EDCTP

The power of sharing science

Annual Report 2023

Supported by the
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About EDCTP

The European & Developing Countries Clinical Trials Partnership (EDCTP) is a public–public partnership between 15 European and 28 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 (BRCCH, 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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Message from the EDCTP Association Board Chair

2023 was a very exciting milestone year for EDCTP. In Paris in November 2023, we not only celebrated the 20th anniversary of EDCTP but also had the largest EDCTP Forum to date, where representatives from many EDCTP-funded projects presented findings from their studies. As a delegate, I appreciated the opportunity to hear first-hand some of the highly impactful results presented by EDCTP grant-holders. For me, this is testament to the fact that EDCTP funding and approaches have contributed immensely not only to the fight against poverty-related diseases but also the development of research networks and capacity in sub-Saharan Africa.

Everyone will agree that EDCTP is a true partnership of equals at all levels between European and African partners; it provides a model for how Europe and Africa can effectively collaborate in other areas through equitable partnerships. Moreover, it has brought together the brightest minds from the two continents to jointly work on critical public health challenges in partnership with other funders, product developers and industry. The value of these partnerships is priceless, creating lasting connections and relationships that will underpin research in the next decade and beyond. It is gratifying to see that the impact of EDCTP has been widely recognised in sub-Saharan Africa, with seven new African countries joining the EDCTP Association in 2023, bringing the total number of participating states to 28 from sub-Saharan Africa and 15 from Europe. Notably, African members of the EDCTP Association include English-, French- and Portuguese-speaking countries.

I am very happy that the EDCTP Association and the Global Health EDCTP3 Joint Undertaking are working together to further expand and strengthen this partnership. The EDCTP2 programme has created a springboard that is providing its successor, the Global Health EDCTP3 programme, with a running start. The new programme has broadly the same objectives as EDCTP2, but with a wider scope, which includes global public health priorities such as the health impacts of climate change and antimicrobial resistance, and a new legal basis that will facilitate partnerships with a wider range of global actors.

I take this opportunity to thank Dr Michael Makanga for his dedicated and inspirational leadership of the EDCTP Association Secretariat during his seven years as Executive Director. With Michael now at the helm of Global Health EDCTP3, we can be sure that the new programme is in safe hands. I must also thank the management and staff of the EDCTP Association whose daily efforts have been essential to the successes achieved.

While EDCTP programmes have had outstanding success in the last twenty years, I have the firm belief that the best years are yet to come.

Dr Henning Gädeke
Chair of the Board of the EDCTP Association


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Message from the EDCTP Association Acting Executive Director

As mentioned in our Board Chair's message, 2023 was indeed a milestone year for EDCTP. The second independent interim evaluation of the EDCTP2 programme was published in 2023. It is very pleasing to see that the report highlighted EDCTP's contributions towards the building of equitable research partnerships between Europe and sub-Saharan Africa; and how EDCTP's activities have underpinned major advances in health and strengthened research capacity in sub-Saharan Africa. The evaluation praises the programme's adaptability and its responsiveness to the needs of populations and health research systems in sub-Saharan Africa.

As we report on the achievements of the EDCTP programmes in 2023 we should not forget to thank the European Commission and all founding members of EDCTP for their ingenuity in not only creating EDCTP but also including 'partnership' in the name. I must also thank all EDCTP stakeholders, particularly EDCTP staff, grant-holders, and constituencies, for ensuring that this partnership is a success.

As we entered the closing phase of the EDCTP2 programme, one of our objectives in 2023 was to provide more support to ongoing projects, including operational and financial management support to EDCTP-funded grant-holders, as they complete their studies and disseminate their findings. Our priority has been to ensure they not only successfully close their projects but also avoid incurring ineligible expenses by complying with the general and specific conditions for eligibility as set out in the Article 185 Model Grant Agreement. In fulfilment of this objective, we organised two project and financial management trainings and four site visits in 2023, thanks to the dedication and commitment of EDCTP staff and management.

The COVID-19 pandemic disrupted many of our projects, but the consequences were generally delays, rather than complete termination. In 2023, we worked closely with project coordinators to determine the impact of COVID-19 on project durations. Consequently, we have amended 77 grant agreements to give projects more time to complete their scope and objectives.

A highlight of 2023 was the Eleventh EDCTP Forum, held in Paris, France, in November 2023, which celebrated 20 years of EDCTP and covered both the EDCTP2 and Global Health EDCTP3 programmes. As well as many distinguished speakers, the Forum heard how multiple EDCTP2 projects are generating data of crucial public health importance and provided an excellent opportunity for networking and exchange of ideas and experience. We are already looking forward to the next Forum, which will be held in Rwanda in 2025.

We were also pleased to see seven Global Health EDCTP3 calls for proposals launched in 2023, with a total budget of over €130 million and covering a wide range of topics, including tackling Ebola outbreaks, women's and child health, and improving modes of vaccine delivery.

EDCTP programmes have made significant achievements, as is reflected in this Annual Report. However, we still have much to do. I am confident that the Global Health EDCTP3 Joint Undertaking will achieve even more.

Abdoulie Barry
Acting Executive Director &
Director of Finance and Administration

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EDCTP in 2023

Main events and milestones in 2023:

Eleventh EDCTP Forum and 20th anniversary

- Celebrated the 20th anniversary of EDCTP in Paris during the Eleventh EDCTP Forum, where more than 1,000 delegates gathered to present results of their projects and network (page 18).

Progress in malaria prevention

- A second malaria vaccine, R21/Matrix-M, supported through a phase II study by EDCTP, has been recommended by WHO and will help to meet strong regional demand for malaria vaccination (page 24).
- Two EDCTP-funded studies have shown that a new antimalarial, dihydroartemisinin piperaquine (DHP), is safe to give to women living with HIV to prevent malaria infections during pregnancy (page 29).

Major advances in treatment of HIV-related disease

- A simplified drug formulation for treatment of fungal meningitis in people living with HIV is effective and safer than the current treatment (page 22).
- A new care pathway for people living with HIV with suspected CNS infections has been found to halve mortality rates (page 22).

New clues to TB immunity

- An EDCTP Senior Fellow has identified a type of T cell that may play a key role in protection against TB disease, with potentially significant implications for TB vaccine development (page 44).

New treatment options for neglected infectious diseases

- EDCTP-funded studies have generated the evidence to support:
  - The use of a new version of praziquantel suitable for young children (page 27)
  - The extension of fexinidazole use to treat acute forms of sleeping sickness (page 27)
  - The use of an albendazole–ivermectin fixed-dose combination to provide children with protection against a wider range of soil-transmitted helminths (page 27).

Stronger national systems for oversight of clinical research

- EDCTP-funded projects have contributed to significant strengthening of ethics review and regulatory bodies in multiple countries in sub-Saharan Africa (page 33).

A meeting of EDCTP fellows

- Two pre-Forum meetings examined the contribution of the EDCTP2 fellowship programme to capacity-building (page 38).

A collaborative approach to clinical trial capacity-building

- EDCTP continued to work with other funders to explore how best to strengthen clinical trial capacity in sub-Saharan Africa and achieve World Health Assembly Resolution WHA75.8 (page 45).

More investments under Global Health EDCTP3

- The first grant agreements were signed and more investments announced (page 46).

Towards EDCTP2's objectives

(2014-2023)

Medical interventions

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

371
clinical studies supported by EDCTP2 since 2014. Of these, 61% (228) are interventional (clinical trials) and 39% (143) are non-interventional studies.

65% (101)
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% (25)
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.

215
fellowships grants which supports 362 fellows (145 females and 217 males) to researchers from 39 sub-Saharan African countries.

1,202
trainees from 43 sub-Saharan African countries are supported through EDCTP projects. Trainees include 567 Master's (47%) and 405 PhD (34%).

28
sub-Saharan African countries are members of the EDCTP Association by the end of 2023.

European coordination

Improve coordination, alignment and integration of European National Programmes.

15
European countries are members of the EDCTP Association.

€198.69 M
cash received from the European Participating States to the EDCTP2 programme.

€1.157 Bn
committed through 302 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 19 institutions from other countries.

15% (359 out of 2,371)
of all participation in EDCTP-funded projects involve private-sector institutions. These institutions were awarded €181.2 M by end of 2023.

€26.84 M
has been leveraged from partners for the launch of joint or coordinated calls for proposals.

€432.07 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.

EDCTP2's funding of research and capacity development

(2014-2023)

Total funding
€824.55 M
439 grants awarded to date.

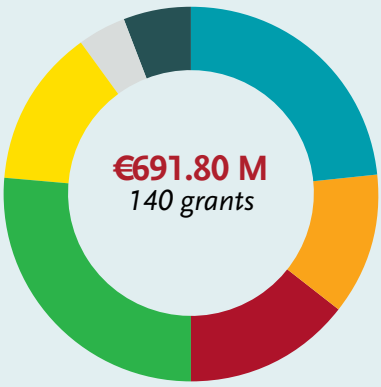
Collaborative clinical trials and clinical studies
€691.80 M
to support **140 collaborative research grants** with large-scale clinical trials and other clinical research activities conducted by European-African consortia.

Clinical research capacity
€87.55 M
to support **93 grants** that strengthen the enabling environment for conducting clinical trials and clinical research.

Fellowship programme
€45.19 M
to support **206 fellowships grants** that focus on the career development of African scientists.

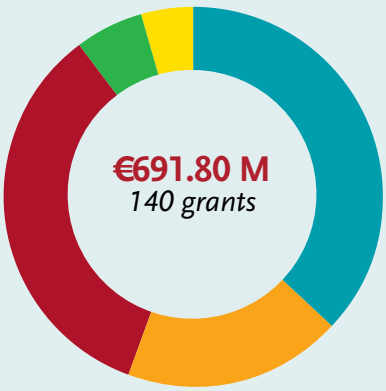
Collaborative clinical trials and clinical studies

By disease



- Tuberculosis, *33 grants* **€194.83 M**
- Malaria, *17 grants* **€138.32 M**
- HIV & HIV-associated infections, *20 grants* **€115.55 M**
- Emerging diseases, *37 grants* **€78.61 M**
- Neglected infectious diseases, *19 grants* **€70.59 M**
- Diarrhoeal diseases, *6 grants* **€53.15 M**
- Lower respiratory tract infections, *8 grants* **€40.76 M**

By intervention



- Drugs, *51 grants* **€283.63 M**
- Vaccines, *26 grants* **€247.49 M**
- Diagnostics, *47 grants* **€121.32 M**
- Non-intervention-specific topics, *8 grants* **€35.37 M**
- Product-focused implementation research, *6 grants* **€3 M**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3.1

EDCTP 20 years on: major achievements and progress made

Established in 2003, EDCTP has grown significantly over the past 20 years. During this period, EDCTP programmes have established a model for how equitable research partnerships should operate. EDCTP has always positioned itself as a partnership of equals, and this covers both the governance of the programme – where European and African partners have equal status – and in the operations of individual research collaborations. This is a highly effective model, and one that has helped to deliver results that could not have been achieved by partners working alone.

Over the past two decades, EDCTP has funded collaborative research partnerships that have advanced multiple much-needed interventions against poverty-related diseases affecting sub-Saharan Africa. Collaborative research culture has been grown and nurtured through four regional Networks of Excellence covering half of the countries in sub-Saharan Africa. EDCTP has also made critical contributions to the development of research capacity in the region, particularly through its comprehensive fellowship programme. Seven more countries joined the EDCTP Association in 2023 for participation in Global Health EDCTP3 – Benin, Guinea-Bissau, Liberia, Malawi, Sierra Leone, Somalia and Zimbabwe. This brings the total number of Association member countries to 43, including 28 African countries.

An independent evaluation of the EDCTP2 programme (covering the period 2017–2021), commissioned by the European Commission and published in 2023, provided a highly positive assessment of EDCTP's activities across a range of criteria including relevance, coherence, efficiency, effectiveness and added value. The report highlighted EDCTP's contributions towards the building of equitable research partnerships between Europe and sub-Saharan Africa, and how EDCTP's activities have underpinned major advances in health and strengthened research capacity in sub-Saharan Africa.

The evaluation praised the programme's **adaptability** and its **responsiveness** to the needs of populations and health research systems in sub-Saharan Africa. This has been underpinned by strong African representation in all aspects of its governance, as well as extensive consultation and partnerships with African stakeholders.

EDCTP2 was also noted to have established a **clear niche** in the global health ecosystem, through its focus on **late-stage clinical trials** and **implementation research**, which are generally less well supported by other funders, and through its prioritisation of **under-served populations**. These include women and pregnant women, people with co-infections (including HIV infections) and co-morbidities, and children and adolescents.

The programme was acknowledged to have responded to past recommendations on efficiency and was found to have been highly effective in supporting activities consistent with its objectives. It has had substantial **added value**, providing ways to support activities beyond the scope of individual funders through a strategic framework with which national funding activities can be aligned.

Delivering on promises

The evaluation also noted that the EDCTP2 programme has been highly effective at ensuring that projects are completed and generate data (although the COVID-19 pandemic inevitably delayed many projects). As illustrated elsewhere in this Annual Report, as projects conclude and results are disseminated, it is clear that EDCTP is having a **major impact on the development and implementation of new medical interventions** for poverty-related diseases, including vaccines, drugs and diagnostics.

Its unique focus on **capacity building** has also had tangible benefits. As summarised in a recent report, EDCTP2 has supported more than 362 fellows, at all stages of a research career, including influential research leaders and up-and-coming scientific talent. The EDCTP fellowship programme is ensuring that African researchers can develop their careers within Africa, while remaining connected to global knowledge networks. This funding has an important multiplier effect, as each fellow supervises and mentors other researchers, growing the size of the science base.

In addition, the programme has taken a holistic view of capacity building, focusing also on creating a **supportive environment** for high-quality clinical research. It has achieved substantial progress in advancing ethics review and regulatory authority capabilities in sub-Saharan Africa, which will be essential if the number of clinical trials organised in the region is to grow further.

Notably, in its supplementary report on implementing World Health Assembly resolution WHA75.8 on building clinical trial capacity, WHO highlighted EDCTP2 as an initiative that had successfully developed capacities and supported local leadership in many African countries.

The principles of **equity, diversity and inclusion** have also been an important focus. The representation of women has been carefully monitored, in terms of applicants and reviewers. Although women are under-represented in sub-Saharan African research, particularly at more senior levels, EDCTP has achieved good representation, including in project leadership and success in fellowship funding – 40% of EDCTP2 fellows, for example, are women.

EDCTP2 has been dedicated to the pursuit of equitable research partnerships. This extends all the way from the governance of the EDCTP Association, an equal partnership between countries in Europe and sub-Saharan Africa, through to the expectations of how international research partnerships funded through EDCTP2 will operate.

The programme has also made multiple efforts to provide opportunities to **countries with less well-developed research bases**. Regional Networks of Excellence have incorporated institutions from such settings in their networks and the Senior Fellowship Plus scheme enables experienced researchers to nurture colleagues from less well-established institutions. Efforts have also been made to ensure researchers from French- and Portuguese-speaking countries are not disadvantaged.

The full impact of EDCTP2 has yet to be felt, as many studies are still completing and analysing data. Even now, however, it is clear that it has delivered on its promises, and has laid a solid foundation for even greater progress during the expanded Global Health EDCTP3 programme.

EDCTP in 20 years: key facts and figures

Invested **€1.03 Bn to support 692 projects** (€208 M EDCTP1; €824.30 M EDCTP2).

Supported **477 clinical studies** (102 EDCTP1; 375 EDCTP2).

Generated more than **2,000 peer-reviewed publications** (>700 EDCTP1; >1,300 EDCTP2)

Supported **150 phase II and III clinical studies of drugs and vaccines** (52 EDCTP1; 98 EDCTP2)

Supported **58** studies targeting **pregnant women and their children** (9 EDCTP1; 49 EDCTP2)

Funded **121 grants** to enhance ethics and regulatory capacity in sub-Saharan Africa (75 EDCTP1; 46 EDCTP2)

Contributed to the **EU TRUST Project**, which is developing a global framework and practical tools to ensure the application of consistently high ethical standards in research.

Created a **Pan-African Clinical Trials Registry**, now with more than 1,000 registrations.

Established four regional **Networks of Excellence** spanning **21 countries and 64 institutions**.

Established an **EDCTP Alumni Network** and online platform.

Supported **epidemic preparedness networks** spanning **18 sub-Saharan African countries**.

Contributed to health systems strengthening, for example through two new consortia building national **pharmacovigilance capacity** in six sub-Saharan African countries.

Received **€246.80 M** in cash contributions from European member countries (€50.44 M EDCTP1; €196.36 M EDCTP2)

Leveraged **€527.75 M** in cash and in-kind support from partners (€72.69M EDCTP1; €455.06 M EDCTP2)

3.2

Eleventh Forum and 20th anniversary

In 2023, we celebrated the 20th anniversary of EDCTP in Paris during the Eleventh EDCTP Forum.

The Forum was the largest EDCTP event ever, attracting 1,118 delegate registrations of which 960 in-person delegates from 64 countries. The six plenary sessions featured 35 speakers (20 female and 15 male). The Forum included 247 physical posters and 70 e-posters, as well as scientific symposia, sponsored satellite meetings, and highly popular 'meet the experts' sessions, at which delegates could discuss any technical or career-related issue with senior researchers.

It featured a wide range of prominent guest speakers, as well as scientific sessions that provided opportunities for EDCTP-funded projects to communicate their findings. Distinguished speakers included the French Minister for Higher Education and Research, the Nigerian Minister of State for Health and Social Welfare, the WHO Regional Director for Africa, the French Ambassador for Global Health, the European Commissioner for Innovation, Research, Culture, Education and Youth, the Director of the People Directorate, the DG Research and Innovation at the European Commission, the Director General of the Health Emergency and Response Authority (HERA), and the Acting Chief Scientist at the Africa Centres for Disease Control and Prevention (Africa CDC).

Thought-provoking keynote addresses were delivered by **Professor Abdoulaye Djimdé**, from the Malaria Research and Training Centre (MRTC) in Mali, on institutional research capacity in sub-Saharan Africa; **Professor Michel Kazatchkine**, from the Graduate Institute for International Affairs and Development, Switzerland, on equitable access to medical interventions; **Professor Salim Abdool Karim**, from the Centre for the AIDS Programme of Research in South Africa (CAPRISA), on African-led discovery and innovation; and from **Professor Claudia Hanson**, from the Karolinska Institute, Sweden, on maternal and neonatal care.

The scientific sessions covered all areas of EDCTP's work, highlighting much exciting progress being made scientifically and in the strengthening of research capacity. The Forum also celebrated the work of the 2023 EDCTP Prize winners, who were announced at the meeting.

Participants arriving at the Forum venue in Paris.

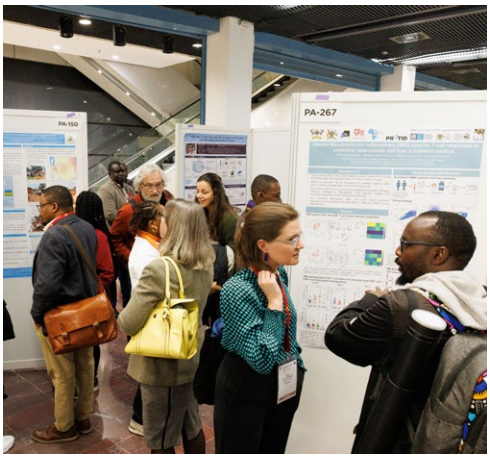
Dr Henning Gädeke at the opening ceremony of the Eleventh EDCTP Forum.

The French Minister of Higher Education and Research, Sylvie Retailleau, giving her welcoming remarks at the Forum.

The Forum was preceded by meetings dedicated to EDCTP Fellows and EDCTP/Africa CDC Epidemiology and Biostatistics Fellows. Sponsored satellite sessions included coverage of the Pandemic Preparedness Platform for Health and Emerging Infections Response (PANTHER), WHO's RTS,S/AS01 malaria vaccine implementation project, and neglected infectious disease control and the work of the Drugs for Neglected Diseases Initiative (DNDi).

In addition, workshop themes included the World Health Assembly WHA75.8 clinical trials resolution, the EDCTP Knowledge Hub, the 'Design, Analyse, Communicate Africa' (DAC-A) clinical trial initiative, Horizon Europe, and Global Health EDCTP3 funding opportunities. Panel discussions explored key issues in maternal and neonatal health, inequalities in global health, and how Global Health EDCTP3 can best work with other global health initiatives.

During the Closing Ceremony, Rwanda was announced as the host country of the Twelfth EDCTP Forum in 2025, which will again jointly cover the EDCTP2 and Global Health EDCTP3 programmes.



2023 EDCTP Prizes

Prizes were awarded at the Eleventh EDCTP Forum in Paris to recognise individuals and groups who have been making outstanding contributions to medical research in sub-Saharan Africa and the strengthening of relationships between Africa and Europe.

The EDCTP Prizes are awarded every other year and are announced at each EDCTP Forum. The 2023 prize winners were:

Outstanding Female Scientist Prize went to **Professor Kogie Naidoo**, Centre for the AIDS Programme in South Africa, CAPRISA). Professor Naidoo was one of the first clinicians to provide antiretroviral therapy to people living with HIV in South Africa, and to offer free antiretrovirals in clinics in rural South Africa. Her work has since focused on disease prevention, vaccine trials and implementation research, particularly around drug-resistant TB. A particularly notable achievement was work demonstrating more than a halving of mortality in HIV/TB co-infected patients. She has supervised and mentored scores of students and early-career researchers, more than 90% of them women.

Outstanding Research Team Prize went to **the Health Research Unit Zimbabwe (THRU-Zim)**. The THRU-Zim team carries out a wide range of research studies across the life-course, particularly in newborns but also in adolescents and more recently older people. The team is highly multidisciplinary, encompassing epidemiologists, statisticians, social scientists, health economists and others. The Unit embeds capacity building in all its work and has hosted several EDCTP fellows.

Dr Pascoal Mocumbi Prize went to **Professor Peter Kremsner**, Universitätsklinikum Tübingen/Institut für Tropenmedizin, Germany, and Centre de Recherches Médicales de Lambaréné (CERMEL, Gabon). Professor Kremsner has played a critical role in establishing CERMEL as a national centre of research excellence in Gabon, focusing primarily on malaria, as well other locally important infectious diseases.

Scientific Leadership Prize went to **Professor Kamija Phiri**, Kamazu University of Health Sciences, Malawi. Professor Phiri has set up an independent research institute, the Training and Research Unit of Excellence (TRUE), which now employs around 150 people and focuses mainly on malaria and anaemia. His most notable achievement has been the development of a WHO-recommended malaria chemoprevention strategy for children discharged from hospital after being treated for severe anaemia, who are highly vulnerable to malaria infection.

3.3

Detecting and treating fungal brain infections

Results from the AMBITION-cm trial have led to an updating of WHO guidelines for treatment of fungal brain infections in people with HIV, and the paper reporting these findings has been awarded a prestigious international award.

Meningitis caused by infection with *Cryptococcus,* a fungal pathogen, is the second-most common cause of death for people with HIV infections. Most such deaths occur in sub-Saharan Africa.

Until recently, the standard treatment for cryptococcal brain infections was a week-long course of two powerful drugs, which required constant monitoring of patients – a challenge in many resource-poor settings.

Through a large study involving 800 patients in five African countries, the **AMBITION-cm** trial, funded by EDCTP and other European partners, showed that a simpler treatment was just as effective. This treatment was based on a revised formulation of one of the two drugs, amphotericin B. Packaged in a liposome, amphotericin B can be delivered through a single high-dose injection.

The AMBITION-cm trial conclusively demonstrated that, as well as being as effective as the standard course of drugs, this new treatment approach also had fewer side effects and was preferred by healthcare providers. An economic analysis suggested it is likely to be highly cost-effective.

The results led WHO to release a rapid update of its treatment guidelines for cryptococcal meningitis. In addition, the AMBITION-cm team's paper reporting its results received a European Hector Research Award in HIV in 2023, which recognises the best paper published in HIV clinical research in the past year.

By focusing on rapid communication of results, the project ensured that WHO guidance was released within a month and patients received the new treatment in routine care within 3 months – remarkably quickly by historical standards. The project therefore also holds important lessons for how research can be linked to policymaking to ensure that patients rapidly benefit from advances in knowledge.

Managing meningitis

A further major advance in meningitis management in patients with HIV has come from the EDCTP-funded **DREAMM study**. This innovative implementation-focused study evaluated the introduction of new approaches for diagnosis and management of patients with HIV and suspected infections of the central nervous system (CNS), within existing health systems in three African countries – Cameroon, Malawi and Tanzania.

Across the sites, the DREAMM approach, based on use of new diagnostics and revised care pathways, greatly improved health outcomes. Overall, it was associated with a halving of mortality at 2 weeks, from 49% to 24%.

The project has therefore demonstrated the feasibility of introducing this new approach to diagnosis and management, which had a dramatic impact on outcomes for an infection that is the leading cause of death of people with HIV infections. The findings strongly argue for its wider implementation elsewhere in sub-Saharan Africa.

3.4 Detecting drug-resistant TB

The DIAMA project has generated important data on the detection of drug-resistant TB, informing WHO recommendations on TB diagnosis.

It is important that TB patients with drug-resistant infections are identified as rapidly as possible, so that they can be placed on the appropriate treatment. Standard culture methods to detect resistant infections are very slow, so there is increasing use of molecular diagnostics that can rapidly detect resistance mutations, particularly those conferring resistance to rifampicin. However, how best to use these tools in routine care has yet to be established.

Working within health the systems of nine African countries, the **DIAMA project** is exploring how a range of tools for detecting multidrug-resistant TB could be implemented, either at the local level or within central facilities. The Deeplex® Myc-TB test, based on targeted next generation sequencing, was implemented in reference labs in Rwanda and Benin, and the data generated contributed to endorsement of the test by WHO.

One important analysis arose from an observation made in Rwanda, where the results from a widely used test, Xpert MTB/RIF, were frequently different when patients were tested more than once. A reanalysis of data revealed a high proportion of false positives – the test was incorrectly indicating the presence of drug-resistant bacteria. In a setting of low prevalence of drug resistance, almost half of cases detected (47%) were not in reality drug-resistant.

The most likely reason was low levels of bacteria in the samples used for diagnosis. The test interprets an absence of signal as evidence of resistance, whereas it may be due to limited quantities of pathogen TB for amplification.

These findings have important implications for how the Xpert test is used to inform clinical decision-making, as patients may be unnecessarily switched to a drug regime for multidrug-resistant TB. The results were communicated to WHO and informed the development of guidelines on TB diagnosis.

The findings highlight the importance of studying innovative new technologies within the health systems of countries, to ensure that evidence is of direct relevance to country decision-makers.

3.5

Malaria vaccines come of age

Children in Africa now have access to two malaria vaccines, both of which have received support from EDCTP during their development.

Malaria kills around half a million young children in Africa every year. After decades of endeavour, effective vaccines are now being introduced which, alongside other preventive measures such as insecticide-impregnated bed nets, will help to reduce this toll.

In 2023, WHO recommended use of the R21/Matrix-M malaria vaccine, supported by EDCTP through phase I and phase II trials. R21/Matrix-M shows good efficacy and has the potential to be manufactured in large volumes, helping to meet strong country demand for malaria vaccines. It has already been approved by several countries in Africa and is due to be introduced during 2024.

R21/Matrix-M is following the path forged by the first effective malaria vaccine, **RTS,S/AS01**. EDCTP also provided support during the development of this vaccine, for example for studies embedded in the Malaria Vaccine Implementation Project in Ghana, Malawi and Kenya, which examined the benefits of a fourth dose of RTS,S/AS01 and potential safety issues. Additional EDCTP-funded studies in Ghana focused on optimising vaccine implementation and in Kenya on impacts of vaccination on brain conditions linked to malaria infections.

In addition, a Participating States Initiated Activity (PSIA) funded by the UK has demonstrated the value of combining RTS,S/AS01 with seasonal malaria chemoprevention – pre-emptive use of antimalarial drug treatments in areas where transmission occurs only during particular months of the year.

A trial involving nearly 6,000 children in Burkina Faso and Mali showed that, after 5 years, the combination of the two interventions substantially reduced hospitalisations and deaths due to malaria compared with seasonal malaria chemoprevention alone. Among those receiving both interventions, deaths from malaria were 66.8% lower than in the group receiving seasonal malaria chemoprevention alone.

The findings, published in *The Lancet* in 2023, suggest the two interventions may be acting synergistically, delivering benefits greater than would be expected on the basis of their individual effects.

3.6 Vaccine disappointments – but key lessons learned

Trials of an HIV and a TB vaccine have generated disappointing results, emphasising the huge challenges facing vaccine developers in these fields.

HIV and TB are the leading causes of disease in sub-Saharan Africa. Although effective treatments exist, long-term control of these pathogens is likely to require interventions able to prevent infection, such as vaccines. However, both HIV and the bacterium responsible for TB, *Mycobacterium tuberculosis*, present major challenges to vaccine development.

The PrEPVacc trial, funded by EDCTP and other partners, has been assessing whether two different combinations of candidate HIV vaccines, when combined with pre-exposure prophylaxis (PrEP, pre-emptive use of antiretroviral drugs to prevent infection), reduce the risk of HIV infection. In 2023, the trial's independent data monitoring committee recommended halting use of the vaccines as there was little prospect that they would be shown to be efficacious by the end of the trial. Participants are continuing to receive the PrEP components of the intervention.

The POR TB consortium has been evaluating use of a candidate TB vaccine, H56:IC31, in a 'prevention of recurrence' (POR) trial in South Africa and Tanzania. After successful treatment with TB drugs, around one in ten TB patients experience recurrence of TB, either due to reinfection or re-emergence of their initial infection. The POR strategy aims to reduce this risk of recurrence.

Although the trial showed that H56:IC31 was safe, well-tolerated and capable of stimulating an immune response, it did not prevent recurrence of TB. In light of the results, development of the vaccine has been halted.

Although both sets of results are disappointing, the two trials have nonetheless made important contributions to the knowledge base and helped to build the capacity for large, high-quality trials in sub-Saharan Africa. The PrEPVacc trial will still be providing valuable data on different versions of PrEP, informing implementation efforts. In addition, the POR TB results will shed light on mechanisms of recurrence and immune responses to *M. tuberculosis*, and inform future TB vaccine development.

3.7

Back-up antiretrovirals for children

The CHAPAS-4 study has identified optimal second-line treatments for children living with HIV who develop drug-resistant infections.

Effective antiretrovirals have transformed treatment of children living with HIV, who now have every chance of surviving into adulthood. However, in some cases, HIV can develop resistance to the most commonly used antiretrovirals, requiring a shift to alternative, second-line drugs. Suitable second-line treatments have been developed for adults, but special studies are needed to identify the optimal drug combinations and doses for children.

In a series of landmark studies, the CHAPAS project team has generated key evidence on optimal treatments for children living with HIV. The latest programme, **CHAPAS-4**, which recruited nearly 1000 children aged 3–15 years in Uganda, Zambia and Zimbabwe, has focused on second-line treatments.

Antiretroviral treatment is based on drug cocktails – with a pair of drugs, known as the 'backbone', being combined with an 'anchor' drug from a different class. Recent years have seen new antiretrovirals become available with advantages over existing treatments. The CHAPAS-4 trial evaluated new options for both backbone and anchor drugs, to assess their suitability for use in children.

The study found that two new options, combinations including tenofovir alafenamide (TAF) in the backbone and dolutegravir as the anchor, were superior to existing treatments. The findings support the WHO recommendation of dolutegravir-based combinations as the preferred second-line option for children, and suggest that TAF-based combinations could also be used as second-line treatments.

The study has also monitored bloodstream levels of antiretrovirals in children receiving different doses according to their weights. These data indicate that levels of TAF in the bloodstream reach those shown to be effective in adults, supporting the dosing schemes. In addition, the data will underpin the development of new fixed-dose combinations and dispersible mini-pills, which will make it easier for children to take their HIV medication.

CHAPAS-4 has also gathered other important data on children with resistant infections. For example, one in five had low bone mineral density, emphasising the need to monitor and address bone weakness as children transition to adolescent and adult HIV care.

3.8 Not so neglected

Three EDCTP-funded projects have made major advances in the development of treatments for neglected infectious diseases.

Neglected infectious diseases cause untold misery while, as their name implies, generating comparatively little interest. Three success stories from 2023 show how children and adults can benefit from a focus on developing new treatments.

Schistosomiasis

Through the PZQ4PSAC project, EDCTP and the Japan-based Global Health Innovative Technology (GHIT) Fund have been supporting the Paediatric Praziquantel Consortium's development of a child-friendly version of praziquantel. This drug is used to control schistosomiasis, a parasitic worm infection that affects around 250 million people worldwide. Praziquantel is used in mass drug administration programmes to control the spread of the parasite, but is not suitable for use in children 6 years of age and younger.

EDCTP and GHIT funded a phase III trial of a new form of praziquantel, known as arpraziquantel, which dissolves in water or in the mouth, and can be given to young children. The trial showed that arpraziquantel was efficacious, safe and well-tolerated by young children. In late 2023, arpraziquantel received a positive scientific opinion from the European Medicines Agency (EMA), leding to WHO prequalification and listing of the drug on the WHO Essential Medicines List. In parallel, EDCTP and GHIT are supporting the ADOPT project, an implementation research project that will identify optimal ways to provide access to and introduce arpraziquantel into endemic countries.

Trypanosomiasis

In 2023, the EMA also delivered a positive scientific opinion on fexinidazole as a treatment for sleeping sickness caused by the *Trypanosoma brucei rhodesiense* parasite. Fexinidazole is already approved for the most common form of sleeping sickness (human African trypanosomiasis, HAT), caused by *T. b. gambiense* (gHAT). The HAT-r-ACC project showed that the drug was also effective against the less common but potentially lethal rHAT form of the disease, caused by *T. b. rhodesiense,* which is found in parts of East and Southern Africa. Fexinidazole is already being used in multiple countries in sub-Saharan Africa to treat gHAT, and the positive scientific opinion is a key step to extending its use to rHAT.

Soil-transmitted helminths

An estimated quarter of the world's population is infected with soil-transmitted helminths, a group of parasitic worms transmitted via contaminated soil. The standard treatment for these infections is albendazole, but this drug is not effective against all species of helminth and there is growing evidence of parasite resistance (as shown for example by the EDCTP-funded PROFORMA consortium in Ethiopia).

Greater breadth of protection could come from combining albendazole with a second drug, ivermectin. In the phase II/III ALIVE trial in Ethiopia, Kenya and Mozambique, the EDCTP-funded STOP Consortium demonstrated the efficacy of a fixed-dose combination of ivermectin and albendazole for the treatment of soil-transmitted helminths in nearly 4000 children. The findings formed part of a submission to the EMA made in 2023.

The Consortium's work has also been supported by a UK-funded Participating States Initiated Activity (PSIA). This funding enabled the project team to respond to scientific advice received from the EMA relating to the new fixed-dose combination. To avoid delays in appraisal, the EMA recommended carrying out a preparatory study to demonstrate that the two drugs given together have broadly the same activity as when given separately (a bioequivalence study) as well as a phase II safety trial in Kenya as a prelude to the main ALIVE trial.

Further development of the new fixed-dose combination will take place through the recently launched STOP2030 project, funded through the Global Health EDCTP3 programme. This project is testing the safety and effectiveness of the fixed-dose combination in mass drug administration campaigns in Kenya and Ghana.

3.9

Malaria prevention in pregnant women living with HIV

Two major studies have identified a suitable drug combination that could be used to prevent malaria infections in pregnant women living with HIV.

During pregnancy, women are at particular risk of malaria, which can have severe detrimental impacts on both mother and child. These risks are multiplied if women also have HIV infections.

To prevent malaria infections during pregnancy, WHO recommends that women are given an antimalarial drug combination, sulfadoxine–pyrimethamine, a strategy known as 'intermittent preventive treatment in pregnancy' (IPTp). However, the standard antimalarial therapy used in IPTp is not suitable for women living with HIV who are taking co-trimoxazole, which is routinely given to prevent opportunistic infections, because of the risk of side effects when the two medications are given together.

A previous EDCTP-funded study showed that IPTp with a different antimalarial, mefloquine, could safely prevent malaria in pregnant women living with HIV, and could be used alongside co-trimoxazole. However, mefloquine was not well-tolerated by women. Two recent trials have examined whether a different antimalarial combination, dihydroartemisinin–piperaquine (DHP), is a suitable alternative to mefloquine.

The **IMPROVE-2** study, carried out in Kenya and Malawi, areas with moderate to high levels of malaria transmission, found that the risk of malaria was halved in women receiving both DHP and co-trimoxazole (7% versus 15%). Adverse events were similar across the two groups and the DHP treatment was well tolerated.

The **MAMAH** study, carried out in Gabon and Mozambique, areas of low malaria transmission, also found that DHP was protective. Although parasite levels in the bloodstream at delivery (the trial's main outcome measure) were not lower, women receiving DHP experienced fewer episodes of clinical malaria and malaria parasite infections.

These studies provide strong evidence that IPTp with DHP, used alongside co-trimoxazole, provides good protection against malaria in women living with HIV who are taking antiretroviral drugs. This will help to protect a group of women highly vulnerable to malaria during pregnancy.

3.10

One Health and pandemic preparedness

The EDCTP-funded PANDORA-ID-NET consortium has made a major contribution to a suite of publications on One Health approaches to health security.

During the COVID-19 pandemic, the EDCTP-funded PANDORA-ID-NET Consortium, which brings together researchers and public health experts from Central Africa and Europe, played a key role in supporting pandemic responses and preparedness. Its contributions spanned a diverse range of areas, from risk analysis of virus introduction by air transport routes to the impacts of lockdown in African countries on the virus and communities.

The pandemic illustrated the catastrophic consequences that can follow when an infection jumps species and begins to spread between people. Globally, many efforts are underway to improve the capacity of countries to identify and respond to new zoonotic spill-overs, and to reduce the risk of their occurrence.

A major focus of these activities is the One Health framework, which recognises the interdependence of human, animal and environmental health. Human health security cannot be achieved without considering interactions with wild and domesticated animals and the impact of environmental disruption.

PANDORA-ID-NET has been highly active in this area. It played a critical supportive role in the drafting, consultation and finalisation of the Framework for One Health Practice in National Public Health Institutions published by the Africa Centres for Disease Control and Prevention (Africa CDC). The document sets out a set of principles and guidance for national ministries of health and national public health institutions in Africa on how to address priority zoonotic diseases.

In addition, the network's researchers have made major contributions to a set of papers published in 2023 by the *Lancet* on One Health and Global Health Security. The four-part series includes an analysis of the current landscape of the One Health approach and evidence of its effectiveness, a review of international One Health collaborations, shortcomings in currently used frameworks for assessing preparedness and response capacities, and regional and global governance around One Health.

Collectively, the articles provide a comprehensive summary of the current state of the One Health field and priorities for its future development.

3.11 Long-term impacts of Ebola treatments

Monoclonal antibodies improve the short-term survival of Ebola patients, but may impair immune responses and put survivors at increased risk of infection further down the line.

The 2018–2020 Ebola outbreak in the Democratic Republic of the Congo (DRC) did not ignite into a major conflagration at least in part because newly developed interventions could be deployed. These included a vaccine as well as new treatments, including antivirals and monoclonal antibodies to block infection.

With EDCTP support through the **PEAU-EBOV** project, researchers have been following up a cohort of survivors of the DRC outbreak to determine how these treatments have affected long-term immune responses to Ebolavirus.

The project examined antibody responses in 358 survivors who had been treated with either a monoclonal antibody or an antiviral, remdesivir. On discharge, nearly a quarter (24%) of survivors had no detectable antibodies to three key Ebolavirus proteins. Antibody levels declined over time, and after 3 years the proportion of survivors producing antibodies to two or more proteins ranged from 53.6% to 78.5%.

The findings, published in The Lancet Infections Diseases in 2023, raise concerns that, although monoclonal antibodies may be effective during acute Ebolavirus infection, they may leave survivors at risk of recurrence or reinfection. Indeed, isolated cases of infection after monoclonal antibody treatment have been reported.

The findings highlight the importance of tracking survivors, for example to assess the need for vaccination and to monitor for virus persistence – particularly variants that are resistant to monoclonal antibody treatments.

3.12

Enhancing newborn and child health

The EDCTP-funded GELA project has published landscape analyses of clinical practice guidelines for newborn and child health in three African countries, as part of its efforts to strengthen the use of evidence in national health policymaking and practice.

Although there has been great progress in reducing neonatal and child mortality in sub-Saharan Africa, the region is not on course to achieve Sustainable Development Goal targets in this area. The **GELA Consortium**, including representatives from Malawi, Nigeria, Norway, South Africa and the UK, aims to improve healthcare for these groups by building national capacity to use and apply global evidence.

These efforts are leveraging the global clinical practice guidelines (CPGs) developed by WHO. The GELA team is working with the WHO Regional Office for Africa, national policymakers and civil society representatives in Malawi, Nigeria and South Africa to support the adaptation of guidelines according to local context and implementation.

In 2023, the GELA Consortium published landscape analyses for these three countries on the Cochrane-Africa website. These analyses review the current extent of clinical practice guidelines for neonatal and child health in each country, the quality of the guidelines and key gaps. These findings provide an essential foundation for identifying the clinical practice guideline needs in each of the three countries.

In addition, the GELA research team has collated and analysed existing guidelines for neonatal and child health in the three countries, using a validated tool (the Appraisal of Guidelines for Research and Evaluation instrument, AGREE II). This analysed identified significant shortcomings in the processes used to develop guidelines, particularly with regard to rigour of development and editorial independence.

In further work, the project team has applied good practice methodology for priority setting in each of the three countries. Through extensive consultation, priority-setting surveys and consensus meetings, and development of national steering groups, long lists of priority topics were generated and then refined to identify the top three priorities. These priorities differed between countries, emphasising the importance of local context and engagement with key local decision-makers.

3.13 Strengthening ethics review

EDCTP-funded projects have contributed to significant strengthening of ethics review and regulatory bodies in Cameroon, Rwanda, Senegal and Uganda.

EDCTP earmarks specific funding for projects aiming to strengthen the research oversight capacity of countries in sub-Saharan Africa, to ensure that clinical studies are performed to the highest possible standards. These projects typically focus on building the capabilities of both national and institutional research ethics committees and national regulatory authorities.

Senegal: ISO9001 certification

The **BCA-WA-ETHICS** project (and its follow-up, **BCA-WA-ETHICS II**) focused on Senegal and other West African countries. In Senegal, it promoted the use of integrated tools for processing clinical trial applications by national ethics committees, which had been developed by the African Vaccine Regulatory Forum (AVAREF) in preparation for an ISO9001 audit in quality management. In March 2023, Senegal became the first African research ethics committee to achieve this globally recognised certification, which demonstrates the committee's compliance with international quality standards for managing systems and organisations, as well as a commitment to continuous improvement.

BCA-WA-ETHICS II has had a strong focus on integrating a gender dimension into the activities of national research ethics committees. The project published several policy documents on research ethics and gender mainstreaming in Africa, including a White Book of recommendations for Gender Mainstreaming in National Research Ethics Committees in West Africa, which provides hands-on guidance on how to address gender equality and sex and gender appraisal issues. In 2023, it also published a Roadmap for the Harmonization of Governance Strategies for National Research Ethics Committees during Health Emergencies and Beyond, laying out a path towards greater cross-country collaboration and adoption of consistent practices for oversight of research in emergency situations.

Rwanda: A new legal framework

In Rwanda, the **BRECOR project** has been instrumental in the development of a new law to protect participants in clinical research studies. Previously, research oversight was enshrined in two Ministerial Instructions, which regulated research activities and the Rwanda National Ethics Committee. However, this level of legal oversight was not considered adequate and was not consistent with the country's constitution.

Supported by the BRECOR project, the National Ethics Committee and other stakeholders undertook an extensive consultation and developed a new law that was passed by the Rwandan Parliament in 2021. The law provides a robust legal framework for governance of clinical research and the activities of the National Ethics Committee. It also gave the Minister of Health powers to draft Ministerial Orders relating to the functioning of the Committee and its operating procedures. The Committee and the BRECOR team also supported the development of these Ministerial Orders, which were formally approved in 2023.

Cameroon: Extending ethics review

In Cameroon, the **BREEDSAFCA project** has played a key role in extending the coverage of regional ethics review committees. Through the project's work, the number of regions covered by an ethics committee has increased from two to six, out of ten in total. The project has also contributed to a new law on the protection of participants in health research studies, as well as delivering various capacity-building activities.

Uganda: Implementing digital systems

In Uganda, the **SCRECU project** has been supporting further development of a National Research Information Management System (NRIMS), created as part of a previous EDCTP-funded project. The project team trained members of 26 research ethics committees on use of the system for online protocol submission and management, and monitored initial use of the system.

During the project, more than 13,000 users were registered on NRIMS, 6,000 applications were received, and 2,500 approvals were granted online. NRIMS has improved institutional workflows, reduced paperwork by over 95%, and cut turnaround times for protocol approvals by 50%, revolutionising the management of clinical research in Uganda.

3.14

Enhancing drug safety and efficacy monitoring

Three EDCTP-funded projects have boosted the ability of countries in sub-Saharan Africa to undertake drug safety and efficacy monitoring.

Pharmacovigilance, surveillance to detect possible adverse events associated with use of new medical interventions, is essential during both the development and introduction of new drugs and vaccines. Systems for detecting adverse events are needed to ensure that participants in clinical trials are not exposed to unnecessary risk, while national systems are needed to identify possible safety signals when an intervention begins to be used at scale.

In addition, monitoring activities can be important for assessing the effectiveness of interventions, to confirm that anticipated beneficial effects are actually achieved and to provide early warning signs of waning effectiveness due to drug resistance.

PAVIA: A blueprint for pharmacovigilance

The **PAVIA project**, focusing on Eswatini, Ethiopia, Nigeria and Tanzania, has carried out a comprehensive set of activities to connect those with an interest in pharmacovigilance across the four countries, and to strengthen human capacity and pharmacovigilance systems. It has collated its learning into a Blueprint which summarises its work and provides detailed guidance for countries looking to strengthen their pharmacovigilance capabilities.

PAVIA has had particularly notable impact in Eswatini, where it supported the development of the country's first standalone pharmacovigilance policy and framework.

PROFORMA: Monitoring drug effects

The **PROFORMA project**, focused on East Africa, has sought to strengthen connections between academia, national medicine regulators and public health programmes, in order to embed pharmacovigilance activities in ongoing practice, particularly mass drug administration and new vaccination campaigns. It has also prioritised education, having developed an undergraduate pharmacovigilance curriculum, which has been adopted by PROFORMA partner universities in East Africa, and a postgraduate programme in pharmacovigilance and pharmacoepidemiology, which has been accredited by the Tanzania Commission for Universities and adopted by Muhimbili University, Tanzania.

The project has also generated critical evidence on the safety, tolerability and effectiveness of drugs used in mass drug administration programmes in East Africa. Treatment monitoring has focused on praziquantel for treatment of schistosome infections in school children in Rwanda, albendazole for soil-transmitted helminths in Rwanda and southern Ethiopia, praziquantel and albendazole co-administration in Rwanda and southern Ethiopia, and ivermectin and albendazole administration for lymphatic filariasis in Tanzania.

These studies have identified limited effectiveness of albendazole against certain soil-transmitted helminths (particularly whipworm, *Trichuris trichiura*), the continuing efficacy of praziquantel against schistosomes, and the general safety of albendazole and praziquantel co-administration, although with more adverse events seen in infected children. Some of these were severe, highlighting the importance of routine pharmacovigilance. The data on ivermectin and albendazole co-administration showed it was generally safe, and fed into the work of the STOP project.

SPaRCS: Engaging community health workers

Building nation pharmacovigilance capacity has also been a key goal of the **SPaRCS project**, which has been promoting pharmacovigilance peer learning across Eswatini, Namibia, South Africa and Zimbabwe, alongside other work on enhancing clinical trial oversight.

An in-person pharmacovigilance workshop was held in Namibia in 2023, with participants from six African countries and Belgium, after which a selection of attendees took part in site visits hosted by the Namibian Therapeutics Information and Pharmacovigilance Centres.

Of particular note has been a focus on equipping community health workers to contribute to pharmacovigilance activities. Training materials and a training manual for facilitators were developed and piloted with community health workers in Namibia and Eswatini. The finalised training manual and training materials were shared with SPaRCS partners and uploaded onto the SPaRCS website. In Namibia, community health workers were for the first time included in the #Med Safety week initiative in September 2023, which included their participation in a panel discussion shown on national television.

3.15 TESA landmarks

In 2023, centres within the Trials of Excellence in South Africa (TESA) network, one of the four EDCTP-funded Regional Networks of Excellence, received WHO Collaborating Centre status and piloted an innovative digital science platform for managing patient data.

EDCTP's four Regional Networks of Excellence bring together research centres across multiple sub-Saharan African countries, to create platforms to support multi-centre trials, coordinate development of research capacity, and train the next generation of African researchers.

Among notable developments in 2023, a member of the TESA network – the Botswana Harvard HIV Reference Laboratory, part of the Botswana Harvard AIDS Institute Partnership – was named a WHO Collaborating Centre of Excellence for HIV drug resistance testing. The centre hit the headlines in 2021 when it was the first to release the sequence of the SARS-CoV-2 omicron variant. In August 2023, WHO Director-General Dr Tedros visited the centre to bestow the honour, at a ceremony also attended by the President of Botswana.

A second TESA site, the Biomedical Research and Training Institute in Zimbabwe, was one of two centres selected to pilot a new initiative established by EDCTP, the Novartis pharmaceutical company, and the TriNetX digital science company. The aim of this initiative is to rollout TriNetX's patient data collection and management systems, which will support involvement in industry-led trials in the region by facilitating access to (anonymised) patient data.

Healthcare centres will gain free access to the platform as well as training in its use, helping to build their capacity to take part in international-standard clinical trials and enhancing patient access to innovative new medical interventions. The Biomedical Research and Training Institute in Zimbabwe is one of two sites piloting the technology, alongside the Noguchi Memorial Institute for Medical Research in Ghana. Wider rollout across the EDCTP networks is planned following the pilots.

3.16

Focusing on fellows

Two pre-Forum meetings examined the contribution of the EDCTP2 fellowship programme to capacity-building and the progress being made by programmes providing master's-level training in epidemiology and biostatistics through a joint EDCTP and Africa CDC initiative.

Fellows' Day Meeting

The Fellows' Day Meeting provided an opportunity to reflect on **EDCTP2's fellowship programme** and its contribution to capacity-building in sub-Saharan Africa. EDCTP2 has had a strong focus on fellowship funding – there was a seven-fold increase in the number of fellows supported by EDCTP between the first EDCTP programme and EDCTP2, with more than 350 individuals supported in total.

The EDCTP2 fellowship programme supports African researchers at all stages of a research career, helping to ensure a continuing supply of scientific talent. Fellows also made invaluable contributions during the **COVID-19 pandemic**, conducting studies and advising policymakers.

Discussions highlighted the need to build a **critical mass** of health researchers in sub-Saharan Africa. Africa is home to 20% of the world's population, and accounts for 25% of the world's disease burden, but generates only 2.5% of the world's scientific outputs. Further progress will depend on strong collaboration across funders to achieve optimal impact and overcoming barriers to research collaboration, including linguistic barriers. Delivering on World Health Assembly resolution WHA75.8 on **strengthening of clinical trial capacity**, it was argued, will require not just investment in physical infrastructure but also in the development of people.

A range of current and former EDCTP fellows discussed the importance of their fellowship funding and wider career development. **Professor Jean Nachega**, who holds positions at Stellenbosch University, South Africa, and the University of Pittsburgh, USA, highlighted the importance of mentorship and the development

of international networks. His EDCTP Senior Fellowship helped to further strengthen his scientific reputation, and he has gone on to secure extensive additional funding, including major capacity-building grants from other funders.

EDCTP Senior Fellow **Professor Dorothy Yeboah Manu**, the first female director of Noguchi Memorial Institute for Medical Research at the University of Ghana, suggested that there were multiple aspects to human capacity development, including technical training and skills development, mentoring, continuing professional development, and learning and broadening perspectives through collaborations. She called for researchers to make more efforts to bridge the **researcher–policymaker divide**, to encourage more local investment in research by demonstrating its value. As well as promoting interdisciplinary team-based approaches, Professor Yeboah Manu also argued for a prioritisation of **leadership training**, and highlighted the importance of **mentoring** and **collaboration** to build capacity.

Industry has a critical role to play in the development of new medical interventions, and **Dr Jutta Reinhard-Rupp**, Head of the Global Health Institute at Merck in Switzerland, reflected on capacity-building and human capacity development from an industry perspective. Merck is part of the Pediatric Praziquantel Partnership that has developed a child-friendly formulation of praziquantel for chemo-preventive mass administration campaigns. Dr Reinhard-Rupp identified a range of key needs for effective human capacity development, including development of **scientific leadership skills**, **mentoring** of early-career researchers, and learning through **international networks**. To ensure sustainability, she argued for more emphasis on **South–South collaborations**, and for greater **engagement with local industry**, as R&D and manufacturing capacity in the region begin to grow.

A final panel discussion touched on other critical areas. These included the importance of structured mentorship programmes, assessing the quality of scientific training, and longer-term sustainability, particularly the need for increased domestic funding on health research in sub-Saharan Africa.

A new EDCTP initiative, the **African Clinical Research Fellows Funders' Group** provides a forum through which funding bodies providing clinical fellowships in sub-Saharan Africa can meet, exchange information and develop collaborations. Launched in 2023, the Group currently has around 12 members, with applications from possible new member organisations welcomed.

Epidemiology and biostatistics fellowships

The 'Epi-Biostat' joint initiative with Africa CDC has been designed to build skills in epidemiology and biostatistics in sub-Saharan Africa, in order to strengthen the capacity of countries to monitor and respond to the spread of infectious diseases and emerging outbreaks. A key goal is to strengthen links between clinical researchers and national disease control programmes.

Ten programmes have been funded through the initiative, each supporting multiple fellows. In all, the programmes have recruited 151 fellows, 63 of them female and 88 male. Nearly all of the programmes are based in sub-Saharan Africa, often with European partners. Institutions in more than 30 sub-Saharan African countries are represented in the programmes.

The initiative sits within the context of Africa CDC's New Public Health Order for Africa, a framework for action launched in 2021 to ensure Africa's health security. The New Public Health Order seeks to develop the region's capabilities in order to achieve self-reliance in health protection and to safeguard the region's health security. Workforce development is one of the five strategic pillars of this new framework.

A panel discussion highlighted several key aspects of the initiative. Selection of fellows has been important, with programmes often working closely with local ministries of health to identify suitable candidates. Importantly, the initiative has shown that high-quality training can be carried out within Africa.

A key theme was the difficulties experienced in recruiting **women**. The programmes had made special efforts to ensure a good representation of women, explicitly encouraging applications from women in programme advertisements and including gender-related considerations in formal programme governance documents and policies. In addition, programmes have sought to provide active support to women during their participation.

Mentorship was felt to be an important component of the programmes. The programmes have adopted different approaches to mentorship, covering technical skills as well as more general support in areas such as career development.

Programmes include groups of English-, French and Portuguese-speaking countries. Several programmes have recruited from multiple countries and been mindful of the need to ensure diverse representation on their courses. One of the biggest challenges related to language barriers, particularly for English-language programmes recruiting students whose first language is not English. The need to provide tailored support for such students was recognised. This illustrates a more general principle of offering individualised support according to need, rather than attempting to build a 'conveyor belt' of new fellows.

The pre-Forum meeting also heard from several of the students themselves, who praised the quality of teaching they had received, the flexibility and high levels of support provided by hosting institutions, and appreciated the opportunity to build professional networks with their peers and other academics.

3.17 HIV testing in fishing communities

EDCTP Career Development Fellow Dr Joseph Matovu has found that working with community-based 'peer leaders' can be a highly effective way to introduce HIV self-testing into remote fishing communities in Uganda.

A behavioural scientist with a doctorate in public health, Dr Matovu has had a particular interest in the health of Ugandan fishing communities, particularly those around Lake Victoria. Those involved in fishing typically work at night and sleep during the day, so often miss out on health services.

In his earlier studies, Dr Matovu piloted a new approach to increase access to HIV testing, an essential step to ensure that people living with HIV receive the essential care they need. His approach has been to leverage social networks – groups of individuals in a community who routinely interact with each other. Key individuals within these networks – 'peer leaders' – are recruited to disseminate HIV self-testing kits through the community.

In his EDCTP fellowship, Dr Matovu has been able to extend his initial pilot study, working with peer leaders in two fishing communities, in Kalangala and Buvuma, island-based communities on Lake Victoria. Across the two sites, 22 peer leaders were enrolled and shown how to use self-testing kits and interpret the results. Each of the peer leaders nominated 20 fellow community members, who registered with the project team and were then directed to collect self-testing kits from a peer leader. Each peer leader was given two kits for each nominee, so 800 kits in total were disseminated.

Of these 800 kits, 782 (98%) were distributed to 400 men who underwent a baseline interview. After 2 months, 361 recipients were tracked down. At the first follow up 355 reported that they had received self-testing kits from peer leaders and 352 said that they had actually used the kits to self-test for HIV. The interpretation of test results in the community showed good agreement with that recorded by the project team.

Overall, among the group tested, the prevalence of HIV was relatively high – 14.5%, much higher than in the general population in Uganda; in Kalangala, nearly one in five of those taking a test were found to be HIV-positive. Nearly three-quarters of those testing positive were linked to HIV care.

Notably, nearly 80% of the men interviewed at first follow up had received two testing kits, and 64% gave the second kit to someone else. Of these, 75% gave the kit to a sexual partner. Hence, secondary distribution of kits by men in these fishing communities could help to improve HIV testing uptake among their female sexual partners.

The study results, communicated to ministry of health, local government and other stakeholders at a seminar in September 2023, suggest that the peer leaders approach has great potential as a way to reach fishing communities in Uganda. The results could potentially also pave the way to a larger randomised controlled trial to assess the impact of the approach on health outcomes. With Uganda having more than 4,000 fishing communities, ultimately the public health benefits could be very great.

Of 361 men interviewed at follow-up, 98.3% (355) received at least one kit; 79.7% (283) received two kits. Of those who received two kits, 64% (181) gave the second kit to anyone else; of these, 74.6% (132/177) gave it to a sexual partner. Being currently married (adjusted prevalence ratio [adj. PR] = 1.39; 95% confidence interval [95%CI]: 1.10, 1.75) and having difficulty in reading text prepared in the local language (adj. PR = 1.26; 95%CI: 1.03, 1.55) were significantly associated with men giving kits to their female sexual partners. Ninety-seven per cent (112/132) of the men reported that they knew their sexual partners' HIV self-test results. Of these, 93.7% (n = 105) reported that their partners were HIV-negative while 6.3% (n = 7) reported that they were HIV-positive. Only 28.6% (n = 2) of the HIV-positive sexual partners were reported to have initiated HIV care. Secondary distribution of HIV self-test kits from males to their female sexual partners is well accepted by women in the fishing communities, suggesting that distribution of kits through men in the fishing communities can help to improve HIV testing uptake among their female sexual partners.

3.18

Mapping timely vaccination

EDCTP Career Development Fellow Dr Oghenebrume Wariri has found that, although The Gambia has achieved relatively high immunization coverage, not all infants are receiving their vaccines at the appropriate age.

Immunization is a highly effective and cost-effective intervention, saving many thousands of lives each year. In the first two years of life, infants should receive multiple vaccinations to protect them against measles, diphtheria and multiple other vaccine-preventable diseases, at ages specified in national immunisation schedules.

Vaccination coverage in The Gambia is higher than the average for sub-Saharan Africa. For DTP3, for example, the standard indicator of vaccination in the first year of life, coverage in 2022 was 79% compared with a regional average of 72%. However, as well as coverage, timing of vaccination is important, and can have a significant impact on protection – too early and a vaccine may not perform well, too late and an infant may be left unprotected.

Following a review of the literature, Dr Wariri has shown that there is no standard way of reporting deviations from timely vaccination and that studies mostly highlight delayed vaccination – at ages later than is ideal. Focusing on The Gambia, he has analysed data on nine tracer vaccines and more than 3000 children from a nationwide Demographic and Health Survey, which revealed high rates of untimely vaccination, mostly delayed vaccination.

In addition, he has pioneered use of a new approach, geospatial modelling, to generate high-resolution maps of immunization timeliness in different areas, again using The Gambia as an example. This approach integrates coverage data from nationwide Demographic and Health Surveys (data on more than 5000 infants) with geospatial information about the country's administrative areas.

Focusing on vaccinations given at different ages – hepatitis B birth dose, third dose of pentavalent vaccine and first dose of measles-containing vaccine – Dr Wariri identified significant variation in timeliness for the three vaccinations across the country. For example, the analysis revealed districts in central and eastern regions where delayed vaccination was particularly frequent, while coastal districts were less likely to see delayed vaccination. The analysis also spotlighted areas where the greatest number of children affected were found.

During his fellowship, Dr Wariri has also carried out notable work examining the trajectory of COVID-19 vaccine introduction in countries across sub-Saharan Africa and the impacts of the pandemic on routine immunisation in The Gambia. Notably, the latter analysis found that, apart from some brief periods when coverage of hepatitis B birth dose and first dose of pentavalent vaccine declined, coverage has been remarkably consistent, suggesting that The Gambian immunization programme has shown good resilience during the challenging pandemic years.

The geospatial modelling work was presented at a seminar in August 2023. The findings are of great value to immunization programme managers looking not only to sustain high coverage, but also to improve the timeliness of immunization in the country. Furthermore, Dr Wariri has gone on to secure a K43 Emerging Global Leader Award from the Fogarty International Center of the US National Institutes of Health (NIH), through which he will apply geospatial modelling to map the distribution of children missing out on timely measles vaccination in The Gambia and how this is connected to suboptimal herd immunity and measles outbreak risks.

3.19 Detecting malaria in pregnancy

EDCTP Career Development Fellow Professor Vivi Maketa is assessing whether highly sensitive rapid diagnostic tests for malaria parasites can be used by pregnant women who would benefit from antimalarial treatment during pregnancy.

Infections with the malaria parasite, typically *Plasmodium falciparum*, are harmful to both mother and unborn child. WHO therefore recommends that pregnant women at risk of malaria should routinely be given antimalarial drugs to protect against infection, an approach known as 'intermittent preventive treatment in pregnancy' (IPTp).

However, there is growing concern about rising levels of resistance to the drugs typically used for IPTp, sulfadoxine–pyrimethamine. An alternative approach is to screen women for *P. falciparum* infections during pregnancy and to provide alternative antimalarials when infections are detected. One drawback of this approach, known as 'intermittent screening and treatment in pregnancy' (ISTp), is that malaria parasites tend to be sequestered within the placenta, so rapid diagnostic tests using peripheral blood samples may deliver false-negative results.

To address this issue, Prof. Maketa is evaluating the use of new ultrasensitive rapid diagnostic tests for the malaria parasite. In previous studies, she has shown that these tests are more sensitive than existing rapid diagnostic tests, so should generate fewer false negatives.

In a trial in Kinshasa, the Democratic Republic of the Congo, she is comparing pregnancy outcomes in women following the standard IPTp approach with sulfadoxine–pyrimethamine with an ISTp strategy incorporating ultrasensitive rapid diagnostic tests followed by treatment with a newly registered antimalarial, pyronaridine–artesunate (Pyramax).

The trial is embedded within the EDCTP-funded PYRAPREG study, which is assessing the safety and efficacy of pyronaridine–artesunate for treatment of uncomplicated malaria infections in pregnant women.

Notably, in 2023 Prof. Maketa was the recipient of an Early Excellence in Science Award by the Bayer Foundation, which honour the outstanding research of early-career researchers globally. Prof. Maketa was the winner in the Medical Sciences category.

3.20

TB, T cells and COVID

EDCTP Senior Fellow Professor Wendy Burgers has identified a potentially critical immune response that appears to protect against TB, and has also made major contributions to COVID-19-related research.

A quarter of the world's population is infected with the bacterium that causes TB, *Mycobacterium tuberculosis* (Mtb) but, of these, only around one in ten go on to develop active TB disease. In most cases, the body therefore seems able to control Mtb infections. Unfortunately, the immune response to Mtb is extremely complex, and it is not clear exactly which elements are most important for protective immunity. This is a major obstacle to the development of new vaccines for TB, as it is unclear what the most desirable immune responses triggered by vaccination should be.

Nevertheless, there is good evidence that T cells play an important role in protection against Mtb. Many different classes of T cell exist, however. Professor Burgers has focused on one particular class, known as Th22 cells, as they produce the intercellular messenger molecule interleukin-22 (IL-22). IL-22 appears to have a wide range of functions, orchestrating responses to infections.

Although Th22 cells were initially thought not to be involved in TB immunity, several lines of evidence began to suggest that they could be contributing to protection. Professor Burgers strengthened this evidence by showing that latent Mtb infection – infection without progression to TB disease – was associated with a strong Th22 response. Moreover, this response was markedly reduced in people living with HIV, who are at heightened risk of active TB disease. Further work provided more information about the functions of Th22 cells and confirmed the reduced response in people living with HIV and in those with active TB disease.

During the COVID-19 pandemic, Professor Burgers has been using her expertise in T cell biology to investigate this aspect of the immune response to SARS-CoV-2. Although much attention has focused on antibody responses, T cells are also likely to have a critical role to play in protection, particularly at later stages of infection and in prevention of severe disease. They may also be important in the development of cross-protective immunity – of great significance, given the capacity of SARS-CoV-2 to evolve so rapidly.

These studies have revealed important features of the T cell response to SARS-CoV-2 variants. For example, a comparison of antibody and T cell responses to the beta variant and the original Wuhan strain revealed that, while some SARS-CoV-2-specific T cells failed to respond to the beta variant, most still did, with T cell responses being preserved much better than antibody responses.

In addition, in vaccinated and previously infected people, most T cell responses to the omicron variant were preserved, despite a significant evasion of antibody responses due to mutations in the omicron spike protein. After a year and a half, South African healthcare workers who had been vaccinated and/or experienced SARS-CoV-2 infections were still mounting strong and broad T cell responses, including to highly mutated forms of omicron, further pointing to the likely importance of T cells in long-term protection against SARS-CoV-2.

3.21 Strengthening partnerships

In 2023, EDCTP continued to strengthen its relationships with key partners, including other organisations funding clinical research in sub-Saharan Africa.

EDCTP is committed to working collaboratively and in partnership with like-minded organisations. It has developed strong relationships with key regional stakeholders and works closely with other bodies funding clinical research in sub-Saharan Africa to maximise the impact achieved.

Highlights from 2023 included a series of events focusing on the **African Clinical Trials Ecosystem**. World Health Assembly resolution WHA75.8, passed in 2022, calls for a strengthening of clinical trial capacity in the Global South, to facilitate the rapid initiation of high-quality trials in the event of a health emergency and to address inequities in access to new medical interventions.

In May 2023, a stakeholder workshop took place in Cape Town, South Africa, organised by the Africa CDC, the African Union Development Agency/New Partnership for Africa's Development (AUDA-NEPAD), the Gates Foundation and EDCTP. The workshop was attended by 60 national, regional and global stakeholders, from research institutes, regional organisations, WHO, industry, the private sector, community organisations and funders. A second African consultation meeting was organised by WHO and its Regional Office in Africa in Zambia in October 2023.

Africa CDC is taking the leading role in developing the vision of an African clinical trials ecosystem and an associated roadmap. Progress during the year was reviewed at an African Clinical Trials Ecosystem Funders meeting, which formed part of the EDCTP Forum in Paris in November 2023. This included representatives from more than 25 funders and other stakeholder organisations.

Furthermore, with financial support from the UK, EDCTP provided funding to WHO in 2023 to support the implementation of WHA75.8 to improve the quality of evidence from clinical trials. This grant will develop a global baseline mapping document of clinical trials and global normative implementation guidance to focus clinical trials on key design features that will increase the quality of evidence for decision-making and support clinical trial ecosystem capacity development. Part of the activities included the organisation of a workshop at the EDCTP Forum in Paris in November 2023.

The year also saw the launch of the **GloPID-R Africa Hub**, hosted by the South African Medical Research Council and co-funded by EDCTP with financial support from the UK. The GloPID-R network brings together funders with an interest in research related to new or re-emerging infectious disease threats. The GloPID-R Africa Hub aims to connect funders and other stakeholders active in the African region, to improve coordination and maximise impacts.

In September 2023, EDCTP organised a side event at the **United Nations General Assembly Science Summit (SSUNGA78)**, focusing on the development of innovative digital health solutions for Africa. The event included brief summaries of multiple EDCTP projects leveraging digital tools in health research and building capacity for their application, followed by a panel discussion including representatives from Africa CDC, the European Commission, and the industry and biotech sectors.

The event also featured the launch of a partnership between EDCTP, the Novartis pharmaceutical company and digital science company TriNetX, which is piloting the introduction of TriNetX's innovative data science platform into clinical sites within EDCTP's Regional Networks of Excellence. Use of the platform will greatly enhance the capacity of these sites to participate in industry-sponsored trials and improve access of African populations to innovative medical interventions in development.

3.22

Global Health EDCTP3: a new beginning

In keeping with EDCTP2, Global Health EDCTP3 remains focused on combating poverty-related infectious diseases and capacity building, with an increased budget and expanded remit that also encompasses global health security, the impacts of climate change on infectious disease and antimicrobial resistance (AMR). European–African research partnerships remain at the core of its work, although there are now greater opportunities for more global involvement of both research collaborators and strategic partners contributing to the programme.

A notable early initiative has been a partnership with the Gates Foundation, which is supporting five genomic epidemiology projects involving nine European and 15 African countries. Channelled through the Africa Pathogen Genomics Initiative (Africa PGI), €29.5 million funding from Global Health EDCTP3 and a €33 million indirect contribution from the Gates Foundation is supporting work on tuberculosis, malaria, HIV, typhoid fever, Rift Valley fever, water-borne diseases and antimicrobial resistance. The projects will work to increase the use of genomic epidemiology by national public health Institutes across Africa. The consortia funded through the scheme met at a Grand Challenges meeting in Senegal in October 2023 to discuss cross-project collaboration.

In 2023, the first grant agreements of the Global Health EDCTP3 Joint Undertaking were signed. Global Health EDCTP3 has so far invested more than €100 million in 28 new projects. Most of these investments went towards supporting clinical trials and product-focused implementation research, while a small proportion of the funding went towards the strengthening of ethics and regulatory oversight systems and establishing a sustainable clinical trials network in sub-Saharan Africa. Furthermore, seven Global Health EDCTP3 calls for proposals were announced in 2023 with a combined budget of over €130 million. These covered a wide range of areas, including tackling Ebola outbreaks, women's and child health, and improving modes of vaccine delivery.

The Global Health EDCTP3 work programme for 2024 was announced at the end of 2023 with a budget of €140 million spread across eight calls: HIV therapeutics, malaria vaccines, interventions for neglected infectious diseases, antimicrobial development to address AMR, vector control, digital health solutions, academia/industry fellowships, and public health emergencies.

4

EDCTP Governance

EDCTP2 is governed by the General Assembly of the EDCTP Association, the legal structure for the implementation of the programme. 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 programme is implemented by the Secretariat. The Association Board also represents the African and European Association members participating in the Global Health EDCTP3 programme on the Global Health EDCTP3 Joint Undertaking Governing Board.

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

Mandated representative entity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National Institute of Public Health


Austria
Medical University of Vienna


Belgium
Department Economy, Science and Innovation


Benin
University of Abomey-Calavi


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-Bissau
Instituto Nacional de Saúde Pública


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

Liberia
National Public Health Institute of Liberia

Luxembourg
Fonds National de la Recherche

Malawi
Ministry of Health

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

Sierra Leone
Ministry of Health and Sanitation

Somalia
Ministry of Health

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

Zimbabwe
African Institute of Biomedical Science & Technology

Summary financial statements 2023

Statement of profit or loss and other comprehensive income

for the year ended 31 December 2023. Expressed in thousands ('000) of euro.

	EC 2023	Donor 2023	Total 2023	Total 2022
Calls (Grants)				
Contributions	(150)	5,963	5,813	7,036
Grant expenditure	150	(5,963)	(5,813)	(7,036)
Results for the year	-	-	-	-
Others				
Contributions	5,189	2,519	7,708	6,385
Other expenditure	(5,189)	(2,519)	(7,708)	(6,385)
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 2023 (after appropriation of result). Expressed in thousands ('000) of euro.

	31 December 2023	31 December 2022
Non-current assets		
Right-of-use assets	1,306	1,451
Debtors and other receivables	57,293	56,715
Total non-current assets	**58,599**	**58,166**
Current assets		
Debtors and other receivables	20,013	111,879
Cash and cash equivalents	68,370	64,833
Total current assets	**88,383**	**176,712**
Total assets	**146,982**	**234,878**
Non-current liabilities		
Grants and other payables	80,347	133,581
Deferred income EC	-	-
Deferred income Donor	-	-
Lease liabilities	1,134	1,279
Total non-current liabilities	**81,481**	**134,860**
Current liabilities		
Grants and other payables	48,802	86,804
Deferred income EC	-	-
Deferred income Donor	16,527	13,042
Lease liabilities	172	172
Total current liabilities	**65,501**	**100,018**
Total liabilities	**146,982**	**234,878**

The financial statements were approved by the Acting Executive Director & Director of Finance and Administration on behalf of the Board:

Mr Abdoulie Barry
Dated: 28 June 2024

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 2022	**-**	**-**	**-**
Total comprehensive income for the year	-	-	-
Balance as at 31 December 2023	**-**	**-**	**-**

EDCTP has no unrestricted reserves.

Statement of cash flows

for the year ended 31 December 2023. Expressed in thousands ('000) of euro.

	2023	2022
Cash flows from operating activities		
Result for the year	-	-
Adjustment for:		
Depreciation charge for right-of-use assets	145	167
Lease interest	40	44
Reversal of depreciation and lease interest	(13)	(16)
(Increase) decrease in debtors and other receivables	751	(854)
Increase (decrease) in grants and other payables	(91,236)	(72,893)
Increase (decrease) in deferred income	93,900	93,878
Net cash flows from operating activities	**3,587**	**20,326**
Cash flows from investing activities		
Interest received/(paid)	122	(79)
Payment of lease liabilities	(172)	(195)
Net cash flows from investing activities	**(50)**	**(274)**
Net increase (decrease) in cash and cash equivalents	**3,537**	**20,052**
Cash and cash equivalents at 1 January	64,833	44,781
Exchange rate effects		
Cash and cash equivalents at 31 December 2023	**68,370**	**64,833**


Whatman
Schleicher & Schuell

Acknowledging our funders

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Colophon

European & Developing Countries Clinical Trials Partnership

The Hague, the Netherlands, July 2024

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Laboratory technician at the Bahir Dar University College of Medicine and Health Science Basic Parasitology Laboratory, in Bahir Dar, Ethiopia, as part of the STOP study.

The power of sharing science