



EDCTP

Annual Report **2024**



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The power of sharing science

About EDCTP

The European & Developing Countries Clinical Trials Partnership (EDCTP) is a public–public partnership between 15 European and 30 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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A technical laboratory agent works at the Day Hospital in Yaoundé, Cameroon, as part of the DATURA project.

Table of contents

1. Message from the Chair of the EDCTP Association Board.....	6
2. Message from the Executive Director	8
3. Towards EDCTP's objectives.....	10
4. 2024 in a nutshell.....	14
5. Impact on health policy and practice	16
5.1. Extending antimalarial use to additional groups.....	16
5.2. Calling a halt to parasitic worm infections	18
5.3. 'Step-down' antibiotics for infants with severe pneumonia	18
5.4. Preventing and treating HIV infection in young children.....	20
5.5. Better HIV treatments for children	22
5.6. Improving TB detection by health systems.....	23
5.7. Rapid advancement of a new TB drug.....	24
5.8. A promising vaccine to prevent diarrhoeal disease	25
5.9. A vaccine to prevent malaria transmission	26
5.10. Accelerating the introduction of new interventions.....	27
5.11. Influencing WHO policy.....	29
5.12. Building capacity for clinical guideline development.....	30
5.13. Progressing an alternative to BCG for TB prevention.....	31
5.14. Optimising yellow fever vaccine dosage.....	31
5.15. Advancing new vaccines for bacterial infections	32
5.16. Advancing drug treatments for parasite infections	32
6. Collaboration and capacity development	34
6.1. Strengthening ethics review and regulatory capacity	34
6.2. Strengthening safety monitoring.....	36
6.3. Being prepared for research in health emergencies.....	37
6.4. Building research expertise in West Africa	38
6.5. A new cohort of epidemiological specialists	39
6.6. Advancing microbiomics in Africa	40
6.7. Dissecting the microbiome's role in lung disease	41
6.8. Leveraging the power of pathogen genomics	42
6.9. Infectious links to cardiovascular disease	42
6.10. Targeted detection of malaria in pregnancy.....	44
6.11. HIV suppression in 'elite controllers'.....	45
7. Strengthening partnerships.....	46
7.1. EDCTP on the global stage.....	46
7.2. Building biomanufacturing capacity	47
8. Organisational activities	48
8.1. Global Health EDCTP3 in 2024.....	48
9. EDCTP Governance.....	50
10. Summary financial statements 2024.....	52
11. Acknowledging our funders.....	56

1. *Message from the Chair of the EDCTP Association Board*

Achieving real impact

As more EDCTP2-funded projects reach completion and publish their findings, it is evident that the programme will have a profound impact on the health of people in sub-Saharan Africa.



As the stories in this Annual Report clearly show, EDCTP2-funded projects are now generating evidence that is influencing policy and practice, ultimately benefiting people who live in sub-Saharan Africa.

EDCTP2 programme has always occupied a distinctive niche. While many other agencies have focused on discovery and early-stage development, EDCTP has focused on **later-stage development and implementation** with the goal of overcoming practical challenges and achieving real-world impact, particularly among populations that are typically excluded from pivotal clinical trials, such as children, pregnant women, and people with co-infections (including HIV) and co-morbidities, who may face delayed access to new interventions.

EDCTP has supported clinical research that led to the development of new medications in forms suitable for young children to take, something that was often lacking. New child-friendly formulations undergo

rigorous development, evaluation and approval processes. In 2024, these steps were completed for **arpraziquantel**, a version of praziquantel suitable for pre-school-age children that was developed by the **Pediatric Praziquantel Consortium** with the support of EDCTP2 and the Japan-based Global Health Innovative Technology (GHIT) initiative. In 2025, the first children received arpraziquantel in Uganda as part of the **ADOPT project**, which is working with national disease control agencies to accelerate introduction.

Similarly, a child-friendly formulation of **albendazole combined with ivermectin**, developed by the **STOP Consortium**, has demonstrated efficacy against a broader range of parasitic worms and will be easier to use in practice. This new fixed-dose combination received a positive scientific opinion from the European Medicines Agency in early 2025, which is expected to expedite national approvals and introductions.

Women living with HIV have been another priority population. The **MAMAH project** has demonstrated that dihydroxyartemisinin–piperaquine (DHP) is suitable for malaria prevention in women living with HIV during pregnancy, who cannot be given other antimalarials because of interactions with drugs used to prevent bacterial infections.

The other key goal of EDCTP2 has been to **build research capacity**, and again there is now strong evidence that its objectives are being successfully achieved. It is essential that clinical research is carried out in accordance with international standards to protect participants and maintain public trust. EDCTP2 has funded multiple projects to strengthen countries' research oversight systems, including **research ethics committees** and **national regulatory agencies**. In addition, the introduction of digital systems has greatly

increased efficiency, making countries more attractive sites for conducting research and reducing the time taken to evaluate urgently needed interventions.

EDCTP has established an extensive **fellowship programme**, with a focus on Senior Fellowships and Career Development Fellowships. Many recipients of the latter are making significant progress, successfully transitioning into independent researchers and emerging as leaders in their respective fields.

EDCTP has also been working to improve the early stages of the research career pipeline, such as through its partnership with the Africa Centre for Disease Prevention and Control (Africa CDC), which has provided master's training in **epidemiology and**

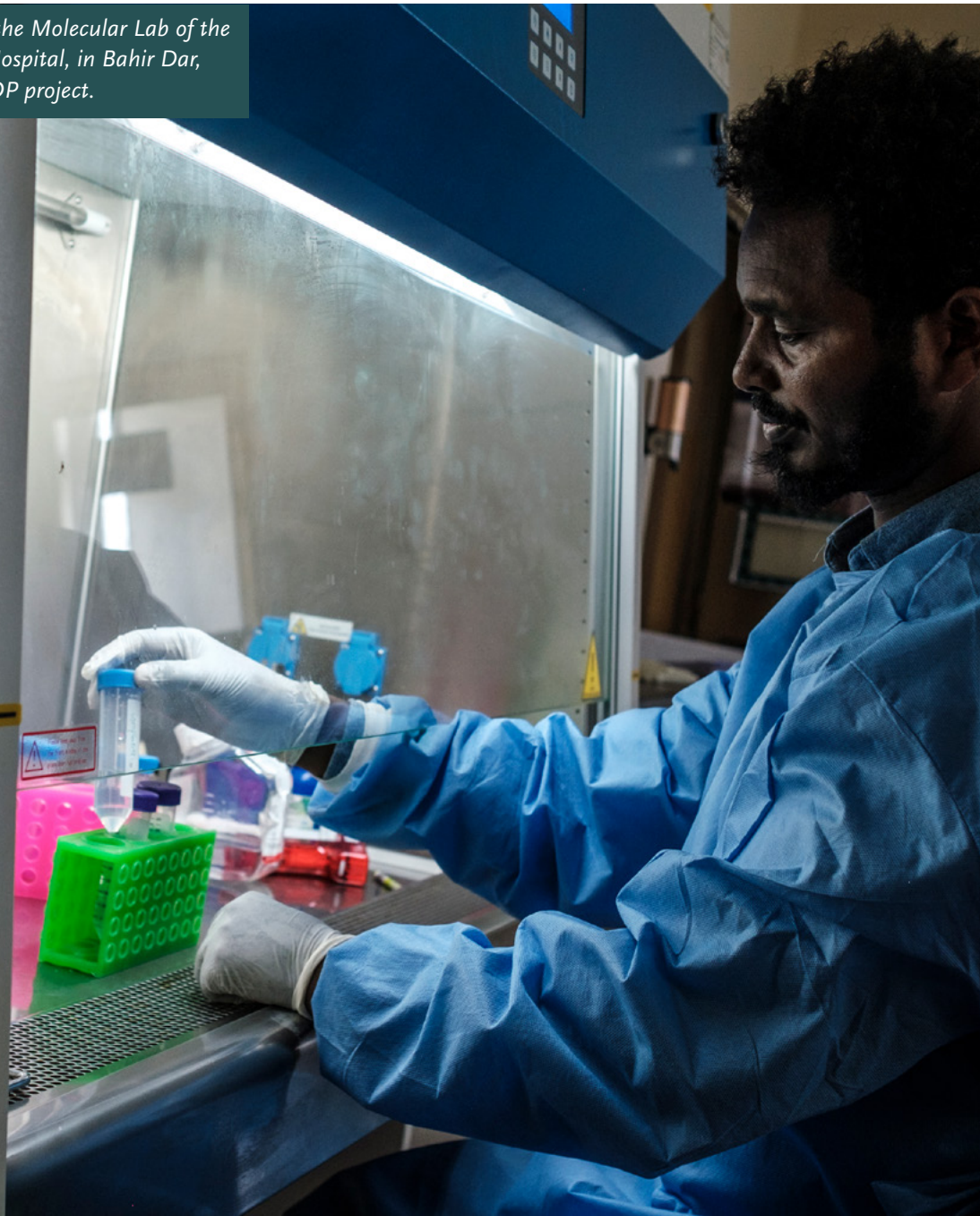
biostatistics to 150 students from sub-Saharan African countries across ten programmes. Additionally, programmes at EDCTP regional Networks of Excellence are supporting **PhD training of women researchers**.

The impact being achieved by EDCTP2 projects demonstrates that the EDCTP approach is highly effective and complements the efforts of other organisations active in global health. The core elements of the EDCTP2 strategy have been maintained in Global Health EDCTP3, which, with its increased budget and scope, is expected to deliver even more impact than EDCTP2.

Dr Henning Gædeke

Chair, EDCTP Association Board

An Immunologist works at the Molecular Lab of the Tibebe Gihon Specialized Hospital, in Bahir Dar, Ethiopia, as part of the STOP project.



2. *Message from the Executive Director*

Strengthening the EDCTP Association

As EDCTP2-funded projects come to an end, our key goals are to successfully conclude the EDCTP2 funding programme and to transition to a new role at the heart of the EDCTP Association.



As we reflect on our achievements since the EDCTP2 programme was launched in 2014, with a planned end date of 31 December 2026, we can take pride in the unwavering commitment and dedication of EDCTP employees and all our stakeholders. This includes, in particular, our constituencies and those charged with governance, who have worked diligently to ensure that the budget implementation tasks entrusted to the EDCTP Association by the European Commission have been carried out successfully, in line with the agreed timelines and expectations. Our key aim between now and 31 December 2026 is to guide and support our funded beneficiaries in bringing the remaining projects to a successful conclusion. In the first quarter of 2027, the EDCTP Association will provide a comprehensive report to the European Commission, detailing EDCTP2's expenditure, activities and achievements. This will mark the formal closure of the EDCTP programme.

As the stories in this Annual Report vividly illustrate, the EDCTP2 programme has been tremendously successful in achieving its key objectives: advancing medical interventions for the poverty-related infectious diseases affecting sub-Saharan Africa and building the capacity of countries, institutions and people in sub-Saharan Africa to conduct high-quality clinical research. In his report, the Chair of the Board highlights some of the many examples of the impact of EDCTP2 projects.

Throughout its existence, the EDCTP Association has embedded the principles of equitable partnerships throughout its work – from governance through to the management of individual projects. This approach has contributed to its recognition as a core part of the EU's Global Health Strategy and as a model for how the EU and Africa can work together as equal partners to address health challenges and promote health security.

Administratively, the EDCTP2 programme has been implemented by a secretariat based in The Hague, The Netherlands, and in Cape Town, South Africa. The third EDCTP programme is being implemented by the **Global Health EDCTP3 Joint Undertaking**, a legal structure that is embedded within the European Commission in Brussels. I am very happy that Global Health EDCTP3 is a partnership between the **European Commission** and the **EDCTP Association**, which represents the European and sub-Saharan Africa participating states.

As the end date of the EDCTP2 programme approaches, our role is now shifting to provide a focal point and support function for the EDCTP Association. One key aspect of this role is to represent and promote the EDCTP Association. With Eswatini and Namibia having joined in 2024, the EDCTP Association now has 45 members (15 European and 30 African countries).

There remains scope to increase representation still further. We will also be coordinating the financial contributions made by participating states, which form a significant part of the overall Global Health EDCTP3 funding envelope.

The EDCTP2 programme has been a concrete sign of the EU's commitment to global health, particularly in addressing the poverty-related diseases affecting sub-Saharan Africa. The expansion of the Global Health EDCTP3 programme illustrates that this commitment remains a key strategic priority.

The success stories summarised here demonstrate what can be achieved when partners in Europe and Africa – and increasingly in other countries – come together with a shared focus on improving the lives of some of the world's most vulnerable populations. While many challenges remain, especially in these uncertain times, these partnerships are saving lives and laying the foundation for stronger health research systems across large parts of sub-Saharan Africa.

Abdoulie Barry

Executive Director, EDCTP Association

Consultation day for children as part of the MULTIPLY project at the Under 5 Clinic in the St. John of God Hospital in Sierra Leone.



3. *Towards EDCTP's objectives* (2014–2024)



Medical interventions

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

232

clinical studies supported by EDCTP2 since 2014 (including phase I-IV interventional studies and diagnostic evaluation studies).

5

new/improved medical interventions, including an albendazole–ivermectin combination treatment for parasitic worm infections, arpraziquantel for treatment of schistosomiasis in young children, fexinidazole Winthrop for treatment of an acute form of sleeping sickness, AmBisome® for treating HIV-associated cryptococcal meningitis, and the R21-Matrix M™ malaria vaccine.

>17

policy documents and guidelines for improved or extended use of existing medical interventions have cited EDCTP-funded research.

>2,000

peer-reviewed publications acknowledging the second programme.



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.

215

fellowship grants which support 362 fellows (145 females and 217 males).

29

researchers (14 females and 15 males) funded through the WHO-AFRO/TDR/EDCTP2 Small Grants Scheme for implementation research on infectious diseases of poverty.

23

trainees (15 females and 8 males) funded through ADVAC Advanced Course of Vaccinology.

1,202

African researchers through long-term trainings (563 females and 639 males).

30

sub-Saharan African countries were members of the EDCTP Association by the end of 2024.



European coordination

Improve coordination, alignment and integration of European National Programmes.

€1.213 Bn

total financial contribution from the European Participating States by the end of 2024. This contribution exceeds the EU target of €683 million related to the matching of funds provided by the European Commission.

€201.16 M

cash contribution received from the European Participating States to the EDCTP2 programme for the implementation of EDCTP2.

€1.033 Bn

committed through 339 Participating States' Initiated Activities (PSIAs) submitted by the European Participating States as part of the EDCTP2 annual work plans (2014-2020) around a common strategic research agenda from 13 European countries and 14 African countries.



External partnerships

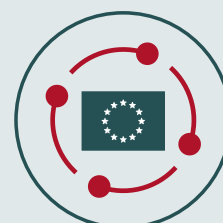
Increase international cooperation with public and private partners.

€ 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.

€26.84 M

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



EU cooperation

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

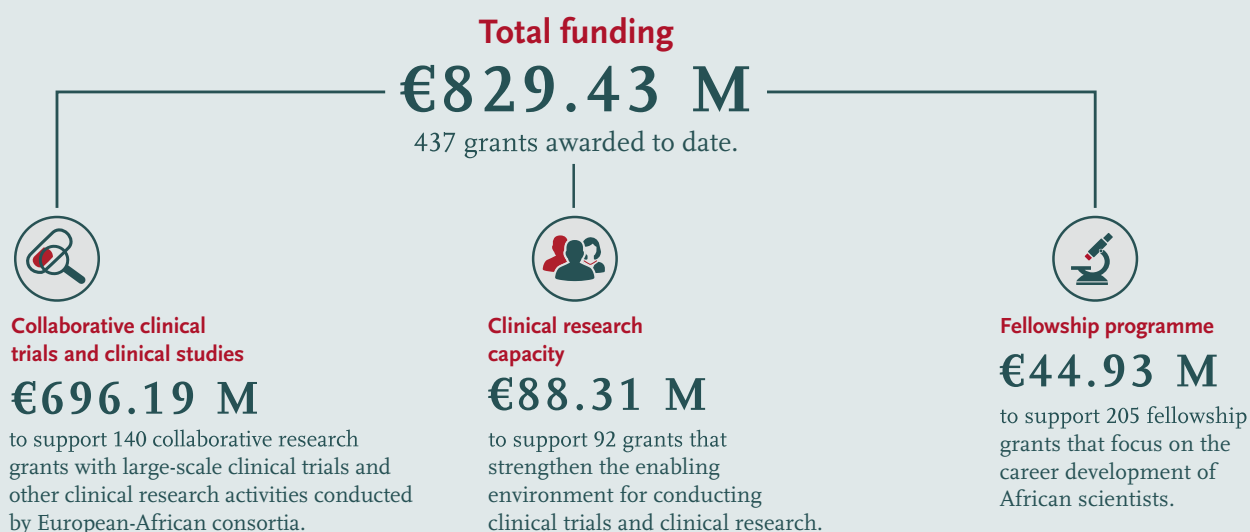
4

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

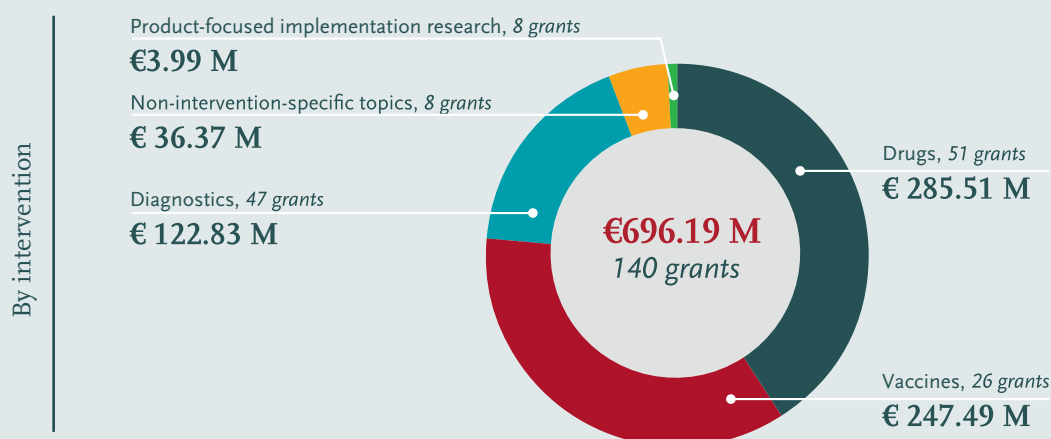
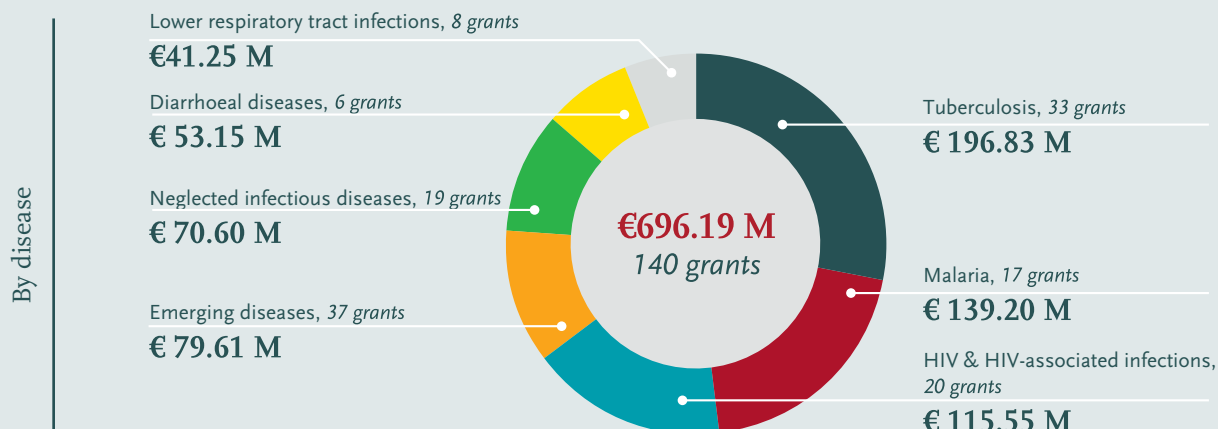
€23.15 M

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
(2014–2024)



Collaborative clinical trials and clinical studies
(2014–2024)





Flow Cytometer Laboratory Manager, works in a laboratory as part of the PREV_PKD at the Hospital of the University of Gondar, Ethiopia.

4. 2024 in a nutshell

Advancing interventions

- ▶ The MAMAH project has shown that dihydroartemisinin–piperaquine (DPQ) is a suitable drug for preventing malaria infections during pregnancy in women living with HIV.
- ▶ A WANECAM network trial has demonstrated the efficacy of a new antimalarial, ganaplacide, in combination with lumefantrine.
- ▶ The PediCAP trial has shown that children with severe pneumonia can be safely switched to oral antibiotics when they show signs of recovery.
- ▶ A trial of the ETVAX vaccine against enterotoxigenic *E. coli* (ETEC) has demonstrated its efficacy against pathogens causing diarrhoeal disease.
- ▶ The NIFTY study has found that smaller doses of yellow fever vaccine are highly immunogenic, potentially enabling more people to be vaccinated when vaccine supplies are limited.
- ▶ The CHAPAS-4 study has identified optimal second-line treatments for children with drug-resistant HIV infections.

Strengthening delivery

- ▶ The PROMISE-EPI and LIFE studies have found that integrating viral load testing into routine care can reduce the risk of mother-to-child transmission of HIV.
- ▶ The TB-CAPT project has identified a potential way to drastically cut the turnaround time for assessment of drug resistance in TB patients.

Recommendations and approvals

- ▶ Arpraziquantel, a child-friendly version of praziquantel, has been prequalified by WHO and the first doses have been administered to children in Uganda.
- ▶ Fexinidazole has been recommended by WHO for treatment of the acute form of human African trypanosomiasis, rHAT.
- ▶ A fixed-dose combination of albendazole and ivermectin has received a positive scientific opinion from the EMA for treatment of parasitic worm infections in young children.

Building capacity

- ▶ Projects have led to the creation or strengthening of research ethics committees in multiple sub-Saharan African countries.
- ▶ Regional pharmacovigilance consortia – SPaRCS in Southern Africa and PROFORMA in East Africa – have strengthened safety monitoring systems across multiple countries.
- ▶ A fellowship programme has enabled more than 30 women to begin PhD training within EDCTP regional Networks of Excellence.
- ▶ The Epidemiology and Biostatistics fellowship programme has supported the training of 150 master's students.

Organisational updates

- ▶ Global Health EDCTP3 launched its emergency funding mechanism for mpox, and had its 2025 budget significantly increased by the EDCTP Association members.
- ▶ The EDCTP Association has continued to work with multiple partners across sub-Saharan Africa to coordinate and enhance support for medical research and to strengthen research capacity.
- ▶ EDCTP organised a high-level event associated with the United Nations General Assembly, highlighting the role of international research partnerships in tackling antimicrobial resistance (AMR).



5. *Impact on health policy and practice*



A Nurse provides vaccines and medication to a child as part of the MULTIPLY project at the Under 5 Clinic in the St. John of God Hospital in Lunsar, Sierra Leone.

5.1. Extending antimalarial use to additional groups

EDCTP2-funded projects have advanced antimalarial treatments for vulnerable groups, including pregnant women with HIV and young children.

Although multiple highly effective antimalarial treatments exist, they are not always suitable for those most in need, such as pregnant women and young children.

Pregnant women are at particular risk of malaria infection, which can affect the health of both mothers and their unborn children. Prophylactic treatment with antimalarial drugs is recommended during pregnancy (intermittent preventive treatment in pregnancy, IPTp). However, the standard antimalarial drug combination used, sulfadoxine–pyrimethamine (SP), cannot be taken by **women living with HIV** who are on antiretroviral

therapy and taking cotrimoxazole to prevent bacterial infections, as SP interferes with the action of cotrimoxazole.

To address this gap, the EDCTP2-funded **MAMAH project** has been evaluating the use of dihydroartemisinin–piperaquine (DPQ) as an alternative to SP. A trial involving more than 650 pregnant women living with HIV in Gabon and Mozambique found that those receiving DPQ were less likely to experience malaria infections than those who did not: six episodes of malaria were seen in the control group versus one in the DPQ group.

Use of DPQ raised no safety concerns and had no impact on birth outcomes, and no effects were seen on the risk of mother-to-child transmission of HIV. Results were equally positive for women taking different kinds of antiretroviral therapy.

The findings suggest that DPQ is suitable for use in IPTp for women with HIV infections, who currently experience a million episodes of malaria a year.

Three-quarters of malaria deaths occur in **young children** under the age of 5 years. However, there is no antimalarial treatment tailored to very young children, those weighing less than 5 kg. Instead, they receive a fraction of the standard dose. However, due to the immaturity of their metabolism, there are concerns that this may lead to harmfully high levels of the active compounds, artemether and lumefantrine.

With EDCTP2 funding, the **PAMAFrica project**, which includes the Medicines for Malaria Venture (MMV) and Novartis, has developed a new formulation of artemether–lumefantrine specifically tailored to babies and children weighing less than 5 kg. In the CALINA trial in Burkina Faso, the Democratic Republic of the Congo, Kenya, Mali, Nigeria and Zambia, the PAMAFrica team showed that the new formulation led to bloodstream levels of the drugs known to be highly effective at killing malaria parasites in older children

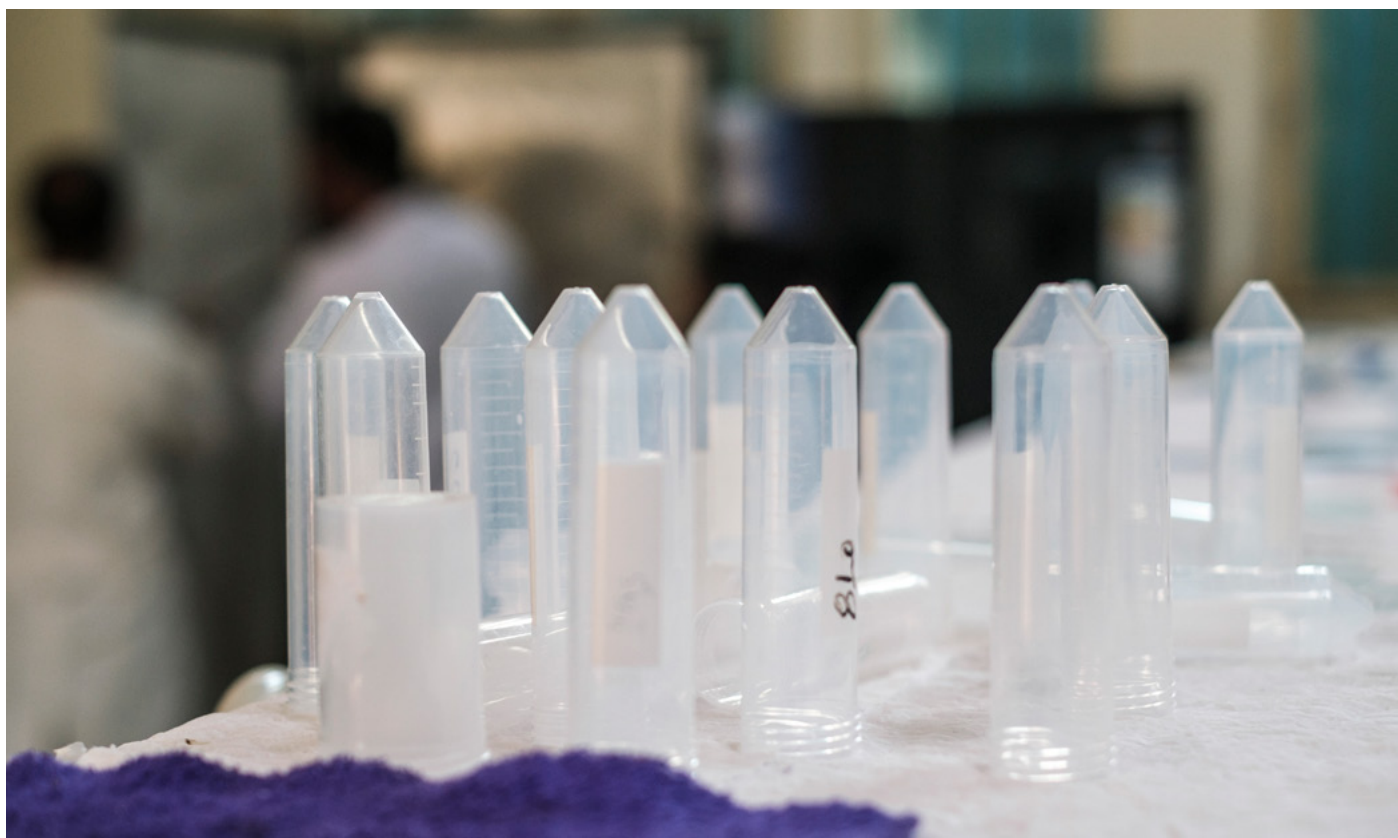
and raised no safety concerns. This suggests that the new formulation will be efficacious and safe to use in young children.

The results were presented at the Multilateral Initiative on Malaria (MIM Society) Eighth Pan-African Malaria Conference in Kigali, Rwanda, in April 2024 and have been submitted for regulatory review.

MMV and Novartis have also been collaborating on the development of a new antimalarial treatment, **ganaplacide**. Although current artemisinin combination therapy (ACT) is highly effective, there are worrying signs that malaria parasites are becoming less susceptible to its effects.

Ganaplacide is an entirely new agent with a novel mechanism of action. In a phase IIb trial in Burkina Faso, Côte d'Ivoire, Gabon, Kenya, Mali and Uganda, involving the EDCTP2-funded **WANECAM2 Consortium**, the project team found that a combination of ganaplacide and lumefantrine was as efficacious as artemether–lumefantrine, cleared parasites just as quickly, and was well-tolerated.

These positive findings are an important step towards a new class of antimalarial to address the rising tide of resistance to existing treatments.



5.2. Calling a halt to parasitic worm infections

With EDCTP2 and PSIA support, the STOP Consortium has developed a new drug combination that could significantly reduce the impact of common parasitic worm infections.

Soil-transmitted helminths, such as *Ascaris lumbricoides* (roundworm), *Strongyloides stercoralis* (threadworm), *Trichuris trichiura* (whipworm) and hookworms, affect a quarter of the world's population, mainly those living in poverty. They have a major impact on health and development, particularly of children and women of reproductive age.

Control of these parasites relies mainly on treatment and mass drug administration with albendazole. However, albendazole is not effective against all species of soil-transmitted helminth, and there are increasing concerns about drug resistance.

Treatment could be improved by combining albendazole with a second drug, ivermectin. A combination of the two has been shown to have higher efficacy than albendazole alone, particularly against *T. trichiura*, without raising any safety concerns.

However, co-administering two drugs to children is not straightforward. The STOP Consortium has therefore been developing a co-formulated version, or fixed-dose combination (FDC), of albendazole and ivermectin. In the ALIVE trial, this FDC was compared with albendazole when given either as a single dose or as a three-dose course.¹ For both *T. trichiura* and hookworms, the three-dose regimen was of markedly higher efficacy than albendazole alone; efficacy of the single-dose treatment was [superior for *T. trichiura* and](#)

[similar to albendazole for hookworms](#). No safety issues were seen.

The study provides strong evidence that the FDC will outperform albendazole. The three-dose approach would likely be favoured for treatment of individual patients, while the single-dose strategy would be suitable for mass drug administration campaigns. The STOP Consortium has been awarded Global Health EDCTP3 funding for an evaluation of the FDC in mass drug administration programmes in Ghana and Kenya (STOP2030 project).

The STOP Consortium's work has been supported by the Mundo Sano Foundation and by a UK Participating States-Initiated Activity (PSIA). This underpinned an early consultation with the European Medicines Agency (EMA), which provided key advice on the evidence it would require in order to provide a positive scientific opinion. This led to a bioequivalence study to demonstrate that the activity of the drugs was the same when combined and to a two-stage trial design in which a safety study was carried out in Kenya before the main ALIVE efficacy trial.

In January 2025, drawing on the ALIVE trial data, [the EMA provided a positive scientific opinion](#) on the new formulation. This will facilitate WHO prequalification and accelerate country regulatory approvals.

5.3. 'Step-down' antibiotics for infants with severe pneumonia

An innovative trial has found that young children with severe pneumonia can be treated with oral antibiotics when they show signs of improvement, enabling them to leave hospital sooner.

Community-acquired pneumonia is one of the leading causes of death among young children in resource-poor settings. The WHO recommends treating severe pneumonia with injectable antibiotics for five days within hospitals. Although this method is highly

effective, it has drawbacks, placing a financial burden on both families and health systems and increasing children's exposure to healthcare-associated infections.

1. Krolewiecki A, Kepha S, Fleitas PE et al. [Albendazole-ivermectin co-formulation for the treatment of *Trichuris trichiura* and other soil-transmitted helminths: a randomised phase 2/3 trial](#). Lancet Infect Dis. 2025;25(5):548-559. doi: 10.1016/S1473-3099(24)00669-8.



Nurse measures a participant in the EMPIRICAL study, at Maputo Central Hospital in Mozambique.

The EDCTP2-funded **PediCAP study** has been evaluating a modified approach to care of severe pneumonia, based on a switch to more convenient oral antibiotics when patients begin to show signs of recovery.

The trial recruited more than 1100 babies and children with severe pneumonia, aged 2 months to 6 years, across sites in five African countries (Mozambique, South Africa, Uganda, Zambia and Zimbabwe). Patients received either the standard WHO-recommended course of injectable antibiotic or were switched to readily available oral antibiotics (amoxicillin or amoxicillin-clavulanate) when they showed signs of clinical improvement. The trial was notable for its innovative design, which compared multiple different treatment options and durations of treatment within the same study.

The study found that children switched to oral antibiotics could, on average, spend one less day in hospital without affecting outcomes. Total treatment duration (inside the hospital and at home) could be safely reduced to 4 days. The oral antibiotics are

available as syrups and dispersible tablets, both of which are suitable for home use. The [initial results](#) were unveiled at the European Society of Clinical Microbiology and Infectious Diseases (ESCMID Global) conference held in April 2024, in Barcelona, Spain.

The PediCAP project is coordinated by the global Penta Child Health Research (PENTA) network. This network is also leading the Global Health EDCTP3-funded **SNIP-Africa** study, launched in 2024. SNIP-Africa is focused on developing suitable treatments for drug-resistant infections causing sepsis in newborns, which are responsible for more than 200,000 deaths a year.

SNIP-Africa will connect neonatal units in Ghana, Kenya, South Africa and Kenya, as well as sites in Europe. It will recruit more than 1000 babies with sepsis and evaluate existing and new antibiotic combinations. A highly innovative trial design has been developed which will enable multiple different antibiotic combinations to be assessed, with the antibiotics evaluated at each site being selected on the basis of local patterns of antibiotic resistance.

5.4. Preventing and treating HIV infection in young children

Two EDCTP2-funded projects have examined novel ways to prevent young babies from becoming infected with HIV.

Although more women than ever are receiving antiretroviral therapy to keep their HIV infections in check, transmission of HIV from mothers to infants is still occurring – an estimated 130,000 cases of mother-to-child transmission were seen in 2022. Many of these cases arise during breastfeeding.

Mother-to-child transmission can be prevented by providing women with antiretroviral drugs during pregnancy, and by prophylactic antiretroviral use in infants of mothers living with HIV. However, for safety and economic reasons, antiretroviral therapy use in infants needs to be targeted to those at highest risk of acquiring HIV – those who are being breastfed by a mother whose HIV is not being adequately controlled and who therefore carries a relatively high viral load.

The EDCTP2-funded **PROMISE-EPI** project has evaluated a novel approach to efficiently identify babies at risk. It took advantage of the high take up of routine vaccination at 6–8 weeks, a contact with the health system that provides an opportunity to assess

the viral load of mothers living with HIV. Using a rapid point-of-care test based on the widely available GeneXpert platform, the project team was able to detect high viral loads on the spot and immediately start antiretroviral use in babies at risk.

In a trial in Burkina Faso and Zambia, with very different health systems, the team screened 34,000 mothers and enrolled more than 1500 who were found to be HIV-positive. When a high viral load was detected at a vaccination visit, the baby was placed on antiretroviral therapy with lamivudine syrup, which was continued for a year or until one month after the end of breastfeeding.

After a year, one new HIV infection was detected in the intervention group, compared with six in the control group.² Although not statistically significant, as the COVID-19 pandemic disrupted recruitment, this suggests that the strategy is an effective way to tackle the last remaining cases of mother-to-child transmission.

2 Kankasa C, Mennecier A, Sakana BLD, et al. [Optimised prevention of postnatal HIV transmission in Zambia and Burkina Faso \(PROMISE-EPI\): a phase 3, open-label, randomised controlled trial](#). *Lancet*. 2024;403(10434):1362-1371. doi:10.1016/S0140-6736(23)02464-9.



A Research Nurse holds blood sample collected from study participant, as part of the VirTUAL project in Uganda.



A Nurse distributes children's health card to mothers as part of the MULTIPLY project at the Mange Community Health Center in Mange, Sierra Leone.

Building on this success, the team has been awarded funding from Global Health EDCTP3 for a successor study, **PROMISE-ZERO**, which is evaluating whether the approach can be applied in a wider range of health centres. Focusing on Zambia, the project will test the integrated approach in two maternal and child health centres in Lusaka and in 26 centres in Zambia's mostly rural Eastern Province.

The EDCTP2-funded **LIFE project** has also focused on point-of-care testing of maternal viral load to identify babies at high risk of infection, as well as HIV testing of infants. In this project, testing was carried out at the time of birth.

Pont-of-care testing for HIV – to detect infection or to measure viral load – is becoming more feasible. It will reach more women if it can be introduced in peripheral primary healthcare facilities, close to communities. The LIFE project team conducted two studies to evaluate the utility of point-of-care testing at such sites.

The first study, which enrolled more than 6000 pregnant women with HIV in Mozambique and Tanzania, explored whether maternal viral load monitoring at delivery could identify more high-risk babies than the standard clinical assessments, leading to more babies benefiting from intensive prevention efforts. Although

the numbers of high-risk babies identified was significantly higher with point-of-care testing, more than 40% of babies did not receive intensive prevention.

The second study assessed whether HIV testing of neonates at birth, rather than at 4–8 weeks as is more usual, was feasible in primary care and would improve outcomes by enabling antiretroviral treatment to start earlier. Although survival benefits were seen at 6 months, these had disappeared by 18 months. The project team speculates that this was due to the lack of child-friendly antiretroviral treatments, leading to reduced adherence.

In LIFE2Scale, the LIFE team is determining whether the two point-of-care testing strategies can be better integrated into primary health care systems to guide initiation of antiretroviral treatment of babies soon after birth. The intervention also includes strengthened engagement with mothers, while more palatable antiretroviral drugs will be provided, to ensure that early identification of elevated risk or infant infection leads to both initiation of antiretroviral therapy and sustained use during infancy and beyond.



A mother reads through the consent documents for her son to be a study participant of the CHAPAS study at UVRI Clinic in Entebbe, Uganda.

5.5. Better HIV treatments for children

Two EDCTP2-funded projects have provided key data to guide the choice of first-line and second-line drugs for children with HIV.

Although cases of mother-to-child transmission of HIV are falling, more children are gaining access to HIV care, leading to increasing demand for child-friendly versions of key antiretroviral treatments. In addition, as treatment is lifelong, growing numbers of infections in children are developing resistance to commonly used drugs, emphasising the need for safe and effective alternatives.

The CHAPAS collaboration has conducted multiple key studies of HIV treatments for children. The **CHAPAS-4** study evaluated potential second-line options for children who are no longer responding to standard treatment. It used an innovative trial design to assess the safety and efficacy of multiple different components of antiretroviral treatments, which are typically cocktails of three drugs – two ‘backbone’ drugs and an ‘anchor’ drug from a different class.

The CHAPAS-4 study, which recruited almost 1000 children aged 3–15 years in Uganda, Zambia and

Zimbabwe, identified that [backbone combinations containing tenofovir alafenamide \(TAF\) provided the best clinical outcomes](#), while dolutegravir was the best-performing anchor drug. Other options also achieved good clinical outcomes and were possible alternatives. TAF and dolutegravir are also less expensive than other options. The results provide robust evidence to back up WHO recommendations on second-line treatments for children with HIV.

The EDCTP2-funded **UNIVERSAL project**, coordinated by PENTA, is developing new treatment options specifically designed for children, for initial therapy and when treatments start to fail because of the development of resistance.

Antiretroviral treatments are typically tablets suitable for adults or bitter-tasting syrups, neither of which is ideal for children. The UNIVERSAL team has been developing a child-friendly formulation of darunavir/

ritonavir, to be used when children are no longer responding to first-line therapy based on dolutegravir. Although a highly effective anti-HIV medication, there are alarming signs that the virus is becoming resistant to this widely used drug.

The team used experimental and modelling approaches to determine the optimal dosing of darunavir/ritonavir for children. In 2024, this crucial information was presented to the US Food and Drug Administration (FDA), to enable it to assess new child-friendly formulations developed by manufacturers. For example,

later in 2024, Laurus Labs [submitted an application](#) to the FDA for approval of a paediatric darunavir/ritonavir formulation.

Meanwhile, alternative first-line treatments for children are still needed. In 2024, the project team began recruiting to the UNIVERSAL 1 trial, which is evaluating a fixed-dose combination suitable for babies and children up to the age of 10 of a new combination – dolutegravir, emtricitabine and TAF – that is already being used in adults.

5.6. Improving TB detection by health systems

Utilising existing tests better may be a way to reduce the ‘missing millions’ who do not receive a TB diagnosis or have undiagnosed drug-resistant infections.

Detecting new cases of TB is highly challenging. It is estimated that 40% of new cases each year are being missed – amounting to millions of people who do not receive treatment and continue to transmit disease. Furthermore, many cases of drug-resistant TB are being missed, so patients are missing out on the most appropriate treatment.

The EDCTP2-funded **TB-CAPT project** is [evaluating different approaches to TB detection within health systems](#), comparing pathways based on centralised testing using the Xpert platform and near point-of-care testing with Trunat technology. Within this project, it has also examined a potential approach for accelerating the detection of drug-resistant TB in South Africa, a country with one of the world’s highest burdens of TB.

The TB bacterium can develop different levels of resistance. Tests are available for the Xpert platform that can detect resistance to rifampicin (Xpert MTB/RIF and Xpert MTB/RIF Ultra). More recently, tests have been developed to identify resistance to second-line drugs (Xpert MTB/XDR).

In the TB-CAPT-CORE study, the team worked with two routine clinical diagnostic laboratories in South Africa, investigating a possible approach for rapid detection of second-line drug resistance.

The standard diagnostic pathway is based on analysis of two patient specimens – one that is tested using the Xpert MTB/RIF Ultra assay and a second that

undergoes further laboratory analysis for drug susceptibility. This was compared with a new pathway which focused on a single patient specimen, which was used both for an initial Xpert MTB/RIF Ultra assay and a follow-up Xpert MTB/XDR testing when the initial assay was positive.

With this new approach, a higher proportion of patients received drug resistance testing results (84% versus 66%) and, crucially, results were available within 24 hours rather than around two weeks. Although it proved difficult to perform the second test within the manufacturers’ recommended time of 4 hours after sample preparation, this did not appear to adversely affect the reliability of results (checked against rigorous laboratory testing).

The study, embedded in routine practice, therefore highlights a potentially straightforward way in which drug resistance testing could be implemented within existing diagnostic practices.

In other work, the Consortium is also exploring a range of approaches for **detecting TB in people living with HIV** when they are admitted at hospital. The study is [assessing Xpert MTB/RIF Ultra testing of sputum, stool and urine samples, as well as lipoarabinomannan lateral flow \(LF-LAM\) testing of urine samples](#), at sites in Mozambique and Tanzania.



A Nurse tests the vital signs of a participant in the TB-CAPT EXULTANT trial, at Mavalane General Hospital in Maputo, Mozambique.

5.7. Rapid advancement of a new TB drug

A combination of PSIA funding and the EDCTP2-funded PanACEA network is accelerating development of BTZ-043, a promising new treatment for TB.

More than 10 million cases of TB occur each year, leading to over a million deaths. It requires extended treatment with multidrug cocktails, and there are growing concerns about the emergence of resistance to components of these regimens. New TB drugs are thus urgently needed.

Through Participating States-Initiated Activities (PSIA) funding, a team in Germany has developed a possible new TB drug, BTZ-043, based on a novel target – DprE1, an enzyme involved in synthesis of the mycobacterial cell wall. Following successful first-in-human studies in Germany, the EDCTP2-funded PanACEA network is now evaluating its safety and efficacy in TB-endemic countries in sub-Saharan Africa.

Using an innovative trial design, the PanACEA team has conducted a two-part phase IB/IIA trial to investigate the safety and efficacy of different doses of BTZ-043, the impact of fed or fasting state, and its potential to affect the metabolism of other drugs.

The first phase of the trial, at specialist sites in South Africa, confirmed the safety of increasing doses of BTZ-043. The second phase confirmed its excellent bactericidal activity, identified a significant food effect (high-fat food leads to better absorption), and detected some minor changes to drug-metabolising enzymes, which would likely have minimal clinical impact on co-administered drugs³.

The trial results strongly support further development of BTZ-043, and have provided key information to underpin the design of future trials. The PanACEA STEP2C phase IIB trial is evaluating BTZ-043 as an alternative to ethambutol. It is also being studied in the phase IIB DECISION and PARADIGM4TB studies, through the UNITE4TB programme.

The innovative study design was a highly efficient way of gathering a large amount of key data in a single study, in people with newly diagnosed TB – optimising the use of resources and accelerating clinical development.

³ Heinrich N, de Jager V, Dreisbach J et al. Safety, bactericidal activity, and pharmacokinetics of the antituberculosis drug candidate BTZ-043 in South Africa (PanACEA-BTZ-043-02): an open-label, dose-expansion, randomised, controlled, phase 1b/2a trial. *Lancet Microbe*. 2025;6(2):100952. doi: 10.1016/j.lanmic.2024.07.015.

5.8. A promising vaccine to prevent diarrhoeal disease

A phase IIb trial of a vaccine against a common gastrointestinal pathogen, enterotoxigenic *E. coli* (ETEC), suggests it may protect against a range of bacterial infections causing diarrhoeal disease.

Enterotoxigenic *E. coli* (ETEC) is one of the most important causes of diarrhoeal disease in low- and middle-income countries (LMICs). It is also the most common cause of travellers' diarrhoea in visitors to these countries. As well as its immediate effects, repeated episodes of diarrhoeal disease can have long-term impacts on children's physical and cognitive development, so disease prevention could have major short- and long-term benefits.

EDCTP2 provided funding for a phase IIb trial of the most advanced vaccine against ETEC, a three-dose vaccine known as **ETVAX**, which covers 90% of ETEC strains. The trial was designed to assess safety and efficacy in young children (6–18 months) in different areas of The Gambia.

An [initial analysis of results](#) indicates that ETVAX has an efficacy of more than 80% against diarrhoeal disease of all causes (excluding parasite infections). Notably, the vaccine appears to offer cross-protection against other causes of diarrhoeal disease, which could enhance its public health value. No significant safety issues were detected during the trial.

These positive results should pave the way to a pivotal phase III trial of ETVAX to provide a definitive assessment of its efficacy against ETEC and diarrhoeal disease more generally.



5.9. A vaccine to prevent malaria transmission

A new malaria vaccine shows the promising ability both to prevent infection and to block transmission of the malaria parasite.

The two licensed malaria vaccines, RTS,S/AS01 and R21/Matrix-M, represent a major step forward in malaria control. However, they are of modest efficacy and do not have any impact on gametocytes, the form of the malaria parasite that is taken up when mosquitoes bite, developing within the mosquito into the stage that initiates new infections. Additional vaccines, including those that can block transmission of malaria parasites, are thus still greatly needed.

One particularly interesting candidate is **ProC6C**, a multi-component vaccine designed to act on multiple stages of parasite development. As well as preventing disease, it also has the potential to block transmission by acting against the gametocyte stage. ProC6C is being developed as part of the EDCTP-funded **PfTBV project**, which has been developing transmission-blocking malaria vaccines and creating an infrastructure for their evaluation in endemic countries. The consortium is led from Mali and includes the vaccine's developers, the Statens Serum Institut (SSI) in Denmark.

ProC6C includes multiple antigens, including circumsporozoite protein (CSP), a common vaccine target, and novel antigens (Pfs48/45 and Pfs230). It has been combined with a powerful adjuvant, Matrix-M, which has also been combined with R21.

Encouraging results have been obtained in phase I studies in Burkina Faso and Mali. In the former, ProC6C was found to be safe and well-tolerated in adults,⁴ and elicited the highest levels of antibodies when combined with Matrix-M. The [vaccine generated antibodies](#) against both the sporozoite and gametocyte stages.

The PfTBV project has also established a platform for evaluating innovative transmission-blocking malaria vaccines. Following the positive phase I results, a phase II human challenge study has begun in Mali, through which healthy adult volunteers will be vaccinated with ProC6C and then challenged with malaria parasites under carefully controlled conditions to determine how well the vaccine prevents parasite multiplication.

4 Tiono AB, Plieskatt JL, Ouedraogo A, et al. [A randomized first-in-human phase I trial of differentially adjuvanted Pfs48/45 malaria vaccines in Burkinabé adults](#). *J Clin Invest*. 2024;134(7):e175707. Published 2024 Apr 1. doi:10.1172/JCI175707.

A Nurse provides vaccines and medication to a child as part of the MULTIPLY project at the Under 5 Clinic in the St John of God Hospital in Lunsar, Sierra Leone.



5.10. Accelerating the introduction of new interventions

Three EDCTP2-funded projects are working with country policymakers to identify the best ways to implement promising new interventions for detection, prevention and treatment of key infectious diseases.

In 2024, [WHO prequalified arpraziquantel](#), a form of the drug praziquantel that is suitable for young children. Praziquantel is a mainstay of mass drug administration campaigns to control schistosome infections. However, the standard praziquantel formulation is not suitable for young children, who have therefore been excluded from such campaigns.

Through the **Pediatric Praziquantel Consortium**, a route was identified to develop and deliver a child-friendly form of praziquantel. A dispersible tablet was developed for children aged from 3 months to 6 years that is palatable, easily administered, and stable in hot and humid environments.

With funding from EDCTP2 and the Japan-based Global Health Innovative Technology (GHIT), clinical studies were conducted to demonstrate that arpraziquantel was safe and efficacious. These data informed an evaluation

by the European Medicines Agency (EMA), which [provided a positive scientific opinion on arpraziquantel](#). WHO prequalification provides a stamp of approval of the quality, safety and efficacy of the product. Together, these endorsements open up routes of procurement by global agencies and can reassure countries about the quality of the product.

Through the EDCTP2-funded **ADOPT project**, project partners have been working with country stakeholders to prepare for introduction of arpraziquantel. Initial work has been carried out in Uganda, where the treatment is being rolled out through the country's Neglected Tropical Disease Mass Drug Administration Platform. The [first pre-school-aged child in Uganda received arpraziquantel](#) through this route in March 2025. Drawing on what has been learned in Uganda, the partners will then engage with additional countries, including Côte d'Ivoire, Kenya, Senegal and Tanzania.

Malaria prevention in pregnancy

Intermittent preventive treatment in pregnancy (IPTp) is a well-established strategy for preventing malaria infections in pregnant women. Such women are given antimalarial drugs at key stages of pregnancy. Although widely adopted, IPTp coverage in many settings is suboptimal.

The EDCTP2-funded **REVIVE-IPTp** implementation project has been evaluating a community-focused strategy for boosting awareness and take up of IPTp. Focusing on two sub-counties in Kenya, the project is [working with community-level health workers and volunteers](#) to raise awareness of the consequences of malaria in pregnancy and of the availability of IPTp to prevent it.

Dialogue with the community provides insights into levels of awareness and barriers to uptake. Although

lack of awareness can be an issue, difficulties accessing services or poor-quality care (such as long queues at facilities) can also be off-putting. Information is being fed back to service providers so that they can improve the quality of services provided. The project is also exploring ways in which men can be best engaged so that they support their partners during pregnancy.

The team has also carried out a systematic review of studies [evaluating community-based strategies to promote IPTp take-up](#). In sum, the evidence suggests that involvement of community health workers increases take up of IPTp (and antenatal care more generally), while key enablers include community sensitisation, engaging with partners, having existing community health worker networks, and community health worker training.

Detecting STIs

In sub-Saharan Africa, STIs are typically managed syndromically – on the basis of symptoms – without specific diagnosis. However, women often experience asymptomatic infections so are not detected by this

approach, yet may still go on to develop long-term reproductive health issues.



A Flow Cytometer Laboratory Manager, works in a laboratory at the Hospital of the University of Gondar in Ethiopia, as part of the PREV_PKDL project.

GIFT, a point-of-care test developed in South Africa, provides a rapid and easy way to detect inflammatory markers of genital inflammation, a common feature of a sexually transmitted infection (STI) or bacterial vaginosis. Its use could identify women currently being missed by syndromic management.

An EDCTP2-funded project has been examining ways in which GIFT could be implemented into health systems. It compared different applications of the tool within the health system, including a ‘test and treat’ approach and triage (using GIFT to identify possible STIs, followed by further tests to provide a specific diagnosis). The most cost-effective approach was found to be a strategy based on an initial screening with GIFT followed by syndromic management, the standard approach for treatment of a presumed STI.

The team has also carried out a Delphi consultation of clinicians, policymakers and other stakeholders to explore possible applications of GIFT. Through this approach, respondents first suggested possible uses of GIFT and responses were then re-circulated for further feedback. The preferred use was as a screening tool, focused on high-risk populations, with updating of guidance of STI syndromic management. The team also plans to explore women’s preferences and cost-effectiveness.

A study has also begun in Madagascar, South Africa and Zimbabwe to evaluate the performance of the prototype GIFT device, and to explore possible routes for integration into routine care.

5.11. Influencing WHO policy

EDCTP2-funded studies have led to updates to WHO policy guidance for the treatment of human African trypanosomiasis and have been cited in other key WHO outputs.

Great strides have been made in reducing the impact of human African trypanosomiasis (HAT, sleeping sickness), particularly the form caused by *Trypanosoma brucei gambiense*. Fexinidazole, a drug developed by the Drugs for Neglected Diseases Initiative (DNDi), has been critical to this success, providing a safe and effective treatment option.

However, a second form of HAT, caused by *T. brucei rhodesiense*, affects parts of sub-Saharan Africa, particularly East Africa. It is responsible for rHAT, a more acute and potentially lethal form of the disease.

The EDCTP-funded **HAT-r-ACC study** [provided key data that underpinned an updating of WHO recommendations on treatment of HAT](#), particularly rHAT. Based on this study, carried out in Malawi and Uganda, [WHO now recommends fexinidazole instead of suramin for the first stage of rHAT](#). In the EDCTP-funded study, 10 out of 10 patients treated with fexinidazole at this stage of disease recovered, and no safety issues were reported.

In addition, WHO now recommends fexinidazole for more advanced disease, as a replacement for melarsoprol. In the fexinidazole study, all but two out of 35 patients had recovered at 12 months following treatment. This is a particularly significant shift, as melarsoprol is a relatively toxic arsenic-containing drug requiring repeated injections.

Fexinidazole has other advantages, being easier to administer and more affordable. In addition, as it can be used at both stages of disease, it eliminates the need for lumbar punctures to assess progression to advanced disease.

Countries have also moved to take advantage of the new option. In 2024, fexinidazole was registered for the treatment of *T.b. rhodesiense* sleeping sickness by the Democratic Republic of the Congo (DRC) and approval for use was granted by Malawi. Fexinidazole is donated by Sanofi to WHO, which distributes it to the National Control Programmes in endemic countries.

Other EDCTP-funded projects were referenced in key WHO publications in 2024. Data generated by the DIAMA project, for example, which is exploring how a range of tools for detecting multidrug-resistant TB could be implemented within African health systems, has contributed to [revised guidelines on TB diagnosis](#).

In addition, the **DATURA** and **5-FC HIV-Crypto trials** have been highlighted in a recent WHO document, [The Advanced HIV Disease Research Landscape](#). The DATURA trial is evaluating an intensified, high-dose TB treatment regimen for hospitalised patients with HIV and TB co-infections, to address the very high mortality rate in such patients. Enrollment in the trial was completed in December 2024.

The 5-FC HIV-Crypto study is developing and testing a long-acting formulation of 5-FC (flucytosine), a critical component of treatments for cryptococcal infections, one of the most common causes of severe disease and death in people living with HIV. Because of its short half-life, 5-FC has to be given every 6 hours. The project team has shown that the new formulation, a sustained release oral pellet that just needs to be given twice a day, generates [satisfactory bloodstream drug levels](#). A phase II trial began in Malawi and Tanzania in 2025 and will provide an initial indication of whether the new formulation is as effective as conventional 5-FC treatment.



A Research Medical Microbiologist works in a laboratory at the Leishmaniasis Research and Treatment Center of Hospital of the University of Gondar in Ethiopia, as part of the PREV_PKDL project.

5.12. Building capacity for clinical guideline development

An EDCTP2-funded project is helping three African countries improve systems for developing child health treatment guidelines.

Clinical practice guidelines are a critical tool for ensuring the quality of health services. They collate evidence in areas of public health and medicine, providing guidance to clinicians and other health workers on the optimal strategies for delivering care and managing health services.

WHO develops guidance documents, but recommends that these are adapted by countries in light of their specific local circumstances and priorities. The **Global Evidence, Local Adaptation (GELA)** project has been working with national stakeholders in three countries – Malawi, Nigeria and South Africa – to develop national capacity and systems for guideline adaptation and development, with a focus on child health.

The GELA approach has been highly participatory, with key individuals from ministries of health and academia being recruited into project teams in each country. The project team undertook a landscape analysis in each country to explore existing guidelines and how they were produced, using a standardised tool to assess the quality of outputs and the rigour of the development process.

Landscaping identified multiple gaps and shortcomings in guideline development. To address these issues, the project teams in each country undertook a range of activities, identifying priority local questions and assessing existing guidance material and gaps. The national groups then began a process to develop guidelines in their priority areas.

Importantly, the project's activities have helped to establish relationships across national stakeholders, in government departments and academia, and with multilateral partners such as WHO. The project has also raised awareness of the approaches needed for systematic assessment of evidence in guideline development. This will have long-term value, building national capacity to effectively use research evidence to inform clinical practice and optimise the delivery of care to populations.

Furthermore, the learnings from the project will provide valuable insights into the challenges and most effective ways to build national capacity in guideline development across sub-Saharan Africa more generally.

5.13. | Progressing an alternative to BCG for TB prevention

A study in South Africa has identified the optimal dose of MTBVAC, a promising alternative to BCG, to be used in crucial efficacy trials.

Prevention of TB infections in children relies on BCG, a vaccine developed more than a century ago that has a range of shortcomings. BCG is derived from *Mycobacterium bovis*, a close relative of the human pathogen, *M. tuberculosis* (Mtb). MTBVAC is an engineered version of Mtb designed to elicit a broader immune response to Mtb than BCG, without triggering TB disease.

In an EDCTP2-funded phase II trial in South Africa, an international team of researchers has assessed the safety and immunogenicity of different doses of MTBVAC compared to BCG.

The vaccine was found to be highly immunogenic,⁵ with the two highest doses tested generating immune responses significantly higher than those elicited by BCG. Reactions to vaccine administration depended

on the dose delivered. Based on these data, a dose was identified that optimised the balance between immunogenicity and reactogenicity, and this dose was selected for use in a follow-on phase III trial.

Although the trial was not powered to assess the vaccine's efficacy, it is encouraging that, of the eight infants diagnosed with TB during the study, four had received BCG and four the lowest dose of MTBVAC. No cases were seen among infants who received the two higher doses of MTBVAC.

Additional trials are now underway to assess the efficacy of MTBVAC in infants, adolescents and adults, including the EDCTP2-funded **MTBVACN3 phase III study in newborns**, which is taking place in Senegal, Madagascar and South Africa.

5.14. | Optimising yellow fever vaccine dosage

An EDCTP2-funded trial has found that lower doses of yellow fever vaccine still generate immune responses predicted to be protective against infection, potentially enabling more people to be protected when vaccine supplies run low.

Yellow fever outbreaks continue to affect tropical regions, particularly equatorial Africa. An estimated 100,000 severe cases occur each year, with mortality of up to 60%.

A highly effective yellow fever vaccine exists but is not straightforward to manufacture. This can lead to supply shortages, particularly during large outbreaks. To address this issue, when necessary, WHO recommends 'fractional dosing', use of one fifth of the regular dose, which still provides good protection.

However, this recommendation is based on relatively old data and it is unclear what the minimal effective dose is. The EDCTP2-funded **NIFTY trial** set out to address this gap in knowledge.

The trial compared immune responses to four doses of the yellow fever vaccine produced by the Institut Pasteur Dakar, Senegal – 250, 500 and 1000 international units (IU) – to those induced by the full-dose vaccine (13,803 IU). Almost 500 participants in Kenya and Uganda were randomly assigned to receive one of the four doses.

The trial assessed seroconversion, defined as a boost to yellow fever antibody levels to four times baseline levels 28 days after vaccination. The 1000 IU and 500 IU doses were found to be non-inferior to the regular dose,⁶ while the 250 IU was borderline.

Fractional dosing currently delivers a dose of 1000 IU. These results suggest that a lower dose would also be effective, perhaps including 250 IU in situations of severe shortage, allowing many more people to be protected.

5 Tameris M, Rozot V, Imbratta C, et al. [Safety, reactogenicity, and immunogenicity of MTBVAC in infants: a phase 2a randomised, double-blind, dose-defining trial in a TB endemic setting](#). *EBioMedicine*. 2025;114:105628. doi:10.1016/j.ebiom.2025.105628.

6 Kimathi D, Juan-Giner A, Bob NS, et al. [Low-Dose Yellow Fever Vaccine in Adults in Africa](#). *N Engl J Med*. 2025;392(8):788-797. doi:10.1056/NEJMoa2407293.

5.15. Advancing new vaccines for bacterial infections

Two EDCTP2-funded vaccine trials began recruiting in 2024, targeting pathogens responsible for the deaths of tens of thousands of young children in sub-Saharan Africa every year.

Sub-Saharan Africa is particularly badly affected by invasive *Salmonella* infections. Certain strains of *Salmonella* escape from the gut into the bloodstream, causing severe and potentially fatal disease. These strains are distinct from those that cause typhoid fever, so are known as ‘invasive non-typhoidal *Salmonella*’ (iNTS).

iNTS is responsible for the deaths of an estimated 50,000 young children a year. About one in seven of those infected do not survive. Although antibiotic treatments exist, drug resistance is a growing problem. An iNTS vaccine is thus urgently needed.

In February 2024, the [first patients were recruited](#) to the EDCTP2-funded **PEDVAC-iNTS** phase II trial. This study, involving seven European and Ghanaian institutions, is assessing the safety, reactogenicity and immunogenicity of an iNTS vaccine developed using ‘GMMA’ (generalised module for membrane antigens) technology. Developed by GSK, the GMMA technology is based on engineered bacterial cells, which bud off vesicles from their outer membranes and display target antigens to the immune system. It has the advantage of being a scalable and low-cost vaccine production technology.

The PEDVAC-iNTS study will assess the iNTS GMMA vaccine in adults, older children and infants. If results

are favourable, the vaccine would progress to a phase III efficacy trial.

Another EDCTP2-funded trial of a vaccine against a gut pathogen launched in 2024. The phase I **SUNSHINE** study is [evaluating a candidate vaccine to prevent *Shigella* infections](#), one of the most common causes of diarrhoeal disease in children, particularly in countries where rotavirus infections have been reduced by vaccination. An estimated 165 million infections occur each year, leading to 64,000 deaths. In addition, repeated infections have major long-term implications for children’s physical and cognitive health.

The trial, organised by the **ShigaPlexIM** consortium, is evaluating a vaccine known as Invaplex_{AR-Detox}/dmLT, a multiantigen subunit vaccine combined with a powerful immune-boosting adjuvant, dmLT. The latter component is designed to address the issue that immune responses to oral vaccines are often attenuated in endemic countries, probably because of gut damage following multiple enteric infections.

In October 2024, the first participant in The Netherlands received the vaccine. The vaccine dosage is gradually being increased and, if safety criteria are met, participants in Zambia will then be vaccinated.

5.16. Advancing drug treatments for parasite infections

Two projects developing treatments for common parasite infections – malaria and leishmaniasis – began recruiting to key clinical trials in 2024.

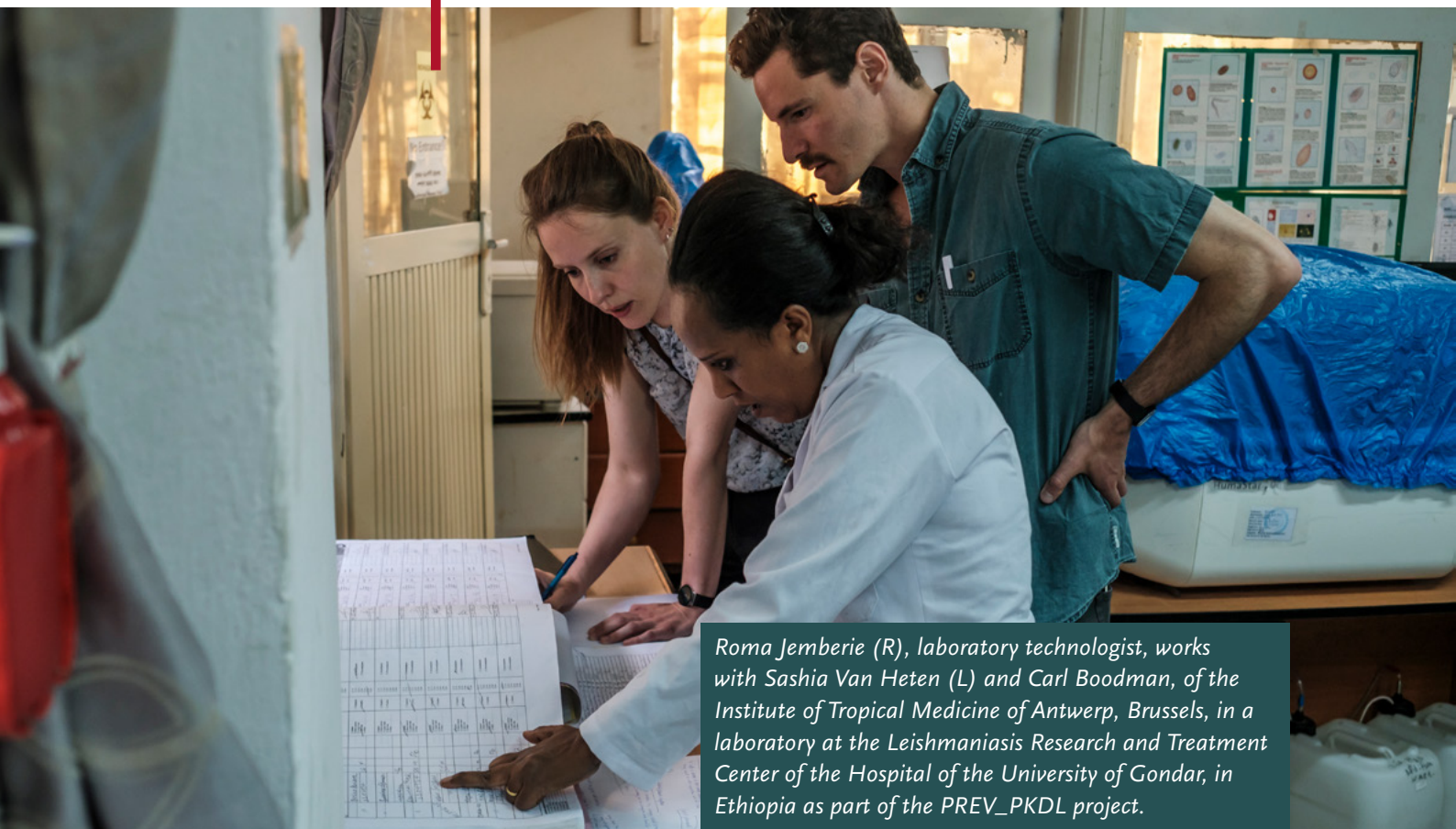
Primaquine is an important and often unheralded contributor to malaria control. It has distinctive features that distinguish it from generally better-known antimalarial drugs, such as artemisinin combination therapy (ACT), including activity against *Plasmodium vivax*, a relative of the more common *P. falciparum*, and the ability to kill late-stage parasites and therefore prevent transmission.

Because of these features, WHO recommends that primaquine is used alongside ACTs in low-transmission areas to reduce community transmission. However, in

practice, primaquine is rarely used for this purpose, mainly because it is not available in a form that can easily be given to children – adult tablets are large and bitter-tasting.

The EDCTP2-funded **Developing Paediatric Primaquine (DPP) Consortium** is developing new quality-assured and child-friendly primaquine formulations. It aims to produce four smaller tablets suitable for different ages plus a granular formulation, which will include flavourings to mask primaquine’s bitter taste.

6. Collaboration and capacity development



Roma Jemberie (R), laboratory technologist, works with Sashia Van Heten (L) and Carl Boodman, of the Institute of Tropical Medicine of Antwerp, Brussels, in a laboratory at the Leishmaniasis Research and Treatment Center of the Hospital of the University of Gondar, in Ethiopia as part of the PREV_PKDL project.

6.1. Strengthening ethics review and regulatory capacity

Research ethics committees have been established and strengthened in multiple countries in sub-Saharan Africa, as part of efforts to create an enabling environment for clinical research while safeguarding participants' interests.

Oversight of clinical research relies upon the effective functioning of national and institutional **research ethics committees (RECs)** and **national regulatory authorities (NRAs)**. EDCTP2 has awarded multiple grants to support the strengthening of ethics review and regulatory capacity in sub-Saharan African countries. Several projects achieved significant steps forward in 2024.

ZERCaP: The Zimbabwe Ethics and Regulatory Capacity Project (ZERCaP) set out to strengthen the capabilities of the Medical Research Council of Zimbabwe (MRCZ) and its associated RECs. In particular, it focused

on establishing and building capacity at RECs at three institutions – the University of Zimbabwe and Parirenyatwa Group of Hospitals, Africa University, and Bindura University of Science Education.

Following an initial benchmarking of these RECs, the project delivered a programme of activities including training of REC members, providing them with opportunities to attend meetings of the MRCZ's National Ethics Committee, enabling remote participation in international meetings, and in-person visits and assessments by MRCZ personnel.

The three RECs were re-evaluated and found to have significantly developed their capabilities. They received letters of recognition from the National Ethics Committee confirming their status as centres of excellence and have begun to contribute to protocol review and acceptance.

SNECFA: The Strengthening National Ethics Committees in West and Francophone Africa (SNECFA) project concluded with a final workshop in Cameroon in October 2024. The project organised training on health research ethics in Cameroon, Chad, Mali and Niger, and helped Chad, Mali and Niger develop standard operating procedures for review of research protocols in emergency and routine situations.

The project also catalysed the creation of stronger ties across the participating countries, facilitating

the sharing of experiences. All the countries began contributing information to the Clinical Trials Community Online platform.

BoCTRe: The Botswana Clinical Trials Regulation (BoCTRe) project has focused on establishing and strengthening RECs within Botswana.

The project helped to establish two institutional review board offices, for Ngamiland District at Letsholathebe Primary Hospital and for Mahalapye District at Mahalapye Primary Hospital. As well as training on research ethics and governance, the project also provided support to establish functioning administrative centres at the two sites.

Doctor Nicaine Ngakam checks patients' files in her office in the Jamot Hospital in Yaoundé, Cameroon, as part of the DATURA project.





A Nurse takes a blood sample from a participant in the TB-CAPT EXULTANT trial in Mavalane General Hospital in Maputo, Mozambique.

6.2. Strengthening safety monitoring

Two projects have made a substantial difference to pharmacovigilance capacities in Eastern and Southern Africa.

Systematic monitoring for drug safety issues, during clinical trials and after licensing of new products, is critical for identifying possible safety signals for further investigation, and ultimately for maintaining public trust in new medicines. Two EDCTP2-funded projects have built international partnerships to strengthen national pharmacovigilance systems.

SPaRCS: The Strengthening Pharmacovigilance and Regulatory Capacity across four Southern Africa Countries (SPaRCS) project strengthened connections between Eswatini, Namibia, South Africa and Zimbabwe. The project began by mapping existing pharmacovigilance systems in the four countries, identifying strengths and areas requiring further development. Multiple events were organised around key thematic areas and to encourage sharing of experiences. The project had a particular focus on adverse drug reaction reporting, particularly the role that can be played by community health workers.

The partnership has remained together and secured further EU funding for the **CEPSA (Centre of Excellence for Pharmacovigilance in Southern Africa) project**, which now includes the Belgian Institute of Tropical Medicine as a partner.

Building on the links between the four countries established through the SPaRCS project, CEPSA will focus on building regional expertise in pharmacovigilance through training, supporting operational research to generate locally relevant evidence to improve

pharmacovigilance practice, and enhancing dissemination of information to key decision-makers.

PROFORMA: The Strengthening Pharmacovigilance and Post-Marketing Surveillance in East Africa (PROFORMA) project held a concluding meeting in December 2024. The project has supported multiple capacity-building activities across Ethiopia, Kenya, Rwanda and Tanzania, with support from the Karolinska Institute, Sweden.

A major focus of the programme has been on developing the skills of leaders in the different countries, with five senior figures completing PhD studies in association with the Karolinska Institute. Research projects have covered issues such as drug safety monitoring during mass drug administration campaigns and vaccine rollouts. As well as providing valuable pharmacovigilance data relating to specific activities, these projects have also highlighted areas where additional efforts are required to embed pharmacovigilance.

The project oversaw an assessment of baseline pharmacovigilance capabilities in the four countries, which informed the development of country-specific development plans. A particular feature of the project was the strengthening of links between key national stakeholders – programme staff, national regulatory authorities and academics. Collaborations across these sectors were critical to the implementation of developmental roadmaps in the four countries.

6.3. Being prepared for research in health emergencies

The global PREPARED project has been developing practical tools for those facing difficult decisions during health emergencies.

The COVID-19 pandemic raised many challenging issues for policymakers and other groups. Any future pandemic will also inevitably require difficult decisions to be made, usually rapidly and with incomplete knowledge.

With multiple partners from sub-Saharan Africa, Europe and Asia, the **PREPARED project** has undertaken multiple activities and developed a range of resources to promote the adoption of sound ethical principles for decision-making during a health emergency. The project is funded through the EU's Horizon Europe programme and includes the EDCTP Association as a partner.

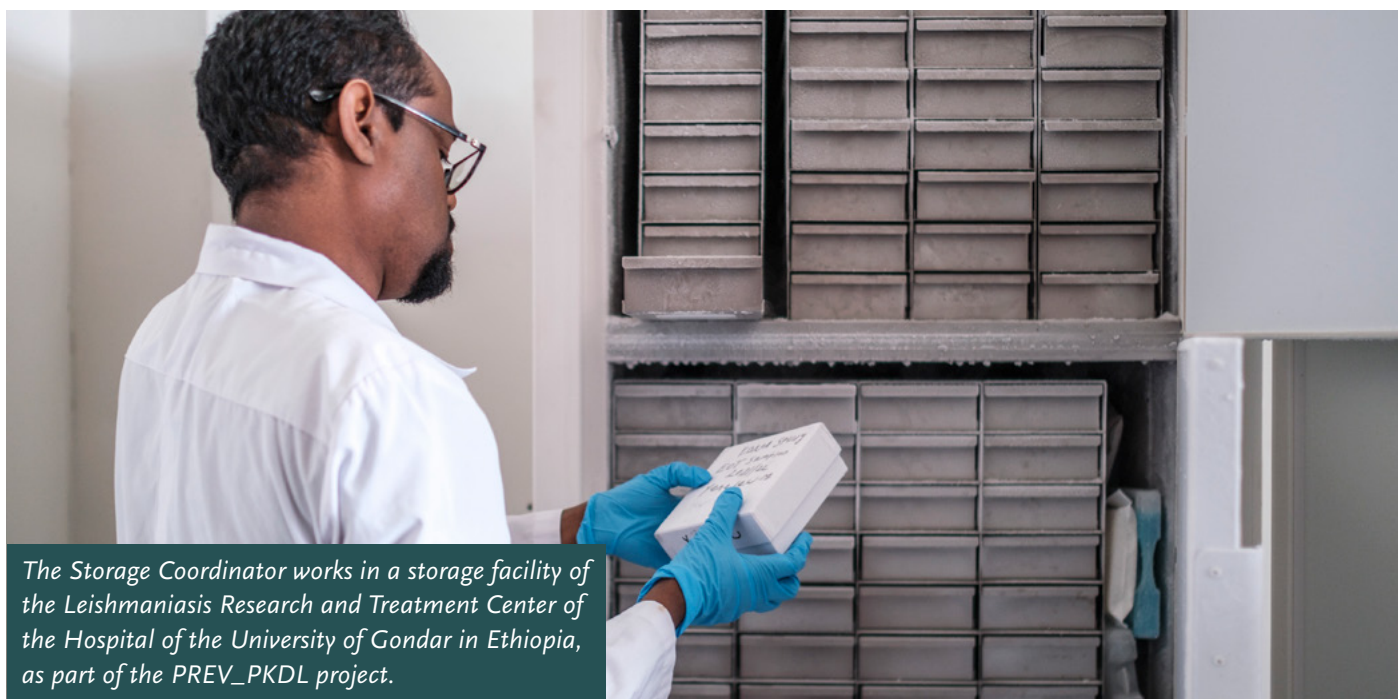
For example, in June 2024, PREPARED submitted comments to the World Medical Association Working Group developing an updated version of the **Helsinki Declaration**, the key global framework for research ethics. These comments, focusing on vulnerable groups and individuals, were taken on board in the [revised declaration published in October 2024](#).

Also during 2024, the project launched the [PREPARED app](#). This learning tool, which includes case studies and short courses, provides key information while also encouraging self-reflection on users' attitudes and practices. It features three case scenarios on

topical issues – human challenge studies, use of AI in crisis situations, and the activities of research ethics committees during the COVID-19 pandemic. It includes informative videos and polls to enable users to check their responses against those of their peers.

A draft '[See-Saw app](#)' was piloted in May 2024. This app explores the trade-offs that need to be made in pandemic contexts, where actions affect different groups in different ways. Having watched video clips, users can place arguments on either side of a see-saw to see how they tilt the balance. A kiosk-based version enables users to compare their results with others. A classroom version has also been developed, allowing responses among a class group to be compared.

In February 2024, the project published a guidance document for publishers, [Guidance on Fair and Fast Desk Appraisal of Submitted Manuscripts during Times of Crisis](#). This resource covers the initial stage of appraisal within a publications office, when a decision is made whether to circulate a manuscript for peer review. The guidance is designed to ensure consistency, efficiency and transparency in this decision-making step. A second document provides guidance to bodies such as [research ethics committees on expediting ethics review during health emergencies](#).



The Storage Coordinator works in a storage facility of the Leishmaniasis Research and Treatment Center of the Hospital of the University of Gondar in Ethiopia, as part of the PREV_PKDL project.

6.4. Building research expertise in West Africa

The West African Network for AIDS, TB and Malaria (WANETAM), an EDCTP2-funded Regional Network of Excellence, has been conducting multiple activities to build research skills across West Africa.

Established in 2009, WANETAM now encompasses 25 sites in 12 West African countries, plus five institutions in four European countries. Its activities focus on TB, malaria, HIV/AIDS and neglected tropical diseases. Activities in these areas, and in a cross-cutting capacity-building workstream, has a strong emphasis on strengthening links between sites to facilitate multisite clinical studies and on developing early-career researchers.

An extensive programme of training activities have been organised in 2024 and 2025. These include:

- Through WANETAM's malaria workstream, training in grant writing and clinical trials management.
- Training for staff from 10 countries of laboratory quality accreditation.
- Training on data management and sharing, for participants from eight countries.

The network has also begun to host intensive training courses previously held at the London School of Hygiene and Medicine in the UK.

- In February 2025, WANETAM supported 11 participants to attend the **Essentials of Clinical Trials** course at the [Medical Research Council Unit The Gambia at the London School of Hygiene and Tropical Medicine](#) (MRC-G).

- In April 2025, WANETAM in collaboration with the [West African Research and Innovation Management Association](#) (WARIMA) and MRC-G, co-organised a training course on **Epidemiology and Biostatistics** in Dakar, Senegal, which brought together 31 early- and mid-career researchers from nine countries in West Africa, with GSK funding.

A key aim of the network is to leverage sites of research excellence, such as MRC-G, to build capacity at weaker sites in West Africa. One approach has been for MRC-G to host researchers and support staff, so that they can gain experience of working at a centre of excellence.

Recent examples have included:

- On-the-job training for two clinical trialists from Ghana and Mali at MRC-G, including the opportunity to contribute to a major international study of yellow fever vaccination taking place in The Gambia.
- A placement for postdoctoral researcher Dr Baltazar Cá from Guinea-Bissau, who completed his PhD in Portugal and undertook a three-month placement in The Gambia, learning new skills and developing contacts that will be valuable during his EDCTP Career Development Fellowship.



6.5. A new cohort of epidemiological specialists

The Epidemiology and Biostatistics training programme, which concluded in 2024, has trained 150 individuals in key skills in infectious disease surveillance and public health protection.

Launched in 2020 and organised in partnership with the Africa Centre for Disease Control and Prevention (Africa CDC), the Epidemiology and Biostatistics training programme was designed to build capacity in the key skills needed to identify and track known and emerging infectious disease threats affecting sub-Saharan Africa.

Through the initiative, ten consortia were funded, which collectively trained 150 fellows. The consortia spanned 42 institutions in sub-Saharan Africa plus nine in Europe, offering high-quality teaching and field experience to fellows.

A survey was conducted towards the end of the scheme, to collect data from fellows and hosting institutions. Fellows expressed high levels of satisfaction with the training programme and the quality of training. Most were applying their new knowledge in their daily work and 97% would recommend the training to others.

Hosting institutions were similarly positive about the scheme. Most of the fellows had returned to their original positions or were working in public health, and they were felt to be making important contributions to public health practice. The survey also identified some areas where a similar programme could be improved.

Overall, the scheme has made a significant contribution to the development of workforce capacity in the region, strengthening preparedness and response to disease outbreaks.

Several programmes concluded with a symposium, enabling their fellows to communicate the results of their research projects and discuss the impact of their training.

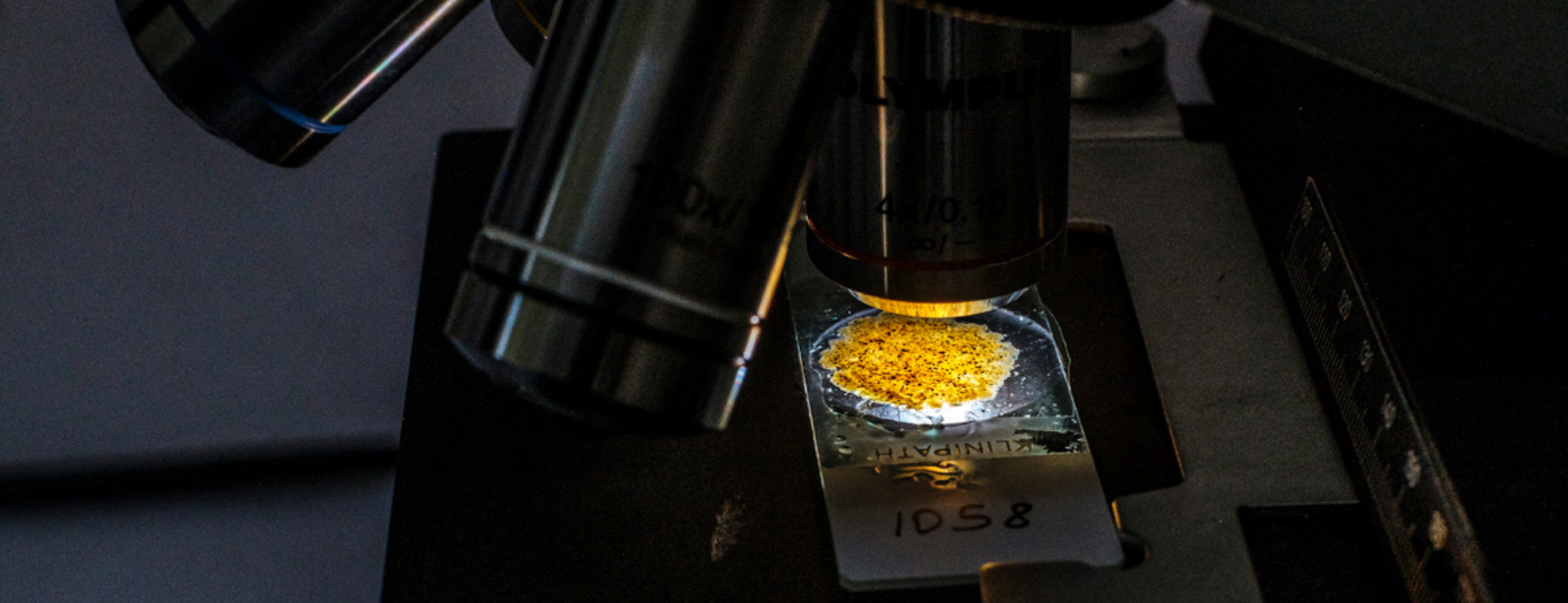
The programmes have also been conducting follow-on activities to build upon the progress made. For example, the **PREP-EPID consortium**, focused on francophone countries, undertook an advocacy mission to Madagascar and Chad, to highlight the programme's successes and to engage with national decision-makers and representatives from global agencies about health security, outbreak preparedness and training needs. This led to the drafting of a memorandum of understanding between the African Institute of Public Health (IASP) and the Ministry of Health of Chad.

In addition, a review and brainstorming session dedicated to epidemiology training was organised with the Ministry of Health of Burkina Faso. The event included a panel discussion chaired by the Minister of Health's Secretary General, which involved six graduates from the PREP-EPID programme who now serve in various public health roles.

The **TEBWA programme**, led from Benin, has also been working to strengthen the impact of its work. It has created a platform to support ongoing networking across programme alumni. Fellows also attended a regional workshop held in Benin in 2023 and joined a new network, the West and Central Africa Biostatistical Modelling Consortium (WesCAB), established as a result.

Furthermore, three fellows were awarded scholarships for further work in their area of interest and one fellow has begun a PhD at Moi University, Kenya. Thanks to the TEBWA project, the London School of Hygiene and Tropical Medicine, UK, and the University of Abomey-Calavi, Benin, have strengthened their collaboration and are exploring ways to support some of the TEBWA fellows to pursue PhDs.

Women alumni of these programmes are also eligible to apply for the PhDs available through EDCTP2-funded training programmes at EDCTP regional Networks of Excellence.



6.6. Advancing microbiomics in Africa

EDCTP Career Development Fellow David Kateete has used large-scale genomic and microbiomic analyses to shed light on TB and other diseases.

In his EDCTP fellowship, Dr David Kateete used high-throughput technologies to explore the microbial make-up of gut and sputum samples taken from TB patients. Although changes to the microbiome have been seen in multiple diseases, including TB, few studies have been undertaken in low- and middle-income countries.

Dr Kateete examined the microbiome of a cohort of TB patients from Uganda, comparing findings in this group with those of their household contacts without TB. His findings suggest that the composition of the microbiome is significantly affected by several factors, including HIV status, clinic visits and nutritional status. They suggest that microbiomic changes could have an effect on TB disease dynamics. He successfully applied for additional NIH funding for further studies to disentangle these effects.

In other research, Dr Kateete assessed the ability of ten machine learning algorithms to predict the susceptibility of *Mycobacterium tuberculosis* isolates to four TB drugs. The best performing tool varied from drug to drug, and performance on Ugandan isolates generally did not generalise well to a dataset from South Africa.⁷ None can therefore be used as a general-purpose tool for predicting resistance on the basis of genome data. Notably, the project also identified a range of new

genetic variants associated with resistance to TB drugs.

As well as TB, Dr Kateete has also applied genomic approaches to SARS-CoV-2 and COVID-19. In the first such analysis in sub-Saharan Africa, he found differences between the gut microbiome of COVID-19 patients and unaffected contacts,⁸ although it is unclear if these are associated with susceptibility to COVID-19 or are a consequence of infection.

In addition, Dr Kateete and colleagues used a novel sequencing technology, MinION, to investigate SARS-CoV-2 samples from Uganda. One advantage of this technology is that it provides information on both single nucleotide changes and larger-scale changes (insertions and deletions). The study found that the samples were closely related to other genomes from Uganda and the DRC, suggesting that SARS-CoV-2 was circulating widely within and between the two countries,⁹ rather than being repeatedly introduced.

Following his fellowship, Dr Kateete is continuing his studies in Uganda. He was recently promoted to Associate Professor and appointed Dean, School of Biomedical Sciences at Makerere University.

- 7 Babirye SR, Nsubuga M, Mboowa G, Batte C, Galiwango R, Kateete DP. [Machine learning-based prediction of antibiotic resistance in *Mycobacterium tuberculosis* clinical isolates from Uganda](#). *BMC Infect Dis*. 2024;24(1):1391. Published 2024 Dec 5. doi:10.1186/s12879-024-10282-7.
- 8 Agudelo C, Kateete DP, Nasinghe E, et al. [Enterococcus and Eggerthella species are enriched in the gut microbiomes of COVID-19 cases in Uganda](#). *Gut Pathog*. 2025;17(1):9. Published 2025 Feb 4. doi:10.1186/s13099-025-00678-4.
- 9 Kia P, Katagirya E, Kakembo FE, et al. [Genomic characterization of SARS-CoV-2 from Uganda using MinION nanopore sequencing](#). *Sci Rep*. 2023;13(1):20507. Published 2023 Nov 22. doi:10.1038/s41598-023-47379-z.

6.7. Dissecting the microbiome's role in lung disease

A Career Development Fellowship co-funded by EDCTP and Novartis has enabled Dr Alex Kayongo to explore the role of the lung microbiome in HIV/AIDS and TB.

The microbial communities that live in different parts of the human body can have a major influence on health and disease. Since the make-up of these communities show geographical variation, studies in Africa are needed to determine the specific contributions of the microbiome to health and disease in the region.

In 2021, Dr Alex Kayongo, based at Makerere University in Uganda, began a Career Development Fellowship focused on the potential role of the microbiome in lung disease in people living with HIV. Even when viral replication is effectively suppressed, such people are at increased risk of lung conditions such as chronic obstructive pulmonary disease (COPD). This vulnerability is becoming increasingly important as antiretroviral therapy can ensure people living with HIV survive into late adulthood and beyond.

In his fellowship, Dr Kayongo studied a group of people from rural Uganda living with HIV, some of whom had developed COPD. He discovered that the lung microbiome was disturbed in individuals with COPD symptoms,¹⁰ even though their HIV was well controlled.

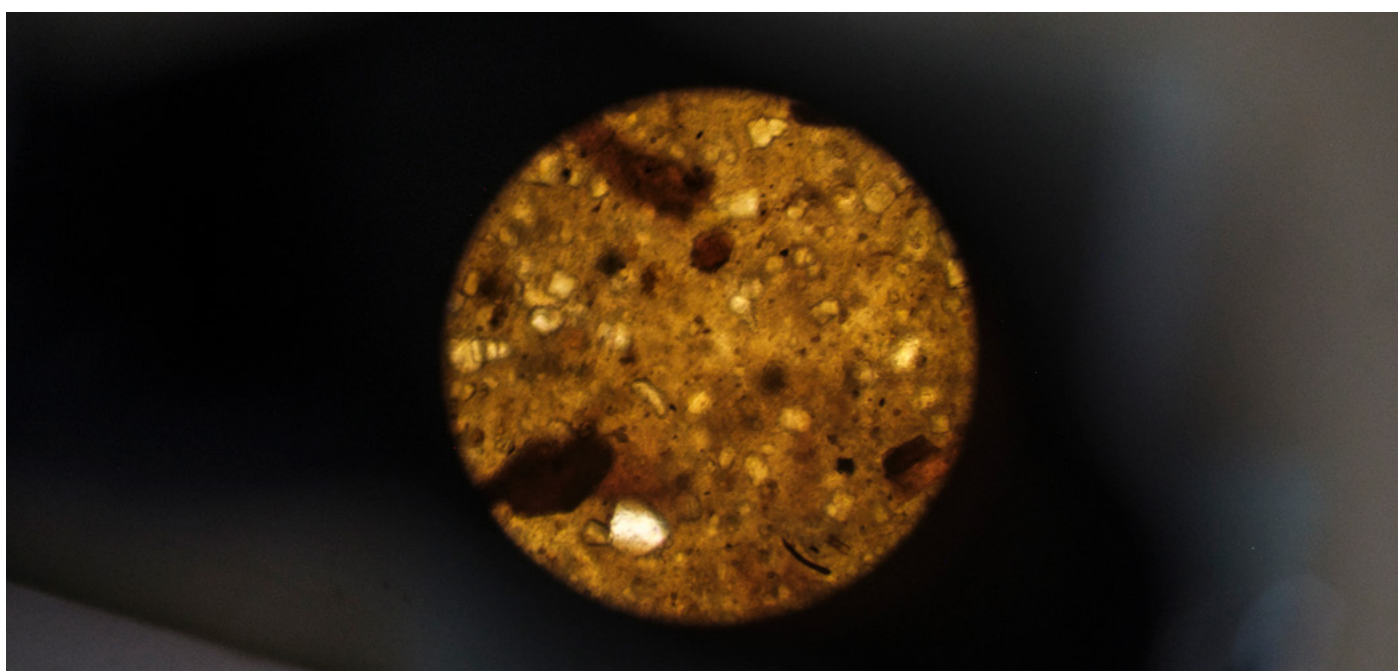
Furthermore, changes to the lung microbiome were associated with the presence of particular inflammatory cells in the lung. He was able to identify microbial species that were associated with damaging lung inflammation, such as *Streptococcus* spp, and particular classes of immune cell, particularly Th17-like cells, that could be key contributors to lung-damaging inflammatory responses.

The findings point to the importance of infection in triggering lung damage in people living with HIV, which has generally been considered a consequence of smoking. Furthermore, they suggest a possible way to prevent lung disease developing.

Dr Kayongo is continuing his work on the lung microbiome, having secured funding from the US National Institutes of Health (NIH). He has investigated the lung microbiome of TB patients and people with latent mycobacterial infections, identifying a microbiomic signature that discriminates between those with active and latent infections.¹¹ This could provide the basis of a new test to distinguish such groups, which is difficult to achieve with existing tools.

10 Kayongo A, Bartolomaeus TUP, Birkner T, et al. [Sputum Microbiome and Chronic Obstructive Pulmonary Disease in a Rural Ugandan Cohort of Well-Controlled HIV Infection](#). *Microbiol Spectr*. Published online February 15, 2023. doi:10.1128/spectrum.02139-21.

11 Kayongo A, Ntayi ML, Olweny G, et al. [Airway microbiome signature accurately discriminates *Mycobacterium tuberculosis* infection status](#). *iScience*. 2024;27(6):110142. Published 2024 May 28. doi:10.1016/j.isci.2024.110142.



6.8. Leveraging the power of pathogen genomics

Former EDCTP Career Development Fellow Dr Gerald Mboowa is utilising skills in pathogen genomics to address the health challenges of sub-Saharan Africa.

In his EDCTP fellowship project, begun in 2020, Dr Gerald Mboowa used an innovative new technology, 'shotgun metagenomics', to investigate possible causes of fevers in HIV-positive children with negative malaria test results (non-malaria febrile illness). Shotgun metagenomics involves the sequencing of all microbes in a patient sample, to identify possible causes of disease.

To apply this new approach, Dr Mboowa collaborated with the US Chan Zetterberg Biohub in San Francisco, USA. His analyses of stool and blood samples identified multiple possible causes of non-malaria febrile illness in Ugandan children¹² – nearly 200 bacterial and parasitic pathogens were identified in samples from 144 patients. Given this diversity, targeted approaches to identify specific parasites are unlikely to be feasible. Although not yet established in Africa, shotgun metagenomics might be an alternative way to identify causes of disease and ensure patients receive the most appropriate treatment.

Dr Mboowa has become a leading figure in the application of pathogen genomics in sub-Saharan

Africa. He was a co-author on a *Cell* paper highlighting opportunities for greater use of pathogen genome data in Africa,¹³ if key barriers can be overcome. He has also highlighted the potential benefits of wastewater surveillance for tracking infectious disease threats in Africa.¹⁴

Dr Mboowa is a member of the African Pathogen Genomics Initiative, set up to expand use of genome sequencing in pathogen surveillance. He spent time as an Implementation Science Expert in Bioinformatics at the Africa Centre for Disease Control and Prevention (Africa CDC). After that, he took up a position at the world-leading Broad Institute at the USA, where he is working on potential new genomic tools to address sub-Saharan Africa health challenges, including pipelines for genome sequence analysis to track antimicrobial resistance and HIV drug resistance.

He also supports genomics, bioinformatics and data science training programmes at the African Centers of Excellence in Bioinformatics and Data-intensive Sciences (ACE) and at Makerere University, Uganda.

6.9. Infectious links to cardiovascular disease

Professor Marielle Bouyou-Akotet has identified a possible connection between common infections and the risk of non-communicable disease.

Professor Marielle Bouyou-Akotet was awarded a Senior Fellowship through a scheme organised jointly by EDCTP2 and GlaxoSmithKline (GSK), which focused on links between infections and non-communicable diseases (NCDs), such as diabetes and cardiovascular disease.

Working in Gabon, she has found that asymptomatic intestinal infections are associated with a state of chronic inflammation, a known risk for NCDs.¹⁵ Since such infections are common in sub-Saharan Africa, they could be making a major contribution to long-term health conditions, suggesting that improved prevention

12 Nabisubi P, Kanyerezi S, Kebirungi G, et al. [Beyond the fever: shotgun metagenomic sequencing of stool unveils pathogenic players in HIV-infected children with non-malarial febrile illness](#). *BMC Infect Dis*. 2025;25(1):96. Published 2025 Jan 21. doi:10.1186/s12879-025-10517-1.

13 Mboowa G, Tessema SK, Christoffels A, Ndembu N, Kebede Tebeje Y, Kaseya J. [Africa in the era of pathogen genomics: Unlocking data barriers](#). *Cell*. 2024;187(19):5146-5150. doi:10.1016/j.cell.2024.08.032.

14 Kanyerezi S, Guerfali FZ, Anzaku AA, et al. [Wastewater metagenomics in Africa: Opportunities and challenges](#). *PLOS Glob Public Health*. 2024;4(12):e0004044. Published 2024 Dec 20. doi:10.1371/journal.pgph.0004044.

15 Kono HN, Ada Mengome MF, Pongui Ngondza B, et al. [C-reactive protein and high-sensitivity C-reactive protein levels in asymptomatic intestinal parasite carriers from urban and rural areas of Gabon](#). *PLoS Negl Trop Dis*. 2024;18(5):e0011282. Published 2024 May 20. doi:10.1371/journal.pntd.0011282.

and treatment of infectious diseases could have spin-off benefits by also reducing the burden of NCDs.

As part of these studies, Professor Bouyou-Akotch has also identified a high prevalence of other cardiovascular disease risk factors in Gabon, such as inactivity, smoking and obesity, and mapped how these varied by gender, age, and rural or urban location.¹⁶

Her other studies have focused on infectious diseases common in Gabon, particularly malaria. She explored the impact of the COVID-19 pandemic on health-care-seeking for malaria, finding a sharp increase in self-medication that led to poorer outcomes.¹⁷ In addition, she has contributed to international

collaborations investigating genetic diversity of the malaria parasite, including studies showing that genetic variation affects the severity of disease.¹⁸

Building on the findings from other EDCTP2-funded studies, Professor Bouyou-Akotch also led a study that identified a high prevalence of cryptococcal infections in hospitalised HIV patients with neurological symptoms. Almost one in four patients were positive for a urine-based test for cryptococcal antigen (CrAg). The results argue for the importance of introducing CrAg testing in Gabon to identify patients at high risk of death.¹⁹

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- 16 Mengome MFA, Kono HN, Bivigou EA, et al. [Prevalence of cardiometabolic risk factors according to urbanization level, gender and age, in apparently healthy adults living in Gabon, Central Africa](#). *PLoS One*. 2024;19(4):e0285907. Published 2024 Apr 5. doi:10.1371/journal.pone.0285907.
- 17 Mawili-Mboumba DP, Batchesy Ognagoso FB, M'Bondoukwé NP, et al. [Hospital attendance, malaria prevalence and self-medication with an antimalarial drug before and after the start of COVID-19 pandemic in a sentinel site for malaria surveillance in Gabon](#). *Malar J*. 2025;24(1):28. Published 2025 Jan 25. doi:10.1186/s12936-025-05272-2.
- 18 Ndong Ngomo JM, Mawili-Mboumba DP, M'Bondoukwé NP, et al. [Drug Resistance Molecular Markers of *Plasmodium falciparum* and Severity of Malaria in Febrile Children in the Sentinel Site for Malaria Surveillance of Melen in Gabon: Additional Data from the Plasmodium Diversity Network African Network](#). *Trop Med Infect Dis*. 2023;8(4):184. Published 2023 Mar 23. doi:10.3390/tropicalmed8040184.
- 19 Sibi Matotou RH, Mawili-Mboumba DP, Manomba C, et al. [High Cryptococcal Antigenuria Prevalence in a Population of PLHIV with Neurological Symptoms Hospitalized in the Infectious Diseases Wards of the Centre Hospitalier Universitaire de Libreville, Gabon](#). *Trop Med Infect Dis*. 2024;9(12):312. Published 2024 Dec 23. doi:10.3390/tropicalmed9120312.

Researchers process a sample from a study participant of the TB-CAPT EXULTANT trial at Maualane General Hospital in Maputo, Mozambique.





The sickle cell focal person performs blood tests on mother and child patients to detect signs of anemia, as part of the MULTIPLY project at the Under 5 Clinic in the St. John of God Hospital, in Lunsar, Sierra Leone.

6.10. Targeted detection of malaria in pregnancy

Professor Vivi Maketa has been assessing whether ultra-sensitive rapid diagnostic tests could ensure pregnant women are better protected against malaria.

Malaria poses a particular threat to pregnant women, affecting both maternal health and the risk of adverse birth outcomes. An estimated 125 million women are at risk of malaria in pregnancy each year.

The cornerstone of malaria prevention in pregnancy is intermittent preventive treatment during pregnancy (IPTp), where women are given antimalarial drugs at various points during their pregnancy, to prevent infection. However, resistance to the main drug used in IPTp, sulfadoxine–pyrimethamine, is encouraging the search for alternative approaches.

Recently, ultrasensitive malaria rapid diagnostic tests (RDTs) have been developed, which can detect very low levels of parasitaemia (important in pregnancy, where parasites are sequestered in the placenta). In her Career Development Fellowship, Professor Maketa has been exploring whether use of these ultrasensitive RDTs could be combined with an artemisinin combination therapy (ACT), pyronaridine–artesunate, in a ‘test-and-treat’ strategy. This would not require an antimalarial drug to be given to all pregnant women, reducing selection pressures driving the development of drug resistance.

In a trial in the Democratic Republic of the Congo (DRC), this strategy was found to be non-inferior to IPTp²⁰ – cases of asymptomatic parasitaemia during pregnancy were not significantly higher in the test-and-treat group. There were no significant differences in outcomes for either mother or child, suggesting that it is also as safe as conventional IPTp.

The test-and-treat approach is highly dependent on the sensitivity of the RDT. In this first field trial in the DRC, the ultrasensitive RDTs showed only a marginal improvement on standard RDTs.²¹ Overall, the study has demonstrated that the test-and-treat approach is a potential option for malaria control in pregnant women, but needs careful evaluation and studies of cost-effectiveness.

Alongside this project, Professor Maketa has also made contributions to multiple other studies in the DRC. These have included work on the mpox outbreak in the DRC²² and studies of Ebola vaccination²³.

- 20 Tshiongo JK, Khote FL, Kabena M, et al. [Intermittent screening using ultra-sensitive malaria rapid diagnostic test and treatment with pyronaridine-artesunate compared to standard preventive treatment with sulfadoxine-pyrimethamine for malaria prevention in pregnant women in Kinshasa, DRC](#). *Malar J*. 2025;24(1):58. Published 2025 Feb 21. doi:10.1186/s12936-025-05260-6.
- 21 Kabalu Tshiongo J, Luzolo F, Kabena M, et al. [Performance of ultra-sensitive malaria rapid diagnostic test to detect Plasmodium falciparum infection in pregnant women in Kinshasa, the Democratic Republic of the Congo](#). *Malar J*. 2023;22(1):322. Published 2023 Oct 23. doi:10.1186/s12936-023-04749-2.
- 22 Malembi E, Escrig-Sarreta R, Ntumba J, et al. [Clinical presentation and epidemiological assessment of confirmed human mpox cases in DR Congo: a surveillance-based observational study](#). *Lancet*. 2025;405(10490):1666-1675. doi:10.1016/S0140-6736(25)00152-7.
- 23 Larivière Y, Matuvanga TZ, Lemey G, et al. [Conducting an Ebola vaccine trial in a remote area of the Democratic Republic of the Congo: Challenges, mitigations, and lessons learned](#). *Vaccine*. 2023;41(51):7587-7597. doi:10.1016/j.vaccine.2023.11.030.

6.11. HIV suppression in ‘elite controllers’

Dr Christina Thobakgale has shed light on how a select group of individuals can keep HIV in check even without antiretroviral drug treatment.

A tiny proportion of those infected with HIV appear to be able to suppress viral replication and remain healthy even without antiretroviral therapy. There is great interest in understanding how such ‘elite controllers’ suppress HIV, which could point the way to new treatments or preventive measures.

In South Africa, EDCTP2 Senior Fellow Dr Christina Thobakgale is focusing on a class of immune cells known as natural killer (NK) cells. NK cells are known to have an impact on HIV control but their contribution to elite control is not completely clear.

In earlier work, Dr Thobakgale identified mutations in the HIV Gag protein that enhance the binding of certain NK cell receptors to HIV-infected cells,²⁴ which promotes a state of tolerance and inhibits immune responses against these cells.

Conversely, HIV can evolve mutations that abolish binding of NK cell receptors²⁵ that typically trigger a stronger NK response. These studies demonstrated the tendency of HIV to evolve in ways that enable it to evade host immune responses.

In work published in 2024, Dr Thobakgale and colleagues examined the properties of NK cells from elite controllers. She was able to identify particular classes of NK cells that were present in higher or lower numbers in elite controllers compared to progressors.²⁶ The findings point to an NK cell phenotype that may be particularly associated with HIV control.

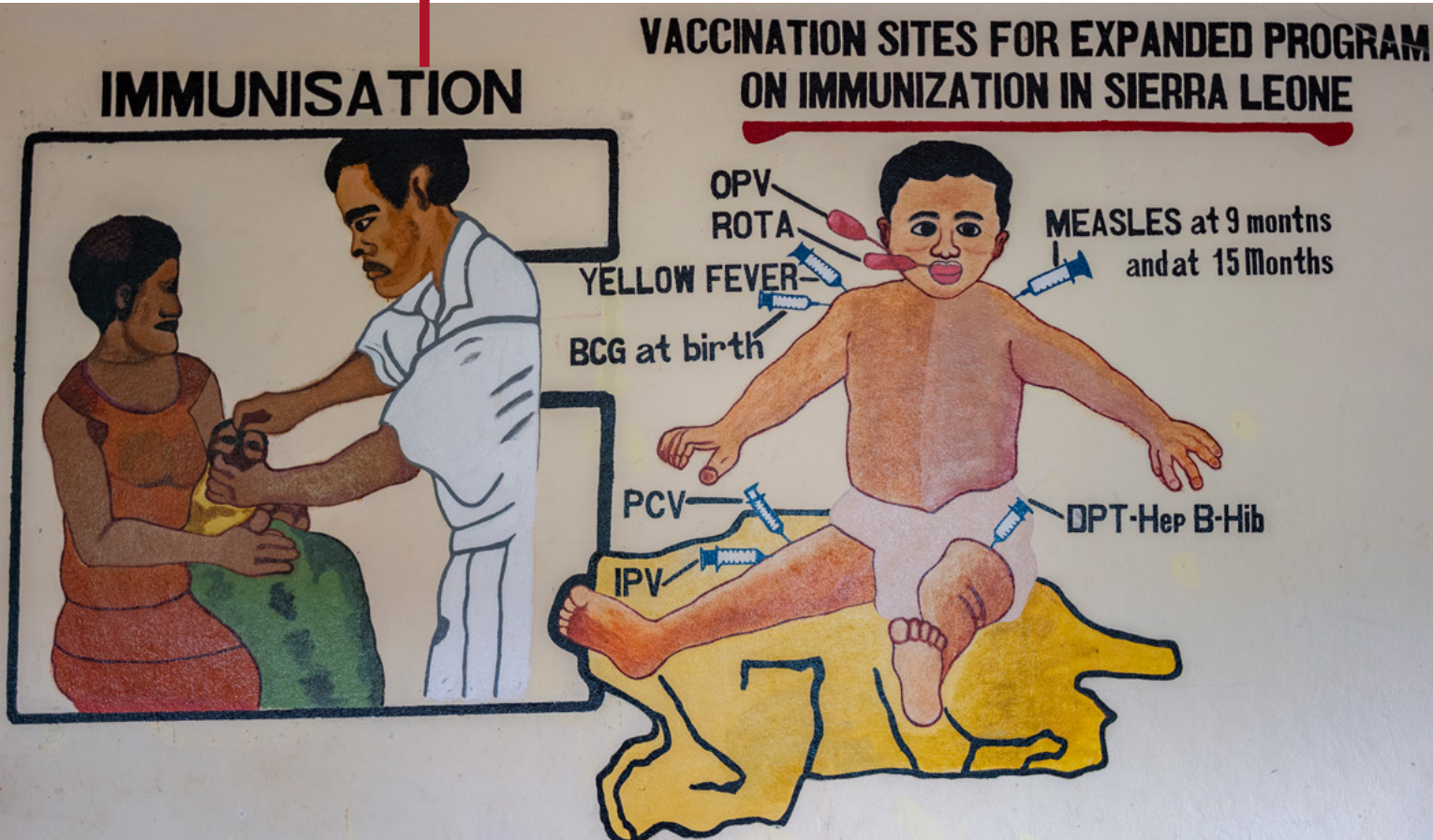
Dr Thobakgale was also appointed Head of the Division of Immunology at the University of the Witwatersrand in 2024, where she has established the Wits Immunology Research Programme (WIRP).

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- 24 Hölzemer A, Thobakgale CF, Jimenez Cruz CA, et al. [Selection of an HLA-C*03:04-Restricted HIV-1 p24 Gag Sequence Variant Is Associated with Viral Escape from KIR2DL3+ Natural Killer Cells: Data from an Observational Cohort in South Africa](#). *PLoS Med.* 2015;12(11):e1001900. Published 2015 Nov 17. doi:10.1371/journal.pmed.1001900.
- 25 Ziegler MC, Naidoo K, Chapel A, et al. [HIV-1 evades a Gag mutation that abrogates killer cell immunoglobulin-like receptor binding and disinhibits natural killer cells in infected individuals with KIR2DL2+/HLA-C*03:04+ genotype](#). *AIDS.* 2021;35(1):151-154. doi:10.1097/QAD.0000000000002721.
- 26 Batohi N, Shalekoff S, Martinson NA, Ebrahim O, Tiemessen CT, Thobakgale CF. [HIV-1 Elite Controllers Are Characterized by Elevated Levels of CD69-Expressing Natural Killer Cells](#). *J Acquir Immune Defic Syndr.* 2024;97(5):522-532. doi:10.1097/QAI.0000000000003518.

A Nurse carries samples from the TB-CAPT EXULTANT trial to the laboratory at Mavalane General Hospital in Maputo, Mozambique.



7. Strengthening partnerships



7.1. EDCTP on the global stage

EDCTP continued to work with a wide range of partners in 2024, contributing to multiple global initiatives.

EDCTP has a strong commitment to working in partnership, with key stakeholders from sub-Saharan Africa and funders with a shared interest in equitable partnerships to advance global health.

During 2024, with funding from the UK Department of Health and Social Care, EDCTP provided support for the WHO to produce global guidance on [best practice for clinical trials](#). The guidance is designed to optimise trial conduct to ensure that trials deliver high-quality evidence, to reduce duplication and research 'waste', and to strengthen the global ecosystem for clinical trials, including studies during pandemics.

EDCTP also organised a high-level side event at the [Science Summit during the 79th United Nations General Assembly](#) in September 2024. Focused on antimicrobial resistance (AMR), the event highlighted key AMR challenges and how international research collaborations between Europe and sub-Saharan Africa are helping to address them.

In April 2024, EDCTP participated in discussions in Nairobi, Kenya, on [clinical trials in Africa](#), alongside the Clinical Trials and Research Community (CRTC) programme of the Science for Africa (SFA) Foundation, the Global Health EDCTP3-funded Clinical Trials African Network ([CTCAN](#)) consortium, and the EDCTP Regional Networks of Excellence. Discussions focused

on how the EDCTP Regional Networks of Excellence can support the implementation of the CTCAN project, and how the SFA Foundation and the EDCTP Association can work together to amplify the impact of their activities across sub-Saharan Africa.

The EDCTP Association Africa Office, led by Dr Thomas Nyirenda, is based in Cape Town and hosted by the South African Medical Research Council (SAMRC). It is undertaking a greater range of activities within Global Health EDCTP3. In March 2024, Dr Nyirenda represented EDCTP at the 35th Meeting of the **African Advisory Committee for Research and Development (AACHRD)**. AACHRD was set up to advise the WHO Africa Regional Director on research related to health policies and development strategies. The meeting focused on manufacturing, technology transfer, and R&D in the African Region, and Dr Nyirenda presented on the role of clinical trials in the R&D landscape in Africa.

On his first mission to South Africa, **Mr Marc Lemaître**, **Director General of the Directorate-General for**

Research and Innovation (DG RTD), visited Cape Town, South Africa, accompanied by Dr Michael Makanga, Executive Director of Global Health EDCTP3, and Dr Nyirenda from the EDCTP Association Africa Office. The mission included a visit to **Afrigen**, which is playing a key role in developing biomanufacturing capacity in sub-Saharan Africa, and to the **SPaRCS project** at University of the Western Cape, which is helping to build national pharmacovigilance capacities in the region.

EDCTP was instrumental in the creation of the **Pan-African Clinical Trials Registry (PACTR)**. In November 2024, EDCTP and PACTR co-hosted a [virtual workshop](#), to unveil changes to the platform and to stimulate discussions on its use and future development.

Other key activities during the year included a relaunch of the [EDCTP Alumni Network web platform](#), with a refreshed look and feel and enhanced functionality, and planning for the **Twelfth EDCTP Forum**, in Kigali, Rwanda, in June 2025.

7.2. Building biomanufacturing capacity

Thanks to an EDCTP partnership with the International Centre for Genetic Engineering and Biotechnology (ICGEB), members of EDCTP's regional Networks of Excellence have benefited from intensive training in the principles and practice of high-tech biomanufacturing.

A lack of manufacturing capacity for medical interventions in sub-Saharan Africa, including vaccines and biological therapeutics such as monoclonal antibodies, is one key factor limiting access of sub-Saharan African populations to new medical products. To address this issue, many efforts are now being made to build manufacturing capacity in the region.

In recognition of the growing importance of genomic and other technologies, in 2022 EDCTP signed a memorandum of understanding with the ICGEB, an intergovernmental organisation that aims to widen access to new technologies through research, training and technology transfer. The agreement covered three areas – bringing genomic technologies into EDCTP-funded networks, joint work on capacity-building, and co-funding of projects.

One of the fruits of this collaboration was an intensive two-week training programme in biomanufacturing for representatives from the four EDCTP-funded regional Networks of Excellence. Researchers and technicians received personalised training in areas such as Quality Management Systems (QMS) and Good Manufacturing Practice (GMP), and gained end-to-end insights into biosimilar production.

Held at ICGEB's Biotechnology Development Unit in Trieste, Italy, the training has provided a major boost to biomanufacturing expertise within the EDCTP networks.

As part of the collaboration between EDCTP and ICGEB, in May 2024, Dr Thomas Nyirenda, Head of the EDCTP Association's Africa Office, participated in a seminar organised by ICGEB International. Dr Nyirenda highlighted EDCTP's efforts to strengthen the clinical trials ecosystem within Africa.

8. Organisational activities



Researchers work on measuring HIV viral load at the Center for Research on Emerging and Re-emerging Diseases (CREMER) in Yaoundé, Cameroon, as part of the DATURA project.

8.1. Global Health EDCTP3 in 2024

The Global Health EDCTP3 programme continued to expand in 2024, with a boost to funding and new countries from Africa joining the EDCTP Association.

The successor to the EDCTP2 programme, Global Health EDCTP3, was launched in 2022. It is structured as a partnership between the European Union (represented by the European Commission) and the EDCTP Association, a coalition of European and African countries. In 2024, **Eswatini and Namibia joined the EDCTP Association**, which now numbers 15 European and 30 African countries. The UK joined the Horizon Europe programme in 2024, meaning UK institutions are now again able to apply for EDCTP funding.

Global Health EDCTP3 has been identified as a key initiative within the [EU Global Health Strategy](#), which sets out the EU's global health objectives and how they

will be achieved. Research, equitable access to medical interventions and partnerships of equals, central to EDCTP's mission, are at the heart of the strategy.

The EU has multiple structures active in global health. In September 2024, EDCTP, in partnership with editors of *Lancet* journals, convened a forum to discuss Europe–Africa collaboration in global health and how greater impact could be achieved. The Forum identified several concrete steps to promote coordinated action across different EU bodies working in global health.

Other important developments in 2024 included the publication of the **2025 Global Health EDCTP3 work programme**. It includes four calls covering seven topics, including TB vaccines, malaria therapeutics, neglected tropical disease (NTD) vaccines, training hubs for fellowships in public health, strengthening of EDCTP networks in Africa, diarrhoeal disease and climate impacts, and transformative innovations in global health.

The **budget for the 2025 work programme** has received a significant boost, thanks to additional resources committed by contributing partners and the EDCTP Association. The budget for training hubs for fellowships in public health has more than doubled, to €15 million, with 11 rather than five projects likely to be funded. The budget for network strengthening has increased from €40 million to €53 million, and the budgets for the calls on diarrhoeal disease and climate impacts, and transformative innovations in global health have also been increased.

Global Health EDCTP3 also activated its **emergency funding mechanism** to support projects on the **mpox epidemic** in sub-Saharan Africa, declared a Public Health Emergency of International Concern (PHEIC) in 2024. Following an extra injection of funding from members of the EDCTP Association, €12.1 million was awarded to [support nine research projects focusing on mpox epidemiology, prevention and treatment](#). The projects bring together 43 institutions in nine African, 13 European and two North American countries.

Global Health EDCTP3 also agreed to make funds available to complete **EDCTP2-funded clinical trials** that had been severely delayed by the COVID-19 pandemic. [Eight projects were funded](#) through the €14 million initiative.



Consultation day for children as part of the MULTIPLY project at the Mange Community Health Center in Sierra Leone.

9. 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

	Angola (Aspirant member) National Institute of Public Health		The Gambia Ministry of Health and Social Welfare
	Austria Medical University of Vienna		Germany Bundesministerium für Bildung und Forschung
	Belgium Department Economy, Science and Innovation		Ghana Ghana Health Service
	Benin University of Abomey-Calavi		Guinea-Bissau Instituto Nacional de Saúde Pública
	Burkina Faso Centre National de Recherche et de Formation sur le Paludisme		Guinea Centre National de Formation et de Recherche en Santé Rurale
	Cameroon Ministry of Public Health		Ireland Irish Health Service Executive
	Congo University Marien Ngouabi		Italy Istituto Superiore di Sanità
	Côte d'Ivoire Ministry of Higher Education and Scientific Research		Kenya National Research Fund
	Democratic Republic of the Congo Université de Kinshasa		Liberia National Public Health Institute of Liberia
	Denmark Statens Serum Institute		Luxembourg Fonds National de la Recherche
	Eswatini National Tuberculosis Program		Malawi Ministry of Health
	Ethiopia Armauer Hansen Research Institute		Mali University of Science, Techniques and Technology of Bamako
	Finland Academy of Finland		Mozambique Ministry of Health
	France Aviesan, Institut thématique multi-organismes		Namibia Ministry of Health and Social Services
	Gabon Centre de Recherches Médicales de Lambaréné		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



A Research Medical Microbiologist works in a laboratory at the Leishmaniasis Research and Treatment Center of Hospital of the University of Gondar in Ethiopia, as part of the PREV_PKDL project.

10. Summary financial statements 2024

Statement of profit or loss and other comprehensive income

for the year ended 31 December 2024. Expressed in thousands ('000) of euro.

	EC 2024	Donor 2024	Total 2024	Total 2023
Calls (Grants)				
Contributions	-	6,881	6,881	5,813
Grant expenditure	-	(6,881)	(6,881)	(5,813)
Results for the year	-	-	-	-
Others				
Contributions	3,799	1,105	4,904	7,708
Other expenditure	(3,799)	(1,105)	(4,904)	(7,708)
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 2024 (after appropriation of result). Expressed in thousands ('000) of euro.

	31 December 2024	31 December 2023
Non-current assets		
Right-of-use assets	1,160	1,306
Debtors and other receivables	11,054	57,293
Total non-current assets	12,214	58,599
Current assets		
Debtors and other receivables	28,660	20,013
Cash and cash equivalents	75,848	68,370
Total current assets	104,508	88,383
Total assets	116,722	146,982
Non-current liabilities		
Grants and other payables	34,397	80,347
Deferred income EC	-	-
Deferred income Donor	-	-
Lease liabilities	988	1,134
Total non-current liabilities	35,385	81,481
Current liabilities		
Grants and other payables	57,668	48,802
Deferred income EC	-	-
Deferred income Donor	23,497	16,527
Lease liabilities	172	172
Total current liabilities	81,337	65,501
Total liabilities	116,722	146,982

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

Mr Abdoulie Barry
Dated: 16 June 2025

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 2023	-	-	-
Total comprehensive income for the year	-	-	-
Balance as at 31 December 2024	-	-	-

EDCTP has no unrestricted reserves.

Statement of cash flows

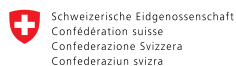
for the year ended 31 December 2024. Expressed in thousands ('000) of euro.

	2024	2023
Cash flows from operating activities		
Result for the year	-	-
Adjustment for:		
Depreciation charge for right-of-use assets	175	145
Lease interest	36	40
Reversal of depreciation and lease interest	(8)	(13)
(Increase) decrease in debtors and other receivables	131	751
Increase (decrease) in grants and other payables	(37,083)	(91,236)
Increase (decrease) in deferred income	44,042	93,900
Net cash flows from operating activities	7,293	3,587
Cash flows from investing activities		
Interest received/(paid)	389	122
Payment of lease liabilities	(204)	(172)
Net cash flows from investing activities	185	(50)
Net increase (decrease) in cash and cash equivalents	7,478	3,537
Cash and cash equivalents at 1 January	68,370	64,833
Exchange rate effects		
Cash and cash equivalents at 31 December 2024	75,848	68,370



A researcher performs a tuberculosis screening for a patient sample at the Mange Community Health Centre in Mange, Sierra Leone, as part of the MULTIPLY project.

11. Acknowledging our funders



Swiss Confederation

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



SWISS NATIONAL SCIENCE FOUNDATION



Colophon

European & Developing Countries Clinical Trials Partnership

The Hague, the Netherlands, July 2025

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Panos Pictures

Cover photo:

The technical laboratory agent talks with a Doctor at the Day Hospital in Yaoundé, Cameroon, as part of the EDCTP2-funded DATURA project.



The power of sharing science