



EDCTP  
*The power of sharing science*

# Annual Report 2020



Focused delivery on promises

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## About EDCTP

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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 post-registration clinical studies, with emphasis on phase II and III clinical trials. Our approach integrates conduct of research with development of African clinical research capacity and networking.

The second EDCTP programme is implemented by the EDCTP Association supported under Horizon 2020, the European Union's Framework Programme for Research and Innovation. Cofunding from the following organisations is gratefully acknowledged: Agence nationale de recherche sur le sida et les hépatites virales (ANRS, France), Botnar Research Centre for Child Health (BRCC, Switzerland), Bundesministerium für Bildung und Forschung (BMBF, Germany), Calouste Gulbenkian Foundation (Portugal), Department of Health and Social Care (DHSC, United Kingdom), Fondation Botnar (Switzerland), Fonds National de la Recherche (FNR, Luxembourg), Foreign, Commonwealth & Development Office (FCDO, United Kingdom), Foundation for Science & Technology (FCT, Portugal), Fundación Mundo Sano (FMS, Argentina/Spain), GlaxoSmithKline (GSK, United Kingdom), Institut national de la santé et de la recherche médicale (Inserm, France), Instituto de Salud Carlos III (ISCIII, Spain), Joint Global Health Trials Scheme (JGHT, United Kingdom), Leprosy Research Initiative (LRI, Netherlands), Medical Research Council (MRC, United Kingdom), Ministère de l'Enseignement supérieur, de la Recherche et de l'Innovation (MESRI, France), Novartis International AG (Switzerland), NWO-WOTRO Science for Global Development (NWO-WOTRO, Netherlands), South Africa Department of Science and Innovation (DSI, South Africa), South African Medical Research Council (SAMRC, South Africa), Swedish International Development Cooperation Agency (Sida, Sweden), Swiss Agency for Development and Cooperation (SDC, Switzerland), Swiss National Science Foundation (SNSF, Switzerland) and The Special Programme for Research and Training in Tropical Diseases (TDR, Switzerland).

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# The benefits of a strong science base

*Africa's response to the COVID-19 pandemic has illustrated the value of investing in national scientific capabilities.*

For most of us, 2020 will be remembered as the year of COVID-19. On 30 January 2020, WHO declared COVID-19 a Public Health Emergency of International Concern. Within weeks it had spread to nearly every country on the planet, including those in sub-Saharan Africa.

In the light of this challenge, COVID-19 has demonstrated the value of the EDCTP programme, particularly its investments in research capacity-building. The response to COVID-19 in sub-Saharan Africa has in large part depended on the repurposing of capacity put in place to investigate other infectious diseases. Laboratories, for example, have rapidly been adapted so that they can undertake testing for SARS-CoV-2, including mobile laboratories for testing in the community.



Moreover, the demographic surveillance systems initially established for other diseases have formed the bedrock for COVID-19 epidemiologic surveillance and response.

Scientific expertise has also been repurposed. Many researchers working on infectious diseases have turned their attention to understanding COVID-19 and supporting national responses to the pandemic. EDCTP fellows have been playing key roles in many countries, acting as national advisers on COVID-19 and setting up testing programmes.

In particular, EDCTP-funded epidemic preparedness networks – ALERRT and PANDORA-ID-NET – have been undertaking coordinated efforts to enhance countries' abilities to manage the pandemic, as well as raising awareness of its impact on other infectious diseases. Much of this work has been carried out in partnership with EDCTP regional Networks of Excellence.

In response to the pandemic, EDCTP rapidly activated its emergency funding mechanism, supporting 26 projects exploring key issues such as diagnostics, immune responses to SARS-CoV-2, and possible control strategies. Many of these projects have built on existing collaborations between institutions in sub-Saharan Africa and Europe. Furthermore, several have taken advantage of clinical research infrastructure provided by previous EDCTP funding, for example by adding COVID-19 investigations to already active cohort studies.

COVID-19 has therefore demonstrated the fundamental importance of investment in the national science base, as well as the specific value of EDCTP funding. Planning is now underway for the successor to the EDCTP2 programme, the Global Health EDCTP3 Joint Undertaking, which will build on the foundation laid by EDCTP to deliver further benefits to sub-Saharan Africa.

Due to launch in the first quarter of 2022, EDCTP3 will retain its focus on poverty-related infectious diseases, but it will have additional resources and a stronger commitment to collaborative and coordinated approaches

to address them. COVID-19 has illustrated the fundamental importance of global collaboration to accelerate new medical product development, offering lessons that can be applied to other diseases.

EDCTP3 will also maintain its focus on the development of interventions for vulnerable populations, such as children, adolescents and pregnant women. Recognising the importance of 'end to end' product development, it will increase its investments in late-stage phase III and IV studies and product-focused implementation research, helping to overcome the obstacles that prevent the use of potentially life-saving interventions in practice. It will also promote more patient-centred approaches that span different diseases, including the interaction between infectious diseases and non-communicable diseases, and support interdisciplinary research and studies designed to exploit the power of new technologies to support integrated patient care.

EDCTP3 will be forward-looking, focusing not just on known infectious disease threats, but also epidemic preparedness and response to emerging and re-emerging infections, as well as

the growing challenges posed by antimicrobial resistance and climate crises.

As in EDCTP2, capacity-building will lie at the heart of EDCTP3's activities. It will continue to strengthen the technical infrastructure for clinical and laboratory studies in sub-Saharan Africa and build intellectual expertise and leadership through training and fellowship schemes. It will also aim to strengthen national and regional systems for ethical and regulatory oversight of research.

The response to COVID-19 has catalysed many changes that could accelerate clinical research in sub-Saharan Africa. Inevitably, however, it has also drawn attention and resources away from other infectious diseases, significantly setting back control efforts. It is essential over the next decade that the lessons learned from COVID-19, and the opportunities it has created, are exploited to address the other key infectious disease threats facing the region and to ensure better preparedness for the next global pandemic.

**Professor Yazdan Yazdanpanah**  
*Chair, EDCTP Association Board*

## Realising EDCTP's potential

*Despite the challenges of COVID-19, the EDCTP2 programme is living up to its promise, providing sub-Saharan Africa with the knowledge, infrastructure and international collaborations it needs in order to address its infectious disease challenges.*

EDCTP2 was launched in 2014 and is planned to conclude in 2024; 2020 was the final year in which new calls were launched, to allow enough time for trials to conclude before the end of this programme and for plans to be put in place for a seamless transition to its successor programme. The year was inevitably overshadowed by the spectre of the COVID-19 pandemic, which had a significant impact on both central EDCTP operations and recruitment in the field. Nevertheless, despite the need for remote working and other challenges, all EDCTP's planned funding-related activities were carried out in 2020.



In 2017, an independent interim evaluation of the EDCTP2 programme identified a number of notable successes in the early years of the programme, and made several recommendations to enhance its impact. In the years since, significant progress has been made in addressing these recommendations:

### **Being a more proactive strategic player:**

Over the past five years, EDCTP has worked extensively at the national level to raise awareness of EDCTP and to encourage participation in EDCTP activities. In particular, EDCTP High Representatives for Africa and Europe are engaged in international diplomacy to promote participation and coordination in both regions. More countries than ever before are now involved in EDCTP activities.

At a regional level, EDCTP has forged close working relationships with key bodies, including the Africa Centres for Disease Control and Prevention (Africa CDC), the African Development Agency (AUDA), the African Academy of Sciences (AAS) and the WHO Regional Office for Africa (WHO AFRO). To cement this strategic alliance, a memorandum of understanding was signed with WHO AFRO in 2020, covering cooperation in three key areas – strengthening of national health research systems, optimisation of regulatory systems, and development of technical expertise in clinical research and product development.

The four EDCTP Regional Networks of Excellence and two epidemic preparedness networks – ALERRT and PANDORA-ID-NET – are also increasingly playing important leadership and coordinating roles in the region, not least in response to COVID-19.

EDCTP has also sought to address regional disparities in funding, including those linked to language barriers. Special grant-writing workshops have been held in French-speaking and Portuguese-speaking countries. In addition, one key function of the EDCTP Regional Networks of Excellence is to build the capacity of institutes in countries with less

well-developed science bases and connect them to regional and international networks. The new EDCTP Senior Fellowship Plus scheme is also creating opportunities for Senior Fellows to mentor and support the research of more junior researchers in countries with underdeveloped health research systems.

At a global level, EDCTP has increasingly been developing partnerships with other funders and key stakeholders such as product development partnerships. These have led to a number of joint initiatives, such as joint calls for proposals, and strategically coordinated co-funding, where EDCTP funding is conditional on financial contributions from partners. Joint fellowship calls, for example, have been organised with Novartis and Fondation Botnar. Co-funding initiatives have seen major investments with the Medicines for Malaria Venture in development of new antimalarials and with the TB Alliance on shortened treatments for TB.

In addition, EDCTP has been undertaking a range of activities to facilitate high-quality clinical research and greater coordination of research efforts. These include support for the development of an R&D roadmap for TB vaccine development, in close liaison with WHO, and the launch of the EDCTP Knowledge Hub, an open-access platform with toolkits to support clinical research in low-resource settings.

The growing number of EDCTP projects has also led to an increasingly strategic and focused approach to funding. EDCTP has established a solid and well-balanced portfolio, with all priority disease areas well covered and with particular strengths in studies involving infants, children, adolescents, pregnant women and women of childbearing age. These include the development of new formulations for young children for prevention and treatment of parasite infections (e.g. praziquantel for schistosomiasis through the PZQ4PSAC and ADOPT studies, moxidectin for onchocerciasis through the MiniMox project, and acoziborole for human Africa trypanosomiasis through the ACOZI-KIDS project), fixed-dose combinations of antiretrovirals for children (e.g. CHAPAS 4, UNIVERSAL projects), and vaccines against key diarrhoeal diseases affecting children (e.g. ETEC Vaccine Efficacy, ShigOraVax and PEDVAC-INTS projects).

Multiple projects are evaluating antimalarials for use in pregnancy (e.g., MAMAH and

IMPROVE-1 and -2 projects), and new approaches are being explored for HIV prevention in women, including broadly neutralising antibodies (e.g., CAP012 SAMBA project), implantable antiretrovirals (CAPRISA 018 study) and behavioural studies of attitudes to pre-exposure prophylaxis (UPTAKE). For adolescents, the CHAPS study is specifically focusing on pre-exposure prophylaxis in male and female adolescents, while the BREATHER-PLUS project is evaluating alternative treatment regimens for adolescents on antiretroviral therapy.

**Strengthening capacity and scientific leadership:** EDCTP has established a comprehensive fellowship scheme spanning all career stages, including senior fellowships and career development fellowships. The Senior Fellowship Plus scheme is particularly innovative, enabling senior fellows to nurture upcoming researchers in other institutions.

To support the networking of African researchers, EDCTP established the EDCTP Alumni Network, which now covers more than 160 researchers in 31 countries. Sub-networks have been established covering EDCTP priority disease areas.

The value of this expertise was vividly demonstrated in 2020 in response to the COVID-19 pandemic. Many current and former EDCTP Senior Fellows have played leading roles in national COVID-19 advisory bodies, and numerous fellows have had hands-on roles during the pandemic, for example establishing and managing testing facilities.

By the end of 2020, 40% of fellows were females. We have been actively trying to improve women's representation, a topic discussed at a disparities workshop organised with Africa CDC, a report from which was published in 2020. We recognise the challenges that many women face when applying for funding, and are taking a range of steps to ensure that women are not disadvantaged by EDCTP procedures and are encouraged to apply. In addition, EDCTP Regional Networks of Excellence manage schemes specifically designed to support women's participation in research.

We constantly monitor the numbers of applications submitted and grants received by women, as well as representation of women on funding panels and as grant reviewers. While

we recognise we still have some way to go, representation of women in EDCTP fellowship funding is increasing significantly – a proxy for a positive trend towards sustainable scientific excellence and leadership among women.

**Enhancing coherence and added value:**

As discussed above, EDCTP has been strengthening its relationships with other key stakeholder organisations to coordinate activities and maximise the impact of its work.

EDCTP's Strategic Business Plan and multi-annual strategic agenda provide long-term and short- to medium-term strategic frameworks to prioritise research responses to poverty-related infectious diseases. As such, they provide a mechanism to ensure coherence around a shared Europe-wide research agenda for poverty-related infectious diseases. A recent analysis found that both centrally managed EDCTP-funded projects and Participating States Initiated Activities – projects run by national agencies but forming part of the overall EDCTP portfolio – were both closely aligned with annual priorities. A few of the Participating States Initiated Activities for which 2020 final reports have been received are highlighted in this report.

The portfolio approach adopted by EDCTP is also making an important contribution to coherence. Cooperation with product development partnerships and our involvement in alliances such as GloPID-R are helping to ensure that EDCTP funding complements that of other funders. In TB, our funding is enabling the Tuberculosis Vaccines Initiative (TBVI) to provide support across our TB vaccine projects, while the draft TB Vaccines Roadmap developed in partnership with the Amsterdam Institute for Global Health and Development (AIGHD) is already supporting a more coherent global approach to TB vaccine development.

More generally, EDCTP supports research that could not be delivered by a single EU Member State alone. EDCTP has been identified as a prime example of the added value of European cooperation, and demonstrates the greater impact that can be achieved by coordinated action, particularly in areas such as capacity-building. EDCTP has catalysed the formation of new partnerships that transcend established historical links and overcome language barriers, including collaborations uniting anglophone, francophone and lusophone countries in sub-Saharan Africa.

**Enhancing visibility and advocacy:** EDCTP has launched a range of outreach activities to promote engagement with key audiences. As well as a dynamic website, social media presence and a regular 'e-Magazine', EDCTP has developed accessible and attractively presented summaries of its funded projects. It has also recently produced country profiles summarising EDCTP funding in each Participating State and other countries involved in EDCTP-funded projects.

**Improving efficiency:** EDCTP constantly monitors its operational performance against benchmarking standards. In 2020, COVID-19 presented a major challenge to office operations. Even so, all calls for proposals were launched as planned and all other activities were delivered according to the 2020 EDCTP work plan, except for the Tenth EDCTP Forum, as a delayed face-to-face event was felt to be preferable to an online meeting. A hybrid Forum incorporating virtual sessions will now be held in Mozambique in October 2021.

As can be seen, great strides have been made since the interim evaluation. I would like to thank all staff, advisers, reviewers and panel members for their great efforts and flexibility during a very difficult year. I also appreciate the resourcefulness that project teams have shown in keeping projects going, and the dedication they have demonstrated in responding to the COVID-19 pandemic in their own countries.

The past year has shown how EDCTP is living up to its potential, making a critical contribution to the region's response to COVID-19. The projects that are currently ongoing, promise to make a major difference to the lives of people in sub-Saharan Africa, particularly children, adolescents, women, and individuals with co-infections and co-morbidities. EDCTP2 is helping to lay the foundation for a concerted effort, led from Africa, to reduce the burden associated with infectious disease in sub-Saharan Africa and to strengthen global health security. Its successor programme, the Global Health EDCTP3 Joint Undertaking, will build on and extend this platform, working with global and regional partners to tackle existing and emerging infectious disease threats.

**Dr Michael Makanga**  
*Executive Director*



## Investment to calls

(2014-2020)



- Investment to call for proposals by year
- Cumulative investment to call for proposals by year

(Indicative amounts based on signed grant agreements and proposals approved for funding)

## Towards EDCTP's objectives

(2014-2020)



### Medical interventions

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

**293**

clinical studies supported by EDCTP2 since 2014. Of these, 68% (199) are interventional (clinical trials) and 32% (94) 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.*

**40**

sub-Saharan African countries participate in EDCTP projects involving 252 African organisations. They receive 59% of the total EDCTP grant value.



### 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.*

**67**

countries participate in EDCTP-funded activities: 40 sub-Saharan African and 19 European countries as well as 8 others.



### EU cooperation

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

**8**

grant consortia were established through two dedicated calls requiring collaboration with development cooperation initiatives with cofunding secured from Sida, USAID, Gavi, The Global Fund, UNITAID, AECID and Médecins Sans Frontières.

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**64% (83)**

of clinical trials are phase II and III studies of drugs and vaccines which aim to deliver key evidence on safety and efficacy, as well as provide data to support product registration.

**16% (21)**

of the clinical trials 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% (22)**

of all studies target pregnant women and their children. Other key populations are also involved in the studies, such as newborns and infants (40; 18%), children (67, 31%) and adolescents (63; 29%).

**36**

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

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**37**

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

**196**

fellowships have been awarded (through 192 fellowship grants) that focus on the career development of researchers from 25 sub-Saharan African countries.

**11,851**

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. These members committed €67 million through 120 Participating States' Initiated Activities (PSIAs) in the EDCTP workplans 2014-2020.

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**€171.09 M**

cash received from the European Participating States to the EDCTP programme.

**€1.16 B**

committed through 301 Participating States' Initiated Activities (PSIAs) submitted by the European Participating States by end of 2020.

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**448**

institutions are involved in EDCTP projects, including 252 sub-Saharan African institutions, 179 European institutions, and 17 institutions from other countries.

**284**

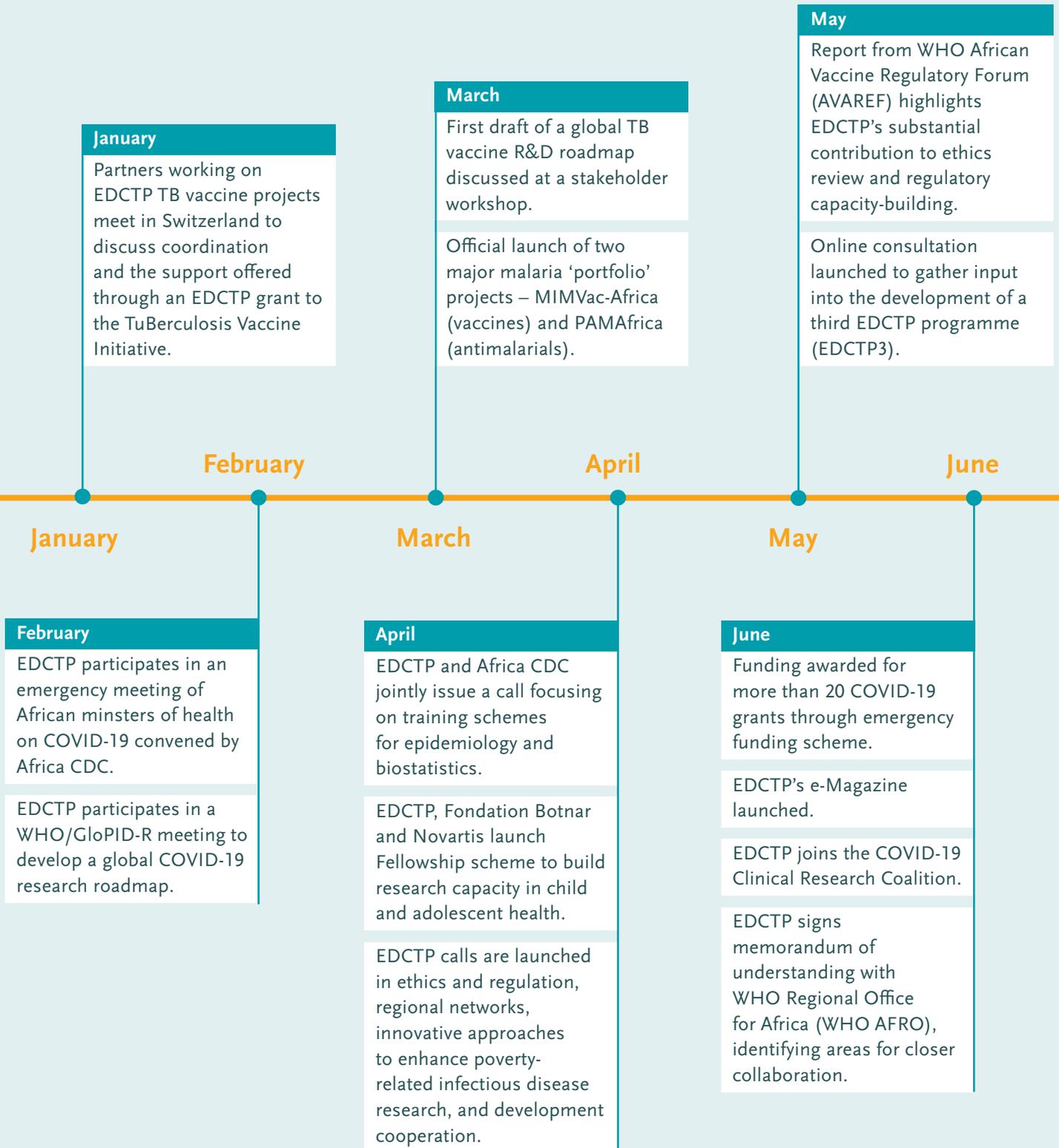
private sector entities are involved in EDCTP projects. By the end of 2020, these organisations have received 21% of EDCTP grant value.

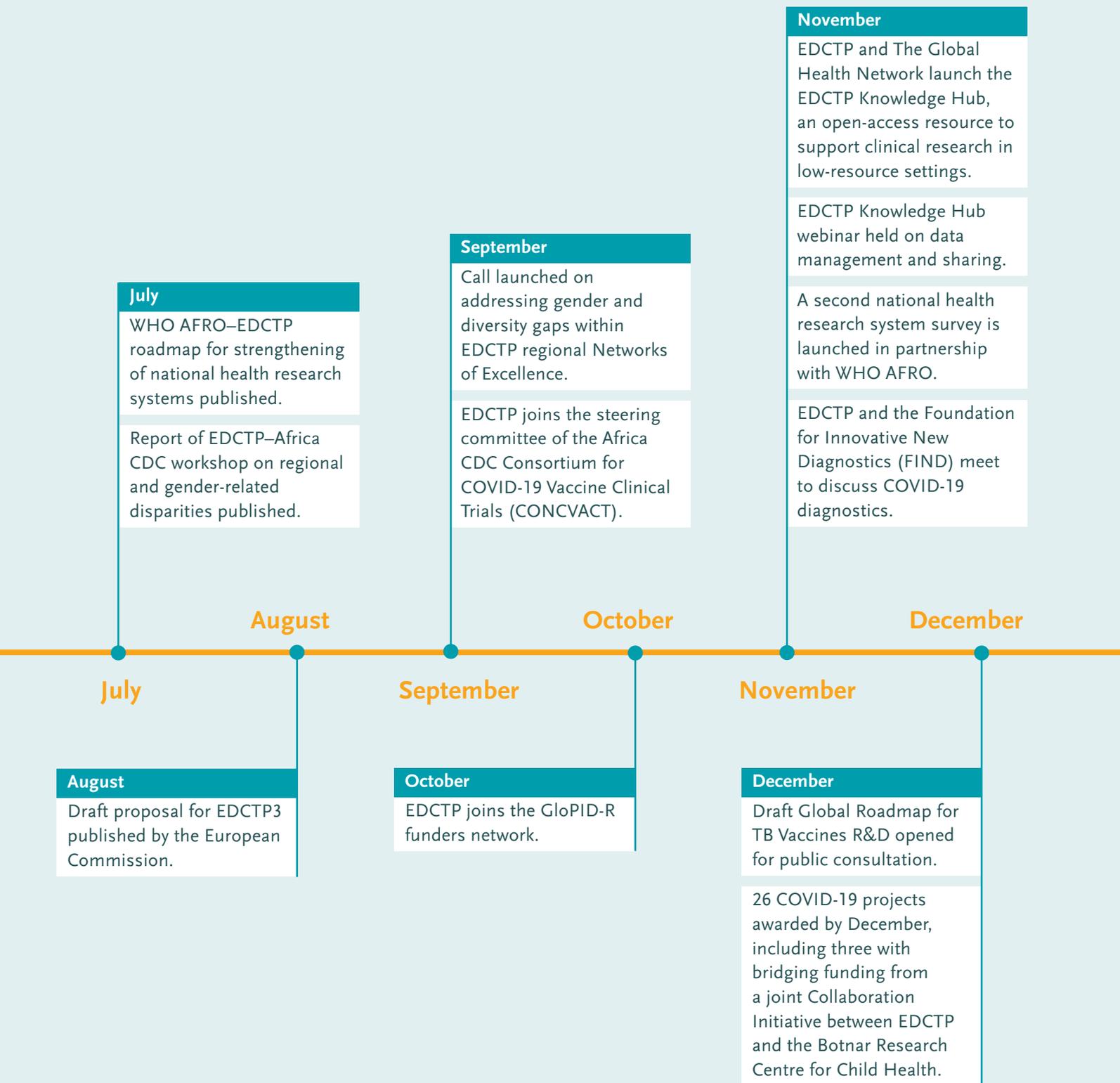
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**10**

projects to support training of 150 fellows were awarded through a joint initiative with Africa CDC to boost disease outbreak and epidemic response in sub-Saharan Africa.

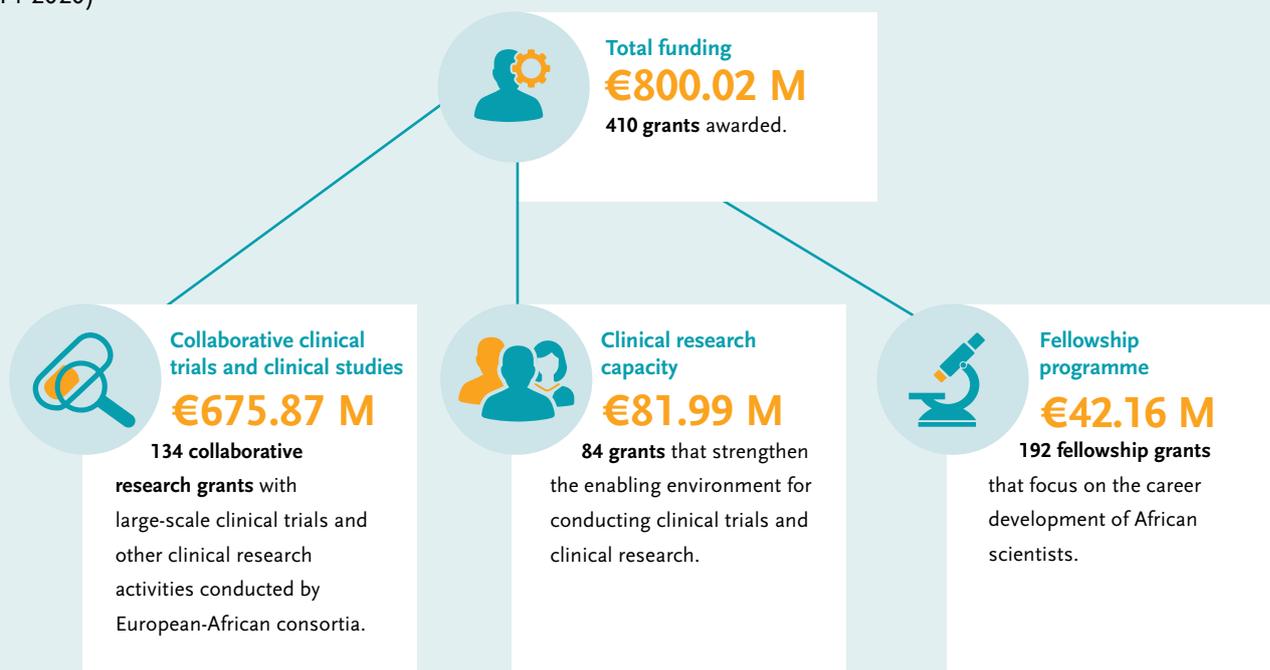
## EDCTP in 2020





## EDCTP's funding of research and capacity development

(2014-2020)



(Indicative amounts based on signed grant agreements and proposals approved for funding)

## Collaborative clinical trials and clinical studies

### By disease



- Tuberculosis, 33 grants  
**€194.83 M**
- Malaria, 16 grants  
**€133.06 M**
- HIV & HIV-associated infections, 20 grants  
**€113.05 M**
- Emerging diseases, 34 grants  
**€81.31 M**
- Neglected infectious diseases, 19 grants  
**€70.59 M**
- Diarrhoeal diseases, 5 grants  
**€45.49 M**
- Lower respiratory tract infections, 5 grants  
**€29.54 M**
- Non-disease specific topics, 2 grants  
**€8 M**

### By intervention



- Drugs, 50 grants  
**€283.82 M**
- Vaccines, 27 grants  
**€247.77 M**
- Diagnostics, 44 grants  
**€107.42 M**
- Non-intervention-specific topics, 6 grants  
**€27.89 M**
- Product-focused implementation research, 7 grants  
**€8.97 M**





## Emerging and re-emerging diseases

*By the end of 2020, the EDCTP2 portfolio had rapidly grown to 34 major clinical projects on emerging and re-emerging infections (12.03% of the total by number, €81.31 million by value).*

Many of these projects were funded following emergency calls for proposals to address Ebola and COVID-19. The projects predominantly

focus on diagnostics and implementation or social science research, although vaccine-related studies have also been supported.

### Emerging and re-emerging diseases in numbers



34 grants

€81.31 M



Drugs  
2 grants

€0.69 M



Vaccines  
7 grants

€49.21 M



Diagnostics  
15 grants

€7.42 M



Non-intervention  
- specific topics,  
10 grants

€23.99 M

### Responding to COVID-19

*EDCTP responded rapidly to the COVID-19 pandemic, launching an emergency funding mechanism. Currently, EDCTP supports 26 projects in sub-Saharan Africa.*

COVID-19 presented an unprecedented challenge to African health systems. Initially, very little was known about COVID-19 in an African context and many countries were poorly equipped to identify, track and respond to SARS-CoV-2 infections.

Given the potentially disastrous impact of COVID-19 in sub-Saharan Africa, in April 2020 EDCTP activated its emergency funding mechanism, launching an open call for proposals from international consortia. Following accelerated peer review, initially 23 projects were funded, 12 led by researchers based in sub-Saharan Africa. More than half of the projects (13) are coordinated by female investigators. EDCTP Participating States independently funded an additional complementary study, bringing total research

investments to nearly €12 million by the end of 2020. Additional projects will be funded in 2021.

The call was designed to address key unknowns, including COVID-19 epidemiology, community surveillance and evaluation of diagnostics. Several projects sought to characterise immune responses to SARS-CoV-2. Others tested possible approaches to prevention of infection and treatment.

Several projects took advantage of existing EDCTP-funded infrastructure in order to rapidly launch COVID-19-related projects. For example, COVID-19-related research has been carried out in cohorts recruited as part of other EDCTP-funded studies, and researchers have built on past EDCTP-funded community engagement activities to involve populations in research.

Later in 2020, EDCTP established a new COVID-19 funding partnership with the Botnar Research Centre for Child Health (BRCH), a Swiss-based research centre jointly founded

by the University of Basel and ETH Zurich. The centre was established to facilitate multidisciplinary research in paediatrics, with financial support from Fondation Botnar. Like EDCTP, the BRCCH funded a range of COVID-19-related projects in 2020. Recognising the potential for coordination of efforts, EDCTP and the BRCCH brokered a dialogue between principal investigators of their respective COVID-19 projects to explore opportunities for collaboration. BRCCH–EDCTP consortia that wished to establish collaborative projects were then invited to submit formal applications.

After peer review, three collaborative projects were awarded further funding under the joint BRCCH–EDCTP Collaboration Initiative, building on the work carried out by the teams involved in the EDCTP-funded **TREATS-COVID**, **Suitcaselab** and **COVAB** projects and the

BRCCH-funded Fast Track Call projects. The projects are exploring a range of key questions, including the immunology of SARS-CoV-2 responses, diagnostics, and health screening strategies for COVID-19 in low-resource settings.

Collectively, the projects EDCTP supports are helping to provide a clearer picture of how COVID-19 spreads through a range of different types of communities in sub-Saharan Africa, exploring how immune responses differ from those seen in high-income countries, and providing insights into locally appropriate methods of disease control. They have also helped to build vital capacity in disease surveillance, provided important data on suitable diagnostics, and provided health authorities with key data on the prevalence of disease.

## EDCTP fellows and the battle against COVID-19

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### *EDCTP-funded fellows are playing a major role in the fight against COVID-19 in sub-Saharan Africa.*

EDCTP2 fellowship funding has provided support for nearly 200 sub-Saharan African researchers at various stages of their careers. Many of these researchers are now making key contributions to regional and national responses to COVID-19.

One important contribution is the provision of expert advice to national governments. For example, EDCTP Senior Fellow Professor Pauline Byakika-Kibwika is a member of the Scientific Advisory Committee to the Ministry of Health in Uganda, advising on multiple aspects of the national COVID-19 response. Dr Christine Sekaggya (EDCTP Career Development Fellow) is a member of Uganda's Scientific Committee for case management, which provides advice to the Ministry of Health on treatment guidelines and occupational health guidance for health workers.

EDCTP-funded fellows are also making key contributions to COVID-19 research in the region, including that funded by EDCTP. For example, Dr Francis Ndungu (Senior Fellow) is leading the ImmunoCov study, which is validating antibody-based tests for COVID-19 and exploring the evolution of immune

responses to SARS-CoV-2, while Senior Fellow Dr Dawit Wolday is coordinating the Profile-Cov project, which is investigating immune responses in people from Ethiopia and evaluating a range of COVID-19 diagnostics.

In addition, Dr Stephanus Malherbe (Career Development Fellow) is contributing to the TOGETHER 3 trial, funded by the Bill & Melinda Gates Foundation, which is investigating use of lopinavir/ritonavir (LPV/r) for treatment of SARS-CoV-2 infection among high-risk outpatient adults early in disease. Dr Jonny Peter (SF) has begun studies examining genetic predispositions to COVID-19. Dr Moses Masika (Career Development Fellow) is contributing to research characterising COVID-19 infections in Kenya, while Dr Marisa Klopper (Career Development Fellow) is helping to develop an app to characterise coughs as part of symptom screening. Dr Stella Mpagama (Career Development Fellow) has been characterising COVID-19 cases and using data collected to develop algorithms to guide clinical management.

Finally, many EDCTP-funded researchers have also become involved in efforts to communicate with the general public about COVID-19 and to tackle myths and misconceptions. Senior Fellow Dr Barbara Castelnuovo, for example, has led a study exploring perceptions of

COVID-19 among people living with HIV in Uganda. Dr Sekaggya has participated in radio and TV talk shows on COVID-19-related issues, including a COVID-19 'myth-buster' TV show, Dr Masika has also appeared on national

and international TV, radio and social media, and Dr Michael Owusu (Career Development Fellow) has contributed to public education in Ghana.

## EDCTP networks and COVID-19

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### *EDCTP-funded networks have played a critical role in the response to COVID-19 in sub-Saharan Africa.*

EDCTP supports two epidemic-preparedness networks – **ALERRT** and **PANDORA-ID-NET** – that span multiple African and European institutions, as well as four Regional Networks of Excellence in Central, Eastern, Southern and Western Africa. All rapidly adapted their work in 2020 in response to the COVID-19 pandemic.

In January 2020, the PANDORA-ID-NET and ALERRT consortia convened emergency meetings to discuss how to respond to COVID-19. In February 2020, representatives from EDCTP, ALERRT and PANDORA-ID-NET attended the landmark meeting on SARS-CoV-2 organised by WHO and the funders network GloPID-R to establish a global COVID-19 research agenda. Members of PANDORA-ID-NET have subsequently published multiple papers highlighting key issues related to COVID-19 in Africa and its impact on other public health challenges.

The same month, ALERRT revised its **FISSA** (Febrile Illness in Sub-Saharan Africa) study protocol to include a research response component in the event of a public health emergency declaration by national or international health authorities. FISSA is an observational study taking place in 16 healthcare centres in sub-Saharan Africa, and aims to recruit 10,000 participants, including children. FISSA study procedures now incorporate care of individual patients and the collection of data relevant to COVID-19.

The FISSA study has sought input from social science experts to gain insight into the perspectives of communities, patients and caregivers. Similarly, ALERRT teams partnered with the UK Nuffield Council on Bioethics and the Wellcome Centre for Ethics and Humanities at the University of Oxford to host a two-day international consultative workshop in Dakar,

Senegal, entitled 'Community engagement in and for ethical research in outbreaks of infectious disease and other humanitarian crises'.

ALERRT also went on to secure funding from the Wellcome Trust and the UK Foreign, Commonwealth and Development Office (FCDO) for the COVID-19 Clinical Characterisation Protocol. It has worked with local partners such as the WHO Regional Office for Africa, Africa CDC and EACCR, the EDCTP Regional Network of Excellence in East Africa, to adapt the protocol for use in Africa.

Additionally, in February 2020, the Institut Pasteur of Dakar in Senegal – a member of ALERRT – hosted one of the first COVID-19-specific laboratory training courses in sub-Saharan Africa. In March 2020, PANDORA-ID-NET and Africa CDC held a joint workshop hosted by Zambia-based PANDORA-ID-NET members, which covered key topics such as laboratory diagnostic skills, clinical case management, and risk assessment at points of entry.

PANDORA-ID-NET is engaging policymakers, global public health bodies and communities on ethical, administrative, regulatory and operational obstacles to research during outbreaks. The project also organised media training for public health officials to promote effective communication with the public during outbreaks.

Members of PANDORA-ID-NET have been conducting laboratory skills workshops in different countries and produced publicly available reference materials, including an instructional video, on COVID-19 diagnostics. The Consortium has initiated several research activities, including surveys on the impact of lockdowns in selected sub-Saharan African countries, sero-epidemiological studies, validation of diagnostics, autopsy studies to explore the pathology of SARS-CoV-2 infections

in different organs, and the effects of COVID-19 on the control of other infectious diseases. By the end of 2020, PANDORA-ID-NET members, in collaboration with other networks, had published more than 50 articles addressing the ongoing response to the COVID-19 pandemic.

The two epidemic networks have also collaborated with Regional Networks of Excellence. For example, in December 2020, the network for the Southern African region (TESA) organised a workshop on 'Research ethics during epidemics' in collaboration with PANDORA-ID-NET and ALERRT. Partners of EACCR (East African Consortium for Clinical Research) are now working with ALERRT and PANDORA-ID-NET to build capacity for research during epidemics.

Moreover, many of the networks' scientists and institutions are at the forefront of the research response to COVID-19. For example, EDCTP Senior Fellow Professor Marielle Bouyou-Akotet (a member of **CANTAM**, the Central African network) is president of the COVID-19 scientific advisory committee established in Gabon. In addition, the EACCR's coordinator, Professor Pontiano Kaleebu, and Dr Julius Lutwama are key members of the national task force for COVID-19 in Uganda. In Kenya, Dr Erick Mouk, coordinator of EACCR's neglected infectious disease node, is part of the COVID-19 national task force. EACCR is also working with The Global Health Network to establish an African COVID-19 knowledge hub.



## Repurposing research capacity for COVID-19

*The technical infrastructure provided through past EDCTP funding has been mobilised in the fight against COVID-19.*

Capacity strengthening is core to EDCTP's work, and this includes the laboratory capacity required to support clinical studies. In a time of crisis, this infrastructure has been repurposed to aid the public health response to COVID-19.

One of the most important contributions made by EDCTP-funded technical infrastructure has been to support SARS-CoV-2 testing, with EDCTP-funded researchers playing a key role in national testing efforts.

In Ghana, for example, the Noguchi Memorial Institute for Medical Research (NMIMR) at the University of Ghana, the host institute of EDCTP Senior Fellow Dr George Kyei, is the largest centre in Ghana testing for SARS-CoV-2. During 2020, its virology labs have been working 24 hours a day, 7 days a week, with Dr Kyei acting as head of NMIMR's data team.

In Zimbabwe, EDCTP Senior Fellow and Scientific Advisory Committee member Professor Collen Masimirembwa, President and Chief Scientific Officer of the African Institute of Biomedical Science and Technology (AiBST), is ensuring that AiBST plays its part in the national response to COVID-19. It has become an officially designated SARS-CoV-2 testing centre, with medical virologist Dr Justen Manasa leading a multidisciplinary team of volunteers providing testing services and technical support.

In Cameroon, EDCTP Career Development Fellow Dr Joseph Fokam coordinates molecular testing of SARS-CoV-2 in his laboratory, liaising closely with the Ministry of Public Health of Cameroon. Career Development Fellow Dr Michael Owusu is involved in the testing of samples from northern Ghana.

Professor Bourema Kouriba, a former EDCTP Senior Fellow, is Director General of the Charles Mérieux Center for Infectiology (CMCI) in Bamako, Mali, and leads a team focusing on diagnostics of emerging and re-emerging infectious diseases. His group has been making use of a mobile laboratory donated by Germany to test for SARS-CoV-2 at remote locations. In Zambia, a mobile laboratory used for TB diagnosis in the EDCTP-funded **TREATS**

project has been adapted so it can be used for SARS-CoV-2 testing in the community, thanks to emergency EDCTP COVID-19 funding. In addition, Career Development Fellow Dr Michael Frimpong is leader of a mobile laboratory platform for COVID-19 testing using a mobile van laboratory targeting infection hotspots in Ghana. In South Africa, laboratories used by the EDCTP-funded **CHAPS** project have been repurposed for COVID-19 vaccine research.

In addition, capacity-building projects in ethics review and other regulatory activities have contributed to the COVID-19 response. The **BCA-WA-ETHICS** project, for example, has led development of a practical guide for ethics committees on a gender-sensitive evaluation of COVID-19 research project proposals. A number of EDCTP-funded ethics committees have developed Standard Operating Procedures for protocol review during emergencies. The **PAVIA** project developed a webinar on post-licensure pharmacovigilance for SARS-CoV-2 vaccines in Africa, in collaboration with the WHO Regional Office for Africa, the African Vaccine Regulatory Forum (AVAREF), and the newly established African Advisory Committee on Vaccine Safety.

The Zimbabwe Ethics and Regulatory Capacity Project (**ZERCaP**) played an important catalytic role in the national research response to COVID-19. It encouraged the the Medical Research Council of Zimbabwe to establish multidisciplinary teams to identify and address key local research issues, the results of which have informed national policymaking.

These and other examples illustrate the importance of developing health research capacity, which in times of crisis can be repurposed to support urgent emergency responses.

## Partnerships for COVID-19 and other emerging infections

*EDCTP has worked with multiple other bodies to coordinate responses to COVID-19 and enhance preparedness for emerging infections in sub-Saharan Africa.*

EDCTP is committed to working with like-minded organisations, to align activities, avoid duplication of efforts and achieve important synergies. The COVID-19 pandemic, and emerging and re-emerging infections more generally, has illustrated the importance of timely and coordinated responses.

For example, in June 2020 EDCTP joined the **COVID-19 Clinical Research Coalition**, which was launched in April 2020 to promote international research collaboration and coordination to support African, Latin American, Eastern European, and Asian countries to respond effectively to the pandemic and accelerate research in resource-limited settings. By the end of 2020, membership had increased to 155 members from 56 countries. The Coalition's Steering Committee includes Professor Francine Ntoumi, coordinator of CANTAM, the EDCTP Regional Network of Excellence for Central Africa, and a member of the PANDORA-ID-NET epidemic preparedness network.

EDCTP has also started a collaboration with the **Africa Centres for Disease Control and Prevention (Africa CDC)** to develop capacity for outbreak and epidemic responses in sub-Saharan Africa. Reliable epidemiological data are critical to effective responses, but are rarely available in sub-Saharan Africa, and there is a significant shortage of individuals trained in epidemiology and biostatistics. EDCTP and Africa will be working together to develop epidemiological capacity in the region, to support improved routine surveillance and public health research, as well as timely responses to disease outbreaks.

Through this partnership, EDCTP funding of €7.47 million will be available to institutions in sub-Saharan Africa and Europe that provide master's-level training in epidemiology and biostatistics, as part of Africa CDC's framework for public health workforce development.

Finally, EDCTP has also joined the **GloPID-R funders network**, an alliance of global research funding organisations set up to facilitate research into new or re-emerging infectious disease with epidemic and pandemic potential. GloPID-R is enabling funders to track COVID-19-related investments in research, avoid duplications of effort, and identify key gaps in knowledge.



## Successful surveillance

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*The SORMAS project has facilitated the introduction of a highly effective digital infectious disease surveillance system in Nigeria and Ghana.*

Surveillance systems are essential for detecting the early signs of an infectious disease outbreak and ensuring a rapid response to prevent its wider dissemination. They are also vital tools for tracking the spread of infections and assessing the success of control activities.

In many countries in sub-Saharan Africa, surveillance systems are rudimentary and based on manual record keeping. Digital tools hold great potential for ensuring more efficient and flexible data capture, management and sharing, to underpin rapid and coordinated responses to outbreaks.

The Surveillance and Outbreak Response Management System (**SORMAS**) was initially developed by a German–Nigerian collaboration to improve the efficiency and timeliness of surveillance activities during the West African Ebola outbreak. SORMAS is a multifunction, cloud-based system accessible via smartphones and tablets, capturing key information on cases and follow up. Synchronous exchange of data ensures that field workers and central outbreak management staff always have access to the same up-to-date information.

In 2017, Nigeria experienced its first outbreak of monkeypox for 40 years. Faced with unacceptable delays in its paper-based reporting, the Nigeria Centre for Disease Control (NCDC) decided to implement SORMAS, following a successful piloting for Ebola surveillance in 2015.

In collaboration with the NCDC and other stakeholders, SORMAS was rapidly adapted for use in monkeypox surveillance, field tested and deployed in 30 of the most badly affected areas in eight states. A before-and-after comparison revealed that SORMAS significantly outperformed manual recording in data timeliness and completeness.

While still responding to the monkeypox outbreak, the NCDC decided to deploy SORMAS in 120 more local areas in six states. Its ultimate goal is to roll out SORMAS in all 774 local government areas in Nigeria's 36 states and the national capital by the end of 2021.

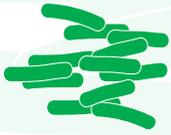
Many digital initiatives never progress beyond piloting stages. The SORMAS team used the 'global good maturity model' (GGMM) for digital health software tools to assess its state of development. By 2019, it was scoring 100% in all three GGMM domains (global utility, community support and software maturity) – becoming the first electronic health tool for disease surveillance and the first outbreak management tool to achieve such a score.

In the follow-up SORMAS-LBDS (low-bandwidth database synchronisation) project, funded by the German Ministry of Education and Research, the surveillance system is being further developed and adapted to regions with low mobile bandwidth – thus improving the reach and sustainability of this digital epidemic control tool.

Nigeria went on to allocate its own funds to adapt SORMAS to support control of a Lassa fever outbreak, while Ghana has also implemented SORMAS in two regions of the country. In addition, the platform has also been adapted for COVID-19 surveillance – in European countries as well as Africa, providing a notable example of 'reverse innovation'.

*The SORMAS project was an EDCTP Participating State Initiated Activity supported by Germany through its Federal Ministry of Education and Research.*





## Tuberculosis

*At the end of 2020, the EDCTP2 portfolio included 33 projects on TB and TB–HIV co-infections (28.83% of the total by number, €194.83 million by value).*

There is a strong focus on TB diagnostics, although multiple projects are addressing TB treatments. Several major vaccine development projects are also being supported.

Important goals are to improve methods of TB detection and monitoring of response to therapy, and to shorten the duration of treatment.

### Tuberculosis: grants in numbers



33 grants  
€194.83 M



Drugs  
11 grants  
€79.66 M



Vaccines  
4 grants  
€51.17 M



Diagnostics  
18 grants  
€64 M

## Intensive treatment of tuberculous meningitis

*The INTENSE-TBM study, which is evaluating new treatments for tuberculous meningitis, has established a platform that will enable it to recruit its first participants in 2021.*

On occasion, *Mycobacterium tuberculosis*, the bacterium responsible for TB, can establish infections in the brain, causing a potentially deadly form of meningitis. Tuberculous meningitis occurs mainly in young children and has high mortality rates, particularly for children living with HIV. Around half of survivors experience long-term disabilities.

Treatment of tuberculous meningitis is challenging, as commonly used anti-TB drugs cannot easily gain access to brain tissue. To provide a better evidence base for treatment, the **INTENSE-TBM** project is evaluating a more intensive treatment regimen, including a week of high-dose intravenous rifampicin, linezolid, other anti-TB drugs and corticosteroids, followed by a two-month oral regimen and seven months of a simplified antibiotic

regimen. The potential benefit of a host-directed therapy, aspirin, will also be assessed.

Patients with HIV infections will receive antiretroviral treatment after four weeks, as well as dexamethasone to reduce the risk of immune reconstitution inflammatory syndrome (IRIS) – when a recovering immune system launches a powerful response against TB infections.

Due to recruit in four sub-Saharan African countries, Côte d'Ivoire, Madagascar, South Africa and Uganda, the project spent 2020 setting up systems enabling Côte d'Ivoire and Madagascar to recruit its first participants early in 2021. In total, the project plans to recruit 768 participants.

The clinical study should provide firm evidence of the benefits of the intensive approach to treatment of tuberculous meningitis. The project team anticipates that the intensified treatment will reduce mortality by 30% and also reduce long-term disability.

## Enhancing BCG

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*The priMe study, which is evaluating a modified and more potent version of the BCG vaccine against TB, recruited its first participant in 2020.*

BCG is a mainstay of many national vaccination programmes, but offers limited protection against highly contagious pulmonary forms of TB. Recent years have also seen global shortages of BCG, so alternative vaccines are urgently required.

The team behind the **priMe** study has developed a modified form of BCG, known as VPM1002, that has several advantages over BCG. BCG is a whole-cell vaccine based on a relative of *Mycobacterium tuberculosis* that infects cows. Like *M. tuberculosis*, BCG invades and survives within host macrophages. VPM1002 is an engineered form of BCG designed to promote intracellular digestion of the BCG bacillus, increasing the exposure of antigens to the host immune system. Pre-clinical and phase I studies have shown that VPM1002 has a better safety profile than BCG, while phase II studies

suggest it is at least as effective at stimulating immune responses in both HIV-unexposed and HIV-exposed infants.

The phase III priMe trial aims to recruit nearly 7,000 newborns in five sub-Saharan African countries to provide definitive evidence of the efficacy of VPM1002 in comparison to BCG. To streamline trial approvals, the priMe team engaged with the African Vaccine Regulatory Forum (AVAREF) so that a joint review could be organised for the regulatory authorities and ethics committees in the countries participating in the trial.

A consolidated list of questions was prepared and discussions held with the individual authorities. This streamlined approach enabled the team to rapidly secure all necessary approvals and recruit its first participant in Kenya in November 2020. The first clinical centre in South Africa was initiated in December 2020 and other sites will open in Gabon, Tanzania and Uganda in 2021.

## Testing statins to combat TB

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*The StatinTB trial, which is evaluating whether patients being treated for TB also benefit from statins, began recruiting in 2020 despite the challenges of COVID-19.*

TB disease recurs in 3–5% of successfully treated TB patients, and patients may also experience a long-term decline in lung function due to persistent infection. Notably, there is some evidence that people taking statins are at reduced risk of active TB disease. Statins lower levels of cholesterol, which is required by *Mycobacterium tuberculosis* for survival, and also reduce levels of inflammation, which could limit damage to the lungs during TB infection.

The **StatinTB** trial is aiming to gather rigorous evidence from a randomised trial to determine whether use of statins, in addition to standard antibiotic therapy, reduces the risk of disease recurrence and damage to the lungs. After the end of their antibiotic treatment, patients will be given a 24-week course of statins and will undergo detailed chest scans to determine

whether active disease is present and the extent of lung damage.

Recruitment into the StatinTB trial was due to start in South Africa in 2020 just as COVID-19 hit. The StatinTB team had to revise its approach to recruitment so it could be carried out in a COVID-safe way, enabling the first potential recruits to be screened in July 2020. Contacting potential participants via a phone call rather than in person presented challenges, and has led recruiters to modify how they go about building trust with potential participants.

Despite the setback, the team hopes to complete recruitment by the end of 2021, potentially by involving additional TB clinics in the trial. The team has also developed plans for a systematic review to synthesise evidence on the use of statins to reduce inflammation in TB and other chronic diseases. This evidence synthesis aims to identify the most powerful anti-inflammatory statin, with a view to informing the design of future clinical studies.

## Test and treat for TB

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*The TREATS study completed the majority of its follow-up visits in 2020, as part of its efforts to determine whether a combined HIV and TB prevention intervention reduces the community burden of TB.*

The HPTN (PopART) trial was the largest trial ever undertaken of a combined HIV and TB intervention, involving around one million people. It found that targeting entire populations in a 'test-and-treat' strategy significantly cut the number of new HIV infections. The **TREATS** study is using the unique infrastructure provided by the PopART trial to determine whether similar impacts were seen for TB, which is frequently found alongside HIV infections.

Focusing on 14 communities in South Africa and Zambia, the project has been collating PopART data on population-level TB notification, the prevalence of TB, and the incidence of TB disease and TB infection. A cohort of more than 4,500 young people aged 15–25 have been

recruited and are being followed to determine whether the PopART intervention reduced TB infection. Follow up of most of this cohort was completed in 2020.

The study has also undertaken qualitative research on the impact of the intervention, finding that people diagnosed with TB often experience significant social isolation, which can delay treatment-seeking and lead to mental health issues. The project has also been exploring how newer TB diagnostic tools, including molecular Xpert Ultra and computer-aided analysis of digital chest X-rays, could be used to determine the prevalence of TB.

The results of the TREATS study should reveal the impact of the PopART intervention on the TB disease burden, as well as its overall cost-effectiveness. The demonstration of benefits for TB as well as HIV control would provide further evidence to encourage wider take up of test-and-treat strategies for HIV and TB.

## Detecting multidrug-resistant TB

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*The DIAMA project has recruited more than 2,000 patients into its study evaluating new technologies for rapidly characterising multidrug-resistant TB (MDR-TB), and is exploring the potential to share results with national TB control programmes in real time.*

MDR-TB is difficult and time-consuming to detect by conventional culturing methods. As a result, patients are often maintained on ineffective drugs, leading to poor clinical outcomes and providing more opportunities for drug-resistant infections to spread. Building on past EDCTP-funded collaborations, the **DIAMA** project is assessing whether more rapid molecular testing for MDR-TB could be implemented in sub-Saharan African settings.

Two countries involved in the partnership, Benin and Rwanda, have established facilities capable of carrying out 'Deeplex' assays, which can simultaneously detect mutations linked to resistance to 14 key anti-TB drugs. Use of this assay is being compared with conventional phenotypic analysis of drug susceptibility as well as whole genome sequencing.

The project is also assessing the potential use of field-based molecular tests, such as the Xpert platform and MolBio TrueNat, which do not detect as many resistance-related mutations but can be used closer to patients. In addition, it is testing a range of methods that will provide more rapid feedback on patients' responses to treatment, including the molecular bacterial load assay.

Furthermore, using 'DataToCare' software developed by one of the project partners, the results of molecular testing are being communicated in real time to national TB control programmes. A pilot study in Benin is providing an initial assessment of the added value of this system.

The project's preliminary data on use of Xpert XDR were presented to the WHO Guidelines Development Group meeting in December 2020. Over the longer term, the project's results could have a major impact on the detection and management of MDR-TB, a condition with a disturbingly high mortality rate.



## Detecting extrapulmonary TB

*A new test provides a readily implementable tool for diagnosing TB infections outside the lung.*

Although most cases of TB involve infection of the lungs, a significant proportion – estimated at 15–40% – affect a wide range of other body tissues. These extrapulmonary cases are particularly common in young children and people living with HIV.

Extrapulmonary TB presents a diagnostic challenge, as the samples generally used to detect TB typically contain low levels of bacteria. More accurate and easy-to-use diagnostics are therefore required for extrapulmonary TB so that appropriate treatment can be commenced as rapidly as possible.

In a search for alternative markers of TB infection, a team from Norway found that the MPT64 protein is secreted by *Mycobacterium tuberculosis* but not by other mycobacteria or the BCG vaccine. An MPT64-based antigen-detection test, which can be used on a range of biological samples and biopsies, was found to be as sensitive and specific as molecular testing using the polymerase chain reaction (PCR).

In follow-up work, the team developed a version of the test suitable for use in resource-poor settings, and evaluated its performance in a

routine diagnostics laboratory in a tertiary care hospital in Zanzibar, a semi-autonomous region of Tanzania.

This study showed that it was feasible to use the **MPT64** test in such settings. Importantly, it improved the diagnosis of extrapulmonary TB, especially in children and in infections affecting the lymph nodes, achieving a sensitivity of 83% in confirmed cases of TB. It could be particularly useful in identifying lymph node infections, for which tissue samples can readily be collected.

The team has also shown that the test might also have a useful role to play alongside other rapid tests in a high-income, low-prevalence setting (Norway). It has also begun to explore the potential of a test to detect IP-10, an inflammatory marker, on dried blood spots as a convenient way to track responses to treatment in low-resource settings.

The findings suggest that the MPT64 test could provide a robust, rapid and sensitive test for TB, particularly of lymph node infections and childhood TB, alongside clinical assessments.

*The MPT64 test project was an EDCTP Participating State Initiated Activity supported by Norway through the Research Council of Norway.*



## Malaria

At the end of 2020, the EDCTP2 portfolio included 16 projects on malaria (19.69% of the total by number, €133.06 million by value). Most clinical projects are focusing on drug treatments and vaccine development.

EDCTP's malaria portfolio has a strong focus on prevention and treatment of malaria in pregnant women, accelerating the development

of new combination drug treatments, and advancing candidate malaria vaccines.

### Malaria: grants in numbers



16 grants  
€133.06 M



Drugs  
9 grants  
€73.77 M



Vaccines  
5 grants  
€52.84 M



Diagnostics  
1 grant  
€3 M



Non-intervention - specific topics,  
1 grant  
€3.45 M

## Screening pregnant women for malaria

*The IMPACT team has used modelling to assess the potential advantages of screening for malaria during antenatal visits.*

Intermittent preventive treatment in pregnancy (IPTp) is a proven approach for preventing the harmful effects of malaria in pregnant women. However, it is not fully implemented in malaria-endemic regions of sub-Saharan Africa. In addition, in many settings there is growing parasite resistance to the main drug used in IPTp, sulfadoxine–pyrimethamine (SP).

A possible alternative to IPTp is a strategy known as intermittent screening and treatment in pregnancy (ISTp) – testing of all women at antenatal visits using rapid diagnostic tests, followed by treatment of those testing positive with highly efficacious artemisinin combination therapies (ACTs). However, with current diagnostic technologies, ISTp has not been found to perform better than IPTp-SP. WHO has suggested that more evidence is needed on

whether 'test-and-treat' strategies such as ISTp have a place in malaria control.

The **IMPACT** team carried out an EDCTP-funded knowledge translation project to provide health authorities in sub-Saharan Africa with the tools to make evidence-based decisions on the use of malaria control strategies in pregnancy, taking into account factors such as local patterns of malaria transmission and SP resistance levels. In addition, the team recently used modelling to explore the potential advantages of antenatal screening with existing or more sensitive rapid diagnostic tests to improve protection of pregnant women.

An analysis of test performance data suggests that rapid diagnostics are particularly good at picking up infections in first-time mothers and at first antenatal visits, when parasite levels are relatively high. The modelling suggests that both IPTp and ISTp are highly effective, but ISTp is not superior to IPTp. However, a combination



of the two approaches, as currently used in Tanzania, holds promise, particularly where levels of SP resistance are high, and first-trimester screening could be a suitable alternative where IPTp-SP is no longer effective.

Moreover, the modelling suggests that, with highly sensitive tests, early screening and use of highly efficacious ACTs could deliver substantial public health benefits.

## Preventing malaria in pregnancy

*The MAMAH and IMPROVE studies, which are both aiming to improve malaria care in pregnant women with HIV infections, hit important recruitment milestones in 2020.*

Malaria infections in pregnancy have particularly harmful consequences for both mother and offspring. Co-infections with malaria and HIV are particularly hazardous, and increase the risk of mother-to-child transmission of HIV.

To protect women against malaria, alongside insecticide-impregnated bednets, WHO recommends prophylactic treatment with

antimalarial drugs, using a strategy known as intermittent preventive treatment in pregnancy (IPTp). The most commonly used drug for IPTp in sub-Saharan Africa is sulfadoxine–pyrimethamine (SP). However, resistance to SP is becoming more common, highlighting the need for alternatives.

Because of its long half-life and good tolerability, dihydroartemisinin–piperaquine (DP) is seen as a good candidate for IPTp, and has been shown to provide good protection in HIV-uninfected women. However, more evidence is required on pregnancy outcomes before it can be recommended for use in IPTp.

The **IMPROVE** project is carrying out two clinical trials to gather key data on DP use in pregnancy. The IMPROVE-1 study, focusing on women without HIV infections, is assessing the efficacy of DP, with and without azithromycin, in comparison to SP, and also generating new data on key birth outcomes. It completed recruitment in 2019 and the last infant follow up was carried out in April 2020.

However, SP cannot be used in pregnant women living with HIV because of interactions with co-trimoxazole, an antibiotic used prophylactically to prevent infection. The use of DP in such women is similarly held back by uncertainty regarding interactions between DP and antiretroviral drugs and co-trimoxazole. The IMPROVE-2 study, which is also supported by the UK's Joint Global Health Trials scheme,

is therefore generating large-scale data on use of DP in pregnant women living with HIV, including impacts on birth outcomes. Despite hold-ups due to COVID-19, recruitment of nearly 900 pregnant women in Kenya and Malawi continued through 2020 and was completed in January 2021.

Also addressing this uncertainty, the **MAMAH** study is carrying out a trial of DP for IPTp in HIV-infected women using insecticide-impregnated bednets in Gabon and Mozambique. Pharmacokinetic studies will be carried out on a subset of women to examine possible interactions between the different drugs. Aiming to recruit 664 women in total, the project achieved its 50% recruitment milestone in October 2020.

## Preventing malaria in children after hospital discharge

*A study in East Africa has found that pre-emptive treatment of malaria on discharge from hospital can save the lives of children recovering from anaemia.*

Anaemia is the leading cause of childhood hospitalisation in malaria-endemic areas of Africa. Research has tended to focus on improving care of anaemic children in hospital, but more deaths occur in the months following discharge than during hospital stays.

Research in Malawi has shown that full recovery of red blood cell numbers does not occur until two to three months after discharge. This may therefore be a vulnerable period when further malaria infections have a particularly harmful impact, increasing the risk of death.

To test this idea, an international collaborative team evaluated the impact of providing antimalarial drugs to children under 5 years of age for three months after they had been discharged from hospital following treatment for severe anaemia. The randomised controlled trial in Kenya and Uganda found that four three-day courses of dihydroartemisinin–piperaquine (DP) led to a 35% lower incidence of death or readmission to hospital. Mortality benefits were seen only during the period in which DP was used, and not during a longer follow up.

An associated study in Malawi found that post-discharge malaria chemoprevention was highly accepted by caregivers. Community-based delivery of treatment was considered preferable to facility-based care and led to higher adherence.

The results are likely to lead to changes in clinical practice in East African countries affected by malaria and will feed into WHO policymaking.

*The post-discharge malaria chemoprevention project was an EDCTP Participating-State Initiated Activity supported by Norway through the Research Council of Norway.*





## HIV & HIV-associated infections

*At the end of 2020, the EDCTP2 portfolio included 20 projects on HIV and HIV-associated infections (16.73% of the total by number, €113.05 million by value).*

The HIV portfolio includes projects focusing on diagnostics, drugs, and vaccines/neutralising antibodies, with drugs the most common type of intervention being investigated. Many projects involve priority groups such

as children, adolescents and women of childbearing age, with several studies aiming to extend use of proven therapeutics to these populations, for example through new formulations, or to optimise their delivery.

### HIV- & HIV-associated infections: grants in numbers



20 grants  
€113.05 M



Drugs  
12 grants

€64.10 M



Vaccines  
4 grants

€35.59 M



Diagnostics  
4 grants

€13.36 M

### Women-focused HIV prevention

*Recruitment has begun into an innovative trial of broadly neutralising antibodies to prevent HIV infection in young women.*

On very rare occasions, people exposed to HIV develop antibodies that protect against a wide range of different HIV variants. There are great hopes that these broadly neutralising antibodies (bNAbs) could be manufactured and administered to people to provide wide protection against different HIV strains.

The **CAPRISA 012** (CAP012 SAMBA) study is focusing on three bNAbs (known as CAP256V2LS, VRC07-523LS and PGT121) that target different structures on the surface of the HIV virus particle and have been shown to provide excellent protection in animal studies. Two particular combinations have been shown to offer especially powerful protection against the most common type of HIV in Africa.

Initial work has included a phase I trial of 45 participants to assess the safety and pharmacokinetics of the bNAbs individually and in combination. Following a second phase I study to assess safety, pharmacokinetics and acceptability, a phase II trial will be carried out on the optimal combination(s), recruiting up to 900 young South African and Zambian women.

Almost a decade after a patient producing bNAbs was identified in South Africa, the first patient receiving a derivative of these bNAbs was recruited into the CAP012 SAMBA trial in 2020. Positive results from the study would support a phase III trial to generate definitive evidence for a woman-controlled HIV prevention option based on 4- or 6-monthly injections, offering significant advantages over currently used approaches.

## Tailored HIV prevention in adolescents

*In 2020, the CHAPS study – which is working with adolescents to develop and evaluate new approaches for pre-exposure prophylaxis (PrEP) for HIV – completed the bulk of its recruitment.*

Although the numbers of new cases of HIV infection are falling across most of sub-Saharan Africa, progress is slowest among adolescents. Hence there is an urgent need for more effective preventive strategies in this age group.

The pre-emptive use of antiretroviral drugs to prevent infection has been clearly shown to reduce the risk of HIV infection. However, it is costly, has some side effects, and adherence is not optimal in adolescents. Possible alternative approaches include new, less toxic drug combinations, as well as use of 'on-demand' PrEP around the time of sexual activity.

To identify the factors that would affect acceptability and adherence to possible new forms of PrEP, the **CHAPS** study is consulting with male and female adolescents aged 13–24 in Uganda, South Africa and Zimbabwe. Group discussions and in-depth interviews have been used to explore barriers and motivators to daily and on-demand PrEP, and have underpinned development of a survey circulated to 1,500

adolescents in the three countries to generate quantitative data.

These investigations are being complemented by a clinical study designed to identify drug levels able to prevent HIV infection across the foreskin. Adolescent men opting for voluntary circumcision are being randomised to different doses and duration of study drug before circumcision. After circumcision, foreskin tissue will immediately be challenged with HIV to determine how well the prior drug treatment is able to prevent infection.

Despite recruitment delays caused by COVID-19, nearly 100 participants were randomised in the clinical study in 2020, and recruitment was completed early in 2021.

As well as providing key data on possible alternative antiretroviral drug combinations, dosing and schedules for PrEP in adolescents, the CHAPS study will also suggest ways that PrEP can best be delivered in this important group. Such work should provide key input into the design of a definitive phase III trial of the most promising new approach.



## Combining vaccination and antiretroviral drug prophylaxis

*The first participants have been recruited into the ground-breaking PrEPVacc trial, which is assessing a novel combination of pre-exposure prophylaxis (PrEP) and a prototype HIV vaccine to prevent HIV infection.*

Vaccination and the pre-emptive use of antiretroviral drugs to prevent infection are two potentially powerful ways to prevent HIV infection. The **PrEPVacc** trial, which recruited its first participant in 2020, is the first trial that is assessing the preventive efficacy of the two strategies used together.

Although the results of HIV vaccine trials have been mostly disappointing, promising levels of protection have been obtained in studies that have combined DNA-based and protein-based vaccines. PrEP, on the other hand, has been shown to be highly effective, but in practice adherence typically lowers its protective effect.

The PrEPVacc trial is evaluating two combination vaccine regimens, one comprising DNA- and protein-based vaccines and a second that also includes a viral vector-based vaccine. Previous studies have shown that these combinations are safe and stimulate anti-HIV immune responses. The trial will also be evaluating a new form of oral PrEP (known as TAF/FTC) and exploring barriers to its use.

Following extensive community engagement and recruitment of a pre-trial cohort to gather baseline data, the first recruit into the trial was vaccinated in December 2020. A total of 1,668 participants are due to be recruited at six sites in Uganda, Tanzania, Mozambique and South Africa. PrEPVacc is the world's first trial of combined preventive treatment and will provide key data on the efficacy of the new vaccines, the new form of PrEP, and the two used together.

## HIV viral load monitoring

*The SAMBA II platform enables rapid same-day HIV viral load monitoring, even in remote rural locations.*

For individuals on antiretroviral therapy, WHO recommends regular monitoring of HIV viral load, to determine whether viral replication is being kept under control. Increased viral loads could reflect poor adherence to medication or the development of a drug-resistant HIV infection, requiring a shift to a second-line treatment.

However, conventional technologies for viral load monitoring require specialist laboratory facilities. For people living with HIV in remote rural settings, it can take many weeks or months to receive viral load monitoring results.

The Diagnostic Development Unit at the University of Cambridge, UK, and its spin-out company, Diagnostics for the Real World, has developed a semi-quantitative nucleic acid detection platform, known as SAMBA, which can rapidly detect when HIV viral loads exceed WHO thresholds. SAMBA is easy to use, requiring only a finger-prick or heel-prick blood sample – easier to obtain than traditional blood samples – and incorporates innovative technology to filter out white blood cells, avoiding the need for a centrifugation step.

First-generation devices, SAMBA I, are semi-automated and suitable for use at devolved healthcare facilities, such as regional or district hospitals. In the **MICA** project, funded by the UK Medical Research Council (MRC), part of UK Research and Innovation (UKRI), the viral load testing chemistry has been integrated into a more advanced platform, SAMBA II. This allows for rapid, fully automated 'sample in, result out' point-of-care testing using finger-prick or heel-prick blood samples.

Funding has also enabled the performance of the SAMBA II HIV-1 Semi-Q test to be evaluated in Europe and Africa, showing comparable levels of performance to a laboratory assay. Such data will support an application for CE marking – necessary in order for the device to be purchased by donor organisations.

The combination of fuss-free blood sampling and robust point-of-care technology has opened up use of SAMBA II viral load monitoring at highly developed facilities. Results can be obtained within 90 minutes during patient visits, allowing for rapid changes to treatment if required.

*The MICA project was an EDCTP Participating State Initiated Activity supported by the UK through the Medical Research Council and UK Research and Innovation (UKRI).*





## Neglected infectious diseases

*At the end of 2020, the EDCTP2 portfolio included 19 projects on neglected infectious diseases (10.44% of the total by number, €70.59 million by value). Most projects are focused on therapeutic development and reformulation.*

Projects cover the key neglected infectious diseases affecting sub-Saharan Africa, including schistosomiasis, leishmaniasis, onchocerciasis, human African trypanosomiasis and leprosy.

There is a strong focus on the development of tools to facilitate disease elimination, including new formulations of drugs for young children.

### Neglected infectious diseases: grants in numbers



19 grants  
€70.59 M



Drugs  
13 grants

€47.50 M



Vaccines  
1 grant

€8 M



Diagnostics  
5 grants

€15.09 M

### PEP for leprosy

*The PEOPLE project has enrolled more than 100,000 people into its study to identify the best approach for prevention of leprosy infection.*

The neglected tropical disease leprosy, infection with *Mycobacterium leprae*, remains a major public health problem in several sub-Saharan African countries. Elimination efforts have stalled in recent years and new approaches are needed to revitalise control programmes.

Post-exposure prophylaxis (PEP), preventive treatment in those exposed to an infection, is an intervention with great promise, particularly as a highly effective treatment already exists, single-dose rifampicin. However, there is a need to identify the best approach for implementing PEP in endemic settings.

The **PEOPLE** project is running a randomised controlled trial comparing three different approaches to PEP in highly endemic villages in the Comoros and Madagascar. The interventions include providing PEP for

household contacts, all contacts within 100 metres, or household contacts plus individuals within 100 metres testing positive for *M. leprae* antibodies.

By the end of 2020, more than 100,000 people had been enrolled and 410 new cases of leprosy had been identified. The project has also undertaken a qualitative study to examine the possible barriers to (or facilitators of) new approaches to leprosy control. It has also begun evaluating 'Deeplex' technology to genotype *M. leprae* samples, with a view to identifying chains of transmission and understanding more about how the infection spreads.

Preliminary findings suggest that fewer cases of infection are seen among contacts receiving PEP. An analysis of the full results should confirm the advantages of PEP and suggest which approach is likely to be most effective in practice.

## Ensuring access to child-friendly drugs for schistosomiasis

*EDCTP and the Global Health Innovative Technology (GHIT) fund are extending their partnership to accelerate the introduction of a drug designed to protect pre-school-aged children against a key neglected infectious disease.*

Schistosomiasis is a common parasitic disease in sub-Saharan Africa and one of the most important tropical diseases in terms of public health burden and economic impact. A safe and effective treatment is available, praziquantel, and is widely used in mass drug administration campaigns involving adults and school-aged children. However, its use in younger children has been restricted by the lack of a suitable formulation.

To overcome this barrier, a global public–private partnership – the Paediatric Praziquantel Consortium – has been developing a new praziquantel formulation for pre-school-aged children. Funding for development of this new formulation – levo-praziquantel, a dissolvable tablet – has come from GHIT and other sources, while EDCTP has contributed €1.99 million to support clinical studies in sub-Saharan Africa confirming its efficacy and acceptability.

In 2020, EDCTP and GHIT established a new agreement to jointly invest €7.8 million in an implementation study to pave the way for the efficient and rapid introduction of the new formulation. The **ADOPT study** will cover issues such as technology transfer and local manufacturing, social mobilisation, and programmatic integration.

In small-scale pilot projects in Côte d'Ivoire, Kenya and Uganda, the project will assess the feasibility, acceptability and costs of different delivery platforms. The lessons learned will be used to develop an implementation plan and practical toolkit to help countries introduce the new approach.

Ultimately, the project will help to ensure that the estimated 50 million pre-school-aged children who do not currently receive praziquantel are not left behind and are protected against this debilitating infectious disease, providing an important step towards eventual disease elimination.





## Diarrhoeal disease and lower respiratory tract infections

At the end of 2020, the EDCTP2 portfolio included 10 projects on diarrhoeal disease and lower respiratory tract infections (11.10% of the total by number, €75.03 million by value). Studies focus on diagnostics, drugs and vaccine development, including several on vaccine development for infections mainly affecting children.

Diarrhoeal disease and lower respiratory tract infections: grants in numbers



10 grants  
€75.03 M



Drugs  
3 grants

€18.10 M



Vaccines  
6 grants

€50.95 M



Product-focused implementation research  
1 grant

€5.98 M

### Protecting children from ETEC diarrhoea

*The ETEC Vaccine Efficacy project has begun vaccinating its youngest cohort against ETEC diarrhoeal disease – the first time children in sub-Saharan Africa have been vaccinated against this leading cause of childhood mortality.*

Enterotoxigenic *E. coli* (ETEC) causes a potentially deadly diarrhoeal disease, particularly in low-resource settings. By interfering with growth and development, it also has major implications for children's longer-term health and wellbeing.

The most advanced oral vaccine against ETEC is ETVAX, a combination of engineered strains of *E. coli* that produce proteins known to stimulate potent immune responses. The vaccine has been successfully tested for safety in Europe, and in the **ETEC Vaccine Efficacy** trial it is being given first to adults then to children in progressively younger age groups in Zambia.

Following reassuring early experience, in 2020 ETVAX was given for the first time in Zambia to children in the youngest age group, infants 6–9 months old. With no significant safety issues arising, ETVAX is now progressing to a phase IIb study in children 6–18 months old in The Gambia.

The ETEC Vaccine Efficacy studies will provide critical data on safety and efficacy of ETVAX among a particularly vulnerable group, young children in sub-Saharan Africa, who are most at risk of ETEC diarrhoeal disease.

## Antibiotics for childhood pneumonia

*The PediCAP project is aiming to identify the most appropriate oral antibiotic regimen for young children being treated for pneumonia.*

Pneumonia is one of the most common causes of death in young children in sub-Saharan Africa. For children hospitalised with pneumonia, WHO currently recommends two antibiotics, penicillin and gentamicin, given by injection for five days. Longer hospital stays have an impact on children, families and medical services, but there is currently no consensus on the most appropriate 'step-down' treatment based on a switch to oral antibiotics. Clinical decision-making also needs to balance clinical outcomes with minimising the risk of antibiotic resistance through overuse of antibiotics.

The **PediCAP** project aims to fill this gap in knowledge, identifying the most appropriate oral antibiotic (amoxicillin or co-amoxiclav),

the best formulation and the optimal duration of treatment for children aged 3 months to 6 years. Studies embedded within the trial will examine other key issues, such as antibiotic pharmacokinetics to inform dosing, health economic implications for households and clinical facilities, and effects of treatment on the microbiome.

Despite COVID-19-related delays, the PediCAP team was able to secure all necessary approvals for its clinical plans by mid-2020, and recruited its first participant, a 6-month-old boy, in December 2020.

The PediCAP project will generate data of direct relevance to clinical practice, with the potential to rapidly inform global policy and practice for treatment of pneumonia in childhood. It will also inform antibiotic stewardship policies to minimise the risk of antibiotic resistance development.





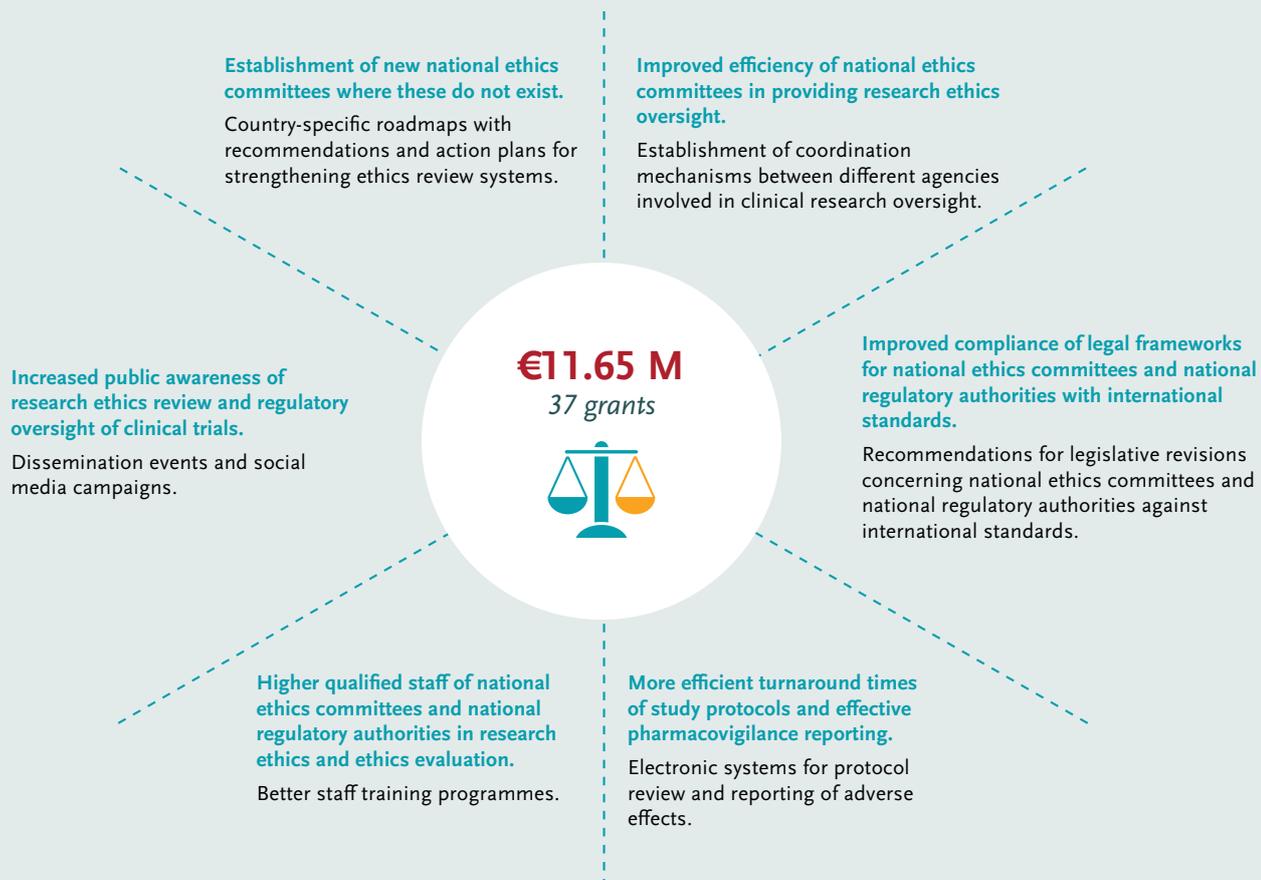
## Ethics review and regulatory capacity

*The capacity of a country to host high-quality clinical research is dependent on its capabilities in ethical review of research proposals and regulatory oversight of clinical research projects.*

Moreover, innovations in trial design and increasing diversity in new product development are creating an increasingly complex set of regulatory challenges. EDCTP provides specific support to strengthen national

capabilities and harmonise activities, through North–South and South–South partnerships. At the end of 2020, 37 countries in sub-Saharan Africa were benefiting from such capacity-building activities.

### Ethics review and regulatory capacity: aspects and grants in numbers



## Enhancing pharmacovigilance in Eastern Africa

*The PROFORMA project has strengthened drug safety-monitoring capacity in four African countries, and collected data on more than 50,000 people involved in mass drug administration campaigns.*

Being able to monitor the safety of experimental and newly introduced medical products is essential to protect populations and maintain confidence in clinical research. The **PROFORMA** project brought together academic institutions and national regulatory authorities in Ethiopia, Kenya, Rwanda and Tanzania to strengthen national pharmacovigilance capacities, supported by a European pharmacovigilance centre.

The project carried out baseline assessments of pharmacovigilance capacities in the four countries, information that was used to create individualised national capacity-development plans. These plans are now being implemented.

The project also reviewed current pharmacovigilance teaching practices in universities in participating countries. It developed a model undergraduate pharmacovigilance curriculum, which was launched in Kenya in 2020 and is due to be adopted by partner universities in the region. To build capacity, the project is also supporting

ten post-graduates, while around 2,000 healthcare professionals and others involved in intervention rollouts have been trained in safety monitoring and data collection.

In each of the four countries, PROFORMA has overseen practical pharmacovigilance projects. These have covered introduction of human papillomavirus (HPV) vaccination and measles/rubella vaccination, as well as mass drug administration campaigns for control of neglected tropical diseases. More than 50,000 people in total have been followed through the initiative.

In 2020, project coordinator Professor Eleni Aklillu was awarded the prestigious Donald Mackay Medal by the UK Royal Society for Tropical Medicine and Hygiene, which recognises outstanding contributions to tropical health. Professor Aklillu is also one of the principal investigators of the EDCTP-funded PREGART trial.

Through its complementary activities, the PROFORMA project has built and is continuing to build significant capacity and established a strong platform for further strengthening, to support safety monitoring for newly introduced medical interventions against poverty-related diseases.



## Gender mainstreaming

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*The BCA-WA-ETHICS project has developed a free virtual helpdesk, held its first international congress on gender mainstreaming in 2020, and also published its first policy brief.*

Women are significantly under-represented in research in sub-Saharan Africa (and other regions). Furthermore, women may be disadvantaged within certain societies, or have particular interests that need to be considered in the design of clinical research studies. It is important that these issues are systematically considered during ethics review of clinical research proposals.

The **BCA-WA-ETHICS** project is an international consortium that is aiming to mainstream a gender perspective into the activities of ethics committees in Senegal, and more generally encourage the adoption of good gender-related practice in clinical research in West Africa.

By enhancing the capacities of West African National Research Ethics Committees (NRECs) in the incorporation of sex and gender perspectives in their research evaluation and follow-up practice, the BCA-WA-ETHICS project is enabling NRECs to become agents of change and advocacy for gender equality throughout West Africa. To this end, one of the main activities of the BCA-WA-ETHICS project is the Gender Mainstreaming Secretariat, a virtual helpdesk available for all ethics committees in West Africa. It provides a wide range of technical services, including the design of Gender Equality Plans, the creation of sex- and gender-sensitive protocol evaluation tools and checklists, and the provision of support in the preparation for external and internal gender audits. All technical services are provided free of charge.

In March 2020, the project held the first (virtual) BCA-WA-ETHICS International Congress on Gender Mainstreaming: Health Research in West Africa, a four-day meeting led from Dakar, Senegal. A summary of the meeting (in French) is available at [www.bcawaethics.com/media-publications](http://www.bcawaethics.com/media-publications).

Later in the year, the consortium launched its first policy brief, 'A Framework for the Ethical Evaluation of Research Protocols from a Sex and Gender Perspective during the COVID-19 Pandemic and Other Epidemics', which was

published in English, French and Portuguese and is also available on the project website. The policy brief was designed to ensure that the specific interests of women, men and gender minorities are considered during the COVID-19 pandemic and future outbreaks. Its development was led by researchers from Senegal, supported by experts from Côte d'Ivoire, Mali and Spain.

During the year, BCA-WA-ETHICS also developed a 'how-to' guide for national research ethics committees and institutional review boards, 'The ethicist's guide to the evaluation of preclinical research from a sex and gender perspective', which was published in February 2021.

The BCA-WA-ETHICS consortium also received follow-up EDCTP funding in 2020, to extend the project's initial work and more generally strengthen national ethics review capacity. BCA-WA-ETHICS-II has a particular focus on research during health emergencies, including the COVID-19 pandemic, and on building the capacities of members of the West African Network of National Ethics Committees and other researchers involved in ethics review in Benin, Mali and Senegal.

## Building regulatory research skills

*The Reg. Science-Fellows project is building the research skills of regulatory authority staff in southern Africa.*

The Medicines Control Authority of Zimbabwe (MCAZ), the country's national medicines regulatory authority, has for many years provided training to regulators from other countries in Africa. It was designated a Regional Centre of Regulatory Excellence (RCORE) by the African Union Development Agency (AUDA-NEPAD) in 2014.

This experience revealed that some regulators lacked the research skills required to carry out research and analyse data on the work done in their institutions or to address emerging challenges in medicines regulation. Through the **Reg. Science-Fellows** project, MCAZ is aiming to enhance the capacity of regulators, including the capacity for research through two-year fellowships.

The first four fellows, from Botswana, South Africa and Zimbabwe (two), recruited following a competitive application process, have begun

their studies. Each fellow has a mentor from a more experienced regulatory authority in Europe or the USA as well as an academic mentor.

The fellows undertook newly developed competency-based RCORE short courses, are carrying out a research study, and have delivered presentations on their work at various forums in Europe and Africa. At the end of the fellowship, the fellows will take the Regulatory Affairs Professional Society (RAPS) certification exam. A further four fellows were recruited in 2020.

More than 100 regulators and regulatory affairs professionals have so far taken the three new RCORE short courses, which cover special dosage forms, Good Manufacturing Practice, and bioavailability and bioequivalence.



## Ethics review capacity building in Tanzania

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*The SMERT project has undertaken multiple activities to streamline and coordinate ethics review activities in Tanzania.*

Working with Muhimbili University of Health and Sciences (MUHAS) Bioethics Department, the **SMERT** project consortium developed a short research ethics course curriculum, which was delivered to 87 members of Institutional Research Boards (IRBs) across Tanzania. This training contributed to the shortening of the median time-to-approval of research protocols by IRBs from 120 to 32 days. The course is being refined, accredited and will be made available as a free online resource on the Tanzania National Institute of Medical Research (NIMR) website.

In partnership with the Kilimanjaro Christian Medical University College, the project also developed a bioethics curriculum module for postgraduate training and continuing professional development. The new curriculum covers many emerging areas of ethical concern, including ethics in public health emergencies, gender perspectives, gaining consent from adolescents (particularly in reproductive health), and stem cell and genetics research. A total of 76 postgraduates, mostly health professionals, have been trained using the curriculum, and two additional universities in

Tanzania are planning to adopt the curriculum for their postgraduate training in bioethics.

To build organisational capacity, SMERT supported a Master of Bioethics training for a staff member at the National Health Research Ethics Committee (NatHREC) Secretariat, as well as a PhD on medicines quality and safety assessment for a staff member of the *Tanzania* Medicines and Medical Devices Authority (TMDA).

In addition, the project facilitated development of an electronic protocol submission and review system at NatHREC to streamline research protocol submission, review and reporting of feedback to researchers. The system is also likely to be introduced by IRBs. To strengthen pharmacovigilance, with SMERT support, the TMDA established an electronic system to report clinical trial-associated adverse events.

To promote more coordinated oversight, the project helped to introduce joint monitoring of clinical trials research by NatHREC and TMDA. The project also hosted an East African Community member state forum on clinical trial oversight and ethics, partnering with TMDA to promote harmonisation of guidelines across the countries of the East African Community.

## Capacity building in Portuguese-speaking countries

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*Responding to the COVID-19 pandemic, the BERC-Luso project organised virtual training events in 2020, as part of its efforts to build ethical review and clinical research regulatory capacity in five Portuguese-speaking countries.*

Ethical review and regulatory oversight are critical to ensure the quality of clinical research and to protect the interests of research participants. Portuguese-speaking countries are at a disadvantage in this area, as many of the resources developed to support the activities of ethical review committees and regulatory authorities are available only in English.

On the other hand, there are opportunities for Portuguese-speaking countries to collaborate in efforts to develop ethical review and regulatory capacity, to avoid duplication of efforts and to

provide a mechanism for sharing of experiences between countries.

The **BERC-Luso** project is carrying out a range of activities to strengthen national medicines regulatory systems and ethical review of clinical research in five Portuguese-speaking countries – Angola, Cape Verde, Guinea Bissau, Mozambique, and São Tomé and Príncipe. It is bringing together national ethics committees and national regulatory authorities from these countries, as well as experts from Portugal and partners from WHO and UNESCO.

Despite the challenges presented by the COVID-19 pandemic, the project was able to take forward multiple activities in 2020, including training in Cape Verde, online training, and the development of two series of webinars.

The week-long training event in Cape Verde included presentations on prior BERC-Luso project work on defining and establishing legal frameworks for national ethics committees and national regulatory authorities, as well as sessions on multiple aspects of ethical and regulatory practice. The event also saw WHO and UNESCO representatives commit to maintaining collaboration with the five countries.

The Cape Verde event was held before COVID-19 disrupted international travel. Later in the year, online meetings were held to maintain contact with trainees in each of the five countries. In May 2020, a joint online meeting was held to discuss the COVID-19-related needs of partner countries and the development of webinars.

During the year, a series of webinars were organised on COVID-19-related topics, including community manufacture and use of face masks, informed consent during a

pandemic, clinical investigation procedures during a pandemic, and clinical research and innovation. A second set of monthly webinars in June to September 2020 covered a range of topical issues in clinical research, while further one-off webinars were held towards the end of the year on specific topics, such as clinical trial monitoring, biobanking and pharmacovigilance.

Participation in the webinars was high across partners, and the feedback collected was very positive. Online meetings with trainees have continued in 2021.





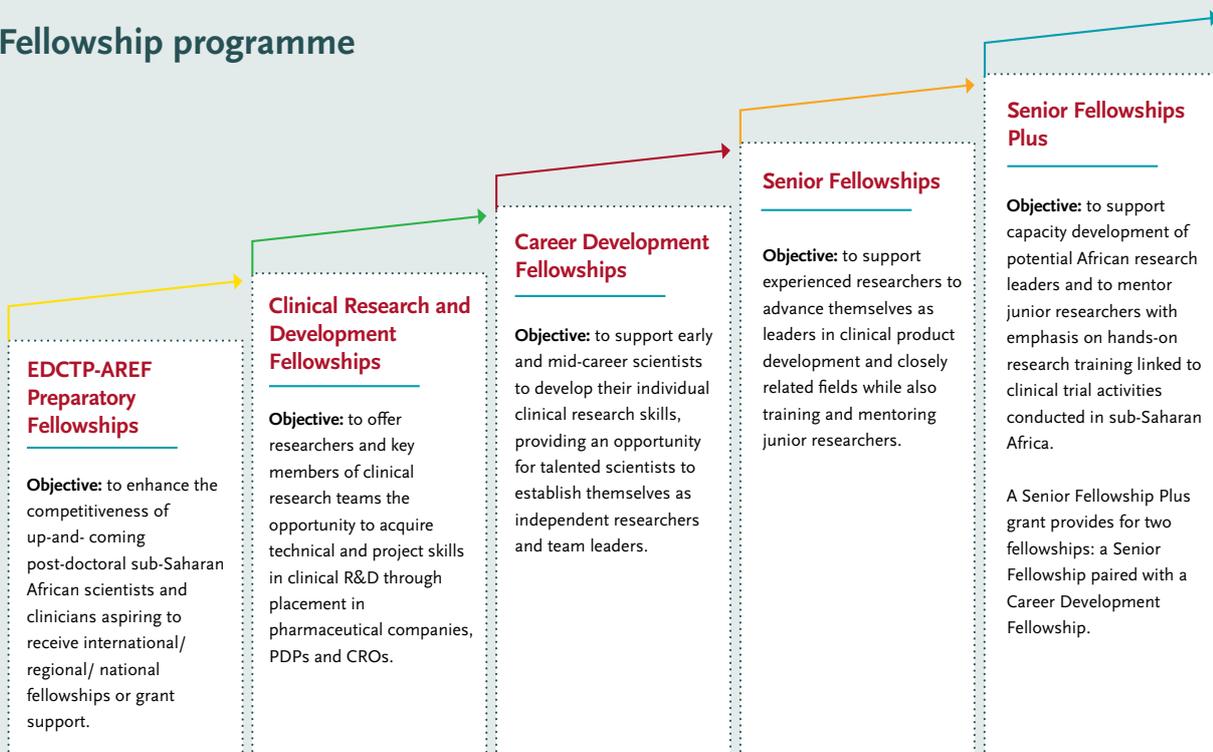
## Fellowship programme

To build intellectual capacity in sub-Saharan Africa, EDCTP provides fellowship support at all career stages, including Senior Fellowships and Career Development Fellowships.

The fellowship programme provides opportunities for promising researchers to establish careers in the region, while having the advantage of links to regional and international networks and access to cutting-edge technology and the latest scientific thinking. At the end of 2020, EDCTP had supported 192 fellowship

grants<sup>1</sup>, including 43 Senior Fellows who are mentoring other researchers as part of their research grants, as well as 260 master's, PhD and postdoctoral researchers. Fellows are based in 25 sub-Saharan African countries, and 40% are female.

### Fellowship programme



## Facilitating clinical research on malaria

*EDCTP Career Development Fellow Dr Clifford Banda helped to develop the WWARN Malaria Clinical Trials Toolkit and is now using it in his research on drug–drug interactions between antimalarials and antiretrovirals.*

Data integrity and data sharing are of fundamental importance in clinical research. To promote good practice in data collection and management, and to ensure data are in a format that can readily be synthesised with those from other sources, the Worldwide

1. Senior Fellowships Plus grants support two fellows per grant, a senior fellow paired with a career development fellow.

Antimalarial Resistance Network (WWARN) has developed a Malaria Clinical Trials Toolkit, a database template and other supporting resources that provide a step-by-step guide for researchers on how to plan, design and carry out trials.

During his EDCTP Career Development Fellowship, **Dr Clifford Banda** has been using these tools in his studies of drug–drug interactions between antimalarial and antiretroviral drugs. He has been liaising closely with the WWARN team, feeding back valuable insights from real-world use of the tools that have led to further refinements.

Dr Banda's fellowship project, IMPROVE DDI, is part of the EDCTP-funded IMPROVE-1 and -2 studies, which are exploring the use of dihydroartemisinin–piperaquine (DP) to prevent malaria infections in pregnant women with or without HIV infections, respectively. His studies are examining whether co-administration of DP and dolutegravir-based antiretroviral therapy affects bloodstream levels of either drug.

The project builds on Dr Banda's extensive previous work exploring the pharmacokinetics of antimalarials and antiretrovirals and drug–drug interactions.

## Treatment and diagnosis of neglected infectious diseases

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*EDCTP Senior Fellow Professor Richard Phillips has been exploring the use of molecular diagnostics for a range of neglected infectious diseases, and has published the results of a major clinical trial on treatment of Buruli ulcer.*

**Professor Richard Phillips** (Kwame Nkrumah University of Science and Technology, Ghana) is a world-leading authority on Buruli ulcer, a neglected infectious disease caused by *Mycobacterium ulcerans* that mainly affects people in rural regions of West Africa. It is characterised by large, unsightly ulcers that lead to extensive scarring.

For more than a decade, Professor Phillips has been exploring ways to improve treatment of Buruli ulcer. In 2020, he and his international collaborators published the results of a major WHO-funded trial confirming that oral antibiotic treatment is as effective as the standard treatment involving intramuscular injections and was associated with fewer side effects. He has also carried out research showing that the oral regimen is associated with higher treatment completion rates, highlighting its potential to be used as part of devolved community-based care.

Professor Phillips has also led projects with EDCTP Career Development Fellow **Dr Michael Frimpong**, examining the use of molecular diagnostics, including a newly developed rapid isothermal nucleic acid amplification test capable of distinguishing two clinically similar infections causing chronic skin ulcers, *Treponema pallidum* (yaws) and *Haemophilus ducreyi* (chancroid).

This highly sensitive and specific test could make an important contribution to yaws control and elimination campaigns.

Dr Frimpong and Professor Phillips have also evaluated a test based on similar technology for rapid diagnosis of *Schistosoma haematobium*, a cause of the common neglected infectious disease schistosomiasis. Laboratory studies suggest that the rapid test is also highly sensitive and specific, and a possible alternative to more technologically complex polymerase chain reaction (PCR) testing. In previous work, Dr Frimpong and Professor Phillips also developed a similar test for *M. ulcerans* based on similar technology, which again has the potential to replace PCR.

In his EDCTP Senior Fellowship research project, Professor Phillips is exploring whether a dressing designed to release nitric oxide speeds up healing of Buruli ulcer.



## Improving adherence to antiretroviral therapy

*Dr Ilse Sumari-de Boer is exploring whether innovative digital tools can enhance young people's adherence to antiretroviral therapy, while also mentoring an early-career researcher in Rwanda.*

An estimated 1.7 million children and more than 1.5 million adolescents in sub-Saharan Africa are living with HIV. More than 300,000 new cases of HIV infection in these age groups occurred in 2017. Although access to antiretroviral therapy is improving, young people face the need to take daily medication for the rest of their lives, and adherence is proving a significant challenge.

During her EDCTP Career Development Fellowship, **Dr Sumari-de Boer** has developed particular expertise in digital health technologies while working at the Kilimanjaro Clinical Research Institute (KCRI) in Tanzania. She helped to establish a data management unit at KCRI, which she continues to run.

She is also involved in other EDCTP-funded projects, including the PanACEA Consortium, a platform for TB-related studies, and the PAVIA project, which is building pharmacovigilance capacity in four sub-Saharan African countries. In addition, she is overseeing data management for the East African Consortium of Clinical

Research (EACCR), one of EDCTP's Regional Networks of Excellence. During her Career Development Fellowship, she also successfully applied for three major grants and has expanded her research interests to adherence to anti-TB drugs, contraception, and to guidelines and laws.

In her Senior Fellowship, awarded in 2020, Dr Sumari-de Boer is exploring new ways to improve adherence to antiretroviral therapy. Tools such as text messaging and internet-enabled medication dispensers, which send reminders and also notify healthcare workers if drugs are not taken when due, have potential to significantly improve adherence. In a two-step project, Dr Sumari-de Boer is first consulting with young people and adolescents, then using these insights to inform the design of interventions to be evaluated in a clinical trial. The trial will compare usual care with a text messaging-based approach and with use of a digital adherence tool.

The Senior Fellowship Plus will help to build capacity at KCRI, particularly in social science. Dr Sumari-de Boer will also be mentoring **Dr Brenda Kateera**, enabling her to become involved in research again following several years dedicated to managing HIV programmes in Rwanda.

## The long-term effects of lung infection

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*Dr Marieke van der Zalm is filling an important gap in the knowledge about the long-term effects of childhood lung infections, while also helping to build Southern African research capacity in paediatric health.*

It is increasingly clear that TB infections have long-term implications for lung health – up to 80% of patients experience symptoms after the end of treatment. However, at least 20% of the global TB disease burden falls on children, and most of this burden reflects pulmonary TB. Children are particularly vulnerable as their lungs are continuing to develop, yet very little is known about the long-term effects of TB or other lung infections on their health and development.

In her EDCTP Career Development Fellowship, **Dr van der Zalm** set up a cohort of 300 South African children aged up to 13 years who have been systematically investigated for pulmonary TB and respiratory virus infections. In her Senior Fellowship, awarded in 2020, she plans to follow up this cohort to assess the long-term effects of TB and other lung infections on lung function.

During her Career Development Fellowship, Dr van der Zalm has established herself as a leading figure in the field of the long-term impacts of childhood lung infection. She helped to organise the first ever international post-TB lung health symposium, as well as a post-TB

symposium at the 50th Union Conference in India. She was also invited to join the South African TB Think Tank, an advisory body to the South African National Department of Health. During 2020, she also carried out important work on children hospitalised following COVID-19 infection.

Her Senior Fellowship research aims to determine the long-term impacts of childhood lung infection and risk factors for poor health outcomes, as well as the trajectory of lung function following investigation of pulmonary TB. The work will fill an important gap in knowledge, providing evidence of long-term disease burdens and highlighting possible points of intervention.

As well as developing her own skills, the Senior Fellowship Plus is also enabling Dr van der Zalm to mentor an early-career researcher in Mozambique – **Dr Justina Bramugy**, a clinical scientist at the Centro de Investigação em Saúde de Manhica (CISM). With support from Dr van der Zalm, Dr Bramugy will be leading her own related study on the impact of pulmonary TB and viral infections on lung health in young Mozambican children, drawing on a cohort of children with presumptive TB enrolled in the EDCTP-funded Stool4TB project. The project will help to develop Dr Bramugy's research skills, as well as the research capacity of CISM more generally.

## Diagnosing the causes of pneumonia

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*EDCTP Career Development Fellow Dr Charles Sande has identified a range of markers that may be able to distinguish different causes of pneumonia.*

Pneumonia is the biggest killer of young children in low-resource settings. It can be caused by a range of viral and bacterial pathogens, which require different clinical management, but identifying causative agents depends on technologies that are often not available in low-resource settings. As well as suboptimal care for very sick children, this also leads to unnecessary use of antibiotics, contributing to the development of antibiotic resistance.

In his Career Development Fellowship, **Dr Sande** aims to identify host biomarkers that could be used to distinguish between bacterial and viral infections. He and his colleagues have developed a microarray chip to quantify levels of 15 proteins that pilot studies have suggested are differentially expressed in bacterial and viral infections. This chip was then tested against 150 virologically confirmed cases of pneumonia and a similar number of bacterially confirmed cases.

This analysis identified three biomarkers that performed best at distinguishing viral and bacterial illness. In 2021, Dr Sande will be

evaluating these markers in a prospective paediatric cohort in a real-life setting. Ultimately, this study could be a step towards a much-needed diagnostic tool to improve clinical management of childhood pneumonia and address the growing challenge of antibiotic resistance.

Dr Sande is based at the KEMRI–Wellcome Trust Research Programme in Kenya. His project builds on his extensive experience of childhood pneumonia, particularly the impact of respiratory syncytial virus, one of the major viral causes of pneumonia in sub-Saharan Africa.

## Fellows attracting additional funding

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### *Current and past EDCTP fellows have successfully applied for international funding.*

Former Senior Fellow **Professor Nicaise Ndembe** (now with Africa CDC and previously with the Institute of Human Virology, Nigeria), was awarded a US\$5 million grant from the US National Institute of Allergy and Infectious Diseases (NIAID) in 2020. His NIAID-funded studies will focus on the impact of particular HIV subtypes on second-line protease inhibitor regimens in Africa. Professor Ndembe collaborates with several members of the EDCTP Alumni Network HIV Working Group, including Dr Joseph Fokam, Dr Deogratius Ssemwanga and Dr Cissy Kityo.

EDCTP Career Development Fellow **Dr Dziejdom de Souza** (Noguchi Memorial Institute for Medical Research, University of Ghana) has been awarded funding from the UK Foreign, Commonwealth & Development Office (FCDO), for research on those who choose not to participate in campaigns to eradicate lymphatic filariasis. His FCDO proposal drew on research findings he obtained during his EDCTP-funded fellowship.





## Facilitating research

*EDCTP supports a range of supplementary activities to facilitate high-quality clinical research in sub-Saharan Africa and to enhance the value of its investments in research.*

Recent examples include funding to support the development of a Global Roadmap for TB Vaccines R&D, organising a workshop to discuss regional and gender-related disparities

in research in the region, and launch of a new web platform to support clinical research in low-resource settings.

### A TB vaccine development roadmap

*A newly developed Global Roadmap for TB Vaccines R&D outlines the short-term and long-term steps that need to be taken to ensure the rapid development and implementation of TB vaccines.*

Promising recent progress is leading to hopes that safe and effective vaccines for TB could soon be a reality. EDCTP, for example, is supporting three major late-stage TB vaccine studies (see Box). To expedite the development of TB vaccines and ensure that they reach people in need in low- and middle-income countries, EDCTP is supporting a global collaborative consultation to identify the key barriers to progress and how they can be overcome. The resulting Global Roadmap for TB Vaccines R&D will provide a framework for wider coordination on priority issues.

#### EDCTP TB vaccine studies

**MTBVAC-Newborns:** Phase IIa dose-defining safety and immunogenicity study of MTBVAC in newborns.

**POR TB:** Phase II efficacy trial of the multistage vaccine H56:IC31 for prevention of recurrent TB disease.

**priMe:** Phase III study of VPM1002 in comparison to BCG.

The project has been designed to complement other key global initiatives in TB vaccine development. It has taken as its starting point the three types of TB vaccine prioritised by WHO – for adults and adolescents, for neonates and infants, and a therapeutic vaccine – as well as their agreed preferred product characteristics. It has also adopted an ‘end-to-end’ perspective, considering all stages of clinical development

as well as issues related to post-licensing implementation, access and product availability.

Led by the Amsterdam Institute for Global Health and Development (AIGHD), the roadmap has been developed following extensive desk review and consultation with global stakeholders individually and collectively. In March 2020, a wide range of stakeholders gathered in Amsterdam, The Netherlands, to discuss and build consensus on the elements, challenges and objectives of the new roadmap.

Consultations through 2020 led to the development of a draft global roadmap, which was made available for public comment in December 2020. It lists both the short-term and long-term strategic objectives for global TB vaccine development, and focuses on developing and delivering affordable and effective vaccines for use in low-resource settings, where the vast majority of people affected by TB currently live.

The roadmap focuses on three priority areas: diversifying the product pipeline, accelerating clinical development, and ensuring public health impact. It also identifies three ‘enabling’ areas: funding, open science, and stakeholder engagement. The roadmap concludes with a section on the actions needed to ensure that commercialisation of vaccines and manufacturing capacity meet global public health needs.

After the public consultation, the roadmap will be finalised and shared among global stakeholders to guide their work, support more effective coordination of activities, and catalyse the development of further global partnerships.



## Regional disparities in research funding

*EDCTP is taking steps to understand and address geographical disparities in its funding across sub-Saharan Africa.*

Through its support of clinical trials and specific capacity-building funding, EDCTP has made major contributions to the health research base in sub-Saharan Africa. However, an analysis of funding from the first two EDCTP programmes has shown wide variation between countries in the numbers of applications and success rates.

In part, this is a consequence of EDCTP's commitment to scientific excellence. Poor quality research and innovation is wasteful and potentially dangerous, giving a misleading picture of the efficacy, effectiveness, and safety of interventions. Competitive calls and rigorous peer review is used to ensure high scientific standards.

However, this approach favours existing centres of excellence and disadvantages countries and institutions without a strong history of health research. These countries typically face major health challenges, and require tailored support to be able to develop their health research systems so that they can play a lead role in addressing their health challenges. Strengthening of health research systems can ensure they are more competitive when applying for funding from EDCTP and other agencies.

EDCTP has taken several steps to understand and address regional disparities. For example, one objective of the EDCTP Regional Networks of Excellence is to connect existing centres of excellence to less well-developed sites, building their physical infrastructure and connecting researchers to regional and global networks.

In addition, the Senior Fellowship Plus scheme provides an opportunity for Senior Fellows to mentor and oversee the work of a researcher at a less-established institution. The EDCTP Alumni Network also enables researchers to strengthen links with other colleagues in the region. Practical support for French-speaking and Portuguese-speaking researchers, who are underrepresented in EDCTP-funded projects, has been provided at several grant-writing workshops.

In 2020, EDCTP published a report of a workshop, organised in partnership with the Africa Centres for Disease Control and Prevention (Africa CDC), which explored the major causes of gender-related and geographical disparities in EDCTP funding. Participants made a number of recommendations on ways in which EDCTP could improve gender and geographical balance, several of which are already being implemented.

## EDCTP Knowledge Hub goes live

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*The EDCTP Knowledge Hub, an online platform providing multiple open-access resources for researchers conducting clinical research in low-resource settings, was launched in November 2020.*

To support its capacity-building activities, EDCTP has commissioned The Global Health Network (TGHN) to develop a digital knowledge hub to provide researchers with tools and guidance that enable them to undertake high-quality health research.

Following a landscape analysis of current resources and consultation with researchers in sub-Saharan Africa, TGHN identified key gaps in information provision. The EDCTP Knowledge Hub includes three key areas:

**Protocol Development Toolkit:** A step-by-step guide to developing a health research protocol, practical tools for producing a protocol and soliciting feedback from other Knowledge Hub users, plus advice on turning a protocol into a successful study.

**Data Management Portal:** Step-by-step guidance and tools, from preparing a data management plan to effective data management.

**Data Sharing Toolkit:** Practical tools and guidance to support the depositing and sharing of research data, including an online decision tree to help users select an appropriate repository.

These interactive and comprehensive toolkits are designed to cover the essential steps of a clinical health research study, from protocol development to gold-standard clinical data management practices, and appropriate data sharing. The EDCTP Knowledge Hub also provides access to free e-learning courses and webinars.

In November 2020, EDCTP and TGHN convened the first in a series of webinars to present and elicit feedback on the EDCTP Knowledge Hub. The webinar focused on data management and data sharing, and was attended by more than 650 participants from across the globe. The webinar included a live demo, as well as a panel of speakers who provided feedback, followed by an open conversation about users' experiences and issues related to increasing requirements for open-access data. A second webinar, focusing on protocol development, was held in February 2021.

The wider TGHN platform also includes areas dedicated to each of the four EDCTP Regional Networks of Excellence, the ALERRT and PANDORA-ID-NET epidemic-preparedness consortia, and the PediCAP trial.





## Global and regional partnering

*EDCTP is committed to working with like-minded organisations to ensure strategic alignment of activities and avoid duplication of efforts.*

EDCTP organises joint calls with partners, such as focused calls within its fellowship programme, and co-funding initiatives, where EDCTP funding is conditional on financial contributions from partners, including product development partnerships. These mechanisms leverage significant levels of additional external funding.

More generally, EDCTP has been building stronger relationships with bodies representing global funders, such as GloPID-R, and with key organisations with interests in health research in sub-Saharan Africa, including the Africa Centres for Disease Control and Prevention (Africa CDC) and the WHO Regional Office for Africa.

### Partnering with PDPs

*In 2020, multiple new EDCTP projects involving product development partnerships (PDPs) were launched, and EDCTP remains committed to working with PDPs at multiple levels.*

Globally, PDPs play a critical role in the development of medical interventions for poverty-related infectious diseases, where there are few incentives for commercial investment, as well as in the production of new formulations for underserved populations such as children. PDPs typically bring together the complementary expertise of academia, non-profit agencies, large pharmaceutical enterprises and small biotech companies to accelerate the development and implementation of new interventions.

PDPs are contributing to multiple EDCTP-funded projects. In 2020, for example, EDCTP and the Coalition for Epidemic Preparedness Innovations (CEPI) jointly awarded €22.9 million to the **LEAP4WA** phase IIb Lassa fever vaccine trial, which is being coordinated by **IAVI** and is evaluating an innovative new Lassa fever vaccine developed by a global consortium.

Other PDPs involved in EDCTP-funded projects launched in 2020 include **Medicines Development for Global Health (MDGH)**, a not-for-profit biopharmaceutical company developing products for use in low-resource settings. Through the **MiniMox project**, it is co-funding the development of a young children's formulation of moxidectin, a highly effective new drug protecting against onchocerciasis,

a parasitic disease causing river blindness. In addition, through the **ACOZI-KIDS study**, the **Drugs for Neglected Diseases initiative (DNDi)** is coordinating clinical studies to extend the use of acoziborole, a highly effective drug against sleeping sickness (human African trypanosomiasis, HAT), to young children. Newborn children are the likely beneficiaries of the **MTBVACN3 project**, which involves the **TuBerculosis Vaccine Initiative (TBVI)** as a partner and is evaluating MTBVAC, a potential alternative to BCG vaccine developed by an international public-private partnership.

Collectively, €30.1 million has been awarded to support participation of PDPs in 31 EDCTP projects, 11 of which are coordinated by a PDP. As well as the examples above, other PDPs involved in EDCTP-funded projects include the **Foundation for Innovative New Diagnostics (FIND)**: e.g. **RaPaed project**, evaluation of tools for diagnosis of TB in children), the **Medicines for Malaria Venture (MMV)**: e.g. **WANECAM-II**, evaluation of ganaplacide/KAF156) and the **European Vaccine Initiative (EVI)**: **ShigOraVax**, evaluation of a novel *Shigella* vaccine).

In a careful selection of cases, EDCTP enters into a more strategic funding relationship with PDPs, in which EDCTP typically contributes half the costs of a substantial programme of work. One example is the **PAMAfrica project**, to which EDCTP is contributing €22 million and **MMV** €19.9 million, which is supporting the development of promising antimalarial drugs in the MMV portfolio to address a range of unmet

needs. EDCTP has also provided €12 million to the **Simplici-TB study**, a global initiative managed by the **TB Alliance** that is aiming to develop simplified and shorter treatments for TB, with the TB Alliance contributing a further €20.4 million. Other strategic partnerships have been established with **FIND (CAP-TB**, performance of TB diagnostics in real-life settings) and **IAVI (GREAT**, HIV vaccine development).

EDCTP recognises the valuable contribution made by PDPs in developing interventions against poverty-related infectious diseases. It is committed to working collaboratively

with these partners, which play an essential role in enabling EDCTP to achieve its aims. EDCTP maintains regular dialogue with a range of PDPs and also participates in the **PDP Funders Group**, an informal network of public and private organisations providing financial support to PDPs. PDPs recognise the important strategic role of EDCTP in global health and have voiced strong support for the continuation of the EDCTP programme beyond EDCTP2.



## Strengthening African relations

*During 2020, EDCTP has been strengthening its relationships with key African organisations with an interest in infectious disease, health research and capacity building.*

EDCTP operates as a partnership of equals between African and European partners. It makes extensive efforts to ensure that its work is closely aligned with African priorities and advocates strongly for African ownership of health research in the region. In support of these principles, EDCTP has established strong working relationships with many of the key bodies in Africa with an interest in health, development and health research.

EDCTP has forged close links with the **African Union**, particularly the African Union Development Agency (AUDA-NEPAD). Under the umbrella of AUDA-NEPAD's African Medicines Vaccine Regulatory Harmonisation (AMRH) initiative, EDCTP has worked closely with the **African Vaccine Regulatory Forum (AVAREF)** and the **African Medicines Quality Forum**. EDCTP is a member of the AVAREF Technical Coordination Committee and its Steering Committee. EDCTP is represented in four of the five AMRH working groups.

In 2020, AVAREF conducted a digital survey of the state of regulatory activities and ethical review in Africa, which highlighted EDCTP's role in strengthening the capacity for ethics review in African countries. Of the 29 countries responding to the survey, 27 have received EDCTP support for strengthening of ethics review and regulatory capacity.

Since it was established in 2017, the **Africa Centres for Disease Control and Prevention** (Africa CDC) has become pivotal to infectious disease control on the continent. EDCTP has developed strong links to the Africa CDC, with close collaboration of responses to COVID-19. In February 2020, EDCTP participated in the Emergency Meeting of the African Ministers of Health on COVID-19 convened by Africa CDC, and in September 2020 EDCTP was invited to join the Steering Committee of the Africa CDC Consortium for COVID-19 Vaccine Clinical Trials (**CONCVACT**), established to accelerate progress on COVID-19 vaccine trials in Africa. EDCTP is also represented on Africa CDC's Africa Task Force for Novel Coronavirus (AFCOR), which was set up to oversee

preparedness and response to the COVID-19 pandemic and has been preparing various guidelines for African countries.

EDCTP and Africa CDC also launched a joint call in 2020 for institutions organising master's courses in epidemiology and biostatistics, in order to build regional capacity and enhance infectious disease surveillance and epidemic preparedness.

The **WHO Regional Office for Africa** (WHO-AFRO) is a further key strategic partner. EDCTP participates in the annual meetings of WHO's African Advisory Committee on Health Research and Development (AACHRD) and WHO-AFRO has an observer position on the EDCTP Scientific Advisory Committee and its General Assembly.

EDCTP has been working with WHO-AFRO since 2018 to further develop national health research systems in sub-Saharan Africa. In 2020, EDCTP published a roadmap for strengthening such systems in EDCTP participating states, based on a survey conducted with WHO-AFRO in 2018. A second survey was developed and launched in November 2020.

In June 2020, EDCTP signed a memorandum of understanding with WHO-AFRO that formally established a framework of cooperation. Joint activities will focus on strengthening of national health research systems, optimisation of regulatory systems, and development of technical expertise in clinical trials research and product development.

Relationship building in Africa is aided by EDCTP's office in South Africa, as well as the work of its High Representative, Dr Leonardo Simão, whose role includes engaging with governments in the region to encourage greater interest in health research and EDCTP activities. In June 2020 Dr Simão spoke at a virtual conference on Africa's Leadership Role in COVID-19 Vaccine Development and Access hosted by Africa CDC and presided over by the Chairperson of the African Union, HE President Cyril Ramaphosa and the Chair of the African Union Commission, HE Moussa Faki Mahamat.

## Fondation Botnar partnership

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*EDCTP has established a new partnership with Fondation Botnar, a Swiss-based foundation that champions the use of AI and digital technology to improve the health and wellbeing of children and young people in growing urban environments around the world.*

In 2020, EDCTP teamed up with **Fondation Botnar** and **Novartis** to launch a research capacity development initiative within the framework of the EDCTP's career development fellowship programme. The initiative aims to build capacity for research on child and adolescent health, including interactions between poverty-related infectious diseases and non-communicable diseases.

Following an open call for proposals in 2020, funding was agreed in principle for 25 fellows. Fondation Botnar is contributing €1.5 million to support 15 fellows and Novartis is providing €0.75 million for a further five fellows; EDCTP is funding the remaining 10 fellows, through a contribution of €1.5 million.

The foundation's contribution aims to address the shortage of suitably trained early- to mid-career paediatric researchers in sub-Saharan Africa. It has a special interest in improving the mental health and nutrition of adolescents affected by poverty-related infectious diseases, particularly by harnessing emerging digital technologies.





## EDCTP3 gets green light

*In 2020, the European Commission announced plans for a successor to the EDCTP2 programme – the Global Health EDCTP3 Joint Undertaking.*

The EDCTP2 programme is due to end in 2024. The final major calls for proposals were launched in 2020, to allow time for studies to conclude by 2024. However, it is well recognised that the goals of EDCTP are long term, and that continuing efforts are required to advance the clinical development of interventions for poverty-related infectious diseases in sub-Saharan Africa and to build the region's clinical research capacity.

To provide a seamless transition between programmes, the Global Health EDCTP3 Joint Undertaking will be launched in 2022. The Global Health EDCTP3 programme will build and expand the foundation laid by the first two EDCTP programmes. It will continue to focus on poverty-related infectious diseases and be rooted in the power of partnerships, but it will have additional resources and will aim for still greater strategic alignment with other bodies active in the field of global health and development.

EDCTP3 will also retain its focus on special populations, particularly infants, children, adolescents and pregnant women. To accelerate the introduction of new medical interventions, it will have a stronger emphasis on later-stage phase III and IV trials and product-focused implementation research. With infectious disease typically associated with multiple co-morbidities, including non-communicable diseases, integrated patient-centred care will be an important driver of interdisciplinary research – particularly studies that aim to harness the power of new digital technologies to enhance integrated patient care.

Preparedness for emerging and re-emerging infections will also be a major focus, again building on EDCTP2 activities. In addition, the Global Health EDCTP3 programme will address the growing threats of antimicrobial resistance and climate crises, which are likely to have multiple impacts on infectious disease in the region.

Capacity-building will continue to be a central pillar in the Global Health EDCTP3 programme. This will include the technical infrastructure needed to carry out high-quality clinical and associated laboratory research, as well as the wider aspects of capacity-building needed to strengthen national health research systems, such as ethical review and regulatory capacity. The development of research skills and scientific leadership will be a high priority, with particular attention being given to women in science and countries with less well-developed science bases.

The new programme is one of ten new flagship partnerships announced by the European Commission in 2020, highlighting the strategic importance attached to the Global Health EDCTP3 by the European Union. The Global Health EDCTP3 will be the focal point for European investments in research targeting poverty-related infectious disease in sub-Saharan Africa, and will work closely with other global players to address these challenges and build a healthier world for all.



## 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](http://www.edctp.org).

### Mandated representative entity

	<b>Angola (Aspirant member)</b> National Institute of Public Health
	<b>Austria</b> Medical University of Vienna
	<b>Burkina Faso</b> Centre National de Recherche et de Formation sur le Paludisme
	<b>Cameroon</b> Ministry of Public Health
	<b>Congo</b> University Marien Ngouabi
	<b>Denmark</b> Statens Serum Institute
	<b>Ethiopia</b> Armauer Hansen Research Institute
	<b>Finland</b> Academy of Finland
	<b>France</b> Aviesan, Institut thématique multi-organismes
	<b>Gabon</b> Centre de Recherches Médicales de Lambaréné
	<b>The Gambia</b> Ministry of Health and Social Welfare
	<b>Germany</b> Bundesministerium für Bildung und Forschung
	<b>Ghana</b> Ghana Health Service
	<b>Ireland</b> Irish Health Service Executive
	<b>Italy</b> Istituto Superiore di Sanità
	<b>Luxembourg</b> Fonds National de la Recherche
	<b>Mali</b> University of Science, Techniques and Technology of Bamako
	<b>Mozambique</b> Ministry of Health
	<b>Netherlands</b> NWO-WOTRO Science for Global Development
	<b>Niger</b> 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 Cooperation Agency
-  **Switzerland (Aspirant member)**  
Swiss Tropical and Public Health Institute
-  **Tanzania**  
Tanzania Commission for Science and Technology
-  **Uganda**  
Uganda National Health Research Organisation
-  **United Kingdom**  
Medical Research Council
-  **Zambia**  
Ministry of Health



Members of the EDCTP  
General Assembly

## Summary financial statements 2020

### Statement of profit or loss and other comprehensive income

for the year ended 31 December 2020. Expressed in thousands ('000) of euro.

	EC 2020	Donor 2020	Total 2020	Total 2019
<b>Calls (Grants)</b>				
Contributions	111,067	33,828	144,895	214,676
Grant expenditure	(111,067)	(33,828)	(144,895)	(214,676)
Results for the year	-	-	-	-
<b>Others</b>				
Contributions	5,740	841	6,581	7,484
Other expenditure	(5,740)	(841)	(6,581)	(7,484)
Results for the year	-	-	-	-
<b>Total results for the year</b>	-	-	-	-

The 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](http://www.edctp.org).

## Statement of financial position

as at 31 December 2020 (after appropriation of result). Expressed in thousands ('000) of euro.

	31 December 2020	31 December 2019
<b>Non-current assets</b>		
Right-of-use assets	1,590	-
Debtors and other receivables	154,844	151,450
<b>Total non-current assets</b>	<b>156,434</b>	<b>151,450</b>
<b>Current assets</b>		
Debtors and other receivables	74,769	39,031
Cash and cash equivalents	79,884	114,393
<b>Total current assets</b>	<b>154,653</b>	<b>151,424</b>
<b>Total assets</b>	<b>311,087</b>	<b>304,874</b>
<b>Non-current liabilities</b>		
Grants and other payables	174,858	197,486
Deferred income EC	-	-
Deferred income Donor	-	1,479
Lease liabilities	1,395	-
<b>Total non-current liabilities</b>	<b>176,253</b>	<b>198,965</b>
<b>Current liabilities</b>		
Grants and other payables	128,006	+86,201
Deferred income EC	-	-
Deferred income Donor	6,633	19,708
Lease liabilities	195	-
<b>Total current liabilities</b>	<b>134,834</b>	<b>105,909</b>
<b>Total liabilities</b>	<b>311,087</b>	<b>304,874</b>

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
<b>Balance as at 31 December 2019</b>	-	-	-
Total comprehensive income for the year	-	-	-
<b>Balance as at 31 December 2020</b>	-	-	-

EDCTP has no unrestricted reserves.

## Statement of cash flows

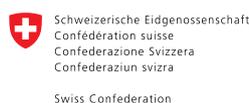
for the year ended 31 December 2020. Expressed in thousands ('000) of euro.

	2020	2019
<b>Cash flows from operating activities</b>		
Result for the year	-	-
Adjustment for:		
Depreciation charge for right-of-use assets	167	-
Lease interest	53	-
Reversal of depreciation and lease interest	(25)	-
(Increase) decrease in debtors and other receivables	149	(10)
Increase (decrease) in grants and other payables	19,177	108,245
Increase (decrease) in deferred income	(53,656)	(111,707)
<b>Net cash flows from operating activities</b>	<b>(34,135)</b>	<b>(3,472)</b>
<b>Cash flows from investing activities</b>		
Interest received/(paid)	(179)	3
Payment of lease liabilities	(195)	-
<b>Net cash flows from investing activities</b>	<b>(374)</b>	<b>3</b>
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>(34,509)</b>	<b>(3,469)</b>
Cash and cash equivalents at 1 January	114,393	117,862
Exchange rate effects		
<b>Cash and cash equivalents at 31 December 2020</b>	<b>79,884</b>	<b>114,393</b>



## Acknowledging our funders

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Swiss Confederation  
Federal Department of Economic Affairs,  
Education and Research EAER  
State Secretariat for Education,  
Research and Innovation SERI



# Colophon

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## European & Developing Countries Clinical Trials Partnership

The Hague, the Netherlands, May 2021

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*The power of sharing science*