



Global Health
EDCTP3

The African and European
research partnership
on infectious diseases

Our lasting benefits for Europe and Africa



EUROPEAN PARTNERSHIP



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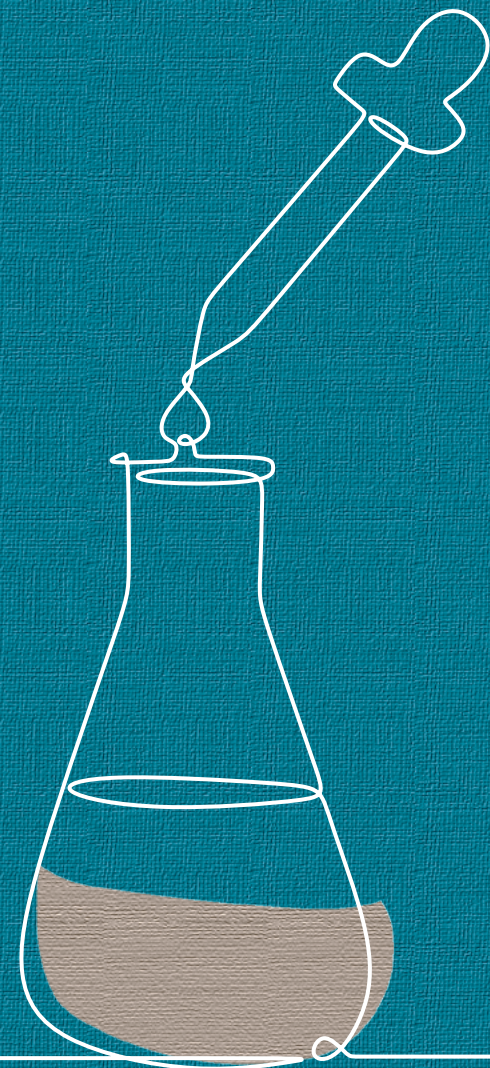
Our lasting benefits for Europe and Africa

The European & Developing Countries Clinical Trials Partnership (EDCTP), now in its third iteration - Global Health EDCTP3 - is one of the world's major funders of cross-continental global health clinical research, and a flagship Africa-Europe partnership.

EDCTP advances clinical research and strengthens health research capacity, including on ethics and regulatory, as well as surveillance, and innovation ecosystems across Africa and Europe. It targets

the world's most urgent and widespread infectious diseases (HIV/AIDS, tuberculosis, malaria, and neglected infectious diseases) affecting over two billion people. It also addresses global challenges such as antimicrobial resistance (AMR) and climate change-driven health outbreaks, while promoting digital transformation, artificial intelligence (AI), and disruptive innovation to accelerate health solutions.

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EDCTP's added value for Europe



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Boosting Europe's competitiveness and scientific leadership

EDCTP strengthens Europe's competitiveness by fostering research excellence and global cooperation to advance health innovations.

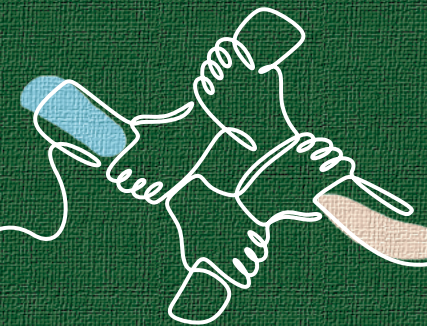
These investments stimulate employment, economic activity, private-sector engagement, and intellectual property development across Europe. The partnership bridges a key challenge for Europe's competitiveness, the EU's innovation gap¹, by supporting late-stage product development, implementation research, and regulatory-readiness. These efforts help overcome the scientific, technical, and legal hurdles to bring innovations to the market.

EDCTP's geographical and technological scope opens opportunities for European companies to expand into new markets and contribute to global health solutions.

EDCTP prioritises cooperation with Africa, the fastest-growing continent² and a vital partner for Europe's security and prosperity. By targeting high-impact areas facing market failure, such as poverty-related infectious diseases affecting vulnerable populations, AMR, and neglected infectious diseases, EDCTP generates strong public returns on investment. EDCTP also helps companies fulfil their corporate social responsibility goals. Fostering equitable, long-term partnerships drives trade, innovation, and investment opportunities across Africa for Europe.

¹ Draghi, M et al. (2024). [The Draghi report on EU competitiveness](#). European Commission.

² Van Teutem (2024). [The UN projects that Africa's population will double by 2070](#). Our World in Data.



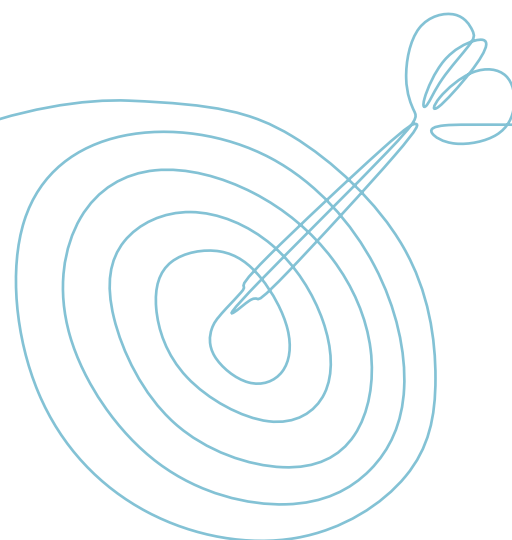
Protecting Europe through stronger global health security cooperation

EDCTP contributes to Europe's health security by addressing climate-sensitive infectious disease threats³ and AMR⁴.

As climate change increases the incidence of infections in Europe, EDCTP supports research to identify and anticipate epidemiological trends and climate-sensitive infectious diseases, strengthen early warning, detection, and surveillance, and accelerate the development of medical countermeasures. It enhances epidemic preparedness and response⁵, including coordinated responses with neighbouring regions and across public and private actors.

EDCTP has also demonstrated exceptional speed and agility in responding to health crises.

During the Ebola, COVID-19, and mpox outbreaks, the partnership quickly mobilised emergency funding to support the rapid start of response projects, providing essential clinical and medical frontline capabilities. Its support involves developing expertise in clinical research, epidemiology, and laboratory diagnostics, crucial for effective outbreak response. EDCTP's ability to act swiftly across countries and regions in health emergencies makes it a credible and effective partner for protecting health security in Europe and beyond.



³ Project examples: [IMPACTING](#) (2025), [ComBac-Africa](#) (2025), [ResTick](#) (2025). CORDIS. European Commission.

⁴ Project examples: [TASP](#) (2025), [PediSEP1](#) (2025), [EX-DR TB](#) (2025). CORDIS. European Commission.

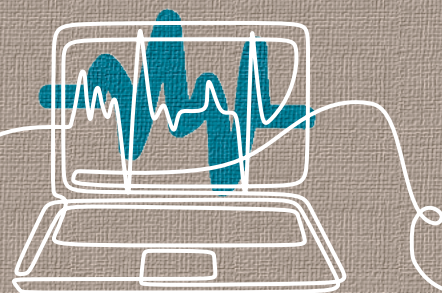
⁵ European Commission (2024) [Preparedness and research response to public health emergencies – the role of Global Health EDCTP3](#).

Spearheading Europe's science diplomacy through equitable partnerships

EDCTP is the largest and most established research partnership between Europe and Africa, working on a shared mission to address infectious diseases, health security threats, and global health challenges.

EDCTP's funding and governance are based on joint Africa-Europe ownership, enabling long-term, equitable cooperation across regions to address shared health security priorities. Its regional and global presence also advances Europe's geopolitical objectives, including strengthening international security, reinforcing global health resilience, promoting international cooperation, and upholding human rights. By building strategic partnerships, EDCTP contributes to a stronger Europe on the global stage and complements key EU initiatives, such as the Global Gateway Strategy.⁶

⁶ European Commission (2021) [Joint Communication to the European Parliament, the Council, the European Economic and Social Committee, the Committee of the Regions and the European Investment Bank – The Global Gateway](#).



Leveraging Europe's digital talent for public health solutions

EDCTP reinforces Europe's strategic leadership for digital transformation and smarter responses to health challenges by investing in digital and AI technologies in health.

This includes the digitalisation of research infrastructure,⁷ diagnosis,⁸ health systems,⁹ remote patient monitoring,¹⁰ and data management and exchange.¹¹ EDCTP also supports training of researchers in biostatistics and modelling,¹² bioinformatics,¹³ and genomic epidemiology,¹⁴ ensuring they can fully harness digital and AI technologies to tackle pressing health challenges.

Through these initiatives, **EDCTP also advances the implementation of key strategies for digital health transformation**, such as the EU Global Health Strategy, the European Strategy for AI in Science, the Africa CDC's Digital Transformation Strategy, and the WHO Global Strategy on Digital Health 2020–2025. Its efforts strengthen Europe's capacity to innovate locally and reduce dependencies in critical technology domains.

EDCTP creates collaboration and investment opportunities for European companies by supporting digital capacity and innovation in Africa.

It also encourages joint ventures, technology transfer, and co-development of new products and services across Europe and Africa, building robust networks and collaborations that advance digital health research, innovation, and economic growth.

Advancing Europe's human rights commitment at the global and local levels

EDCTP contributes to the EU's commitment to human rights by addressing unmet medical needs, promoting gender equality and research equity, and delivering life-saving health technologies for vulnerable populations. It brings together public and private partners to turn global commitments into tangible outcomes, focusing on the Sustainable Development Goals, the EU Global Health Strategy, the AU-EU Innovation Agenda, and other initiatives that advance human rights, the right to health, and shared prosperity.

EDCTP promotes an inclusive innovation ecosystem and prioritises ethical research that responds to historically neglected populations, actively engaging communities¹⁵ in every research stage – from study design to uptake. This approach ensures scientific advancements reach those who need them most, strengthens local scientific capacities and health research ecosystems, advances research equity, and lays the foundations for long-term development in local communities.



7 Project example: [AFRICAI-RI](#) (2025). CORDIS. European Commission.

8 Project example: [MultiplexAI](#) (2025), [SkincAIr](#) (2025). CORDIS. European Commission.

9 Project example: [LINDA-FAMILIA](#) (2025) CORDIS. European Commission.

10 Project example: [IMPALA](#) (2025).

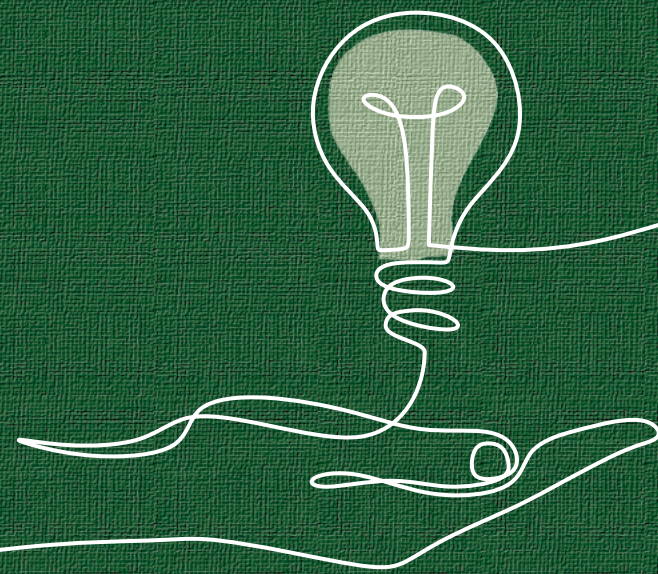
11 EDCTP (2024) [EDCTP Knowledge Hub](#).

12 EDCTP (2025). [Strategic Training Hubs for Fellowships in Public Health covering Biostatistics, Epidemiology and Modelling](#). CORDIS. European Commission.

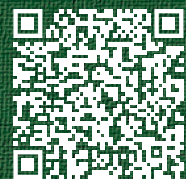
13 Project examples: [GREAT-LIFE](#) (2025), [BRIDGE NETWORK](#) (2025). CORDIS. European Commission.

14 Project examples: [GenPath Africa](#) (2025), [PANGenS](#) (2025); [EpiGen Ethiopia](#) (2025) CORDIS. European Commission.

15 Project example: PREVAC-UP (2025) which developed a training manual on community engagement methods for clinical trials; [CETH](#) (2024) that developed a [comprehensive framework](#) for enhancing community engagement in infectious disease clinical trials in sub-Saharan Africa; EDCTP (2021) [Community engagement, a vital concern in clinical research](#).



EDCTP's added value for Africa



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Boosting Africa's prosperity through better health and wellbeing

EDCTP is dedicated to reducing Africa's infectious disease burden by funding clinical research and strengthening local capacity.

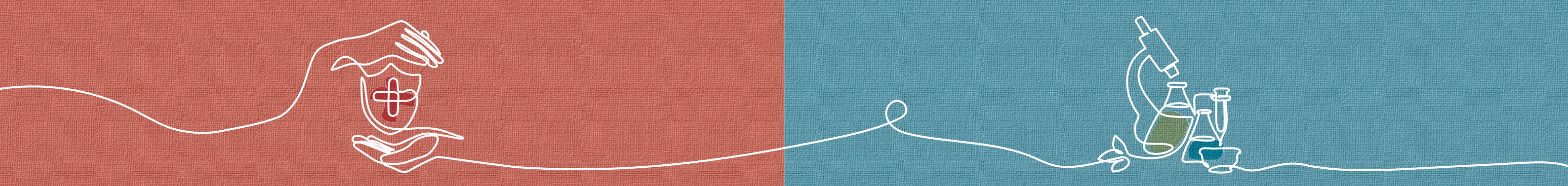
Despite progress, hundreds of millions still suffer from poverty-related and neglected infectious diseases, causing millions of deaths each year. The continent also bears the world's highest mortality from antimicrobial resistance.

EDCTP strengthens African health research systems and empowers local professionals to tackle the continent's health priorities.

It has supported the career development of thousands of globally connected and systemically efficient African researchers, fostered four regional networks of excellence, and funded over 500 clinical studies, driving the development of groundbreaking health innovations.¹⁶ By reducing the burden of infectious diseases, EDCTP helps boost Africa's prosperity, increase productivity, and lessen both their direct and indirect costs on governments, families, and individuals.



16 Global Health EDCTP3 (2025) [20+ years of results - Global Health EDCTP3 JU](#).



Contributing to Africa’s health security and sovereignty

EDCTP contributes to Africa’s health security by supporting clinical research, training, and networks for epidemic preparedness and response.¹⁷

It builds capacity to investigate outbreaks, develop countermeasures, and exchange data and knowledge swiftly.¹⁸ In partnership with Africa CDC,¹⁹ WHO AFRO,²⁰ GloPID-R, CEPI²¹ and others, EDCTP trains epidemiologists, biostatisticians, and infectious-disease specialists, strengthening Africa’s ability to detect and manage threats earlier and more effectively.

EDCTP supports Africa’s response to health threats, including Ebola, mpox, COVID-19,²² Lassa fever,²³ and climate- and AMR-related outbreaks.

Its support spans vaccine, therapeutic, and diagnostic development,²⁴ epidemiological studies,²⁵ surveillance of vectors²⁶ and drug-resistance,²⁷ regulatory and ethics oversight for pandemic preparedness,²⁸ vaccine safety in vulnerable groups,²⁹ and digital tools like AI and mobile health.³⁰ These efforts position EDCTP as a key partner in pandemic preparedness and response,³¹ and in advancing Africa’s health sovereignty and resilience.

17 Project example: [PANDORA-ID-NET](#) (2016) EDCTP.
18 Project example: [ALERTT](#) (2018) EDCTP.
19 EDCTP (2024) [EDCTP and Africa CDC collaborative initiative survey report on the ‘Epi-Biostat’ initiative](#).
20 EDCTP (2017) [EDCTP joins forces with WHO AFRO and TDR to fund implementation research - EDCTP](#).
21 Cf. Footnote 15.
22 Cf. Footnotes 16 and 17.
23 Project example: [LEAP4WA](#) (2021).
24 Project examples: [EPoCA](#) (2024), [ODIN-Mpox](#) (2024), [MOVIE-TRACE](#) (2024) CORDIS. European Commission.
25 Project examples: [JUA KIVU](#) (2024) CORDIS. European Commission.
26 Project examples: [DEFEND](#) (2025), [VectorGrid-Africa](#) (2025) CORDIS. European Commission.
27 Project example: [mfoDx](#) (2021), [CATCR](#) (2024). CORDIS. European Commission.
28 Project examples: [ECOWAS-RegECs](#) (2023), [BREEDIME](#) (2023) CORDIS. European Commission.
29 Project example: [PregInPoxVac](#) (2024) CORDIS. European Commission.
30 See section 4.
31 EDCTP is considered a key pillar for pandemic preparedness research and innovation in the Africa CDC Mpox Continental Preparedness and Response Plan. Cf. Africa CDC (2024) [Mpox Continental Preparedness and Response Plan for Africa](#).

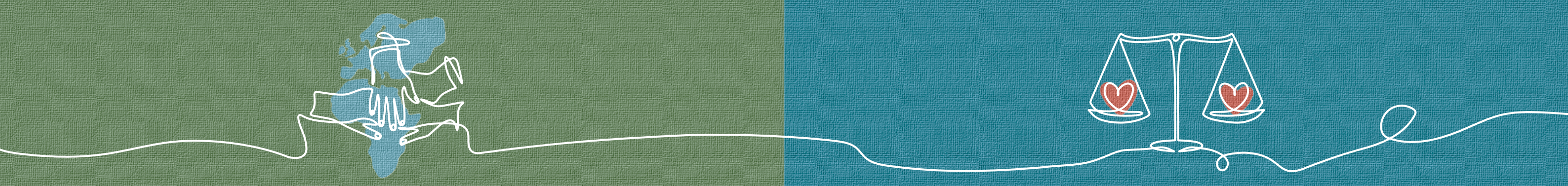
Enhancing Africa’s clinical research ecosystems

Africa hosts only around 4% of global clinical trials; boosting clinical research across the continent is key to improving health outcomes and social and economic development.

EDCTP’s investments build institutional capacity, attract innovation, foster local scientific leadership, and reinforce Africa’s health research ecosystem, aligning with the continent’s goals and strategies.³²

EDCTP has enhanced clinical research ecosystems in Africa by supporting over 3,000 researchers and health professionals through fellowships, postgraduate training, and targeted skill-building. It has also invested in advancing ethics oversight, regulatory systems³³ including pharmacovigilance,³⁴ and digital health capacities, complementing Team Europe Initiatives on Digital Health³⁵ and Manufacturing Health Technologies in Africa (MAV+).³⁶ Flagship initiatives that bolster Africa’s clinical trials ecosystems include the **Clinical Trials Community Africa Network (CTCAN)**³⁷ connecting researchers, regulators and industry to expand trials, and the **Pan African Clinical Trials Registry (PACTR)**³⁸ – Africa’s first WHO-recognised registry – providing a trusted database of planned, ongoing and completed clinical studies conducted in Africa.

32 AUDA-NEPAD (2018) [Health Research and Innovation Strategy for Africa \(HRISA\): 2018–2030](#).
33 Global Health EDCTP3 (2025) [Strengthening regulatory capacity in sub-Saharan Africa](#); EDCTP (2024) [Strengthening ethics review and regulatory capacity](#). Annual Activity Report 2024.
34 EDCTP (2021) [EDCTP portfolio: Pharmacovigilance 2014–2020](#).
35 European Commission (2024) [Team Europe and African partners launch four initiatives to strengthen health systems and social protection in Africa](#).
36 European Commission (2024) [Manufacturing and Access to Vaccines, medicines & health technology products in Africa \(MAV+\)](#).
37 Project example: [CTCAN](#) (2025).
38 Project example: [PACTR](#) (2025).



Advancing health partnerships within Africa and with Africa

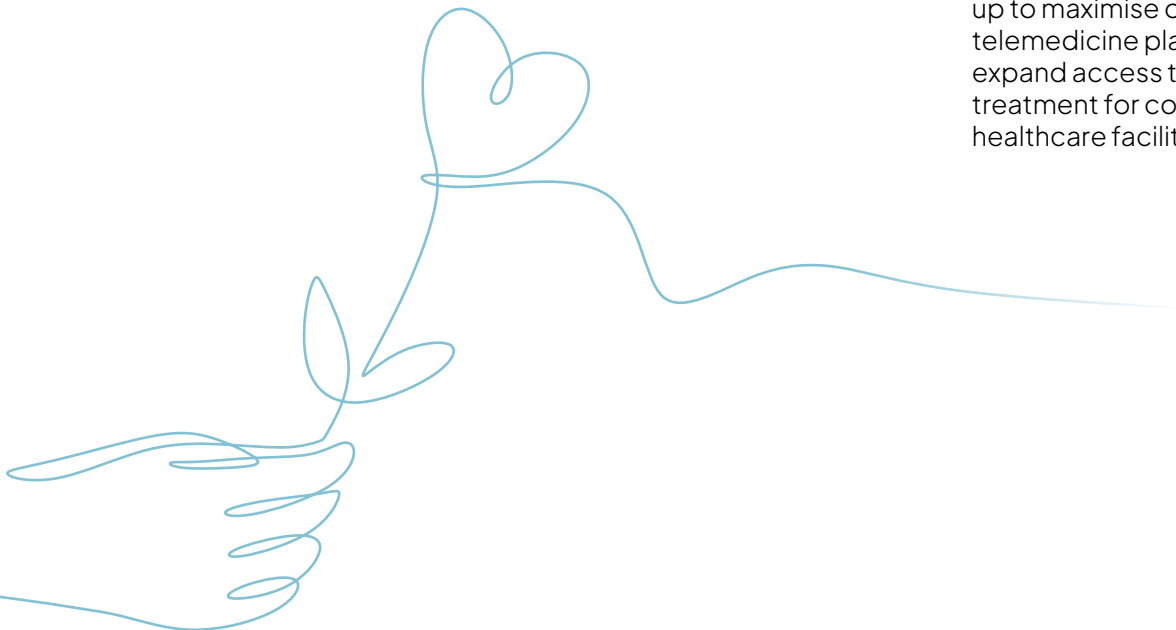
EDCTP advances health partnerships in Africa by aligning research, investments and interventions with the continent’s priorities.³⁹

It fosters Africa-led collaboration through strategic alliances with the Africa CDC⁴⁰, WHO AFRO⁴¹, and AVAREF⁴² among others, ensuring research supports long-term health security and integration.

It has also steered cooperation with the WHO’s Special Programme for Research and Training in Tropical Diseases (TDR)⁴³, the Africa Research Excellence Fund⁴⁴, and private sector partners⁴⁵, while supporting regional networks that connect governments, funders, researchers and industry. These partnerships build skills, mobilise co-investment, and promote coordinated implementation of Africa’s health and research agenda.

As a key implementing partner of the AU-EU Innovation Agenda⁴⁶, EDCTP helps align policy, research and innovation systems between Europe and Africa.

By embedding collaboration in training, clinical research and regulatory readiness, it enhances Africa’s capacity to address shared health challenges and generate long-lasting socio-economic benefits on both continents.



39 African Union (2025) [The African Union Roadmap to 2030](#).
40 Africa CDC (2025) [Africa CDC and Global Health EDCTP3 sign Memorandum of Understanding to promote public health in Africa](#).
41 EDCTP (2017) [EDCTP joins forces with WHO AFRO and TDR to fund implementation research - EDCTP](#).
42 In 2008, EDCTP awarded two grants totalling approximately 700,000 EUR to WHO to establish AVAREF and strengthen regulatory authorisation capacities across Africa. EDCTP1 evaluation. pp 46.
43 EDCTP (2015) [New EDCTP-TDR Clinical Research and Development Fellowships awarded](#).
44 EDCTP (2021) [EDCTP portfolio: EDCTP/AREF Preparatory Fellowships](#).
45 EDCTP (2020) [Fondation Botnar and Novartis support EDCTP Fellowships on child and adolescent health](#); EDCTP (2017) [EDCTP-GSK Senior Fellowships for co-morbidities between poverty-related diseases and non-communicable diseases](#).
46 European Commission (2023) [The AU-EU Innovation Agenda](#).

Driving health equity and trust in Africa

EDCTP drives health equity by prioritising underserved populations – including women,⁴⁷ newborns⁴⁸ and children,⁴⁹ urban poor and rural communities⁵⁰ – helping accelerate Africa’s progress towards Universal Health Coverage.

It funds health technologies that are safe, effective, and suited to real-world conditions: treatments usable without electricity or clean water, medicines that teachers or relatives can administer, and tools adapted for remote settings with patient follow-up to maximise outcomes.⁵¹ EDCTP also backs telemedicine platforms and mobile solutions that expand access to diagnosis, consultation, and treatment for communities with limited access to healthcare facilities.

Equity and trust guide EDCTP’s work: research and resulting technologies are required to be accessible, acceptable, and gender-responsive, developed with high ethical standards and active community participation.

EDCTP has adopted the **TRUST Code**⁵² of Conduct for equitable research partnerships, making it a requirement for all funded projects, and inspired by it, the **PREPARED Code**⁵³ was developed to provide an ethical framework for research during health crises. They help prevent ethics dumping, support local leadership in research ethics, and build trust between researchers and communities, enabling higher-quality, more impactful interventions while reinforcing local health systems.

47 Global Health EDCTP3 (2024) [International Women’s Day 2024: Investing in women to accelerate progress](#).
48 [MTBVAC in Newborns: Phase 2a Dose-Defining Safety and Immunogenicity Study and Capacity Building to Support Vaccine Efficacy Trials in Tuberculosis-Endemic Regions of Sub-Saharan Africa – ERA-LEARN & Evaluating the impact of the global evidence, local adaptation \(GELA\) project for enhancing evidence-informed guideline recommendations for newborn and young child health in three African countries: a mixed-methods protocol - PubMed](#).
49 [CHAPAS-4, PEDICAP, GELA, MTBVAC](#).
50 [COREP - International partnerships against infectious diseases & Feasibility, acceptability and preliminary effects of a social network-based, peer-led HIV self-testing intervention among men in two Ugandan fishing communities, 2022 | Archives of Public Health | Full Text](#).
51 Project examples: [SDx](#) (2024).
52 [TRUST Code](#).
53 [PREPARED Code](#).

**New and better
medical solutions
already saving and
improving lives**



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First-ever malaria vaccines



What it is

RTS,S and R21/Matrix-M are the **first vaccines developed to prevent malaria**, and the first vaccines against a human parasitic disease to be recommended for widespread use. Both vaccines target *Plasmodium falciparum*, the parasite responsible for most malaria cases and deaths in Africa, helping the immune system prevent the parasite from infecting the liver.

Why it matters

Malaria remains a **major public health threat** in sub-Saharan Africa, particularly for young children. In 2024, 282 million people fell ill with malaria and **610,000 died**, with 95% of deaths occurring in the WHO African Region.⁵⁴ RTS,S and R21/Matrix-M vaccines could prevent millions of illnesses and save thousands of children every year.

The story

EDCTP played a pivotal role in the development of the first malaria vaccines, RTS,S and R21/Matrix-M, by funding clinical research and supporting the capacity, infrastructure and networks that made these breakthroughs possible.

RTS,S/AS01, developed by GSK and the PATH Malaria Vaccine Initiative, was tested in a landmark Phase III trial across eleven research centres in seven African countries, one of the largest malaria vaccine trials ever conducted. Published in 2011, the first results showed that RTS,S roughly **halved both clinical and severe malaria episodes in children aged 5 to 17 months**.⁵⁵ EDCTP contributed to this milestone by strengthening clinical trial capacity at research institutions in Mozambique, Tanzania, Kenya and other trial countries, through its Networks of Excellence for Clinical Trials, fellowships and infrastructure investments.⁵⁶

Following a four-year pilot programme that vaccinated more than **two million children** in Ghana, Kenya and Malawi and cut all-cause child mortality by 13%, the World Health Organization (WHO) recommended RTS,S for widespread use among children in malaria-endemic parts of sub-Saharan Africa in October 2021.⁵⁷ EDCTP2 supported this pilot phase directly, funding case-control studies in the three countries to gather further evidence on the vaccine's safety and its effect on severe malaria.⁵⁸

A second vaccine, **R21/Matrix-M**, was developed by the University of Oxford's Jenner Institute together with the Serum Institute of India, using an adjuvant developed by Novavax. EDCTP2 funded the Multi-Stage Malaria Vaccine Consortium investing €15.6 million in grant funding (2018–2025) to support clinical trials of promising vaccine candidates.⁵⁹ The EDCTP2-funded Phase Ib/IIb trial of R21/Matrix-M in Burkina Faso reported **77% efficacy** in children aged five to seventeen months, exceeding WHO's target of 75% for a first-generation malaria vaccine.⁶⁰ Building on these and subsequent Phase III results, **WHO recommended R21/Matrix-M for widespread use in October 2023**.⁶¹ EDCTP had funded the vaccine's development for more than ten years, alongside Wellcome, the European Investment Bank and other funders.⁶²

Both vaccines are safe and effective, and used along with other malaria control strategies, they are expected to significantly reduce malaria mortality and morbidity, especially among young children. Since the pilot began in Ghana, Kenya and Malawi in 2019, uptake has accelerated rapidly: **21 additional countries introduced routine malaria vaccination in 2024 and 2025 alone**, bringing the total to 24 African countries by November 2025, with more expected to follow. More than 40 million doses have been delivered so far, and Gavi aims to help countries protect a further 50 million children between 2026 and 2030.⁶³

Global Health EDCTP3 continues to support malaria vaccine research to boost vaccine effectiveness⁶⁴ and optimise vaccine deployment and use.⁶⁵

Affordable access

RTS,S/AS01 is expected to reduce its price from €9.30 per dose to below US\$5 (€4.4) per dose by 2028 through GSK and Bharat Biotech efforts.

R21/Matrix-M is available at a reduced price of US\$2.99 per dose following a Gavi-UNICEF agreement.



[The Lancet, Volume 397, Issue 10287, P1809–1818, May 15, 2021](#)

54 [World malaria report 2025 | WHO](#).

55 The RTS,S Clinical Trials Partnership. [First results of phase 3 trial of RTS,S/AS01 malaria vaccine in African children](#). *N Engl J Med*. 2011 Nov 17;365(20):1863–1875. doi: 10.1056/NEJMoal102287.

56 [RTS,S/AS01 malaria vaccine: EDCTP contributions and next steps | EDCTP](#).

57 [Shipment of newest malaria vaccine, R21, to Central African Republic marks latest milestone for child survival | WHO](#).

58 [New horizons for malaria vaccines | EDCTP](#).

59 [Driven to end malaria: how the EDCTP Association turns innovation into impact | EDCTP](#).

60 [EDCTP-funded trial of R21/Matrix-M malaria vaccine shows efficacy of 77% | EDCTP](#).

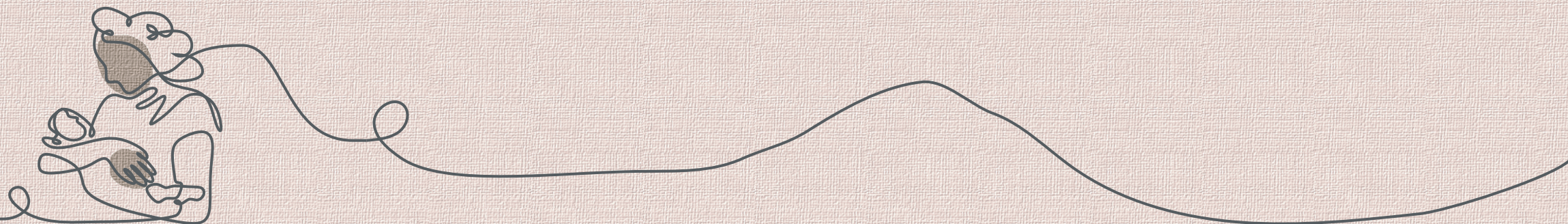
61 [WHO recommends R21/Matrix-M vaccine for malaria prevention in updated advice on immunization | WHO](#).

62 [WHO recommends R21/Matrix-M malaria vaccine | EDCTP](#).

63 [Gavi and UNICEF announce equitable pricing deal for malaria vaccine to protect 7 million more children by end of decade | Gavi](#).

64 [PfVIMT project | Global Health EDCTP3](#).

65 [IMVACS project | Global Health EDCTP3 & MVC-2G project | Global Health EDCTP3](#).



First malaria treatment for newborns and young infants



What it is

Coartem® Baby is the first approved malaria treatment specifically designed for **newborns and young infants** weighing 2 to 5 kg. It is a dissolvable tablet that can be mixed with breast milk, has a sweet cherry flavour to make administration easier and delivers precise dosing.

Why it matters

Malaria is a leading cause of **child mortality** in Africa. For decades, **no approved medicine existed for babies** in this weight range, and clinicians had no choice but to use formulations intended for older children, increasing the risk of dosing errors and toxicity. Coartem® Baby fills this long-standing gap.

The story

Each year, malaria affects more than 250 million people and causes over half a million deaths, the majority among children under five.⁶⁶ Since 2003, EDCTP has supported over 20 malaria research projects,⁶⁷ advancing simpler and improved therapies for children with severe malaria⁶⁸ and for pregnant women.⁶⁹

Between 2020 and 2024, the PAMAFrica consortium⁷⁰ conducted the CALINA trial⁷¹ across Burkina Faso, the Democratic Republic of Congo, Kenya, Mali, Nigeria and Zambia.

The trial demonstrated the safety and effectiveness of a new artemether-lumefantrine dispersible tablet in neonates and infants weighing less than 5 kg, resulting in therapeutic drug levels in the bloodstream and effective parasite clearance: Coartem® Baby.

This evidence contributed to the market authorisation by Swissmedic in July 2025,⁷² the first-ever approval of a malaria treatment for this population. In 2026, Coartem® Baby, developed by Novartis in collaboration with the Medicines for Malaria Venture (MMV), with clinical research co-funded by EDCTP, received WHO prequalification,⁷³ a key step enabling global health procurers to include it in their programmes and **facilitate broader access**. This medicine is also known as **Riamet® Baby** in some countries.

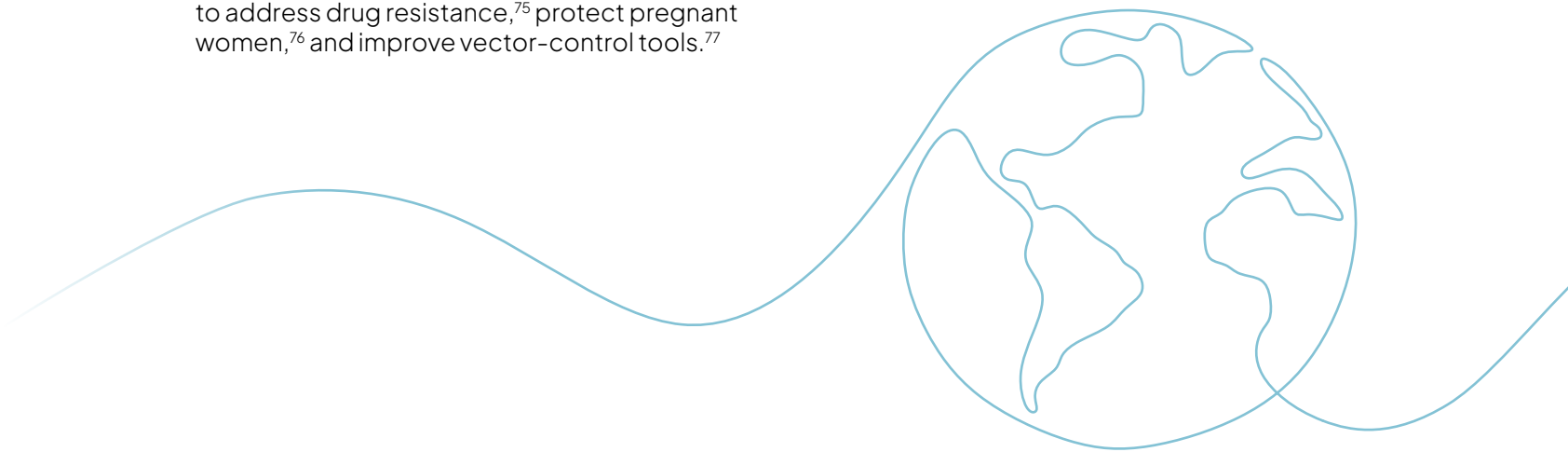
By advancing malaria treatments suitable for the smallest patients, EDCTP helps **reduce child mortality and illness**, alleviates the long-term burden of malaria on families and communities, and supports Africa's public health priorities.⁷⁴ Global Health EDCTP3 continues to drive innovation against malaria, including supporting new formulations to address drug resistance,⁷⁵ protect pregnant women,⁷⁶ and improve vector-control tools.⁷⁷

Affordable access

Novartis supplies the treatment on a largely not-for-profit basis in malaria-endemic regions.



[Trop Med Health 53, 151 \(2025\)](#)



66 [Malaria – Fact sheet | WHO.](#)

67 [EDCTP portfolio: Malaria – International partnerships against infectious diseases | EDCTP & Success stories – Malaria treatment | EDCTP.](#)

68 [Simplified artesunate regimen found efficacious in treating children with severe malaria | EDCTP.](#)

69 [PREGACT: Safety and efficacy of four artemisinin-based combination treatments in African pregnant women with malaria | EDCTP.](#)

70 [PAMAFrica consortium | EDCTP.](#)

71 [CALINA Trial | ClinicalTrials.gov.](#)

72 [Swissmedic grants authorisation for a paediatric antimalarial under the MAGHP procedure | Swissmedic.](#)

73 [WHO prequalification of Coartem® Baby marks breakthrough in treating malaria in newborns and young infants | Medicines for Malaria Venture.](#)

74 [Africa CDC Applauds First-Ever Malaria Treatment for Infants Under 5 kg | Africa CDC.](#)

75 [WANECAM-2 consortium reports positive results from phase 2b study of novel treatment for children with malaria | EDCTP.](#)

76 [SAFIRE Consortium – Safety of Antimalarials in FIRst trimEster | SAFIRE.](#)

77 [DEFEND project | Global Health EDCTP3 & LASR project | Global Health EDCTP3.](#)



Ensuring children have appropriate HIV treatment



What it is

Triomune Baby/Junior became the first fixed-dose combination medicine developed specifically for children with HIV and paved the way for additional improved combination therapies for first- and second-line HIV treatment in children.

Why it matters

While antiretroviral therapy (ART) is lifesaving against HIV, existing formulations are often unsuitable for babies and children. These innovations enhance the acceptability and use of ART in children, helping to save and improve their lives.

The story

HIV can be transmitted from mother to child during pregnancy, childbirth, or breastfeeding. An estimated 1.4 million children aged 0–14 are living with HIV, with 120,000 new infections each year.⁷⁸ While antiretroviral therapy (ART) is recommended for all people with HIV, only half of the affected children receive treatment,⁷⁹ leading to preventable illness, deaths, and the emergence of drug resistance. **Without treatment, 50% of children with HIV die before the age of two and 80% before their fifth birthday.** The limited availability of suitable paediatric HIV medicines drives this. Poor taste, complex preparation and administration (e.g., crushing pills or dissolving tablets), and frequent refills (sometimes every two weeks) disrupt school, impose travel costs on families, and severely undermine adherence to these lifesaving treatments.⁸⁰ Although children in sub-Saharan Africa are most impacted, these barriers hinder access to HIV treatment and prevention for children globally.⁸¹

For more than 20 years, EDCTP has advanced HIV research to address these challenges.⁸² Launched in 2005, the CHAPAS project⁸³ compared and evaluated ART regimens to identify safer, more effective, and child-friendly options that are acceptable and accessible. This research bore fruit in 2007 with the **registration of Triomune Baby/Junior, the first fixed-dose combination medicine for children with HIV.** Although ultimately discontinued due to side effects, it paved the way for safer, more effective paediatric HIV treatments, including fixed-dose combinations and oral granule formulations.

Evidence from CHAPAS studies also informed WHO recommendations on updated treatment options⁸⁴ and in July 2025, the CHAPAS-4 consortium announced⁸⁵ **a new ART regimen for children that improves viral suppression, is easier to administer, and offers sustained long-term health benefits compared to existing alternatives.**

Global Health EDCTP3 remains committed to driving innovation to ensure children living with HIV have access to the best possible treatment and care⁸⁶ while also advancing the development of improved HIV medicines for all.⁸⁷

Affordable access

Multi-year supplier agreements negotiated by Unitaïd and CHAI cut paediatric antiretroviral prices by 80% across 40 countries.



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A unique medicine for worm infections in children



What it is

This new fixed-dose combination therapy of albendazole/ivermectin targets five types of parasitic worms (four soil-transmitted helminth infections and lymphatic filariasis), which will **significantly improve** the efficiency and cost-effectiveness of large-scale interventions.

Why it matters

Soil-transmitted helminths and lymphatic filariasis are neglected diseases affecting one in four people worldwide and **leaving children nutritionally and physically impaired**. This new treatment will enhance the effectiveness of public health interventions against these parasites, benefiting millions worldwide.

The story

Soil-transmitted helminthiases (worm infections) are among the most common infections worldwide, affecting over 1.5 billion people.

Transmitted through contaminated soil or water, these parasitic infections severely undermine the health and development of children. They also worsen blood loss, exacerbating anaemia in women, and increasing the risk of maternal and infant mortality as well as low birth weight.

Current control relies on regular albendazole or ivermectin treatment, along with improved sanitation, but these medicines alone are not effective against all helminth species.⁸⁸

Implemented by the STOP Consortium, EDCTP co-funded⁸⁹ **a new child-friendly combination medicine** (albendazole and ivermectin) that is **safe, more effective against soil-transmitted helminths, and easier to administer**: an oral, mango-flavoured pill.⁹⁰ This innovation provides stronger protection against helminth infections for millions of children over five, supporting their healthy growth and development while lowering the risk of drug resistance in helminth parasites. In January 2025, **the European Medicines Agency issued a positive opinion on this new medicine**,⁹¹ paving the way for a WHO authorisation and its introduction in priority countries.⁹²

In a historic first, the **Ghana Food and Drugs Authority** granted **regulatory approval** for this fixed-dose combination in December 2025, making Ghana the **first country in the world to register the medicine** for clinical and public health use.⁹³ This milestone allows the tablet to be prescribed by physicians and integrated into large-scale deworming campaigns, providing a safer, more effective, and easier-to-administer treatment for soil-transmitted helminths and lymphatic filariasis.

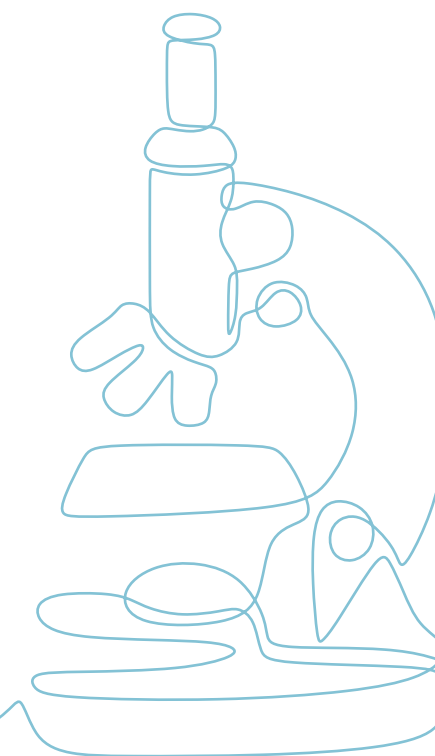
This achievement was made possible under the Global Health EDCTP3 co-funded STOP2030 project, which continues to support research on this treatment⁹⁴ in Kenya and Ghana, assessing its use in mass drug administration campaigns and its potential for treating other neglected diseases.

Affordable access

With no donation mechanism planned, sustainable financing and supply pathways are being mapped ahead of the medicine's introduction.



[The Lancet Infectious Diseases, Vol. 25, P548–559, Issue 5, May 2025](#)



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93 [Ghana FDA approves the fixed-dose coformulation of ivermectin and albendazole](#) | STOP2030 project & [Ghana Approves the Ivermectin-Albendazole Fixed-Dose Combination, an Innovative Drug Promoted by Mundo Sano](#) | Mundo Sano.

94 [Project - A unique approach to helminthiasis treatment](#) | STOP2030.



The first medicine against schistosomiasis for pre-school children



What it is

Arpraziquantel is the **first child-friendly medicine** in an oro-dispersible formulation to treat and cure schistosomiasis. It is **easy to administer** and adapted for rural and tropical settings, offering high efficacy with minimal side effects.

Why it matters

Schistosomiasis affects around 240 million people worldwide and **severely harms children's physical and cognitive development**. This innovation could protect and improve the lives of 50 million children currently at risk.

The story

Schistosomiasis, a neglected infectious disease (NID) caused by blood flukes, is a debilitating disease that can be fatal and is linked to liver and kidney failure, bladder cancer, extrauterine pregnancy, anaemia, and stunted growth in children. **It affects an estimated 240 million people worldwide, with more than 700 million at risk**, predominantly children and women in poor, rural communities.

The Pediatric Praziquantel Consortium, co-funded by EDCTP and the Global Health Innovative Technology Fund (GHIT Fund), has developed **arpraziquantel, a schistosomiasis medicine for children (3 months–6 years)**.⁹⁵

The tablet dissolves in water, has improved taste, and is designed to withstand tropical climates, making treatment safer, more effective, and easier to administer. In December 2023, the European Medicines Agency issued a positive scientific opinion,⁹⁶ paving the way for WHO approval and introduction in endemic countries.⁹⁷

In parallel, the ADOPT project,⁹⁸ co-funded by EDCTP and GHIT Fund, **has supported the rollout of arpraziquantel in Kenya, Uganda, and Côte d'Ivoire**, focusing on ensuring equitable and sustainable access to this critical medicine. The evidence generated by the project has also enabled other initiatives to implement arpraziquantel in additional endemic settings. This includes its administration in **Zimbabwe**, where the paediatric formulation has been integrated into national schistosomiasis control programmes. More recently, **Tanzania** approved the medicine and started its rollout with a landmark pilot in the Lake Zone region, reaching more than 25,000 young children across Itilima, Sengerema, and Kigoma District Council.⁹⁹

Arpraziquantel exemplifies the success of EDCTP programmes in **partnering with public and private actors** and leveraging co-investments to deliver global health solutions. Supported by EDCTP, the GHIT Fund, the Government of Japan, the Gates Foundation, and the lead developer Merck KGaA (which also provided the medicine for the initial rollout in endemic countries), this innovation demonstrates how such partnerships are critical to transform science into tangible impact.

Global Health EDCTP3 continues to support efforts to tackle schistosomiasis, including among women¹⁰⁰ and improving implementation strategies.¹⁰¹ Further work is also needed to strengthen procurement and funding mechanisms for NID treatments, ensuring these essential health technologies remain affordable and accessible across sub-Saharan Africa.

Affordable access

Arpraziquantel will not be donated. Manufacturing has been transferred to Brazil and Kenya to build regional production capacity and lower costs.



[The Lancet Infectious Diseases, Vol. 23, Issue 7, P867–876, July 2023](#)

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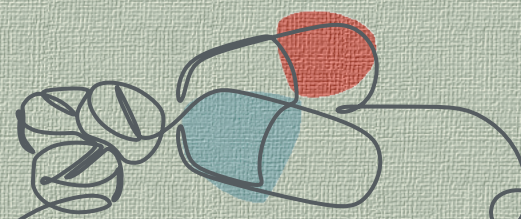
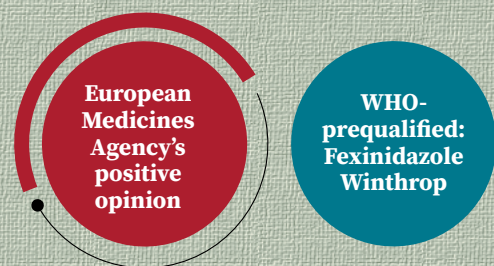
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Patient-friendly oral treatments for sleeping sickness



What it is

Fexinidazole Winthrop and Acoziborole Winthrop are two revolutionary **oral treatments for human African trypanosomiasis (HAT)**, commonly known as sleeping sickness. **Fexinidazole Winthrop**, taken as pills over 10 days, is the first all-oral therapy for the disease. Building on this success, **Acoziborole Winthrop** is the first single-dose one-day oral therapy to treat the most common form of the disease, gambiense human African trypanosomiasis (gHAT).

Why it matters

Although sleeping sickness cases have been greatly brought down over the last years, it persists in the poorest and most remote areas of Africa, where delivering care is a significant challenge. The disease is usually fatal without treatment, making these patient-friendly innovations essential. For decades, treatment relied on toxic, invasive, and logistically demanding therapies, often requiring hospitalisation and painful lumbar punctures.¹⁰²

The story

Human African trypanosomiasis (HAT), or sleeping sickness, is a parasitic disease transmitted by tsetse flies that remains **endemic in 36 African countries**, placing millions at risk.

A major turning point came with the development of Fexinidazole Winthrop, the **first all-oral treatment for human African trypanosomiasis**.¹⁰³ Initially endorsed by the European Medicines Agency (EMA) in 2018 for both first- and second-stage *Trypanosoma brucei gambiense* infection (gHAT), the most common form of the disease, it marked a shift away from complex, hospital-based therapies.¹⁰⁴ Building on this, a 2023 positive opinion from the **EMA extended its use to both stages of the *rhodesiense* form of the disease (rHAT)**, confirming its efficacy across the two clinical phases of this acute variant. Supported by EDCTP programmes and other donors funding through the HAT-r-ACC consortium¹⁰⁵ and developed by DNDi, Sanofi, and partners, this 10-day pill-based regimen has eliminated the need for hospital-based care in many cases and has since been incorporated into WHO treatment guidelines.¹⁰⁶

Building on this progress, a new milestone was reached with Acoziborole Winthrop, a single-dose oral treatment for gambiense human African trypanosomiasis (gHAT).

In 2026, the European Medicines Agency issued a positive scientific opinion on the medicine, marking a transformative step forward in simplifying treatment and expanding access to the people who need it most.¹⁰⁷

Developed through a long-standing partnership between DNDi, Sanofi, and endemic-country researchers, and supported in part by EDCTP funding, Acoziborole Winthrop addresses one of the final barriers in sleeping sickness elimination: **the difficulty of delivering treatment at scale in resource-limited settings**. Its single-dose regimen removes the need for repeated patient follow-up and specialised infrastructure.

In June 2026, the **Democratic Republic of the Congo (DRC)** became the **first country to approve Acoziborole Winthrop for implementation** as part of its national sleeping sickness control programme.¹⁰⁸ The approval designated Acoziborole Winthrop as a single-dose, oral treatment for both early- and advanced-stage *gambiense* human African trypanosomiasis in adults and adolescents aged 12 years and older weighing at least 40 kilograms.

EDCTP-supported projects continue to play a key role in translating these innovations into real-world impact. The **ACOZI-KIDS study** is working to ensure that acoziborole is safe and effective for children,¹⁰⁹ while **STROGHAT**, funded by Global Health EDCTP3, is evaluating a large-scale 'screen-and-treat' strategy to reduce gHAT prevalence and advance disease elimination efforts.¹¹⁰

According to the project coordinator, the Institute of Tropical Medicine (ITM), over the first two years of implementation, the STROGHAT consortium performed more than 450,000 screening tests, reaching 95% of the at-risk population in the study area.¹¹¹

Global Health EDCTP3 continues to support research, clinical development, and implementation strategies to ensure these breakthroughs translate into equitable access. By strengthening the link between innovation and delivery, these efforts are accelerating progress towards the World Health Organization's (WHO) goal of **eliminating gHAT transmission by 2030**.

Affordable access

Sanofi donates both medicines to WHO, which distributes them free of charge through national control programmes.



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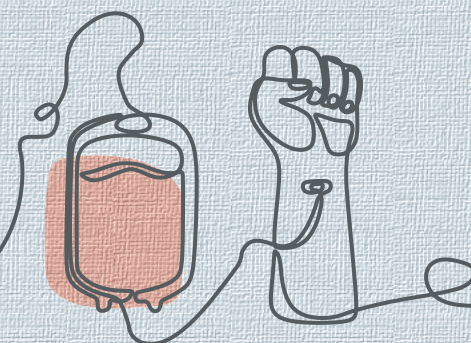
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111 [New single-dose oral treatment approved to fight sleeping sickness | Global Health EDCTP3.](#)



A simpler treatment for HIV-associated cryptococcal meningitis



What it is

This new therapy, a **single high dose of liposomal amphotericin B**, is as effective as the traditional week-long regimen, easier to administer, and causes fewer side effects. It is now the WHO-recommended therapy for cryptococcal meningitis.

Why it matters

Despite highly effective HIV treatments, opportunistic infections such as cryptococcal meningitis continue to cause significant morbidity and mortality, accounting for around 200,000 AIDS-related deaths annually. This new therapy can help save lives and improve the health of people living with HIV.

The story

Decades of progress in antiretroviral therapy (ART) have transformed the fight against HIV, saving millions of lives and dramatically improving the quality of life.¹¹² **Yet HIV remains incurable and intertwined with other severe conditions like tuberculosis, cryptococcosis, and cancer, as well as deep socioeconomic and mental health challenges.**¹¹³ Ending the HIV epidemic requires a deeper understanding of HIV-associated diseases and the development of effective solutions.

Cryptococcosis is a highly infectious airborne fungal disease that can affect the brain, lungs, and other organs. It is one of the most common infections in people living with HIV and a major contributor to severe illness, morbidity, and mortality.¹¹⁴ Even among ART-treated patients, cryptococcal mortality remains high; approximately 70% in low- and middle-income countries and 20–30% in high-income countries.¹¹⁵ **Meningitis caused by cryptococcal disease accounts for roughly 15% of all AIDS-related deaths: close to 200,000 people each year.**

Despite this, cryptococcal meningitis remains severely under-studied¹¹⁶ with current therapies relying on medicines developed over half a century ago. The current treatment involves a complex three-drug regimen: one week of intravenous amphotericin B combined with oral flucytosine and fluconazole, alongside continued ART. This demanding treatment requires specialist monitoring and carries significant toxicity risks. Even with generic formulations, drug availability in Africa is limited, and daily intravenous administration is logistically challenging.¹¹⁷

To address this, EDCTP funded the **AMBITION-cm trial**, the largest clinical study of cryptococcal meningitis in HIV patients to date.¹¹⁸ Building on previous trials, **this study confirmed that a single high-dose intravenous regimen of amphotericin B is as effective as standard therapy, easier to administer, and associated with fewer side effects.**¹¹⁹ This regimen is now the WHO-recommended treatment for cryptococcal meningitis. Its efficacy¹²⁰ and cost-effectiveness¹²¹ have also been reconfirmed in follow-up studies.

Despite these advances, gaps remain in understanding and addressing HIV-related diseases, including cryptococcal meningitis. **Global Health EDCTP3 continues to support the development of new and improved technologies targeting HIV¹²² and HIV-associated diseases,** including tuberculosis,¹²³ and focusing on priority populations such as children and pregnant women.¹²⁴

Affordable access

Preferential pricing has fallen short in practice, so efforts now focus on bringing quality-assured generic versions to market.



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Reducing deaths from a serious HIV complication through early screening and treatment



What it is

A simple, **three-part package** combining screening, preventive treatment and community adherence support significantly **cuts deaths among people starting HIV treatment** with advanced disease.

Why it matters

Cryptococcal meningitis can kill within days and often goes undetected until too late, making the start of HIV treatment one of the most dangerous moments for people with advanced disease. Before REMSTART, routine clinics had **no simple way to catch it early**.

The story

The EDCTP-funded REMSTART trial, an open-label, randomised controlled trial run in **Tanzania** and **Zambia** between 2012 and 2013, tested whether combining cryptococcal antigen (CrAg) screening, preventive fluconazole treatment and short-term community adherence support could reduce mortality among adults starting antiretroviral therapy (ART) with advanced HIV disease.¹²⁵

Participants who received the package had **significantly lower mortality** than those on standard care: a 28% reduction in deaths.¹²⁶ Conducted within routine public-sector HIV clinics rather than a specialist research setting, the trial gave health authorities direct evidence that the approach worked under real-world conditions.

In 2017, the **World Health Organization's guidelines on advanced HIV disease**¹²⁷ recommended that everyone presenting with advanced HIV disease receive a package of screening, prophylaxis, rapid ART initiation and intensified adherence support, building on REMSTART's results and data. **WHO's 2025 guidance**¹²⁸ retained this recommendation.

The trial also **shaped policy in its own participating countries**. Zambia's national advanced HIV disease guidelines¹²⁹ now require cryptococcal screening for every patient, built directly on REMSTART's findings. In Tanzania, the follow-on TRIP project¹³⁰ adapted the approach for 24 sites, feeding into a national screening plan¹³¹ while the Southern African HIV Clinicians Society's 2019 guideline¹³² draws on the trial to recommend both screening and community-based adherence support for all patients with severely weakened immune systems.¹³³

REMSTART's findings also shaped subsequent research efforts. The **EFFECT trial**, running in Tanzania and South Africa, built on the trial's results to design a new phase III trial testing fluconazole plus flucytosine¹³⁴. In parallel, health economists used evidence from REMSTART to demonstrate the cost-effectiveness of the treatment package.^{135,136}

Beyond the trial countries, studies in **Uganda**¹³⁷ and **Zimbabwe**¹³⁸ evaluated national and pilot CrAg screening programmes, contributing further evidence on the feasibility and implementation of cryptococcal screening strategies.

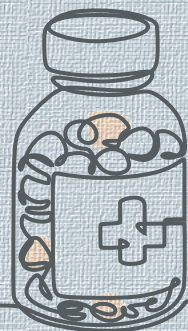
The story of REMSTART is one of **early detection and prevention**. Together with advances in the **treatment** of cryptococcal meningitis, such as those demonstrated by the EDCTP-funded **AMBITION-cm trial**¹³⁹, these approaches address different points along the same pathway, helping prevent advanced disease from becoming fatal and making treatment simpler when severe cryptococcal disease occurs.



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Fast, effective, and easy-to-use treatment for uncomplicated malaria



What it is

Eurartesim® is a fixed-dose artemisinin-based combination therapy (ACT) containing dihydroartemisinin-piperaquine (DHAPQ) for the treatment of uncomplicated malaria.

It combines two complementary medicines:

- Dihydroartemisinin, a fast-acting antimalarial that quickly clears parasites from the bloodstream.
- Piperaquine, a long-acting partner drug that eliminates residual parasites and protects against reinfection for several weeks after treatment.

The combination provides a simple three-day treatment regimen that is highly effective and reduces the risk of recurrent infections.

Why it matters

Malaria remains one of the world's deadliest infectious diseases, particularly among **children under five in sub-Saharan Africa**, where it is still a leading cause of child mortality.¹⁴⁰ When uncomplicated malaria is left untreated or inadequately treated, it can rapidly progress to severe disease and death.

Eurartesim® helps address critical gaps in malaria treatment by providing a well-tolerated, easy-to-administer therapy that reduces both treatment failure and recurrent infections. Its suitability for children is particularly important, as young children remain among those most vulnerable to severe malaria.

The story

For years, malaria treatment faced two major challenges: **drug resistance** and **complex dosing regimens** that made adherence difficult, especially for children. Fixed-dose ACTs such as DHAPQ address these challenges by combining two complementary medicines in a single treatment, ensuring that patients receive the appropriate ratio of both drugs with each dose.

Supported by extensive clinical research, DHAPQ demonstrated **high efficacy** and **good tolerability**, with its long-acting piperaquine component providing extended post-treatment protection and helping reduce recurrent infections.

Through **EDCTP funding**, researchers conducted clinical trials to assess the **safety, optimal dosing and side effects** of DHAPQ, particularly in vulnerable populations including young children across sub-Saharan Africa and people living with HIV.^{141,142} These studies generated essential evidence supporting the safe and effective use of the treatment and contributing to **WHO recommendations**.¹⁴³

The research also contributed to the regulatory pathway for **Eurartesim®**. In 2011, the European Medicines Agency (EMA) issued a positive opinion on Eurartesim® for the treatment of uncomplicated *Plasmodium falciparum* malaria, which was followed by an **EU marketing authorisation**.¹⁴⁴ The medicine has subsequently become an established treatment option for uncomplicated malaria.

Today, DHAPQ is recommended by WHO as an ACT for uncomplicated *P. falciparum* malaria, and Eurartesim® is **WHO-prequalified**.¹⁴⁵ The combination is used across Africa and Asia and has been adopted as a second-line therapy in countries such as Ghana, where studies have reported **efficacy rates above 90% in children under routine use**.¹⁴⁶

Affordable access

Global Fund Access Funds subsidise the treatment for countries diversifying away from a single first-line therapy.



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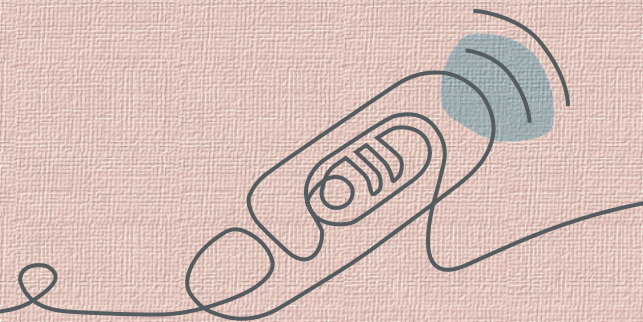
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Bringing rapid tuberculosis diagnosis to the front lines of care



What it is

Molbio Truenat, with MTB-Plus and RIF-Dx assays, is a **portable, battery-powered molecular diagnostic tool** for tuberculosis (TB) testing directly in primary health care settings. Endorsed by the World Health Organization (WHO)¹⁴⁷, it delivers rapid and reliable results for adults with pulmonary TB symptoms, making advanced diagnosis possible even in the most remote and low-resource settings.

Why it matters

Tuberculosis is the world's deadliest infectious disease, with around 10 million people falling ill every year.¹⁴⁸ Early and accurate diagnosis is essential to interrupt transmission and prevent health problems. With point-of-care molecular testing, patients can receive **results and begin treatment on the same day**.

The story

In many parts of sub-Saharan Africa, getting tested for TB can be a long and difficult journey. Diagnostic laboratories are often located only in major cities, meaning patients in rural areas must travel far, wait days or even weeks for results, and risk being lost to follow-up. Even where advanced tools such as GeneXpert are available, they require stable electricity, climate control, and maintenance, conditions rarely met in small health centres.¹⁴⁹

To help address this gap, **EDCTP funding** supported the TB-CAPT CORE study,¹⁵⁰ which tested the implementation of the portable Molbio Truenat platform with MTB-Plus and MTB/RIF Dx assays **in real clinical settings**. Designed to operate with unreliable electricity and limited laboratory infrastructure, Truenat MTB assays enable **accurate TB diagnosis and drug-resistance detection** directly at the point of care.

The impact on patient care was striking. **97% of patients** diagnosed using Molbio Truenat **began treatment within one week**, and **more than 80% started treatment the same day**, compared with 63% who began treatment within one week and only 3.3% who started the same day under the traditional diagnostic system.¹⁵¹ Faster and decentralised diagnosis enables earlier treatment, reduces transmission, and helps prevent severe complications and drug-resistant TB.

Molbio Truenat's portable design makes it resistant to heat and dust, easy to operate, and independent of complex infrastructure. Bringing molecular testing closer to communities enables clinics in resource-limited areas to diagnose TB faster, reducing travel costs and delays for patients. While initial system costs are higher, decentralised testing with Truenat assays appears **at least as cost-effective as centralised models** and is associated with **better diagnostic outcomes**. The approach works best in settings with higher TB prevalence, greater testing volumes, and affordable staffing and monitoring costs.¹⁵²

By validating portable molecular testing in real-world African clinics, the EDCTP-funded study demonstrated how innovative diagnostics can **close the gap between testing and treatment**. With support from EDCTP, this approach provides the evidence needed to expand access to rapid, life-saving TB diagnosis in underserved communities.

In May 2026, a qualitative study expanded the evidence base on the Molbio Truenat platform by examining user perspectives in Mozambique and Tanzania. Using semi-structured interviews with patients, healthcare workers and decision-makers, the study found that the platform was widely perceived as **easy to use, acceptable** and **well-suited for decentralised testing**, particularly due to its portability, ability to deliver same-day results and fewer infrastructure needs.¹⁵³ Participants reported improved patient experience and faster treatment initiation, with the Molbio Truenat platform considered a **preferred alternative** to off-site GeneXpert testing for TB.

Affordable access

Joint negotiation by Stop TB Partnership, USAID, the Global Fund and Molbio Diagnostics brought the price down to US\$7.90 per test.



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Expanding the reach of an established malaria treatment for patients with limited options



What it is

Pyramax® is an established antimalarial medicine whose safety and efficacy have been progressively expanded through EDCTP-supported research to reach more patient groups who lack specific treatment options, including children, pregnant women and patients requiring re-treatment.

Why it matters

Malaria is a leading cause of child mortality in Africa, yet treatment options remain **insufficient for some priority populations**. Extending the use of existing medicines to groups often under-represented in clinical research can be as important as developing entirely new treatments. By supporting the generation of this evidence, EDCTP has helped ensure that more people can access safe, effective treatment.

The story

Each year, malaria affects more than 250 million people and causes over half a million deaths, the majority among children under five.¹⁵⁴ Since 2003, EDCTP has supported more than 20 malaria research projects,¹⁵⁵ advancing simpler and improved therapies for children with severe malaria¹⁵⁶ and for pregnant women.¹⁵⁷

EDCTP-supported research has contributed to broadening the reach of **Pyramax®** (pyronaridine tetraphosphate and artesunate), a fixed-dose artemisinin-based combination therapy used to treat uncomplicated malaria caused by *Plasmodium falciparum* and *Plasmodium vivax*.

In 2012, the European Medicines Agency (EMA) issued a **positive scientific opinion** on Pyramax® under its Article 58 procedure. This procedure allows the EMA to provide a scientific opinion on medicines intended exclusively for markets outside the European Union, in cooperation with WHO.¹⁵⁸ The opinion supported the use of Pyramax® for uncomplicated malaria and helped facilitate its subsequent WHO prequalification and wider access.¹⁵⁸

However, important evidence gaps remained. In particular, there was limited evidence on whether Pyramax® could be safely used to treat **recurrent malaria infections** and whether it could be used safely in **pregnant women** and young children.

EDCTP-supported research helped address these gaps. The **WANECAM study** provided evidence supporting the safety and efficacy of re-treating malaria with Pyramax®,¹⁵⁹ while research contributed to the inclusion of information on its use in **pregnant women** in the product label.¹⁶⁰ EDCTP-supported work also contributed to the development and evaluation of a **paediatric formulation**, helping extend access to children who need age-appropriate treatment.¹⁶¹

Global Health EDCTP3 continues to support innovation against malaria, including research into new treatments and formulations to address drug resistance,¹⁶² improve treatment options for pregnant women,¹⁶³ and strengthen vector-control tools.¹⁶⁴

Affordable access

The Global Fund's Pooled Procurement Mechanism helps countries procure Pyramax® at negotiated prices.



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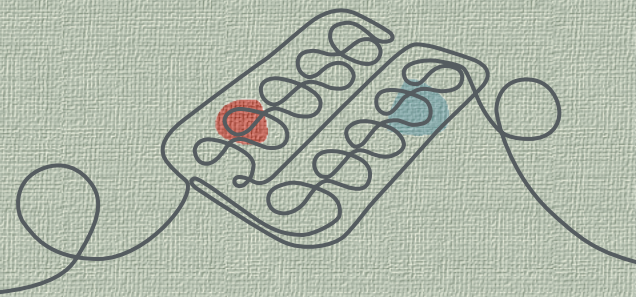
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Expanding the use of a common medicine to prevent dangerous HIV-TB inflammatory reaction



What it is

The **PredART trial** showed that **prednisone**, a common and inexpensive steroid drug used to **treat** TB-IRIS, can also be used to **prevent** it. In patients with both TB and HIV who start HIV therapy, a four-week course of prednisone has been shown to reduce the chance of developing this complication by about **30%**.

Why it matters

For people living with **HIV** and **tuberculosis**, starting antiretroviral therapy (ART) can trigger TB-IRIS, a serious inflammatory reaction caused by the recovering immune system response to the tuberculosis infection. This can rapidly worsen a patient's condition after initial improvement, sometimes leading to **hospitalisation** or even **death**. This not only creates major health risks but can also **disrupt confidence** in HIV treatment. Before the PredART trial, there was no evidence-based way to prevent TB-IRIS.

The story

The journey to this breakthrough began in **Khayelitsha**, a community on the outskirts of Cape Town, South Africa, with very high rates of TB and HIV infections. With funding from the **EDCTP** and the **South African Department of Science and Technology**, a team at the University of Cape Town launched the PredART trial (SP.2011.41304.074) at an integrated HIV-TB clinic.¹⁶⁵

The study involved **240 participants** with advanced HIV who were already receiving TB treatment. Half the participants received a tapering dose of prednisone, while the other half received a placebo.

The results showed that **the preventive use of prednisone at the start of antiretroviral therapy (ART) reduced the incidence of TB-IRIS** from 47% to **32%**.¹⁶⁶ Because prednisone is already off-patent and manufactured globally, this discovery provided an immediate, low-cost solution that could be implemented in resource-limited settings without waiting for the development of new, expensive pharmaceuticals.

In a 2022 sub-study, researchers evaluated the health-related quality of life across physical, psychological and social domains in the PredART trial participants.¹⁶⁷ The analysis confirmed the usefulness of prednisone and showed that it improved the physical health and symptoms.

Today, the **findings from the PredART trial have been included in international guidelines** such as the South African National Standard Treatment Guidelines,¹⁶⁸ the Western Cape Consolidated Guidelines for HIV Treatment,¹⁶⁹ the Southern African HIV Clinicians Society guidance,¹⁷⁰ and US¹⁷¹ and European HIV/TB guidance,¹⁷² providing a clearer path to recovery for thousands of patients across the continent.

Affordable access

Prednisone is a widely available, inexpensive generic drug.



[New England Journal of Medicine, Volume 379, Number 20, P1915–1925, November 15, 2018](#)

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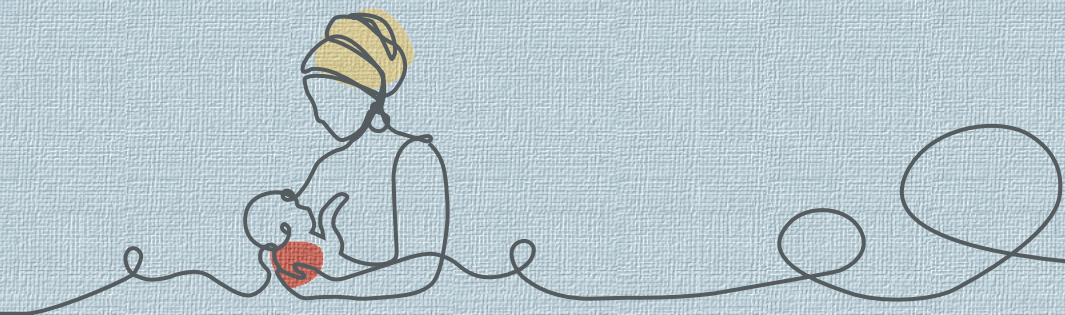
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Making breastfeeding safer for mothers living with HIV



What it is
A three-drug antiretroviral regimen given to HIV-positive women in late pregnancy and through breastfeeding **cuts HIV transmission to babies** safely, without requiring mothers to stop breastfeeding.

Why it matters
Breastfeeding was long seen as **a major HIV transmission risk**, yet avoiding it raised the risk of malnutrition, illness and unsafe feeding, especially where resources were limited. This trial showed the two risks didn't have to be traded off against each other.

The story
The EDCTP-supported Kesho Bora trial enrolled **824 pregnant women living with HIV** at five clinics in **Burkina Faso, Kenya and South Africa** between 2005 and 2008. Women were randomly assigned to receive either a combination of three antiretroviral medicines (AZT + 3TC + LPV/r), started during late pregnancy and continued for six months of breastfeeding, or the treatment approach commonly used at the time: a shorter course of *zidovudine* during pregnancy and a single dose of *nevirapine* during delivery. The study aimed to determine which approach was more effective at reducing HIV transmission to babies.¹⁷³

By 12 months, only 5.4% of babies in the triple-drug group had been infected with HIV, compared with 9.5% in the group on the older short-course treatment, a **43% reduction** in transmission risk. Among mothers who intended to breastfeed, the reduction was even larger, at 48%. The triple-drug regimen was not linked to any increase in serious side effects for mothers or babies, and **infant mortality by 12 months was lower** in the triple-drug group, at 6.2% compared with 9.8% in the control group.^{173,174}

These results helped shape global HIV treatment guidance. In 2010, the World Health Organization (WHO) recommended that women living with HIV who did not yet need HIV treatment for their own health should receive antiretroviral medicines during breastfeeding to reduce the risk of passing HIV to their babies. Building directly on the Kesho Bora trial findings, the medicines are recommended to be given to the baby, or to the mother (an approach known as **Option B**).¹⁷⁵ In 2013, WHO updated its guidelines to recommend lifelong antiretroviral therapy for **all** pregnant and breastfeeding women living with HIV. This approach became known as **Option B+**.¹⁷⁶

Countries gradually adopted Option B+. Malawi was the first country to introduce the approach in 2011, and by 2015, 21 of the 22 priority countries tracked by UNAIDS had adopted it.¹⁷⁷ Between 2005 and 2012, **more than 850,000 child HIV infections were averted** across the priority countries, with sharp declines in new infections among children in Ghana, Namibia, Zimbabwe, Malawi, Botswana, Zambia and Ethiopia. By 2014, new child HIV infections across the 21 African priority countries had fallen below 200,000 for the first time since the 1990s, a **43% decline** since 2009.¹⁷⁷

The impact has reached far beyond the trial itself. Kesho Bora's early results shaped Option B and Option B+, both of which are now improving outcomes on the ground. In Malawi, antiretroviral therapy (ART) initiation among pregnant and breastfeeding women rose by **748%** in the first year after Option B+ launched,¹⁷⁸ while Option B+ implementations in Zimbabwe,¹⁷⁹ Uganda¹⁸⁰ and South Africa¹⁸¹ found broad acceptance of the new regimen.

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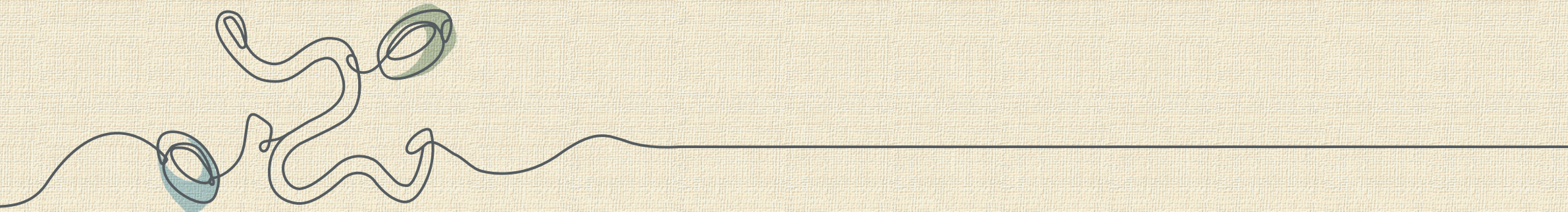
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Reaching more people in the fight against river blindness



What it is

Moxidectin is an oral medicine for onchocerciasis, also known as river blindness. It was first approved by the US FDA in 2018 for people aged 12 and older.¹⁸² Research co-funded through EDCTP2 and continued under Global Health EDCTP3 has since extended its use to children as young as four and generated the safety evidence needed for repeated community-wide dosing.¹⁸³

Why it matters

Onchocerciasis remains a major public health burden. In 2024, at least 252 million people needed preventive treatment, with over 99% of cases in Africa.¹⁸⁴ The disease causes severe itching and disfiguring skin conditions and can lead to permanent blindness.

Ivermectin has been the mainstay of mass treatment for decades, but it does not kill adult worms and cannot be safely used in areas affected by Loa loa, leaving around **15 million people untreated**.¹⁸⁵ Moxidectin reduces the number of larvae more effectively and suppresses them for longer.¹⁸⁶

The story

Moxidectin was developed for onchocerciasis through a World Health Organization-Wyeth/Pfizer collaboration back in the 1990s. After Pfizer withdrew in 2011, WHO continued its development before licensing the data to Medicines Development for Global Health (MDGH) in 2014, which completed the regulatory work. In 2018, the US FDA approved moxidectin as a single dose treatment for people aged twelve and older.¹⁸²

However, this first approval was not enough to support elimination programmes. Countries needed evidence on treating **younger children**, on repeated annual or biannual dosing, and on safety across whole communities. To close these gaps, EDCTP2 funded the **MoxiMultiDoseMod project** in the Democratic Republic of the Congo and Ghana.¹⁸³

In the Democratic Republic of the Congo, a Phase IIIb trial compared annual and biannual dosing of moxidectin against ivermectin over three years. In addition, a large safety study, also covering Côte d'Ivoire thanks to funding from the Gates Foundation, gathered evidence closer to real mass-treatment conditions.¹⁸³ In Ghana, a Phase I trial, sponsored and mainly co-funded by MDGH, identified suitable doses for children aged four to eleven.¹⁸⁷

A complementary project, **MiniMox**, jointly funded by EDCTP2 and MDGH in Cameroon and Ghana, developed a paediatric-friendly formulation for children who struggle to swallow the existing tablet.¹⁸⁸

The paediatric data from Ghana supported two regulatory milestones. In December 2024, the **Ghana Food and Drugs Authority approved moxidectin for adults and children aged four and older**, making Ghana the first river blindness-endemic country to register the medicine.¹⁸⁹ In February 2025, the US FDA extended its own approval to children aged four to eleven weighing at least 13 kilograms.¹⁹⁰ Together, this evidence base contributed to the addition of moxidectin to the WHO Essential Medicines List and the Essential Medicines List for Children in 2025.^{191,192}

Ghana's approval cleared the way for the **first real-world community use of moxidectin**. In January 2025, the Ghana Health Service began distributing the medicine in the Twifo Atti-Morkwa district. Over three years, community volunteers are going to distribute moxidectin door to door every six months.¹⁹³

Global Health EDCTP3 is now building on this evidence through the EMINENCE project, running in Cameroon and the Republic of Congo until 2030. A Phase IIIb trial is comparing annual and biannual moxidectin with ivermectin in areas of persistently high transmission. A separate Phase II trial is testing progressively higher doses of moxidectin in people with progressively higher levels of Loa loa infection, to identify a dose that could safely be used in co-endemic areas.¹⁸⁴

Affordable access

A not-for-profit model supplies moxidectin to low- and middle-income countries at cost, while using existing distribution systems to avoid additional infrastructure costs.

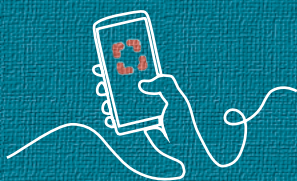


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