



EDCTP

The power of sharing science

Annual Report 2022



About EDCTP

The European & Developing Countries Clinical Trials Partnership (EDCTP) is a public–public partnership between 15 European and 25 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: ANRS | Maladies infectieuses émergentes (France), Botnar Research Centre for Child Health (BRCCCH, Switzerland), Bundesministerium für Bildung und Forschung (BMBF, Germany), Calouste Gulbenkian Foundation (Portugal), Coalition for Epidemic Preparedness Innovations (CEPI, Norway), 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 et de la Recherche (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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Strengthening Europe–Africa relations

The progress made in EDCTP2 has provided an excellent foundation for its successor, the Global Health EDCTP3 Joint Undertaking, to maintain and strengthen collaboration and cooperation between Europe and Africa in global health research.

The independent evaluation of EDCTP2 carried out in 2022 emphasised that the programme has evolved into a globally significant player in global health research. As well as the importance of the research funded through EDCTP2, much of which will have major implications for the future health of sub-Saharan Africa, the way that EDCTP2 operates is also worthy of comment. EDCTP2 strives to be an example of an equitable North–South partnership, in which partners from the South and the North make strategic decisions and set priorities together.

This Annual Report outlines some of the recent achievements of EDCTP2 and the projects that it supports. As many projects are still ongoing, this list will undoubtedly still grow further in the future. European and African Member States are to be congratulated on the support they have been providing to EDCTP2, which is enabling truly remarkable things to happen.

The complete EDCTP2 portfolio consists of centrally managed grants and participating states-initiated activities (PSIAs) – grants awarded by individual member countries

that are aligned with EDCTP2 strategic objects and often have a direct connection with EDCTP2 centrally managed grants. This strong alignment enables still greater impact by focusing on shared goals and building on past investments. The EDCTP2 response to COVID-19 was one in which Member States played a critical role. Recent years have seen a growing emphasis on the search for such synergies through PSIAs. This strategic programme approach remains a priority for the future and will be continued as in-kind contributions to additional activities.

The activities of EDCTP2 since 2014, with a portfolio of more than 400 grants, has created new partnerships, greater awareness, and a set of priorities that can be taken forward in the successor to EDCTP2, the Global Health EDCTP3 Joint Undertaking. EDCTP3 was formally launched in May 2022, alongside its first calls for proposals. As many EDCTP2 grants remain active, the two programmes will initially run side by side. The Global Health EDCTP3 Joint Undertaking is administratively a separate legal entity but the two organisations remain in close contact, ensuring a joined-up approach and a smooth transition to funding through new EDCTP3 mechanisms.

It only remains for me to thank my predecessor, Professor Yazdan Yazdanpanah, for the excellent job he performed as previous Chair of the EDCTP General Assembly. It is a great honour to be taking up this position during this unique period and in advance of the Eleventh EDCTP Forum and 20th anniversary event, which will take place in Paris, France, in November 2023. The Forum theme is ‘Partnering for Global Health Research Innovation and Impact in Africa – Celebrating EDCTP: two decades and beyond’, and will focus on both EDCTP2 and EDCTP3. As this Annual Report confirms, there is much to celebrate, and much to look forward to.

Dr Henning Gädeke
Chair, EDCTP Association Board





Demonstrating impact

Now in its ninth year, EDCTP2 has adhered to its strategic vision, and is delivering significant impact on poverty-related diseases and clinical research capacity in sub-Saharan Africa.

Launched in 2014, EDCTP2 set itself challenging targets in its efforts to advance the development of medical interventions against poverty-related infectious diseases affecting sub-Saharan Africa, while simultaneously strengthening clinical research capacity in the region. As we reach the nine-year mark, it is a timely moment to take stock and consider how EDCTP2 investments – €824 million to date – are contributing to the fight against poverty-related infectious diseases, now and into the future.

It was pleasing to read the second interim evaluation of the EDCTP2 programme, undertaken by an independent review panel in 2022. The evaluation concluded that EDCTP2 is now “well-established and recognised globally”, with EDCTP2 now “one of the most prominent funders of clinical studies in sub-Saharan Africa”. In several areas, EDCTP2 is one of the foremost global funders of clinical research and associated capacity development.

It has achieved this position by being very intentional and strategic in its funding and by adhering closely to a core set of principles, laid out in the EDCTP2 Strategic Business Plan, which have enabled EDCTP2 to carve out a unique niche in the global health research landscape. In each of these seven areas, EDCTP2 has made substantial progress over the past nine years.



A key contributor to EU–Africa partnerships:

EDCTP has become the focal point of EU activities relating to poverty-related infectious disease research. Moreover, EDCTP2 provides a model for the organisation of highly productive partnerships between the two regions. This function was acknowledged in the recommendations made by the **Advisory Group on Research and Innovation (R&I) for Africa–Europe Cooperation** in February 2022, which highlighted the role played by EDCTP in strengthening capacity in Africa and described EDCTP2 as “the most cited joint programme strengthening health research and health systems in Africa and the flagship EU-Africa partnership in health R&D cooperation, with large successful, long-lasting research networks”.

In addition, the multi-annual strategic research agendas developed by EDCTP2 provide a framework for alignment of centrally managed activities across member states. By pooling resources, member states can achieve substantially more than they could by acting independently. Participating states-initiated activities (PSIAs), are country-funded activities that align with EDCTP2 goals and objectives and, alongside centrally managed grants, make a major contribution to the wider EDCTP2 portfolio of projects.

Collectively, these projects are making a key contribution to the twin aims of EDCTP2 – to advance the development and implementation of new medical interventions against poverty-related diseases and to build the health research capacity of countries in sub-Saharan Africa. EDCTP2's impact has been based on its ability to catalyse the formation and strengthening of **international partnerships** between institutions in Europe and sub-Saharan Africa, and increasingly with input from additional countries, and encompassing both academic institutions and product development partnerships.

Neglected populations: EDCTP2 has had a strong focus on populations that are typically excluded from clinical trials, such as infants, children, adolescents, pregnant women, and people with co-infections and co-morbidities. Of the clinical studies funded through EDCTP2, 14% involve pregnant and lactating women and their offspring, 26% involve new-borns and

infants, and 35% involve children as well as adolescents.

For young children, important examples include the development of arpraziquantel for pre-school-aged children through the **PZQ4PSAC** and **ADOPT** projects (see page 30), acoziborole for human Africa trypanosomiasis through the **ACOZI-KIDS** project, and several projects aiming to extend antimalarial use to paediatric populations (**PAMAFRICA**, **DPP**, **WANECAM2**). Additional projects are testing new regimens and formulations of antiretrovirals for children (e.g. **CHAPAS 4**, **UNIVERSAL**). Two projects, **PediCAP** and **EMPIRICAL**, are testing interventions to improve the treatment of pneumonia in children in the community and in hospitals (see page 36). The **RaPaed TB** study explored a range of new tools for diagnosing TB in children.

Multiple projects are enrolling pregnant and lactating women into trials. These include studies evaluating antimalarials (e.g. **MAMAH**, **IMPROVE**, **IMPROVE-2** and **PYRAPREG** projects) and interventions to increase uptake and coverage of preventive malaria therapy in pregnancy (**Revive IPTp**). New approaches are being explored for HIV prevention in women, including broadly neutralising antibodies (**CAP012 SAMBA** project), and behavioural studies of attitudes to pre-exposure prophylaxis (**UPTAKE**). The **PREGART** project is testing antiretroviral regimens for prevention of mother-to-child transmission and treatment of HIV-infected pregnant and breastfeeding women. The **PREPARE** study is speeding up the development of vaccines that protect women, newborns and young infants against group B streptococci.

For adolescents, the **CHAPS** study is focusing on pre-exposure prophylaxis in male and female adolescents (see page 28), while the **BREATHER-PLUS** project is evaluating alternative treatment regimens for adolescents on antiretroviral therapy.

Co-infections are a particular issue for people living with HIV. The **AMBITION-cm** trial has delivered critical evidence on the benefits of a new treatment for cryptococcal meningitis, one of the most common causes of death of people with HIV infections (see page 26). The **DATURA** study is investigating whether intensified treatment of TB can reduce alarmingly high mortality rates in people living with HIV (see page 21).

Implementation research and uptake:

Although the demonstration of safety and efficacy in clinical trials is essential, it does not guarantee the introduction and uptake of new

interventions. Additional data may be required by policymakers and implementation research studies may be needed to identify the most effective strategies and delivery systems of new interventions. In recognition of this critical gap, EDCTP2 also supports preparatory and implementation activities, including product-focused implementation research.

Notable examples include the **ADOPT** study, which is laying the ground for introduction of arpraziquantel for pre-school-aged children (see page 30), and the **DREAMM** project, focused on new approaches for diagnosis and clinical management of central nervous system infections, such as cryptococcal meningitis, in people living with HIV. In addition, the **LeishAccess** project is working with ministries of health to promote greater use of *Leishmania* treatments, including a new therapy evaluated through the **AfriKADIA** project (see page 31). The **PEP4LEP** project is comparing two strategies to prevent transmission of leprosy within affected households (see page 32).

This area of work also provides opportunities to explore synergies with bodies working on complementary areas of development assistance. For example, two joint calls on strengthening of health systems and maximising the impact of research on reducing disease burdens leveraged an additional €23 million from bodies including Gavi, the Vaccine Alliance and the US Agency for International Development (USAID).

Focus on clinical challenges and policy-relevant activities:

Through extensive consultations, EDCTP2 ensures that its annually calibrated strategic research agendas reflect the priorities of sub-Saharan African countries, and that research studies address questions of direct relevance to policy and practice in the region.

Important examples in recent years have included funding of a phase II study of the **R21/Matrix-M** malaria vaccine, the first to achieve the WHO target of 75% efficacy. With the initial results of the phase III trial reported at the American Society of Tropical Medicine and Hygiene meeting in November 2022, the vaccine has already been approved by some sub-Saharan Africa countries, and looks likely to have a huge impact on malaria prevention when introduced.

Although most EDCTP2 projects are still ongoing, some have already delivered results that have influenced global or national policy. These include the **AMBITION-cm** study, the results of which triggered a rapid update to WHO guidance (see page 26), while the **AfriKADIA** project is in discussion with the

WHO Guidelines Development Group for visceral leishmaniasis (see page 32). In malaria, the latest WHO guidelines make a strong recommendation for the use of pyronaridine–artesunate (**Pyramax**), for which key data were generated by EDCTP-funded networks (see page 23).

In September 2022, EDCTP organised a side event at the Science Summit of the **77th United Nations General Assembly (UNGA77)**, showcasing examples where EDCTP-funded projects had generated data that informed local and national guidelines. The event also provided an opportunity to highlight the importance of international partnerships to catalyse collaborative research focused on nationally and globally significant threats to health.

Enhancing research capacity: Activities to build research capacity in sub-Saharan Africa are integrated within clinical studies. In addition, the EDCTP2 programme also includes specific capacity-building grants schemes. The value of this approach was demonstrated during the COVID-19 pandemic, when research capacity could rapidly pivot to work on this new threat to health. Several projects added COVID-19-related activities to their existing work, while EDCTP-funded fellows made major contributions to COVID-19 responses in many sub-Saharan African countries.

The EDCTP2 **fellows programme** has played a vital role in building intellectual capacity in sub-Saharan Africa. A report published in 2022 summarised the programme since its launch in 2003, during which time EDCTP has invested €63.0 million through fellowship programmes, providing support for more than 400 fellows, including nearly 100 Senior Fellows, working in 40 sub-Saharan Africa countries. As those mentored by EDCTP fellows go on to supervise and support a new generation of researchers, fellows have a critical ‘multiplier’ function in developing research capacity.

As well as people and physical infrastructure, wider **health research ecosystems** also need to be strengthened to ensure that clinical research can be safely and ethically carried out, and new interventions monitored effectively when introduced. EDCTP2 has supported capacity-building activities related to **ethics review** and **national regulatory functions** in 37 countries. Projects have had a strong focus on developing the capacity and networking of national and institutional ethics committees, to ensure protection of participants’ interests in clinical research studies (see page 42). Consideration of gender-related issues has been a focus of several

grants. In terms of regulatory strengthening, drug-safety monitoring has been a high priority (see page 46).

Through these activities, EDCTP2 has been building capacity at individual, institutional and national levels. A joint project with WHO is monitoring national health research capacity, with recent results providing encouraging signs of improvement in overall capabilities in multiple countries.

Partnerships: Partnerships lie at the core of EDCTP’s work. These include partnerships with funders, one example being the joint work with the Global Health Innovative Technology Fund (GHIT) on the development of apraziquantel for pre-school-aged children. In all, EDCTP2 has leveraged financial contributions of €434 million (total cash and in kind) from global partners.

EDCTP has also signed memoranda of understanding with key bodies in sub-Saharan Africa, including the **WHO Regional Office for Africa**, the **African Union** and the **Africa Centres for Disease Control and Prevention (Africa CDC)**. A partnership with the latter has seen more than 150 new fellows undergo Master’s training in epidemiology and biostatistics, greatly enhancing the region’s ability to monitor and respond to infectious disease threats (see page 38).

Partnership of equals: Most importantly, EDCTP2 itself operates as a partnership of equals between European and African partners. The latter are fully involved in the governance and priority setting of EDCTP2, ensuring that its activities are tightly focused on the needs of the region.

Our grants portfolio has expanded to 438 grants supporting projects in 44 sub-Saharan African countries. More than 300 African and 200 African institutions are participating in EDCTP-funded projects. These numbers emphasise how embedded EDCTP2 has become in the global health arena. Most importantly, however, is the sustainable impact being achieved in these countries, in terms of strengthened national health research systems able to plan, execute and oversee high-quality clinical research, and the advancement of novel medical interventions to address the region’s unmet medical needs.

Dr Michael Makanga
Executive Director, EDCTP2



2022 in a nutshell

Great progress has been made in 2022
in key areas of EDCTP interest:



Involvement of priority populations:

Of the clinical studies funded through EDCTP2, 14% involve pregnant and lactating women and their offspring, 26% involve new-borns and infants, and 35% involve children as well as adolescents. Key developments in 2022 include exciting progress in **malaria vaccine development** (page 22), developing arpraziquantel for **prevention of the parasitic infection schistosomiasis** in pre-school-aged children (page 30), **catching missed HIV infections in infants** (page 27) and probing **adolescent attitudes to pre-exposure prophylaxis** (page 28).



Impact on policy and practice:

The first countries have approved the **malaria vaccine R21/Matrix-M** (page 22), AMBITION-cm findings on **cryptococcal meningitis** treatment have led to an updating of WHO treatment guidelines (page 26), and AfriKADIA results on **visceral leishmania** are likely to have similar impact in 2023 (page 31).



Advancement of medical interventions:

EDCTP2 funding will advance a new antimalarial, **ganaplacide**, from phase II to phase III trials (page 24), generate phase IIb data to move **ETVAX**, a vaccine against enterotoxigenic *E. coli* (ETEC), to a phase III trial, and provided key phase IIb data on **R21/Matrix-M**, leading to investment in a phase III trial by a vaccine manufacturer.



Support for COVID-19 research:

EDCTP2-funded projects have generated key evidence on the **circulation of SARS-CoV-2 virus and its variants** in multiple sub-Saharan African countries, data on **immune responses** in African populations, and information on the **performance of diagnostics tests** (page 34).



Fellowship programme:

EDCTP2 Senior Fellows have made major contributions in areas such as understanding the **immune response to the malaria parasite** and **molecular characterisation of TB** (page 39), while Career Development Fellows have explored **drug–drug interactions in HIV-positive women**, long-term responses to **oral cholera vaccine**, and use of **primaquine** to prevent malaria transmission.



Ethics and regulatory capacities:

Highlights from 2022 include multiple activities to **strengthen ethics review capacities** in West Africa (page 42) and Portuguese-speaking countries, as well as **regulatory capacity** in Ghana (page 44) and Cameroon (page 46).



Pharmacovigilance capacities:

Two EDCTP2-funded projects have had a significant impact on **reporting of adverse events** in Tanzania (page 46).



Collaborative regional research networks:

The pandemic preparedness network **PANDORA-ID-NET** has made major contributions to COVID-19 projects on SARS-CoV-2 epidemiology and diagnostics (page 35).



Cooperation with African member states:

More than 150 fellows have received funding towards **Master's training in epidemiology and biostatistics** through a partnership with the Africa Centres for Disease Control and Prevention (Africa CDC), creating a new generation of experts contributing to the mapping and response to new infectious disease threats in sub-Saharan Africa. In addition, five additional African countries have joined the **EDCTP Association** – Côte d'Ivoire, Democratic Republic of the Congo, Guinea-Conakry, Kenya and Rwanda.



European coordination:

Closer integration of centrally managed EDCTP2 grants and **participating-states initiated activities (PSIAs)** is reflected in projects that have facilitated the development of a new TB drug, **BTZ043**, as well as large-scale EDCTP2 funding for follow-up of the **PREVAC PSIA-funded Ebola vaccine study** (page 35).



External partnerships and EU development cooperation:

A partnership with the Japan-based **Global Health Innovative Technology (GHIT)** fund is advancing development and implementation of arpraziquantel for prevention of parasitic infections in pre-school-aged children (page 30), while two dedicated calls leveraged €23 million in **co-funding from international organisations**.

Towards EDCTP's objectives

(2014-2022)



Medical interventions

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

375

clinical studies supported by EDCTP2 since 2014. Of these, 60% (225) are interventional (clinical trials) and 40% (150) are non-interventional studies.

63% (98)

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% (24)

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.

14% (49)

of all studies target pregnant women and their children. Other key populations are also involved in the studies, such as newborns and infants (91, 26%), children (123, 35%) and adolescents (125, 35%).

38

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

44

sub-Saharan African countries participate in EDCTP projects involving 309 African organisations.

37

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

206

fellowships have been awarded that focus on the career development of researchers from 24 sub-Saharan African countries.

921

trainees from 36 sub-Saharan African countries are supported through EDCTP projects. Trainees include 375 Master's (40%) and 354 PhD students (39%).

21

sub-Saharan African countries are members of the EDCTP Association by the end of 2022.



European coordination

Improve coordination, alignment and integration of European National Programmes.

15

European countries are members of the EDCTP Association.

€194.76 M

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

€1.157 Bn

committed through 439 Participating States' Initiated Activities (PSIAs) submitted by the European Participating States as part of the EDCTP2 annual work plans (2014-2020).



External partnerships

Increase international cooperation with public and private partners.

71

countries participate in EDCTP-funded activities: 44 sub-Saharan African and 19 European countries as well as 8 others.

538

institutions are involved in EDCTP projects, including 309 sub-Saharan African institutions, 210 European institutions, and 12 institutions from other countries.

15% (347 of 2,304)

of all participation in EDCTP-funded projects involve private-sector institutions. These institutions were awarded €177.51 M by EDCTP in 2022.

€26.84 M

has been leveraged from partners for the launch of joint or coordinated calls for proposals.

€407.21 M

has been leveraged (cash and in-kind) as co-funding to EDCTP projects through the EDCTP strategic calls for proposals, and other EDCTP projects.



EU cooperation

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

4

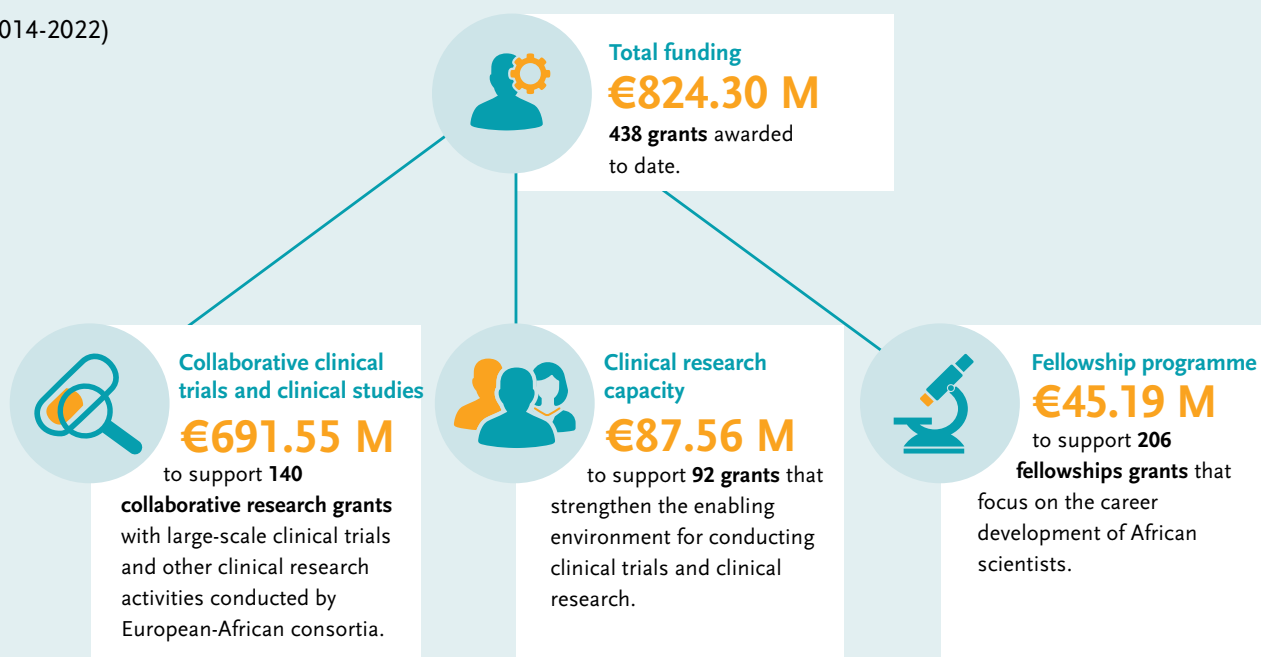
calls have been launched targeting development cooperation initiatives and involving 11 projects with development cooperation partners and co-funders.

€23.15 M

in co-funding has been secured through two dedicated calls requiring collaboration with development cooperation initiatives, with co-funding from Sida, USAID, Gavi, The Global Fund, UNITAID, AECID and Médecins Sans Frontières.

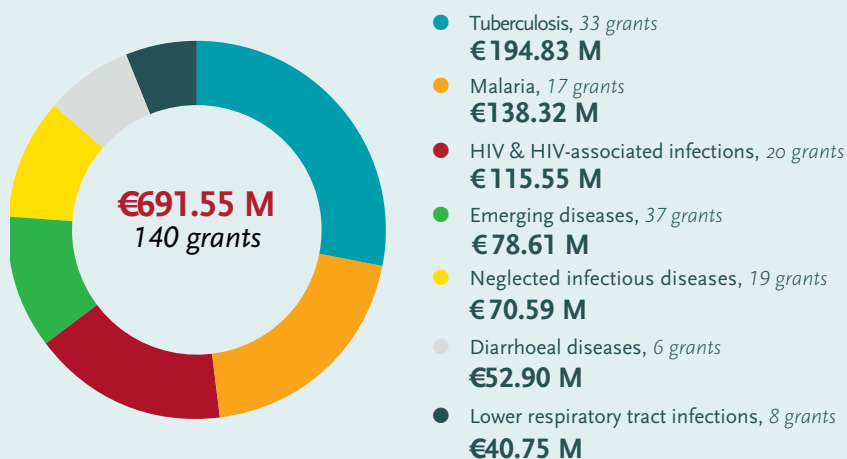
EDCTP's funding of research and capacity development

(2014-2022)

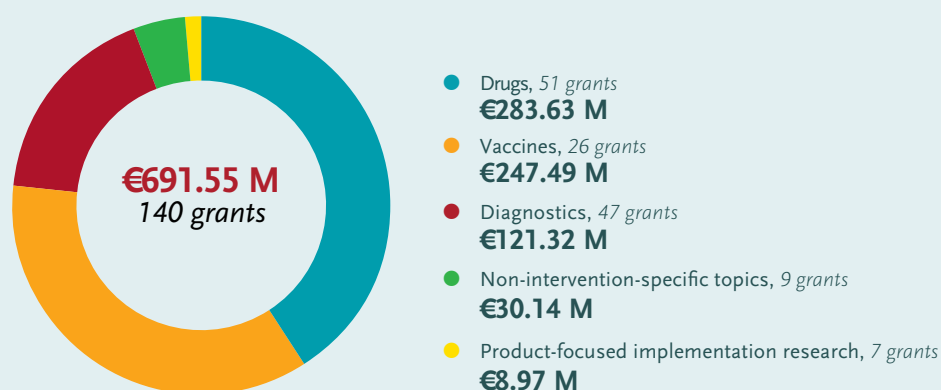


Collaborative clinical trials and clinical studies

By disease



By intervention





W. Clive Beck, MD, MPH
Pathologist

David Gaffner
School of Medicine

EMERGENCY ROOM ORDER
PATIENT INFORMATION: NAME: [REDACTED] DOB: [REDACTED]
DATE OF BIRTH: [REDACTED] SEX: [REDACTED]
ADMISSION DATE: [REDACTED] ADMISSION TIME: [REDACTED]
ADMISSION LOCATION: [REDACTED]
ADMISSION SOURCE: [REDACTED]
ADMISSION REASON: [REDACTED]
ADMISSION STATUS: [REDACTED]
ADMISSION TYPE: [REDACTED]
ADMISSION UNIT: [REDACTED]
ADMISSION WARD: [REDACTED]
ADMISSION ROOM: [REDACTED]
ADMISSION FLOOR: [REDACTED]
ADMISSION BUILDING: [REDACTED]
ADMISSION HOSPITAL: [REDACTED]

EDCTP2 on track

EDCTP2 is achieving its objectives and is now a well-established part of the global health research ecosystem, a second interim independent evaluation has concluded.

In 2022, an independent review panel published the results of a second interim evaluation of the EDCTP2 programme, covering the period 2017–2021. Overseen by the European Commission, the evaluation focused on five key aspects – relevance, coherence, efficiency, effectiveness and EU added value.

The evaluation concluded that EDCTP2 is now well-established and recognised globally. It remains highly **relevant**, in large part due to its sensitivity to stakeholder needs and their involvement in priority setting, including annual Strategic Research Agendas. It has also demonstrated its adaptability, rapidly responding to new outbreaks and pandemics affecting sub-Saharan Africa.

Moreover, it has recognised the need to combine evidence generation to advance new medical interventions with capacity-building to provide a more solid foundation for clinical research in sub-Saharan Africa and the implementation of new interventions.

In terms of **coherence**, the evaluation noted that EDCTP2 has established a clear niche, with a particular focus on late-stage trials and product-focused implementation research, as well as populations typically excluded from clinical trials, including infants, children, adolescents, pregnant women, and people living with co-infections and co-morbidities. The alignment between centrally managed EDCTP2 projects and participating states-initiated activities (PSIAs) promotes further coherence. Recently, adoption of a portfolio approach, in areas of particular strength such as malaria drug development and TB vaccine development, has yielded additional benefits in terms of coherence.

The independent review panel also suggested that EDCTP2 is **efficiently run**, with satisfactory ratings for key performance indicators. It noted that EDCTP2 had successfully addressed the issues raised in the first interim evaluation.

In terms of **effectiveness**, the evaluation concluded that “EDCTP2 has emerged as one of the most prominent funders of clinical studies in sub-Saharan Africa in recent years”. It described its contribution to specific disease areas as “considerable”, noting in particular the extent of its funding in TB and in malaria, where EDCTP2 has been recognised twice in WHO World Malaria Reports. The evaluation also praised EDCTP2’s extensive efforts to build partnerships with global actors and those in sub-Saharan Africa.

Finally, for **added value**, the evaluation concluded that EDCTP2 is having a significant impact, enabling the implementation of projects on a scale, scope and timeframe that would not be possible without its financial and other types of contributions. The programme demonstrates additionality by being able to leverage further funding from private and public sources and by facilitating the development of research networks in sub-Saharan Africa. Overall, it considered EDCTP2 to be an open and transparent partnership.

Please visit the [EDCTP website](#) to download the second interim evaluation.

First 20 years of the EDCTP fellows programme

EDCTP has published a report summarising the first 20 years of the EDCTP fellowship programme, its scientific achievements and its contribution to capacity-building in sub-Saharan Africa.

From its launch in 2003, EDCTP has had a strong focus on capacity-building. This has included a comprehensive fellowship programme, initially focused on Senior Fellowships but later expanding to all stages of a research career.

In 2022, EDCTP published a [summary of the fellowship programme from 2003 to 2022](#). In this period, EDCTP invested €63 million through fellowship programmes for researchers from sub-Saharan Africa, providing support for more than 400 fellows, including nearly 100 Senior Fellows, working in 40 sub-Saharan Africa countries.

Fellowship schemes have helped to **build scientific leadership** within individual countries

and the region as a whole, and enabled fellows to **leverage substantial additional funding**, including more than €20 million of grants in 2021 alone. Furthermore, EDCTP fellows have mentored and supervised more than 400 up-and-coming researchers, helping to **strengthen the pipeline of scientific talent** in the region. As those mentored by EDCTP fellows go on to supervise and support a new generation of researchers, fellows have a critical ‘multiplier’ function in developing research capacity.

The report also provides numerous examples where fellows have led or contributed to projects closing important gaps in knowledge relating to poverty-related infectious diseases affecting sub-Saharan Africa.

By helping to build intellectual capital in health research, EDCTP is ensuring that sub-Saharan Africa is in a position to fully address its current and future health challenges and be in control of its own destiny.

EDCTP3 formally launched

The Global Health EDCTP3 Joint Undertaking was formally launched in 2022 and issued its first calls for proposals.

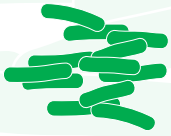
The successor to EDCTP2, the **Global Health EDCTP3 Joint Undertaking** (GH EDCTP3 JU), held its launch event in May 2022. The GH EDCTP3 JU is a partnership between the EU and the EDCTP Association. The meeting was a hybrid event hosted in-person by ANRS Emerging Infectious Diseases in Paris, France.

At the same time, the GH EDCTP3 JU published its [Work Programme 2022](#) and launched its first calls for proposals. Initial themes included strengthening regulatory capacity for supporting conduct of clinical trials; promoting implementation of research results into policy and practice; creating a sustainable clinical trial network for infectious diseases in sub-Saharan Africa; implementing adaptive platform trials,

and genomic epidemiology for surveillance and control of poverty-related and emerging/re-emerging infections in sub-Saharan Africa.

GH EDCTP3 JU also organised an [information day for potential applicants](#) in June 2022.

During 2022, the GH EDCTP3 JU also established its **Stakeholders Group**, which is regularly informed of the activities of the GH EDCTP3 JU and is invited to provide comments on the JU’s planned activities. The Group has a balanced representation of stakeholders from a geographic, thematic and gender perspective, including significant African expertise.



Tuberculosis

Tuberculosis (TB) remains the bacterial pathogen responsible for the greatest burden of disease, causing well over a million deaths every year. Control of TB has been set back markedly by the COVID-19 pandemic, and drug resistance is a growing global challenge. Development of vaccines to prevent TB infection and progression to active disease remains a key goal, alongside improved methods of timely diagnosis and shorter treatment regimens.

Tuberculosis in numbers



33 grants
€194.83 M



Drugs
10 grants
€66.76 M



Vaccines
4 grants
€51.19 M



Diagnostics
19 grants
€76.88 M

Accelerating TB vaccine development

EDCTP is encouraging collaboration across TB vaccine projects in order to accelerate progress.

EDCTP has invested more than €50 million in four TB vaccine projects, focusing on prevention of infection in newborns (**MTBVACN3**, **MTBVAC-Newborns**, **priMe**) and prevention of recurrence in adults treated for TB disease (**POR-TB**). In April 2022, representatives of these projects met to exchange knowledge and experiences, at an event organised by the Tuberculosis Vaccine Initiative (TBVI), which has received funding from EDCTP to promote coordination across projects.

Although affected by the COVID-19 pandemic, the projects have continued to make progress. EDCTP, TBVI and the individual projects are exploring opportunities for collaboration, including on the development of new resources for the TB vaccine R&D community, building on those made available on the [EDCTP website](#) in 2021; these included various guidance documents and templates, as well as a directory of TB vaccine trial sites in Africa.

In May 2022, the **MTBVACN3** project held its kick-off meeting in Spain. This phase III trial is evaluating a live attenuated *Mycobacterium tuberculosis* (Mtb) vaccine, MTBVAC, as a potential alternative or complement to the childhood vaccine BCG. It aims to recruit more than 7000 newborns at six sites in TB-endemic countries in sub-Saharan Africa, with participants being randomised to receive either MTBVAC or BCG.

The MTBVACN3 project is drawing on the related **MTBVAC-Newborns** trial, a phase IIa dose-escalation study which completed recruitment in 2021. This work identified the dose being evaluated in the MTBVACN3 project.

Independently, in 2022 the **priMe** project completed recruitment into its phase III trial of VPM1002. Like BCG, VPM1002 is based on a relative of Mtb, *M. bovis*, which causes bovine TB, but has been precisely engineered so that it retains some of the immune-stimulating components that have been lost in BCG. The priMe trial is being carried out in Gabon, Kenya, South Africa, Tanzania and Uganda, with VPM1002 also being compared with BCG.



The **POR-TB trial** is assessing an innovative use of vaccination against TB – prevention of recurrence (POR). It is evaluating a novel vaccine, H56:IC31, which is designed to prevent latent Mtb infections from progressing to active TB disease. To assess its efficacy, POR-TB trial is undertaking a prevention of recurrence study, to determine whether it reduces the number

of patients who relapse after completion of TB antibiotic treatment – relapse is typically seen in about 1 in 10 patients. This will provide an efficient trial design to determine whether larger-scale efficacy studies are warranted. Dosing of the final participant in the POR-TB trial took place in March 2022.

Gathering field data on TB diagnostics

The DIAMA project contributed to the latest update of WHO guidance on TB diagnostics, and is continuing studies that will feed into future revisions.

The DIAMA project, which brings together groups in nine sub-Saharan African countries, is focusing on the diagnosis and management of patients with multidrug-resistant TB (MDR-TB). Three DIAMA sites generated field data on Cepheid's Xpert MTB/XDR cartridge, which can rapidly detect resistance to second-line drugs such as isoniazid and fluoroquinolones used in the WHO-recommended regimen for rifampicin-resistant TB. This information was considered in the [latest revision of WHO guidance on TB detection](#).

Two of DIAMA's African partners with advanced molecular laboratories (Benin and Rwanda) have established reference laboratories for the 'Deeplex' assay – a novel multiplex deep sequencing-based drug resistance diagnostic platform that provides sequence information on a range of genes that confer resistance to several key anti-TB drugs, including the new drugs recommended by WHO to treat MDR-TB. Moreover, two novel rapid molecular tests for the diagnosis of resistance to second-line TB drugs have also been implemented in recruiting sites – Xpert MTB/XDR and the Molbio Truenat test for resistance to second-line drugs. Results will continue to be shared with WHO and are expected to contribute to updated guidelines in 2023.

Triaging TB

Several EDCTP-funded TB projects that are assessing innovative technologies for more rapid identification of TB cases recruited their first participants in 2022.

Conventional culture-based methods of TB diagnosis are slow, leading to a delay in the start of treatment and providing opportunities for the disease to spread. By contrast, currently used molecular tools provide rapid results but are expensive and not always available at primary healthcare facilities. Several EDCTP-funded projects are evaluating alternative ‘triaging’ methods to rapidly identify possible TB cases at local facilities, which can then be confirmed by molecular diagnosis.

The [SeroSelect Consortium](#) held its first face-to-face meeting in Cape Town, South Africa, in August 2022, and its first participants were enrolled in Tanzania in September 2022 and in Ethiopia in October 2022. The project is assessing a new lateral flow test for active TB, SeroSelectTB, at health posts in Ethiopia, South Africa and Tanzania. The test detects antigens associated with active TB disease but not latent TB infections.

Also in 2022, the [TB-CAPT Consortium](#) enrolled the first patients into two of its three clinical trials, the CORE and EXULTANT trials. The CORE trial is assessing the impact of making the Molbio Truenat diagnostic platform available at primary healthcare facilities. The first participant was recruited in Mozambique in August 2022, with Tanzanian sites starting recruitment soon after.

The EXULTANT trial is assessing the impact of an extended testing strategy for diagnosing TB among people living with HIV. Currently, only those with TB symptoms or advanced HIV disease are tested. Given the risks that TB poses to people living with HIV, the study will assess the potential benefits of testing all patients with HIV admitted to hospital, using sensitive molecular and urine-based tests. The first patient in this trial was enrolled in Mozambique in September 2022.

Recruitment also began in 2022 to the [TB TRIAGE+](#) study in Lesotho and South Africa. The project is assessing whether two tests – an innovative digital chest X-ray analysis system (CAD4TB) and a simple-to-use blood test for detection of C-reactive protein (CRP), a marker of infection – can provide a rapid indication of the likelihood of TB disease in the community. It ultimately aims to recruit 20,000 participants.

Complementing this large community study, the TB TRIAGE+ ACCURACY trial is assessing the diagnostic accuracy of the two methods in a small number of individuals, to help define suitable thresholds for a TB screening algorithm to be used in the community. The study was successfully completed in 2022 and the results are expected to be published in 2023.



Intensified treatments for TB

Two recently initiated projects are assessing whether intensified TB treatments, based on high doses of TB antibiotics, can cut high mortality rates in vulnerable groups.

Mycobacterium tuberculosis (Mtb) is difficult to kill. Treatment regimens are typically based on a cocktail of drugs given for several months. In some groups of patients, and for some less common manifestations of Mtb infection, more drastic approaches to treatment may offer a way to improve outcomes.

The [DATURA](#) study, which recruited its first participant in Conakry, Guinea in April 2022, is assessing whether an intensified initial TB treatment could improve survival of hospitalised adults and adolescents with HIV infections. About 9% of people who develop TB also have HIV infections, but people living with HIV account for 19% of TB deaths; 72% of HIV–TB coinfections are in Africa.

DATURA is assessing whether high-dose TB antibiotics plus corticosteroid improves survival in this highly vulnerable group. By the end

of August 2022, all trial sites in Cameroon, Guinea, Uganda and Zambia had recruited their first participants.

The DATURA project will be liaising with the [INTENSE-TBM team](#), which is evaluating an intensified treatment regimen for tuberculous meningitis (TBM), TB infection of the membranous lining of the brain. Tuberculous meningitis has extremely high mortality, particularly in people living with HIV. The trial is comparing existing treatment with an intensified approach based on high doses of TB antibiotics (rifampicin and linezolid) plus aspirin, an anti-inflammatory.

The protocol of the INTENSE-TBM study was published in November 2022 and the trial recruited its 300th participant at the beginning of 2023.

Malaria

After a prolonged period of falling case numbers, malaria control has stalled in recent years. However, exciting progress in vaccine development may help to re-energise the push towards malaria elimination and eradication.

Malaria in numbers



17 grants
€138.32 M



Drugs
12 grants
€86.60 M



Vaccines
4 grants
€48.72 M



Diagnostics
1 grant
€3 M

R21/Matrix-M confirms early promise

Further promising results on the R21/Matrix-M malaria vaccine have raised hopes that it will soon be available for use in countries.

The world's first malaria vaccine, RTS,S/AS01, is in high demand but supplies are currently limited. Additional malaria vaccines are thus urgently needed.

An EDCTP-funded phase II trial recently found that a second malaria vaccine, R21/Matrix-M, was highly efficacious, meeting WHO's preferred 75% efficacy target. A further report, on two-year follow up of infants in Burkina Faso, is equally encouraging. The research team found that a [booster dose of R21/Matrix-M given 1 year after the three-dose primary regimen maintained high levels of protection against clinical malaria](#).

R21/Matrix-M again hit the WHO's preferred efficacy target. In children given the highest dose of Matrix-M adjuvant, efficacy was 80% 1 year after boosting. In addition, antibody concentrations following booster vaccination showed a close correlation with vaccine efficacy.

Follow up of the Burkina Faso trial is continuing, to assess the value of further booster vaccinations. The findings encouraged investment in a phase III study in Burkina Faso, Kenya, Mali and Tanzania, at sites of seasonal and perennial malaria transmission. Preliminary findings from this trial have confirmed high efficacy at seasonal sites.

Developers of the vaccine, based at the University of Oxford in the UK, have teamed up with the Serum Institute of India to ensure large quantities of the vaccine would be available should it be approved for use in Africa. Although R21/Matrix-M has yet to be assessed by WHO, two countries – Ghana and Nigeria – approved its use early in 2023.



Pyramax recommendation

EDCTP-funded studies have been central to the development of pyronaridine–artesunate (Pyramax), strongly recommended in the latest WHO guidelines for treatment of uncomplicated malaria.

A once-daily, three-day treatment for uncomplicated malaria, Pyramax is a fixed-dose artemisinin-based combination therapy (ACT). It is the only ACT recommended for use against the two principal species of *Plasmodium* in Africa, *P. falciparum* and *P. vivax*. A strong recommendation for its use in treatment of uncomplicated malaria in adults and children is made in the latest WHO Guidelines for Malaria.

Pyramax is available in a child-friendly granule formulation to ensure palatability and therefore correct dosage in this vulnerable population. Both Pyramax tablets and Pyramax granules received positive scientific opinions from the European Medicines Agency (EMA). Data from an EDCTP-supported West African Network for Clinical Trials of Antimalarial Drugs ([WANECAM](#)) phase IIIb/IV [safety and efficacy study](#) were key to the EMA's decision to grant a revised product label for Pyramax tablets in 2018.

Following the positive scientific opinions, a large phase IV study was carried out in five African countries under the umbrella of the EDCTP-supported Central African Network on Tuberculosis, HIV/AIDS and Malaria ([CANTAM](#)), to evaluate the safety and effectiveness of Pyramax under conditions similar to everyday clinical practice. This [study](#), involving more than 7000 patients, reported very high effectiveness (a day 28 cure rate of 98.6%).

An analysis of data from the CANTAM study has also shown that Pyramax is effective against other, less common *Plasmodium* species, including *P. malariae* and *P. ovale*, as well as mixed infections. This is an advantage as it means the treatment could be used without the need to identify the specific type of malaria infection, and also because these species may be responsible for an increasing proportion of malaria cases in Africa.

Progress in malaria projects

Highlights from malaria-based projects in 2022 include the announcement of a phase III trial for an innovative drug treatment, plus the launch of a mass drug administration campaign as a demonstration project in Mozambique.

Ganaplacide, formerly known as KAF156, is a new antimalarial compound, with a novel mechanism of action, being developed through a partnership between Novartis and the Medicines for Malaria Venture (MMV). It has been paired with an existing drug, lumefantrine, in a combination therapy, and a solid dispersion formulation has been developed to facilitate once-daily dosing.

As well as clearing malaria infections, including artemisinin-resistant strains, the ganaplacide–lumefantrine combination has the potential to block transmission of the malaria parasite. In a phase II trial, ganaplacide–lumefantrine was as efficacious as Coartem, the ‘gold-standard’ artemisinin combination therapy (ACT). EDCTP is now providing €10 million funding for a pivotal phase III trial of ganaplacide–lumefantrine in a range of sites, including Burkina Faso, Gabon, Mali and Niger. The German Federal Ministry for Education and Research (BMBF) is providing an additional €1 million funding.

The phase III study will be carried out by the West African Network for Clinical Trials of Antimalarial Drugs 2 (WANECAM 2). Previously with EDCTP funding, the WANECAM consortium carried out influential studies confirming the efficacy of pyronaridine–artesunate (Pyramax) and dihydroartemisinin–piperaquine ACTs.

The long-term goal in malaria control is elimination or even eradication. In Mozambique, the EDCTP-funded **ADAM project** is supporting the implementation of an evidence-based strategy for malaria elimination. With control activities starting in 2022, this demonstration project will generate practical insights that can be applied in a wider roll-out in other areas of the country. The project is co-funded by the South African Medical Research Council.

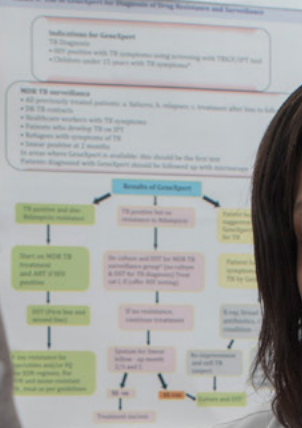
The elimination strategy is based on intensified vector control and six-monthly mass antimalarial drug administration for two consecutive years, followed by reactive targeted mass drug administration in areas where malaria persists. Previous studies have shown that mass drug administration reduced transmission sufficiently to enable initiation of more targeted (focal) mass drug administration, as recommended by WHO.

The Mozambique National Malaria Control Programme now has a goal of elimination of malaria in areas of low transmission intensity. The ADAM project has worked with the National Malaria Control Programme and other stakeholders to develop a delivery strategy and monitoring plan, based on integration of population-wide and follow-up targeted mass drug administration into routine activities. The first mass drug administration campaign was launched in Chidenguele, Mozambique, in December 2022.



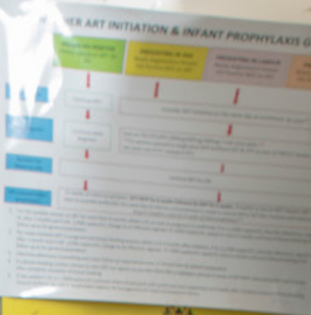
HIV TESTING FOR PREGNANT/POSTPARTUM WOMEN

• All pregnant women with HIV symptoms using screening with TRUCO-SPOT test
• All breastfeeding women with HIV symptoms using screening with TRUCO-SPOT test
• All women with HIV symptoms using screening with TRUCO-SPOT test
• Children under 12 years with HIV symptoms



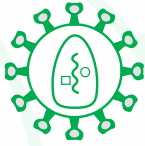
ART IN ADOLESCENTS AND ADULTS WITH TUBERCULOSIS

Parameter	ART regimen	Comments
First-line	First-line	First-line
Second-line	Second-line	Second-line



INFORMED CONSENT AND ASSENT GUIDELINES FOR CHILDREN AND ADOLESCENTS

IC Group: []



HIV and HIV-associated infections

Despite much progress in improving access to antiretroviral therapy and prevention of mother-to-child transmission, HIV/AIDS remains one of sub-Saharan Africa's greatest health challenges. However, new approaches to disease prevention and better treatment for opportunistic infections could significantly reduce the burden of HIV-related disease.

HIV and HIV-associated infections in numbers



20 grants
€115.55 M



Drugs
12 grants
€64.48 M



Vaccines
4 grants
€37.71 M



Diagnostics
4 grants
€13.36 M

Simplified treatment for a key opportunistic infection

The AMBITION-cm study has shown that a simplified treatment for cryptococcal meningitis, one of the major causes of death of people living with HIV, is as good as existing treatments – and could potentially generate cost savings as well.

Cryptococcus, a fungal pathogen, can infect the brain, causing a potentially fatal form of meningitis. It is a particular danger to people living with HIV – globally, it is the second most common HIV-related cause of death, and most deaths occur in sub-Saharan Africa.

The recommended treatment for cryptococcal meningitis has been a week-long course of two drugs, amphotericin B deoxycholate and flucytosine. However, the first of these can trigger damaging adverse reactions, so patients need careful monitoring, which is not always possible in low-resource settings.

The AMBITION-cm phase III trial evaluated a simpler alternative approach, based on a single dose of amphotericin B in a liposomal formulation. This has the advantage of being less toxic, so it can be used at higher doses, has a long half-life, and readily enters the brain.

The trial, which recruited more than 800 patients in five African countries, found that [treatment responses to single-dose amphotericin B](#) matched those to amphotericin B deoxycholate and flucytosine, and significantly fewer serious adverse reactions were seen.

Furthermore, the AMBITION-cm trial team has developed costing tools for cryptococcal management in Botswana, Malawi, South Africa, Uganda and Zimbabwe, and shown that the new regimen is likely to be highly cost-effective. As fewer adverse reactions will be seen and hospital stays are likely to be shorter, it could even lead to cost savings. In addition, in consultations with trial participants and healthcare staff, the new regimen was positively received and thought likely to reduce clinical workload.

The findings have already had an impact on policy. In April 2022, WHO issued a rapid guidance update that strongly recommended use of single high-dose amphotericin B for the treatment of cryptococcal meningitis in people living with HIV.



Catching HIV infections in infants

The PROMISE-EPI study, which is aiming to reduce the burden of HIV disease in newborns, has completed follow up of more than 34,000 mothers and their babies.

Although WHO recommends that all pregnant and breastfeeding women living with HIV should be given antiretrovirals, and all infants at risk of contracting HIV should receive antiretrovirals for six weeks, cases of HIV infection are unfortunately still being missed in both mothers and children.

The **PROMISE-EPI** study is evaluating a back-up strategy, in which HIV detection and treatment are integrated into a country's immunisation programme (generally known as the Expanded Programme on Immunisation, EPI). Its goal is to identify and treat missing HIV cases among infants attending vaccination sessions and to prevent HIV transmission from previously undiagnosed but HIV-infected mothers.

The study has been taking place in Burkina Faso and Zambia, where most babies receive vaccination through the EPI at 6–8 weeks. At each visit, infants were tested for HIV

infection and the extent of suppression of viral replication was assessed in HIV-infected mothers. A total of 34,315 mothers were recruited into the main study, and 1527 infants exposed to HIV were identified and given preventive treatment with antiretrovirals. Mother–infant pairs were followed for a year to determine impacts on HIV transmission to infants, with the last follow-up visit taking place in September 2022.

Analysis of the data will reveal how effective prevention of mother-to-child transmission is in the two countries, and whether the EPI-based strategy has the potential to reduce the number of infant HIV infections and to ensure that more HIV-infected infants receive timely treatment.

Preventing HIV infection in women

EDCTP Participating States' Initiated Activities (PSIAs) have helped to progress an antiretroviral-impregnated vaginal ring now in use in several sub-Saharan African countries.

Women are particularly affected by the HIV epidemic – despite representing only 10% of the total population, young women aged 15–24 account for 25% of new HIV infections. There is therefore great interest in protective measures that women have control over.

The International Partnership for Microbicides (IPM) has overseen the development of a vaginal ring impregnated with an antiretroviral, the monthly dapivirine ring, as a preventive measure, with support from PSIAs funded by The Netherlands, Norway and the Republic of Ireland.

The Ring Study, conducted by IPM, and the ASPIRE trial, conducted by the US National Institutes of Health's Microbicide Trials Network

(MTN), were carried out at 22 sites in sub-Saharan Africa to assess the long-term safety and efficacy of a dapivirine vaginal ring in preventing HIV infection in healthy women. These trials demonstrated that the monthly dapivirine ring reduced HIV infection by about 30% in women aged 18–45. The monthly ring was generally safe and well-tolerated for up to 24 months of continuous use. Follow-on data suggest risk reduction may be greater than demonstrated in the trials, potentially more than 50%.

These and other data were submitted to the European Medicines Agency (EMA), which provided a positive scientific opinion. The monthly dapivirine ring has also been recommended by WHO as an additional prevention choice for women at substantial risk of HIV infection as part of combination prevention approaches. It has been approved for use in several African countries, including Kenya, Rwanda, South Africa, Uganda and Zimbabwe.

Refining PrEP

The CHAPs study has combined user consultations and laboratory investigations to identify potential refinements to pre-exposure prophylaxis (PrEP) for HIV prevention.

Pre-exposure prophylaxis (PrEP), pre-emptive use of antiretroviral drugs to prevent HIV infection, has been shown to be highly effective. However, the need for daily pill-taking leads to challenges with adherence in adolescents and young adults. There is also some uncertainty about the optimal choice and dose of antiviral included as new drugs become available.

The EDCTP-funded **CHAPS study**, which completed data collection in 2022, has been carrying out a mix of consultative research to explore attitudes to PrEP among adolescents and young adults, as well as laboratory studies to establish suitable doses of a new drug, tenofovir alafenamide (TAF), for use in PrEP.

Among more than 1300 adolescents and young adults in South Africa, Uganda and Zimbabwe, 'on-demand' PrEP – taking antiretrovirals when needed rather than daily – was favoured over daily PrEP. However, some variation was seen between sites, according to age, sex and frequency of sexual activity.

The study also found that 39% of respondents reported at least one symptom of post-traumatic stress disorder (PTSD), with PTSD scores correlating with experience of repeated forced sex and self-perception as a risk-taker. However, PTSD scores had no impact on attitudes to PrEP or PrEP preferences. The findings will inform the design of more tailored PrEP demand activities in adolescents and young adults.

TAF has several advantages over the antiretroviral typically used in PrEP, tenofovir. However, a suitable dose for PrEP use by men has not been established. Laboratory studies carried out by the CHAPS team found a sixfold higher take up of TAF by foreskin tissue culture compared to tenofovir. These findings will provide guidance on the appropriate dosage for TAF-based PrEP, and have also highlighted the need for pharmacokinetic studies to shape PrEP dosing.

The CHAPS project also provided a platform for immunological studies, which have explored links between various immune mediators and the drugs used in PrEP. These revealed that, in men, levels of an inflammatory mediator known as CCL4 correlated with bloodstream antiretroviral levels, suggesting that CCL4 could be an important element of the mechanism of action of PrEP.





Neglected infectious diseases

Neglected infectious diseases include some of the world's most common and debilitating conditions. Flatworm and other parasite infections affect millions, typically the poorest populations, and disrupt the growth and development of countless children in sub-Saharan Africa. For many, new treatments are becoming available, but a key challenge is getting them to populations in need.

Neglected infectious diseases in numbers



19 grants
€70.59 M



Drugs
13 grants
€47.49 M



Vaccines
1 grant
€8 M



Diagnostics
5 grants
€15.10 M

Increasing children's access to anti-parasite drugs

Highlights from neglected infectious disease projects in 2022 include completion of regulatory submissions for arpraziquantel, a key drug for control of schistosomiasis.

Through the [Paediatric Praziquantel Consortium \(PZQ4PSAC\)](#) project, EDCTP and the Japan-based Global Health Innovative Technology (GHIT) fund partnered to support a phase III trial of arpraziquantel, an orally dispersible treatment based on praziquantel, a drug widely used in schistosomiasis mass drug administration programmes. The [results](#), announced in November 2021 and presented at the European Clinical Congress on Microbiology and Infectious Diseases (ECCMID) conference in Lisbon, Portugal in April 2022, confirmed that arpraziquantel showed excellent efficacy, achieving cure rates of 90% or above, and was safe and well-tolerated by young children.

In early 2022, WHO launched [new guidelines](#) for the control and elimination of human schistosomiasis, recommending the expansion of preventive chemotherapy to all in need, including preschool-aged children. Approval of arpraziquantel would be a major step towards achieving these new recommendations.

On behalf of the Consortium, Merck applied for a scientific opinion from the European Medicines Agency (EMA). In December 2022, the EMA validated for review the application for arpraziquantel for the treatment of schistosomiasis in preschool-aged children. With this validation, the regulatory application for arpraziquantel is complete and EMA has started the scientific review process. A positive opinion from the EMA will facilitate inclusion of arpraziquantel in WHO's list of prequalified medicinal products as well as regulatory approvals in endemic countries.

At the same time, preparations are being made to make arpraziquantel available on a not-for-profit basis in low-resource settings. The Consortium is preparing for the potential inclusion of arpraziquantel in the WHO list of prequalified and essential medicines, and is exploring mechanisms for providing equitable and sustainable access once arpraziquantel is approved. Through the EDCTP-funded [ADOPT project](#), the Consortium is also preparing the ground for the large-scale delivery of this new treatment in endemic countries, ideally starting in 2024.



Also in 2022, the EDCTP-funded [STOP consortium's ALIVE phase II trial](#) of a fixed-dose combination of ivermectin and albendazole for the treatment of soil-transmitted helminths in children recruited its first participants, at sites in Kenya. Ultimately, more than 1000 children will be recruited at sites in Ethiopia, Kenya and Mozambique.

An estimated one in four people globally have parasitic worm infections, which can have long-lasting impacts on child growth and development. Mass drug administration campaigns with albendazole and mebendazole are effective at controlling infection but these

drugs are not active against all parasitic worms and there is some evidence of resistance developing in one key target, *Trichuris trichiura* (whipworm).

If shown to be effective, the albendazole and ivermectin fixed-dose combination would be a valuable additional drug option, while use of compounds in combination should also delay the development of resistance.

A new treatment for visceral leishmaniasis

The AfriKADIA project has shown that a novel therapy for visceral leishmaniasis is as effective as current treatments and much easier to administer.

Visceral leishmaniasis, due to infection with single-celled *Leishmania* parasites, is the second largest parasite infection after malaria. It is a particular challenge in countries in north and east Africa.

Standard treatment is with a combination of two drugs, sodium stibogluconate and paromomycin, given for 17 days. However, this involves painful daily injections and there is a risk of serious adverse reactions. In a trial spanning seven sites in four East African countries and with more than 400 participants, the [AfriKADIA project](#) compared this existing approach with a new treatment, a combination of two drugs, miltefosine and paromomycin,

given for 14 days. The new combination was 91% effective, at least as good as the current treatment, and reduced time in hospital by 18%.

Visceral leishmaniasis is particularly common in children, who responded very well to this new treatment. It also significantly lowered the risk of post-kala-azar dermal leishmaniasis (PKDL), a common complication of visceral leishmaniasis after treatment; PKDL affected 21% of patients following treatment with sodium stibogluconate but only 4% of patients after miltefosine and paromomycin. As PKDL patients are a source of infection, use of miltefosine and paromomycin could therefore also reduce transmission of *Leishmania* parasites.

These results are informing the activities of the follow-up EDCTP-funded [LeishAccess project](#), which is facilitating the updating of visceral leishmaniasis treatment policy in countries in eastern Africa. Despite some progress, an estimated 50% of patients still do not have access to appropriate diagnosis and treatment.

The LeishAccess consortium is sharing the new evidence with ministries of health in endemic countries and liaising with the WHO Guidelines Development Group, which is expected to produce updated treatment guidelines for visceral leishmaniasis towards the end of 2023.

New routes to leprosy prevention

The PEP4LEP project has identified key reasons for delays in leprosy diagnosis in Ethiopia.

In 2017, EDCTP funded two projects aiming to enhance leprosy control through greater use of 'post-exposure prophylaxis' (PEP) – pre-emptive drug treatment in those coming into contact with people with *Mycobacterium leprae* infections. Although PEP is recommended by WHO, its implementation can be held back by delays in diagnosis of new cases of *M. leprae* infection, which has an incubation time of up to 20 years. The **PEOPLE** study is assessing strategies to enhance take up of PEP in the Comoros and Madagascar, while the **PEP4LEP** study is comparing facility- and community-based approaches for active case searching in districts of Ethiopia, Mozambique and Tanzania.

In 2022, the PEP4LEP study published baseline data on the prevalence of leprosy and treatment delays in study provinces in its three focus countries. In Ethiopia, the numbers of cases declined slightly between 2010 and 2019, although the number of new cases in children increased, suggesting ongoing transmission. The mean case detection delay was more than 22 months. In Mozambique, data from 2015–2019 showed that the mean diagnosis delay exceeded 26 months, and 17% of those diagnosed had significant disability, indicative of late diagnosis. Similarly, in Tanzania study areas, the mean diagnosis delay was around 28 months.

Delays in diagnosis can lead to more serious disability and provide opportunities for additional spread of infection. To explore reasons for diagnostic delays, the PEP4LEP team developed a culturally and context-sensitive nine-question questionnaire for use by local health workers, which was piloted and validated in Ethiopia, Mozambique and Tanzania.

In Ethiopia, use of this tool identified two factors associated with a delay in case detection of more than 12 months – fear of stigma and experiencing painless symptoms. The findings highlight the need to raise awareness of early symptoms in affected communities, and for initiatives to address leprosy-related stigma and build the ability of health workers to identify cases.





Emerging and re-emerging infections

Recent decades have seen the emergence of alarming new threats to health, including Ebola and, most recently, COVID-19. Wherever animals and humans live in close association, the risk that pathogens jump species barriers will persist. As well as new vaccines and treatments, these threats to health require a strong focus on surveillance and preparedness, so new threats can be detected and responses launched as rapidly as possible.

Emerging and re-emerging diseases in numbers



37 grants

€78.61 M



Drugs
1 grant

€0.2 M



Vaccines
6 grants

€43.51 M



Diagnostics
17 grants

€8.42 M



Non-intervention
- specific topics,
13 grants

€26.48 M

COVID-19 projects bear fruit

EDCTP-funded projects have gathered important data on SARS-CoV-2 circulation in different sub-Saharan African countries and on immune responses to infection in different sub-Saharan African populations.

At the onset of the COVID-19 pandemic, EDCTP mobilised its emergency funding mechanism, and launched a call for proposals on research related to COVID-19 in sub-Saharan Africa. A total of 26 projects were eventually funded, alongside three follow-on projects funded in partnership with the Botnar Research Centre for Child Health. Many of these projects gathered data of importance to local policymakers, and results are now increasingly being published in the scientific literature.

Several projects examined immune responses in response to natural infection or vaccination. These have included studies from the **ImmunoCov project** examining the kinetics of antibody production after infection. The **COVAB project** has examined the binding of vaccine-induced antibodies to different viral spike protein variants and to unusual epitopes on SARS-CoV-2 spike protein. The project has

also shown that breakthrough infections in vaccinated individuals generate strong and broadly neutralising antibody responses.

The **Profile-Covid project** generated the first data on antibody responses to infection in Ethiopian populations. The study found that immune responses varied markedly between individuals and across different assays, emphasising the importance of evaluating the performance of assays before their widespread use. The **COVID-19 HCW project** found that omicron variant infections were common in healthcare workers in South Africa, although past infection and high anti-spike IgG antibody levels were seen to be protective against infection with the omicron variant.

Several projects have tracked SARS-CoV-2 in different sub-Saharan African populations, including the spread of variants. Data have been generated from Zambia (**TREATS-COVID**), rural Republic of Congo (**ITAIL/PANDORA-ID-NET**), Senegal (**AIDCO**), Gabon (**AIDCO**) and Cameroon (**PERFECT**).



The **RE-BCG-COV-19** project showed that revaccination with BCG – primarily used to protect against TB – did not offer any protection against SARS-CoV-2 infection or related severe COVID-19 disease in healthcare workers.

A further important focus has been evaluation of diagnostic tools. The **HALT COVID-19** project assessed rapid antigen tests in the South African

omicron wave. While the **PERFECT** project found good agreement between two molecular diagnostic tests widely used in Africa, **PANDORA-ID-NET** identified significant shortcomings in the PCR tests used by the Zambian Government. A project jointly funded by EDCTP and the Botnar Research Centre for Child Health found good evidence for the acceptability and feasibility of self-antigen testing in Lesotho and Zambia.

Ebola vaccine follow up

*The **PREVAC** study, funded through a Participating States Initiated Activities (PSIAs), has generated critical data on Ebola vaccines, while the EDCTP-funded **PREVAC-UP** follow-up study will provide vital data on the durability of protection.*

Two vaccine strategies for the Zaire strain of Ebolavirus – rVSVΔG-ZEBOV-GP and a prime-boost combination of Ad26.ZEBOV and MVA-BN-Filo – have achieved WHO prequalification status and have been used in control of outbreaks. However, limited data have been generated on the safety of these vaccines and the duration of protection.

The **PREVAC Consortium**, supported by the National Institutes of Health and through PSIA funding from France, has carried out two related clinical trials of these vaccine strategies, one in adults and one in children, to gather additional information on safety and immune responses. Each study involved 1400 participants.

The results, published in 2022, revealed no significant safety concerns in either adults or children. At 12 months, antibody responses

were detected in between 41% and 93% of participants, depending on the vaccine strategy, at levels that are believed to be protective.

The study findings provide important additional data on the prequalified vaccines and support their continued use to control Zaire Ebolavirus outbreaks.

The follow-up **PREVAC-UP** study, which has been awarded €15.8 million funding from EDCTP, extends this value still further. It will enable participants from seven sub-Saharan African countries to be followed for five years, providing critical information on the durability of immune responses and any possibility of long-term safety issues. Trial participants who originally received the placebo will be offered one of the prequalified vaccines.

Embedded studies will also examine the potential impact of common parasitic infections, including malaria and helminth worm infections, on responses to the vaccines. Analysis of the immune responses generated may also shed important light on the key immune mechanisms associated with protection.

Lower respiratory tract infections and diarrhoeal diseases

Pneumonia is the world's biggest killer of young children, accounting for one in five deaths of children aged 1 to 5 years. Caused by a wide variety of viral, bacterial and fungal pathogens, new treatments and vaccines are urgently needed, particularly given the growing challenge of antimicrobial resistance.

Lower respiratory tract infections and diarrhoeal diseases in numbers



14 grants

€93.66 M



Drugs
3 grant

€18.10 M



Vaccines
7 grants

€58.36 M



Diagnostics
1 grant

€4.56 M



Non-intervention-specific topics
3 grants

€12.64 M

Diarrhoeal disease remains one of the most important causes of ill-health in low-resource settings. Caused by multiple viral, bacterial and parasitic pathogens, diarrhoeal diseases are potentially fatal but can also have long-

term consequences for children's growth and development. Alongside improvements in water, sanitation and hygiene, advances in vaccine development are beginning to provide additional tools for disease control.

Optimising antimicrobial treatments for children

Two projects focused on treatment of lower respiratory tract infections reached important recruitment milestones in 2022.

Pneumonia is the biggest killer of young children worldwide, responsible for the deaths of nearly 750,000 children under the age of 5 each year. Mortality rates are highest in sub-Saharan Africa. Many of these infections are bacterial and can be treated with antibiotics.

The [PediCAP study](#) is assessing whether children hospitalised for severe or very severe pneumonia can be safely switched from injectable to oral antibiotics. Currently, WHO recommends that such children receive injectable antibiotics for at least five days, as these antibiotics cover a wider range of bacterial pathogens than oral amoxicillin alone. However,

this means that children stay in hospital longer, incur high healthcare costs, and are at risk of acquiring drug-resistant infections.

The [PediCAP trial](#) is comparing the effectiveness of co-amoxiclav or amoxicillin, two possible oral step-down treatments, given for different lengths of time. In August 2022, it hit its 50% recruitment milestone, having enrolled more than 500 children in Uganda, South Africa, Zambia and Zimbabwe; it reached its 75% target in early January 2023, with more than 750 children enrolled.

In July 2022, the [EMPIRICAL study](#) also hit its 50% recruitment milestone. The study is evaluating whether empirical treatment against cytomegalovirus and TB improves the survival of HIV-infected infants with severe pneumonia.



Children with HIV infections are highly vulnerable to respiratory infections, and there is growing evidence that TB and *cytomegalovirus* – a common virus that only rarely causes disease – are major unrecognised causes of death in such children. As diagnostics for these infections are generally not available in many parts of sub-Saharan Africa, the EMPIRICAL trial is evaluating whether empirical treatment against TB and *cytomegalovirus* improves survival of HIV-infected infants with severe pneumonia.

Patients are being enrolled at 19 EMPIRICAL sites in Malawi, Mozambique, Uganda, Zambia and Zimbabwe. In July 2022, patient number 312 out of 614 was recruited. The trial's external Data and Safety Monitoring Board reviewed the initial data and found no safety issues, recommending that the study continue as planned.

Advancing ETVAX for ETEC

The ETEC ETVAX phase IIb trial completed recruitment in 2022, with results due to feed into a pivotal phase III study of this much-needed new vaccine.

Enterotoxigenic *E. coli* (ETEC) is a common cause of diarrhoeal disease in many sub-Saharan African countries. The most advanced vaccine candidate against ETEC is a preparation of ETEC cells engineered to make large quantities of proteins likely to stimulate a strong immune response, alongside an adjuvant known as dmLT.

An EDCTP-funded phase IIb trial in The Gambia is evaluating the safety and efficacy of ETVAX in children. The project team is also developing a new formulation of ETVAX that will be better suited to young children, as well as a convenient device for administering the vaccine. In October 2022, the last participant in the ETEC ETVAX trial was vaccinated, with data analyses likely to be available in 2023.

If positive results are confirmed, the new all-in-one formulation will then be tested in an EDCTP-funded phase III trial in Zambia in infants 6–22 months in age.



Building human capacity – EDCTP Fellows

As part of long-term sustainable development, research on Africa's health challenges needs to be led by Africans, plugged into global knowledge networks. To build the expertise, experience and exposure of African scientists to global science, EDCTP runs a range of career schemes, from Preparatory Fellowships for those embarking on a career in research, through Career Development Fellowships for those showing early promise, and Senior Fellowships for the most outstanding research leaders. Through the Senior Fellowship Plus scheme, Senior Fellows also mentor an up and coming researcher from a country with a less well-established research base.

A new cohort of epidemiologists and biostatisticians

More than 150 new epidemiologists and biostatisticians will be trained, thanks to a partnership between EDCTP and the Africa Centres for Disease Control and Prevention (Africa CDC).

In 2021, EDCTP and Africa CDC formed a partnership to support the training of a new generation of epidemiologists and biostatisticians, to increase regional capacity for disease detection and pandemic response, within the context of Africa CDC's framework for public health workforce development. Following a call for proposals, ten international consortia were funded to provide Master's training in epidemiology and biostatistics to groups of promising individuals based in sub-Saharan Africa.

By the end of 2022, 151 '[Epi-Biostat Fellows](#)' had been enrolled, undertaking training at a range of universities in Africa and Europe, including Kinshasa School of Public Health in the Democratic Republic of Congo, Jomo Kenyatta University of Agriculture and Technology in Kenya, Busitema University in Uganda, London School of Hygiene and Tropical Medicine in the UK, and the University of Cape Verde.

These new fellows will provide a significant boost to sub-Saharan Africa's capacity to monitor, prevent and respond to infectious disease outbreaks, and will make an important contribution to the region's pandemic preparedness capabilities.



Senior Fellows in 2022

In 2022, EDCTP Senior Fellows have contributed key findings on immunity to malaria, asymptomatic malaria infections, characterisation of TB infections, and control of neglected infectious diseases.

EDCTP Senior Fellowships provide support for established researchers in sub-Saharan Africa working on poverty-related diseases. As well as specific research projects, Senior Fellowships also enable fellows to oversee the work of early-career researchers, helping to nurture the next generation of researchers and build research capacity in the region.

Professor Faith Osier maintains a group at the KEMRI/Wellcome Research Programme at Kilifi, Kenya, which focuses on immune responses to the malaria parasite to inform vaccine development. These studies include studies of both natural infection and controlled human infection in specially designed clinical research facilities.

Much research focuses on the invasion of red blood cells by merozoites, but less on subsequently infected cells. In 2022, results from a human malaria infection study were published, demonstrating that participants who controlled malaria infection and did not experience symptoms showed high levels of antibody-dependent phagocytosis of infected red blood cells. This effect was associated with the presence of merozoite proteins on the surface of the red blood cells. Antibodies against these merozoite proteins can block invasion of red blood cells, and these results suggest that they may also be important in clearing infected red blood cells and keeping infections in check.

Human challenge studies have also shown that the most abundant protein on the surface of merozoites, MSP-1, may be a critical target of several protective immune responses. Previous studies have tended to focus on fragments of MSP-1, but Professor Osier's group found that antibodies to full-length MSP-1 protein correlated with protection against malaria. These antibodies trigger five different protective immune responses, each of which seems to independently contribute to protection. The results could have important implications for vaccine development targeting MSP-1, which has to date had limited success.

Also in the malaria field, Senior Fellow **Dr Makhtar Niang** has been exploring the contribution of asymptomatic malaria infections to the continuing transmission of disease. As cases numbers fall and elimination becomes a realistic possibility, asymptomatic infections could provide an important reservoir of parasites, sustaining transmission.

Focusing on two villages in Senegal, Dr Niang has undertaken a detailed mapping of individual cases and infections over a four-year period. The results provide strong evidence that the presence of asymptomatic infections leads to transmission to other household members. The findings suggest that mass testing and treatment could contribute to malaria elimination at the village level.

Professor Alexander Yaw Debrah's Senior Fellowship project focuses on trials of potential new treatments for parasitic worm infections, onchocerciasis and lymphatic filariasis. Preparatory work, published in 2022, has generated data on the presence of lymphatic filariasis in two 'hotspots' in Ghana and the performance of different detection technologies. Following mass drug administration at the sites for many years, microfilariae were detected in less than 1% of those sampled, suggesting that transmission has been halted. However, positive antigen tests were more common and above the threshold for elimination, raising questions about the suitability of current thresholds for assessing elimination status.

In her Senior Fellowship project, **Professor Stelah Mpagama** is running a clinical trial to determine whether N-acetylcysteine (NAC) could reduce the severity of adverse reactions associated with treatment regimens for multidrug-resistant TB. These regimens are based on use of multiple drugs taken for prolonged periods, some of which have harmful effects that may require treatment to be stopped. There is some evidence that NAC can protect cells from the damage caused by TB treatments but there is currently little data relating to its potential amelioration of side effects arising from treatment of MDR-TB.

Professor Mpagama is supervising the work of several early-career researchers in Tanzania and is also assessing the use of new technologies in TB research and practice. This includes use of

whole-genome sequencing to identify resistance mutations and guide choice of treatment, and application of a relatively new method, the molecular bacterial load assay, to detect and quantify mycobacterial growth. Culture methods for TB are slow and conventional molecular tests do not distinguish between

DNA from live or killed cells. Recent studies have demonstrated the ability of the molecular bacterial load assay to distinguish between ongoing TB disease and post-TB lung disease, and also its use to compare the killing ability of different treatment regimens for MDR-TB.

Career Development Fellows in 2022

In 2022, EDCTP Career Development Fellows have contributed key findings on malaria treatments, cholera vaccines and the impact of schistosome infections.

Career Development Fellows have shown outstanding promise in their early research careers and are ready to make the transition to independent researchers. EDCTP fellowships provide funding for their research at this critical stage of their research career, setting them up for future success.

Dr Clifford Banda has been exploring the potential impact of interactions between treatments for HIV/AIDS and malaria, particularly in pregnant women. Malaria infection in pregnancy is associated with a range of health issues, which are exacerbated by HIV infection. Prevention of malaria in pregnancy is therefore a high priority.

Antimalarial drugs are given to pregnant women to prevent infection. However, many women in sub-Saharan Africa are also living with HIV, and there are concerns that antimalarial drugs could affect the metabolic processing of antiretroviral drugs, or vice versa, rendering them less effective.

In pharmacokinetic studies, Dr Banda has assessed the impact of a potential antimalarial for preventive use in pregnancy, dihydroartemisinin–piperaquine (DP), on levels of the antiretroviral dolutegravir, and how dolutegravir-based regimens affect DP levels. DP was found to slightly increase dolutegravir levels, but no safety issues were identified. Similarly, use of dolutegravir-based regimens led to greater persistence of DP but no increase in its maximum concentration. The findings suggest that the two treatments can be used together safely in pregnant women.

Dr Caroline Chisenga has been exploring factors that could potentially affect responses to oral cholera vaccine (OCV) in the Lukanga Swamps area of Zambia. Although OCV was immunogenic in people living with HIV, responses were lower in people with HIV infections, particularly those with low CD4 counts and high viral load. However, serum retinol levels, a marker of poor nutrition, were not associated with reduced responses to vaccine. Although ABO blood group has been identified as a possible influence on vaccine responses, no significant differences were seen in responses across blood types in this population.

Four-year follow up revealed that bactericidal antibody levels fell rapidly within the first year following vaccination, and hence may not be a good marker of long-term immunity. Antibody levels began to rise again at three years, possibly because of natural infection, suggesting a possible need for revaccination in high-risk areas.

There are suggestions that mass drug administration with praziquantel to control schistosome transmission may provide additional health benefits. To explore the possible basis for this, **Dr Justin Komguez Nono** has assessed the impact of repeated treatment cycles in a mouse model of schistosome infection. Although animals with the highest numbers of treatment cycles remained susceptible to infection, they had a lower egg burden and showed elevated levels of protective immune responses.

In addition, Dr Nono has found that, in both mice and children, chronic schistosome infections lead to impaired responses to vaccination. This effect was associated with the death of immune cells in bone marrow, which could be halted by removal of parasites by treatment with praziquantel, leading to



some restoration of vaccine-induced immune responses. The findings highlight a mechanism whereby schistosome infections can reduce responses to vaccination, strengthening the case for strategies to reduce the disease burden in children before vaccination.

In malaria, **Dr Richard Mwaiswelo** has shown that a single low dose of primaquine is safe and can reduce transmission of malaria parasites even in individuals with genetic variants that affect its metabolism and bioavailability. Unlike most malaria treatments, primaquine acts on gametocytes, the parasite stage taken up by mosquitoes, so its use as a supplement to artemisinin-based therapies is recommended for the elimination of malaria in low-transmission settings.

However, primaquine is a pro-drug that is metabolised into its active form in the body by cytochrome P450 (CYP) enzymes. Genetic variants that reduce primaquine processing activity are common in sub-Saharan Africa, particularly CYP2D6. Even so, lower levels of primaquine may still reduce transmission by sterilising rather than killing gametocytes. Using mosquito feeding assays, Dr Mwaiswelo showed that parasite survival and infectiousness was not dependent on CYP2D6

status. No safety issues were identified for any CYP2D6 variant or in individuals with G6PD deficiency, another genetic variation common in Africa.

In TB, **Dr Sean Wasserman** has generated important data on the safety of linezolid, commonly used to treat drug-resistant TB. Although effective at killing mycobacterial cells, linezolid also interferes with host cell metabolism, which can lead to nerve damage and other side effects that can mean treatment has to be stopped.

To gather additional data on a sub-Saharan African population, Dr Wasserman followed a cohort of more than 150 TB patients, 61% of whom were HIV-positive. Linezolid was discontinued in 21% of patients due to toxicity but toxicity was not associated with HIV status. Modelling suggested that a minimum concentration of 2.5 mg/L should be used for therapeutic monitoring of patients receiving linezolid.



Ethics and regulatory capacity building

Strong ethics review and regulatory capacity is essential for ensuring that clinical research studies are ethically conceived and conducted, and monitored effectively. Regulatory capacity is also essential for monitoring and ensuring the safety of newly introduced medical interventions. EDCTP supports projects specifically designed to strengthen national ethics review and regulatory capacities, particularly through South–North and South–South collaborations.

Ethics capacity in West Africa

The BCA-WA-ETHICS-II and LiberHetica projects have made substantial progress in 2022 in their efforts to build ethical review capacity in West Africa.

The **BCA-WA-ETHICS-II** project is strengthening the capacities of national research ethics committees (NRECs) and other key bodies in West Africa to conduct ethical review of project applications, with a particular emphasis on gender issues. In 2021, it published a ‘White Book’, which presents practical recommendations for gender mainstreaming in NREC governance, organisational culture, education programmes for members and local researchers, and the monitoring and evaluation of gender mainstreaming interventions, especially those included in an institutional gender equality plan. It is expected to be the cornerstone document for all francophone West African ethics committees.

Follow-up activities in 2022 included a webinar on ‘Sex and gender data visualisation for health research’, held in French and English in March. The webinar focused on the fundamentals of the GBDcompare software developed by the University of Washington, USA, for visualising sex-disaggregated health research data.

In June 2022, BCA-WA-ETHICS-II and the [Africa Bioethics Network](#) held a five-day training programme, ‘The fundamentals of research ethics’. The programme covered a wide range of themes, including ethical principles in research, the composition and functions of review committees, research design and ethics, informed consent, and reaching vulnerable populations. More than 130 participants from 31 countries in East, West, Central and Southern Africa and Europe attended the training. Training materials can be [accessed online](#).

In addition, the project published an [advocacy paper](#) raising awareness of examples of research ethics violations in Africa related to COVID-19 and other health emergencies. The paper provides recommendations and practical guidelines on how to implement best practices and learn lessons from past mistakes.

BCA-WA-ETHICS-II also worked with the Ministry of Health and Social Action of Senegal on a ‘[Note de politique: la gestion de la vulnérabilité dans la revue éthique des protocoles de recherche sur la COVID-19](#)’ (Policy note: Vulnerability management in the ethics review of COVID-19 research protocols). The policy brief discusses the management of vulnerability in COVID-19 research and provides recommendations for future ethical research conduct. It mainly targets evaluators in NRECs, institutional review boards, as well as researchers developing a mental health research protocol. The guidelines were developed from an African perspective and could also be applied in other low-resource settings. The brief was published in the *African Journal of Bioethics*.

Also in 2022, the project launched the first [website and digital platform](#) for the Guinea-Bissau National Health Research Ethics Committee (CNEPS), in the presence of the Guinea-Bissau Minister of Health. The website is designed to raise awareness of research ethics at a national level and enables researchers to learn more about the procedures of protocol submission. It also makes available protocol evaluation tools, integrating sex and gender considerations.

Other project outputs included ‘[Guidelines for the ethical review of mental health research protocols from a culturally-sensitive perspective](#)’, also published in the *African*

Journal of Bioethics. In most African countries, mental illness is a 'silent epidemic' due to factors such as inadequate healthcare infrastructure, insufficient numbers of mental health specialists, stigma and discrimination related to mental illness, and lack of access to all levels of care. There is an urgent need

for guidelines on the ethics of research on mental health with human participants. The BCA-WA-ETHICS-II project created a 54-item assessment tool to guide the process of mental health research protocol evaluation taking into account ethical, gender and sociocultural factors in Africa.

LIBERHetica

The **LiberHetica project** focused on strengthening the capacity of research ethics committees in the review of clinical and social science research protocols in Liberia. In response to a lack of educational materials on research ethics for university students and researchers, the project developed a National Training Manual for Research Ethics Education – the first curriculum developed for research ethics education in Liberia.

During 2022, the project also organised a free webinar on 'Lessons learned by ethics and regulatory bodies during COVID-19 – Experience sharing between Liberia and Ghana'. The webinar enabled participants to share

ethical- and regulatory-related experiences and discuss challenges and opportunities. It provided an opportunity to facilitate knowledge exchange and strengthen multi-country collaborations, for the review, approval and oversight of clinical research-related activities during public health emergencies.

The project also published the results of its survey of past and current research ethics committee members in Liberia, which identified a range of challenges to research ethics capacity-building in the country and suggested possible ways forward.





Building regulatory capacity in Ghana

The BERC-Africa project has been strengthening the capacity of a key regulatory authority in Ghana.

A wide range of training activities were organised under the umbrella of the **BERC-Africa project** in 2022. In August 2022, the Food and Drugs Authority (FDA) Ghana, a designated Regional Centre of Regulatory Excellence (RCORE) in Clinical Trials Regulation in Africa, organised a fifth round of clinical trials fellowship training, in collaboration with the University of Ghana. The training was originally intended for 10 participants, but 15 African regulators were ultimately trained thanks to additional sponsorship from the Paul Ehrlich Institute, Germany. For the first time since its inception, the training had six francophone participants.

The RCORE training aims at building capacity in clinical trials within the sub-region to enhance the conduct of clinical trials and improve access to medicine by harmonising regulatory requirements. The intensive 4-week programme was attended by participants from Benin, Cameroon, Gabon, The Gambia, Ghana, Guinea Conakry, Kenya, Liberia, Nigeria, Rwanda and Senegal.

As well as covering all key areas of clinical trial regulation, the training included a practical regulatory attachment where participants gained hands-on experience on clinical trials authorisation and Good Clinical Practice (GCP) inspections.

During the year, two regulatory staff from the FDA Ghana undertook a ‘Train-the-Trainer’ regulatory attachment in Germany at the Paul Ehrlich Institute. The trainees play leading roles as trainers in FDA Ghana’s RCORE clinical trials fellowship training programme. The training was originally scheduled to be a 45-day on-site training at the Paul Ehrlich Institute but, due to the pandemic, it was ultimately delivered in two parts: a two-week online theoretical part and a four-week practical, hands-on session in Germany. An additional 23 regulators from the FDA Ghana (and other regulatory authorities in Africa) took part in the virtual theoretical sessions.

This high-level training and consulting programme from the Ghana RCORE for Clinical Trials was specifically designed to build their regulatory skills and knowledge, particularly in the area of evaluating clinical trial applications and monitoring the benefit–risk balance of vaccines and biologics.

In November–December 2022, the Ghana FDA also held its first advanced RCORE fellowship training in clinical trials, in collaboration with the University of Ghana and with support from the New Partnership for Africa’s Development (AUDA-NEPAD). Regulatory officers from national medicine regulatory authorities in The Gambia, Liberia, Nigeria, Sierra Leone, Tanzania, Uganda and Zambia attended the training.

Building ethics capacity in Portuguese-speaking countries

The BERC-Luso and LusoAfro-BioEthics projects have been building ethical review capacity in Portuguese-speaking countries during 2022, and also helping to prepare Cape Verde for its first clinical trials.

One of the key challenges for Portuguese-speaking countries looking to develop their regulatory and ethics capacity is the lack of suitable training materials, which are mostly produced in English. The **BERC-Luso project** had a specific focus on Portuguese-speaking countries and strengthening cross-national collaborations to support capacity-building.

During 2022, the BERC-Luso coordination team made visits to several participating countries. In February–March 2022, the team visited São Tomé and Príncipe, taking part in a workshop on clinical trials and biomedical research held at the Portuguese Cultural Centre, which involved more than 50 participants from various areas of health sciences, social sciences and others.

In April 2022, a visit was made to Cape Verde. The visit included meetings with national authorities, political authorities, the Portuguese Ambassador to Cape Verde, a conference on ‘The importance of biomedical research in Cape Verde’ and meetings with various national bodies relevant to the project.

In the same month, the team visited Guinea Bissau and in July 2022 it travelled to Angola. The latter trip included meetings with national authorities, a meeting with the Portuguese Ambassador to Angola, and a conference on ‘The importance of biomedical research in Angola’ in Luanda.

In March 2022, the **LusoAfro-BioEthics** project organised a virtual course on ethics in health research. The course covered issues such as the history of ethics in health research and legislative frameworks in ‘PALOP’ countries (Países Africanos de Língua Oficial Portuguesa, Portuguese-speaking African countries), as well as the functioning of ethics committees and the documents submitted to them in Angola, Cape Verde, Guinea-Bissau, Mozambique, Portugal, and São Tomé and Príncipe. EDCTP’s High Representative for Africa, Dr Leonardo Simão, opened the course.

In 2020, a consortium of researchers from Cape Verde, Denmark, Guinea-Bissau, Mozambique and Portugal were granted [emergency funding](#) to study the impact of the BCG vaccine on healthcare worker absenteeism during the pandemic. The **BCG-COVID-RCT** study was designed as a multi-centre trial, with 350 healthcare workers enrolled in each African country. It would include the first clinical trial to be carried out in Cape Verde.

However, as clinical trials regulations were not yet in place in Cape Verde when the clinical trial was planned to start, the Cape Verde ethical review committee was unable to approve the trial protocol, and studies were conducted only in Guinea Bissau and Mozambique. As a result, the Ministry of Health in Cape Verde created a National Task Force on Clinical Research Legislation to coordinate development of a legal framework for biomedical research, clinical trials, and public health research. The BERC-Luso project played an important role in this process.

The Cape Verde team maintained contact with the BCG-COVID-RCT consortium. In 2022, after more than 100 online meetings, the consortium met for a workshop in Cape Verde. The workshop was opened by representatives from the Ministry of Health and the University of Cape Verde. They praised the important role the consortium has played in helping to establish the legal framework for clinical trials in Cape Verde and the research capacity-building that has taken place.

Facilitating clinical research in Cameroon

The BREEDSAFCA project has catalysed the finalisation of key legislation for regulation of clinical research in Cameroon.

Until recently, Cameroon has had limited legal infrastructure governing clinical research. The **BREEDSAFCA project** has helped to address this deficit by developing new regulatory instruments relating to different aspects of clinical research. The process of reviewing these proposed regulations stimulated the finalisation of the draft law on medical research that has been undergoing development since 2013.

Furthermore, most of the regulatory instruments developed by BREEDSAFCA were

integrated into the new law, which was formally adopted in April 2022. This has transformed the landscape for medical research involving human participants in Cameroon.

In addition, the project has been enhancing the infrastructure for ethical review in Cameroon. Given its sociocultural diversity, the country recognised the need for devolved ethical review structures. However, only two of the 10 regions of Cameroon had regional ethics committees. BREEDSAFCA has helped to establish two additional regional committees in the North West and North Regions of Cameroon, and two others are in the process of being created.

Enhancing drug safety monitoring in Tanzania

The SMERT and ASCEND projects have led to dramatic improvements in the reporting of adverse drug events in Tanzania.

The reporting of adverse drug events (ADEs) is important for monitoring the safety of newly introduced medicines and for detecting issues with how drugs are being administered. However, pharmacovigilance systems are under-developed in many sub-Saharan African countries.

The EDCTP-funded **SMERT** and **ASCEND** projects have established international partnerships to support the development of ethical review and regulatory capacities in Tanzania, particularly at the **Tanzania Medicines and Medical Devices Authority (TMDA)**. One strand of work has focused on pharmacovigilance systems.

The TMDA coordinates a pharmacovigilance system that was introduced in Tanzania in 1989. It is based on spontaneous ('passive') reporting of ADEs and limited information is collected.

To improve reporting, an awareness and training programme was developed, the **structured stimulated spontaneous safety monitoring (SSSSM) programme**. This includes a training package for various health professionals on the importance of ADE monitoring and on mechanisms for monitoring and reporting.

The SSSSM programme was piloted at seven tertiary hospitals in Tanzania and evaluated in a quasi-experimental design, by comparing reporting for 18 months before and after introduction.

The programme led to a dramatic increase in reporting – out of 16,557 ADEs in total, 16,332 (98.6%) were reported after introduction of the SSSSM programme. Reporting increased from two reports per million inhabitants in 2018 to 85 reports per million inhabitants in 2019.

The degree of improved performance varied markedly between sites. Most notably, reports increased from 20 pre-SSSM to 11,637 post-SSSM in Dar es Salaam. However, reporting remained low at some other sites.

The reporting identified novel ADEs associated with use of a newly introduced antiretroviral regimen. It also detected a cluster of cases associated with administration of an antibiotic at a particular site, which was addressed through training of health workers on the correct administration procedures.

The findings argue for the wider introduction of the SSSSM programme, alongside other measures to raise awareness of drug safety monitoring during the training and professional development of health workers of all kinds.



Global ethical frameworks for research

EDCTP is supporting global initiatives aiming to strengthen ethical frameworks for research in resource-poor settings.

In May 2022, the influential global journal *Nature* published an editorial announcing some of the steps it would be taking to address exploitative research practices and ‘ethics dumping’ – jettisoning of high ethical standards when work is conducted in low-income settings.

The journal has released guidance for authors, editors and reviewers that outline expectations of research practice. This guidance recommends use of the [Global Code of Conduct for Research in Resource-Poor Settings](#), developed by the EU-funded TRUST initiative, of which EDCTP is part. EDCTP was one of the first adopters of the Global Code, in 2018.

In addition, in September 2022, the Pro-active Pandemic Crisis Ethics and Integrity Framework (PREPARED) project was officially launched. This three-year project, funded through the EU’s Horizon Europe programme, will develop an ethics and integrity framework to support rapid and effective research during global crises.

The project builds on the insights and results from the TRUST project on equitable research partnerships. EDCTP is a partner on the project and will contribute to several of its work packages.



Organisational activities

During 2022, EDCTP2 has retained its focus on developing partnerships with other stakeholders and promoting access to the results of EDCTP-funded research.

Building partnerships

EDCTP's contribution to Europe–Africa partnerships has been flagged in an influential EU report, while the EDCTP Association has added five new member states and an additional memorandum of understanding has been signed with an international body with a strong presence in Africa.

On 17 February 2022, the **Advisory Group on Research and Innovation (R&I) for Africa–Europe Cooperation** highlighted the role played by EDCTP in strengthening capacity in Africa. Health is one of four themes in this report, alongside R&I capacities, technology and innovation, and green transition. The Advisory Group's [recommendations on how to make R&I a driver for sustainable development in AU–EU relations](#) will help to shape the future of African–European policies and partnerships.

The recommendations recognise the need for increased investments in institutional capacities and training, R&I policy and governance, infrastructure and institutions, human capacity development, knowledge management and funding, and cooperation and partnerships. EDCTP is specifically highlighted as “the most cited joint programme strengthening health research and health systems in Africa”.

Furthermore, EDCTP is one of the action lines of the [EU Global Health Strategy](#) published in 2022, which aims to ensure that innovative vaccines, treatments and diagnostics are developed and used in sub-Saharan Africa. In the working document of the [African Union – European Union Innovation Agenda](#), also published in 2022, EDCTP is listed as one of the key public health initiatives to support networking, capacity-building and technology transfer.

The **EDCTP Association** continued to expand in 2022, with the incorporation of Belgium, Côte d'Ivoire, the Democratic Republic of the Congo, Guinea-Conakry and Rwanda. By the end of 2022, the Association consisted of 15 European and 21 African member countries.

Six new appointees were made to the **EDCTP Association Board** in June 2022. The Board is responsible for managing the EDCTP Association and supervising the Secretariat on behalf of the EDCTP General Assembly. The appointees include representatives from France, Germany, South Africa, Sweden, Uganda and Zambia. EDCTP wishes to thank outgoing Association Board members for their invaluable support and guidance.

In December 2022, the EDCTP Association and the International Centre for Genetic Engineering and Biotechnology (ICGEB) signed a memorandum of understanding to encourage and promote cooperation in areas of mutual interest. Key areas of focus will include incorporation of genome engineering technology into EDCTP-funded networks, joint activities in capacity-building, and co-funding of projects in areas of mutual interest. ICGEB has 66 member states, 23 of which are in Africa.

Sharing knowledge

The EDCTP Knowledge Hub, an online resource for those planning clinical studies, has been praised in new WHO guidance, while EDCTP has also joined Europe PMC (PubMed Central) and encourages its researchers to submit articles to this open-access repository.

An article published in the journal *Trials* in 2022 summarised development of the EDCTP Knowledge Hub, an online platform that provides access to a range of essential tools to guide the planning and implementation of high-quality clinical studies. Developed in collaboration with the Global Health Network (TGHN), the Knowledge Hub is designed to address some of the key barriers to clinical protocol development in low- and middle-income countries.

The Knowledge Hub includes a range of resources to help researchers develop research questions into a protocol and to adopt gold-standard clinical data-management practices. It includes interactive and comprehensive toolkits covering the essential steps of a clinical health research study. It also raises awareness of the importance of data sharing, and provides practical advice and guidance on how to share data.

The EDCTP Knowledge Hub was featured in new WHO guidance on sharing of research data, published in April 2022. The guidance outlines WHO's position that sharing research data is a global public good. The policy requires WHO-supported researchers to share data in ways that are equitable, ethical and efficient, and follow the 'FAIR' principles – that data are findable, accessible, interoperable and reusable. This position is in keeping with EDCTP's policy on clinical trials registration, publication and data sharing.

WHO's guide also directs researchers to comprehensive resources, including the [EDCTP Knowledge Hub](#). According to the guidance document, the Knowledge Hub “provides a wealth of good research practice resources, reading material and explanatory videos as well as a search function to identify the best online repository to share your research data”.

In 2022, EDCTP became a member of [Europe PMC \(PubMed Central\)](#), an open science platform that maintains a worldwide collection of scientific articles and other research outputs. Joining Europe PMC enables EDCTP-funded researchers to share their publications via one central location and ensures that they also satisfy the EDCTP requirement for publications to be openly accessible as soon as possible.

In March 2022, EDCTP arranged a training webinar for grantholders to introduce the EDCTP open-access policy and to provide step-by-step guidance on how to comply with the policy and deposit research manuscripts in Europe PMC.

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.

Mandated representative entity

	Angola (Aspirant member) National Institute of Public Health
	Austria Medical University of Vienna
	Belgium Department Economy, Science and Innovation
	Burkina Faso Centre National de Recherche et de Formation sur le Paludisme
	Cameroon Ministry of Public Health
	Congo University Marien Ngouabi
	Côte d'Ivoire Ministry of Higher Education and Scientific Research
	Democratic Republic of the Congo Université de Kinshasa
	Denmark Statens Serum Institute
	Ethiopia Armauer Hansen Research Institute
	Finland Academy of Finland
	France Aviesan, Institut thématique multi-organismes
	Gabon Centre de Recherches Médicales de Lambaréné
	The Gambia Ministry of Health and Social Welfare
	Germany Bundesministerium für Bildung und Forschung
	Ghana Ghana Health Service
	Guinea-Conakry Centre National de Formation et de Recherche en Santé Rurale
	Ireland Irish Health Service Executive
	Italy Istituto Superiore di Sanità
	Kenya National Research Fund

	Luxembourg Fonds National de la Recherche
	Mali University of Science, Techniques and Technology of Bamako
	Mozambique Ministry of Health
	Netherlands NWO-WOTRO Science for Global Development
	Niger Ministry of Public Health
	Nigeria Federal Ministry of Health
	Norway Research Council of Norway
	Portugal Foundation for Science and Technology
	Rwanda Rwanda Biomedical Centre
	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

Summary financial statements 2022

Statement of profit or loss and other comprehensive income

for the year ended 31 December 2022. Expressed in thousands ('000) of euro.

	EC 2022	Donor 2022	Total 2022	Total 2021
Calls (Grants)				
Contributions	684	6,352	7,036	143,874
Grant expenditure	(684)	(6,352)	(7,036)	(143,874)
Results for the year	-	-	-	-
Others				
Contributions	5,391	994	6,385	6,151
Other expenditure	(5,391)	(994)	(6,385)	(6,151)
Results for the year	-	-	-	-
Total results for the year	-	-	-	-

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.

Statement of financial position

as at 31 December 2022 (after appropriation of result). Expressed in thousands ('000) of euro.

	31 December 2022	31 December 2021
Non-current assets		
Right-of-use assets	1,451	1,618
Debtors and other receivables	56,715	155,375
Total non-current assets	58,166	156,993
Current assets		
Debtors and other receivables	111,879	98,137
Cash and cash equivalents	64,833	44,781
Total current assets	176,712	142,918
Total assets	234,878	299,911
Non-current liabilities		
Grants and other payables	133,581	167,922
Deferred income EC	-	-
Deferred income Donor	-	-
Lease liabilities	1,279	1,423
Total non-current liabilities	134,860	169,345
Current liabilities		
Grants and other payables	86,804	125,356
Deferred income EC	-	-
Deferred income Donor	13,042	5,015
Lease liabilities	172	195
Total current liabilities	100,018	130,566
Total liabilities	234,878	299,911

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

Dr Michael Makanga

Dated: 25 May 2023

Statement of Changes in EC and Donor's Equity

Expressed in thousands ('000) of euro

	Reserve: EC	Reserve: Donor	Total
Balance as at 31 December 2021	-	-	-
Total comprehensive income for the year	-	-	-
Balance as at 31 December 2022	-	-	-

EDCTP has no unrestricted reserves.

Statement of cash flows

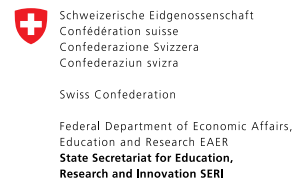
for the year ended 31 December 2022. Expressed in thousands ('000) of euro.

	2022	2021
Cash flows from operating activities		
Result for the year	-	-
Adjustment for:		
Depreciation charge for right-of-use assets	167	167
Lease interest	44	48
Reversal of depreciation and lease interest	(16)	(20)
(Increase) decrease in debtors and other receivables	(854)	(143)
Increase (decrease) in grants and other payables	(72,893)	(9,586)
Increase (decrease) in deferred income	93,878	(25,205)
Net cash flows from operating activities	20,326	(34,739)
Cash flows from investing activities		
Interest received/(paid)	(79)	(169)
Payment of lease liabilities	(195)	(195)
Net cash flows from investing activities	(274)	(364)
Net increase (decrease) in cash and cash equivalents	20,052	(35,103)
Cash and cash equivalents at 1 January	44,781	79,884
Exchange rate effects		
Cash and cash equivalents at 31 December 2022	64,833	44,781



Acknowledging our funders

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Colophon

European & Developing Countries Clinical Trials Partnership

The Hague, the Netherlands, June 2023

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IMPROVE study participant, Kenya

The power of sharing science