will support research on the interplay between poverty-related infectious diseases and non-communicable diseases in women and children.

Women and children remain vulnerable groups in sub-Saharan Africa. Child and maternal mortality remain high by global standards, and populations increasingly face the double burden of infectious disease and non-communicable diseases, exacerbated by food insecurity and malnutrition. Conversely, there are opportunities to deliver integrated care across infectious and non-communicable diseases, maximising the benefit of each contact with health systems.

The call was designed to address the shortage of mid-career researchers in the region working on maternal and child health. It will provide an opportunity for promising early-career researchers to establish themselves as independent researchers, and for researchers gaining skills abroad to return to the region, helping to build a critical mass of appropriately skilled and trained researchers.

5 Ngowi KM, *et al*. Technical and Psychosocial Challenges of mHealth Usage for Antiretroviral Therapy Adherence Among People Living With HIV in a Resource-Limited Setting: Case Series. *JMIR Form Res* 2020;4(6):e14649.

EDCTP Governance

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

For more information on the EDCTP governance, please consult the EDCTP website: *www.edctp.org*.

General Assembly of the EDCTP Association

	Mandated representative entity
	**Angola (Aspirant member)** National Institute of Public Health
	**Austria** Medical University of Vienna
	**Burkina Faso** Centre National de Recherche et de Formation sur le Paludisme
	**Cameroon** Ministry of Public Health
	**Congo** University Marien Ngouabi
	**Denmark** Statens Serum Institute
	**Ethiopia** Armauer Hansen Research Institute
	**Finland** Academy of Finland
	**France** Aviesan, Institut thématique multi-organismes
	**Gabon** Centre de Recherches Médicales de Lambaréné
	**The Gambia** Ministry of Health and Social Welfare
	**Germany** Bundesministerium für Bildung und Forschung
	**Ghana** Ghana Health Service
	**Ireland** Irish Aid, Department of Foreign Affairs
	**Italy** Istituto Superiore di Sanità
	**Luxembourg** Fonds National de la Recherche
	**Mali** University of Science, Techniques and Technology of Bamako
	**Mozambique** Ministry of Health
	**Netherlands** NWO-WOTRO Science for Global Development
	**Niger** Ministry of Public Health

Nigeria
Federal Ministry of Health

Norway
Research Council of Norway

Portugal
Foundation for Science and Technology

Senegal
University Cheikh Anta Diop

South Africa
Department of Science and Technology

Spain
Instituto de Salud Carlos III

Sweden
Swedish International Development Agency

Switzerland (Aspirant member)
State Secretariat for Education and Research

Tanzania
Tanzania Commission for Science and Technology

Uganda
Uganda National Health Research Organisation

United Kingdom
Medical Research Council

Zambia
Ministry of Health

Photo: Members of the EDCTP General Assembly

Summary financial statements 2019

Statement of profit or loss and other comprehensive income

for the year ended 31 December 2019. Expressed in thousands ('000) of euro.

	EC 2019	Donor 2019	Total 2019	Total 2018
Calls (Grants)				
Contributions	138,343	76,333	214,676	162,478
Grant expenditure	(138,343)	(76,333)	(214,676)	(162,478)
Results for the year	-	-	-	-
Others				
Contributions	6,754	730	7,484	7,703
Other expenditure	(6,754)	(730)	(7,484)	(7,703)
Results for the year	-	-	-	-
Total results for the year	-	-	-	-

EDCTP Association has no other comprehensive income.

All income and expenditure relate to continuing activities.

For the full statements and accompanying notes, please visit www.edctp.org.

Statement of financial position

as at 31 December 2019 (after appropriation of result). Expressed in thousands ('000) of euro.

	31 December 2019	31 December 2018
Non-current assets		
Debtors and other receivables	151,450	73,450
Total non-current assets	**151,450**	**73,450**
Current assets		
Debtors and other receivables	39,031	45,569
Cash and cash equivalents	114,393	117,862
Total current assets	**151,424**	**163,431**
Total assets	**304,874**	**236,881**
Non-current liabilities		
Grants and other payables	197,486	145,304
Deferred income EC	-	-
Deferred income Donor	1,479	20,648
Total non-current liabilities	**198,965**	**165,952**
Current liabilities		
Grants and other payables	86,201	30,138
Deferred income EC	-	-
Deferred income Donor	19,708	40,791
Total current liabilities	**105,909**	**70,929**
Total liabilities	**304,874**	**236,881**

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

Dr Michael Makanga
Dated: 8 June 2020

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 2018	**-**	**-**	**-**
Total comprehensive income for the year	-	-	-
Balance as at 31 December 2019	**-**	**-**	**-**

EDCTP has no unrestricted reserves.

Statement of cash flows

for the year ended 31 December 2019. Expressed in thousands ('000) of euro.

	2019	2018
Cash flows from operating activities		
Result for the year	-	-
Adjustment for:		
(Increase) decrease in debtors and other receivables	(10)	(182)
Increase (decrease) in grants and other payables	108,245	88,103
Increase (decrease) in deferred income	(111,707)	(48,173)
Net cash flows from operating activities	(3,472)	39,748
Cash flows from investing activities		
Interest received	3	4
Net cash flows from investing activities	3	4
Net increase (decrease) in cash and cash equivalents	**(3,469)**	**39,752**
Cash and cash equivalents at 1 January	117,862	78,110
Exchange rate effects		
Cash and cash equivalents at 31 December 2019	**114,393**	**117,862**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Colophon

European & Developing Countries Clinical Trials Partnership

The Hague, the Netherlands, August 2020

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

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IMPROVE study participant, Kenya

The power of sharing science