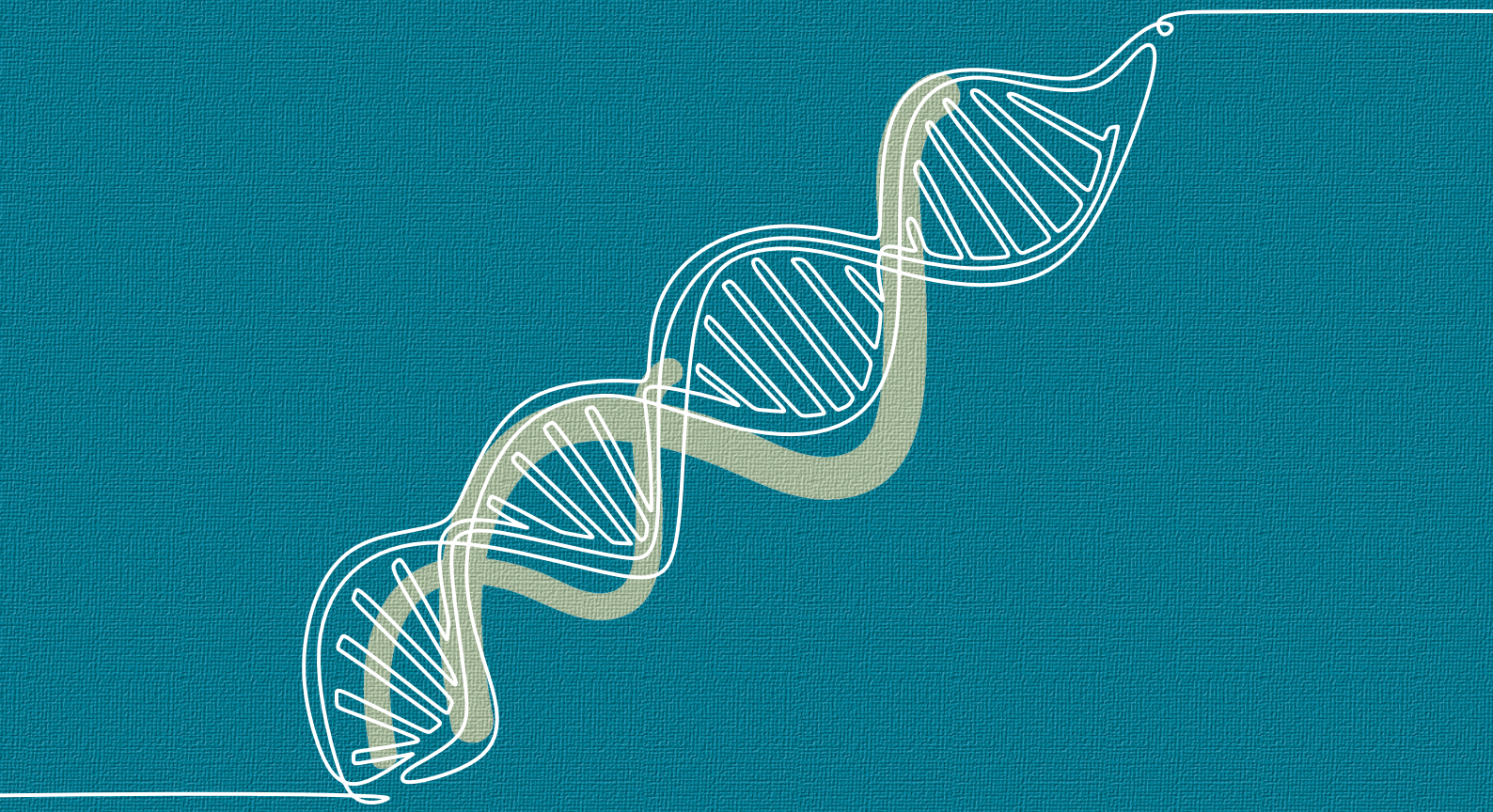
Global Health
EDCTP3

The African and European research partnership on infectious diseases

Our lasting benefits for Europe and Africa

EUROPEAN PARTNERSHIP

Co-funded by the European Union



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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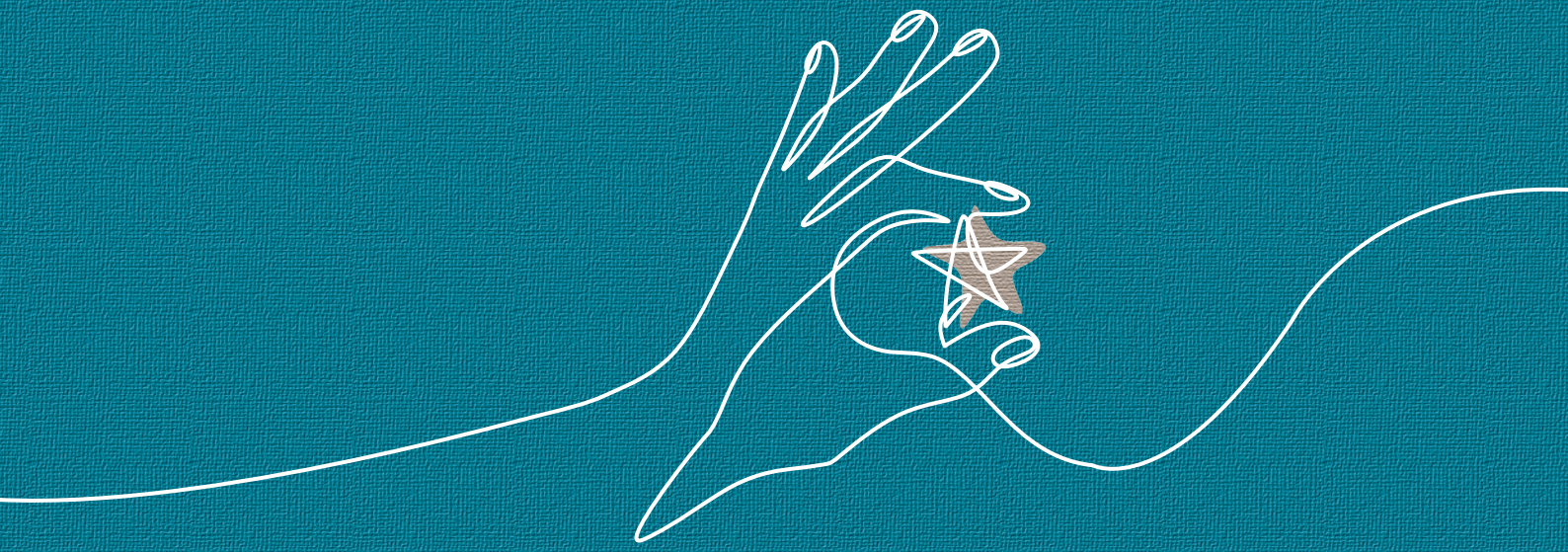
New and better medicines already saving and improving lives



EDCTP's added value for Europe

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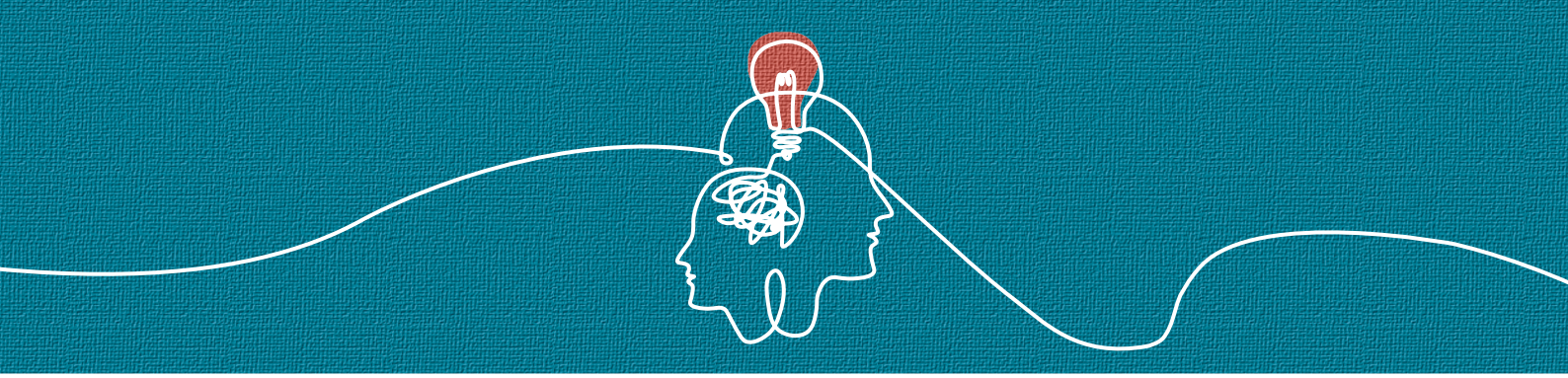


Boosting Europe's competitiveness and scientific leadership

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

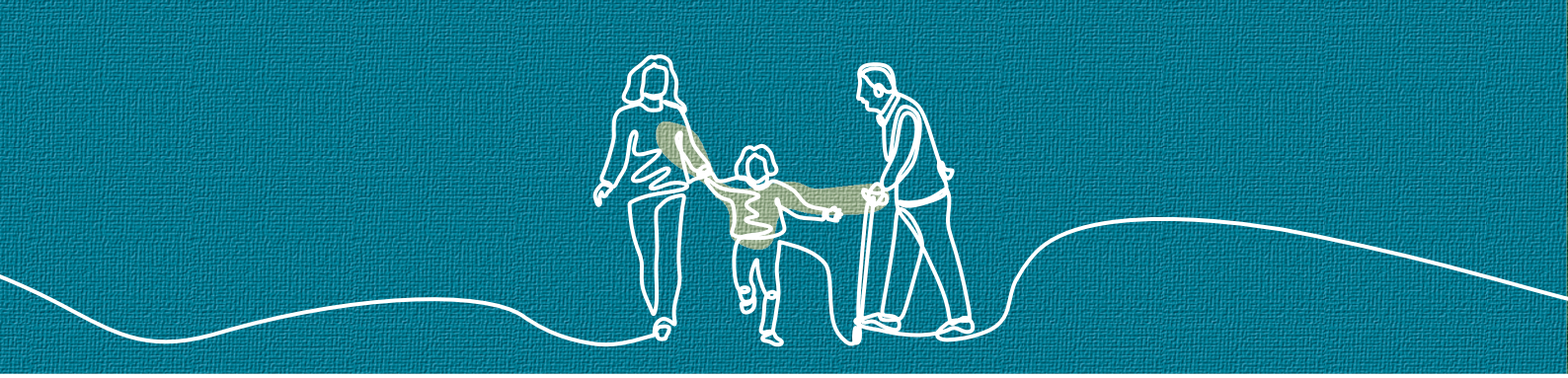
These investments stimulate employment, economic activity, private-sector engagement, and intellectual property development across Europe. The partnership bridges a key challenge for Europe's competitiveness, the EU's innovation gap[1], by supporting late-stage product development, implementation research, 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 continent[2] 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.



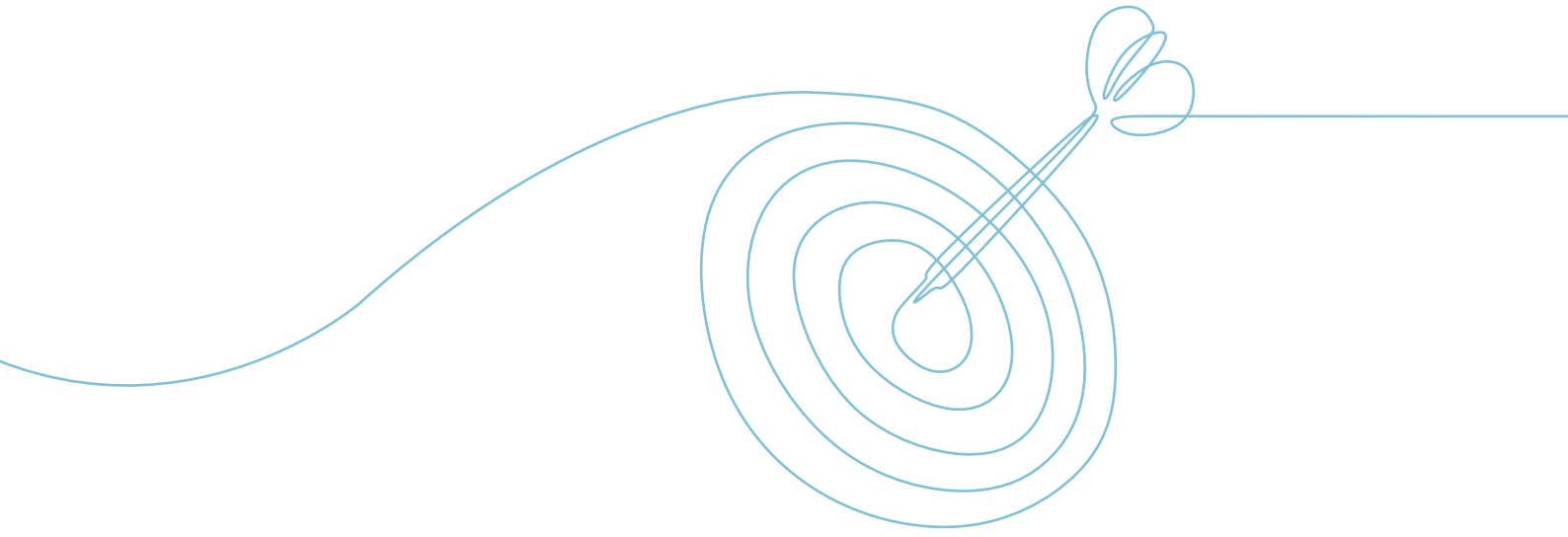
Protecting Europe through stronger global health security cooperation

EDCTP contributes to Europe's health security by addressing climate-sensitive infectious disease threats[3] and AMR[4].

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 response[5], 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.

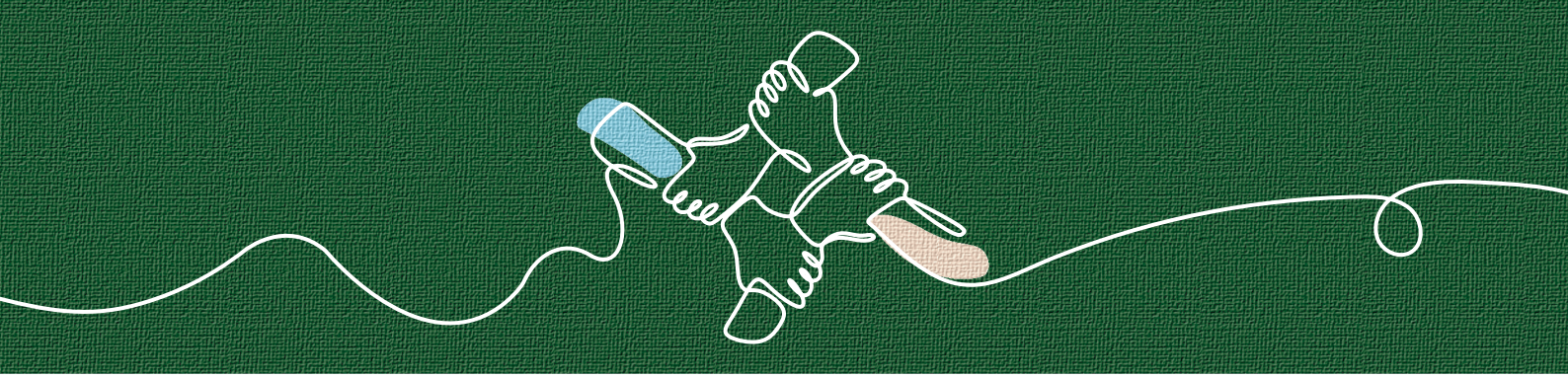
During the Ebola, COVID-19, and mpox outbreaks, the partnership quickly mobilised emergency funding to support the rapid start of response projects, providing essential clinical and medical frontline capabilities. Its support involves developing expertise in clinical research, epidemiology, and laboratory 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]

EDCTP ensures that research consortia operate equitably and uphold high ethical scientific standards, actively discouraging 'helicopter' research and preventing exploitative practices in lower-income settings. By promoting fair global partnerships that respect local needs and ownership, EDCTP strengthens the EU's credibility and legitimacy, making it a powerful actor in science diplomacy.

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.

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.

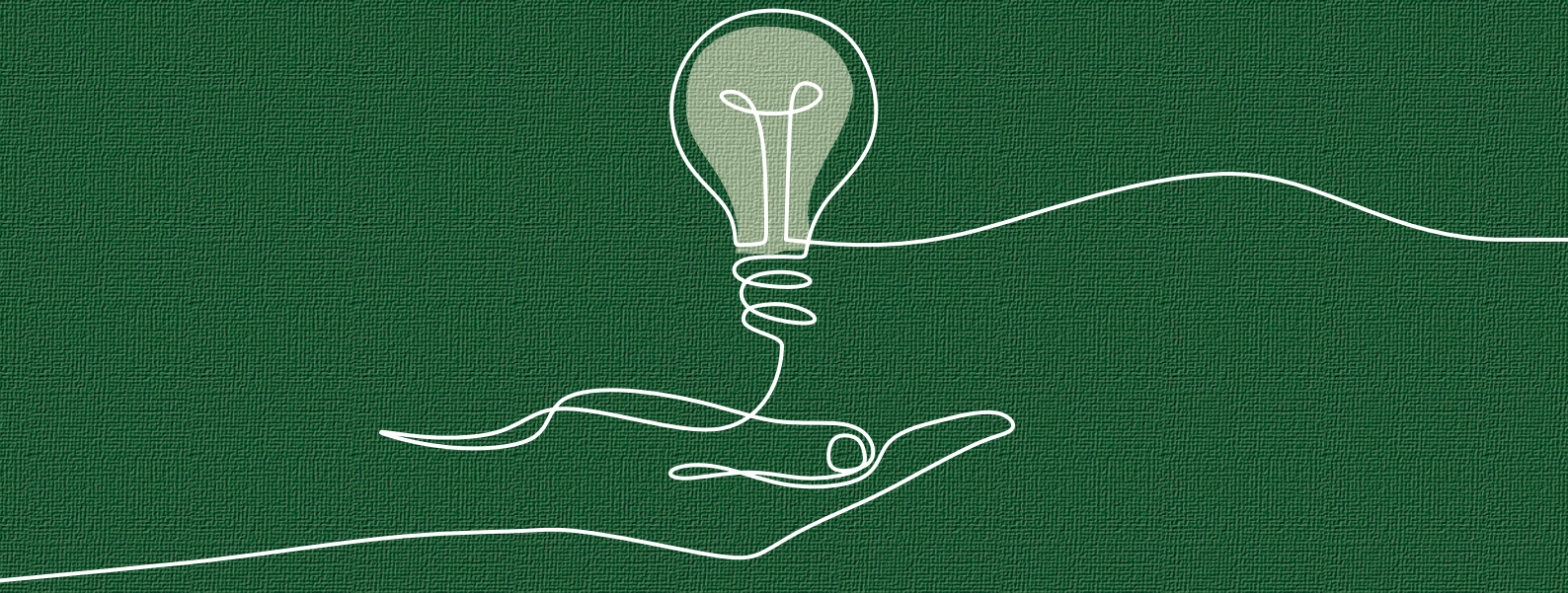
14 Project examples: GenPath Africa (2025), PANGenS (2025); EpiGen Ethiopia (2025) CORDIS. European Commission

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 communities[15] 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.

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

Scan here for the updated version online

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, CEPI[21] 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 vectors[26] 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.

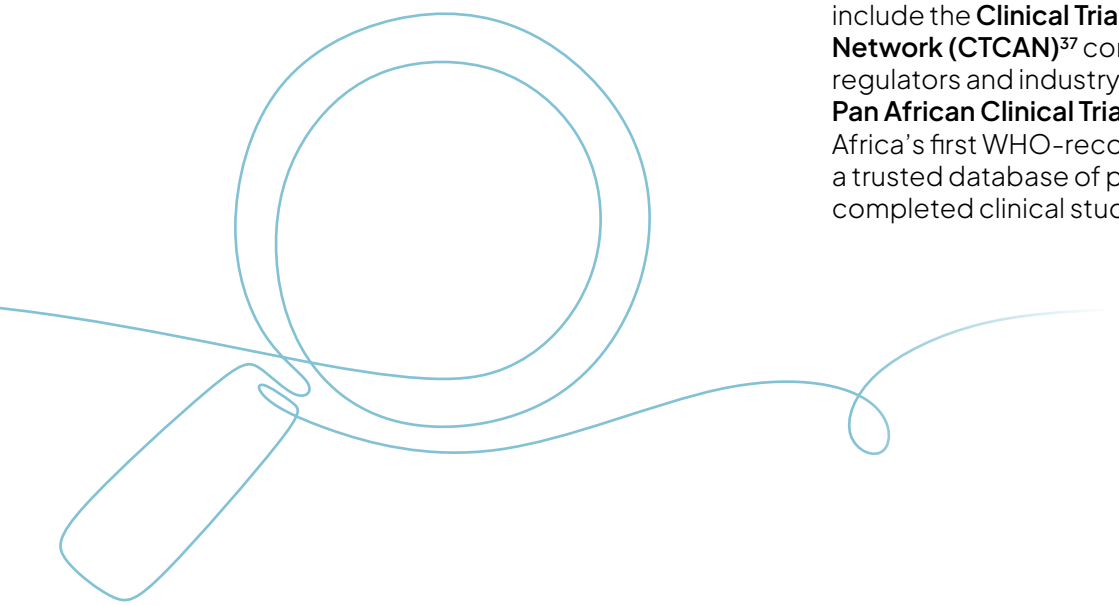
17 Project example: PANDORA-ID-NET (2016) EDCTP
18 Project example: ALERRT (2018) EDCTP
19 EDCTP (2024) EDCTP and Africa CDC collaborative initiative survey report on the 'Epi-Biostat' initiative
20 EDCTP (2017) EDCTP joins forces with WHO AFRO and TDR to fund implementation research - EDCTP
21 Cf. Footnote 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: mfloDx (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 systems[33] including pharmacovigilance,[34] and digital health capacities, complementing Team Europe Initiatives on Digital Health[35] 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.

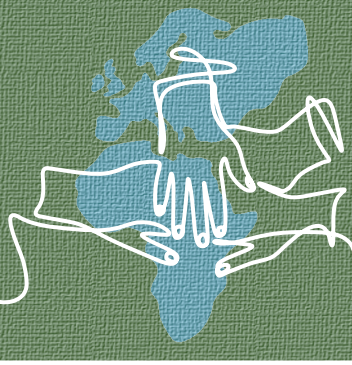
34 EDCTP (2021) EDCTP portfolio: Pharmacovigilance 2014–2020

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 CDC [40], WHO AFRO [41], and AVAREF[42] 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 Fund [44], and private sector partners[45], 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 Agenda [46], 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

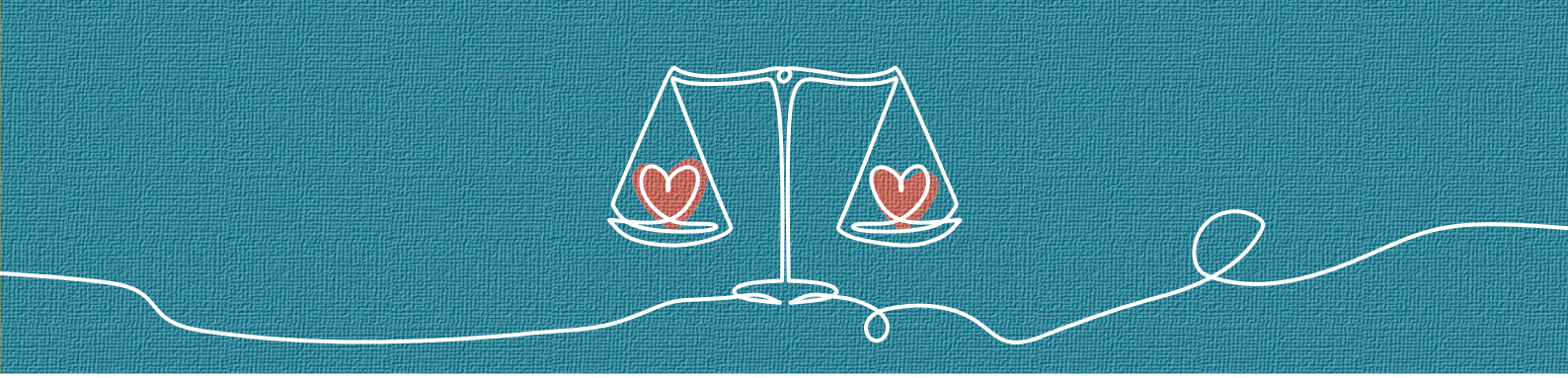
42 In 2008, EDCTP awarded two grants totalling approximately 700,000 EUR to WHO to establish AVAREF and strengthen regulatory authorisation capacities across Africa. EDCTP1 evaluation. pp 46.

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] newborns[48] and children,[49] urban poor and rural communities[50] – 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

EDCTP impact stories

New and better medicines already saving and improving lives

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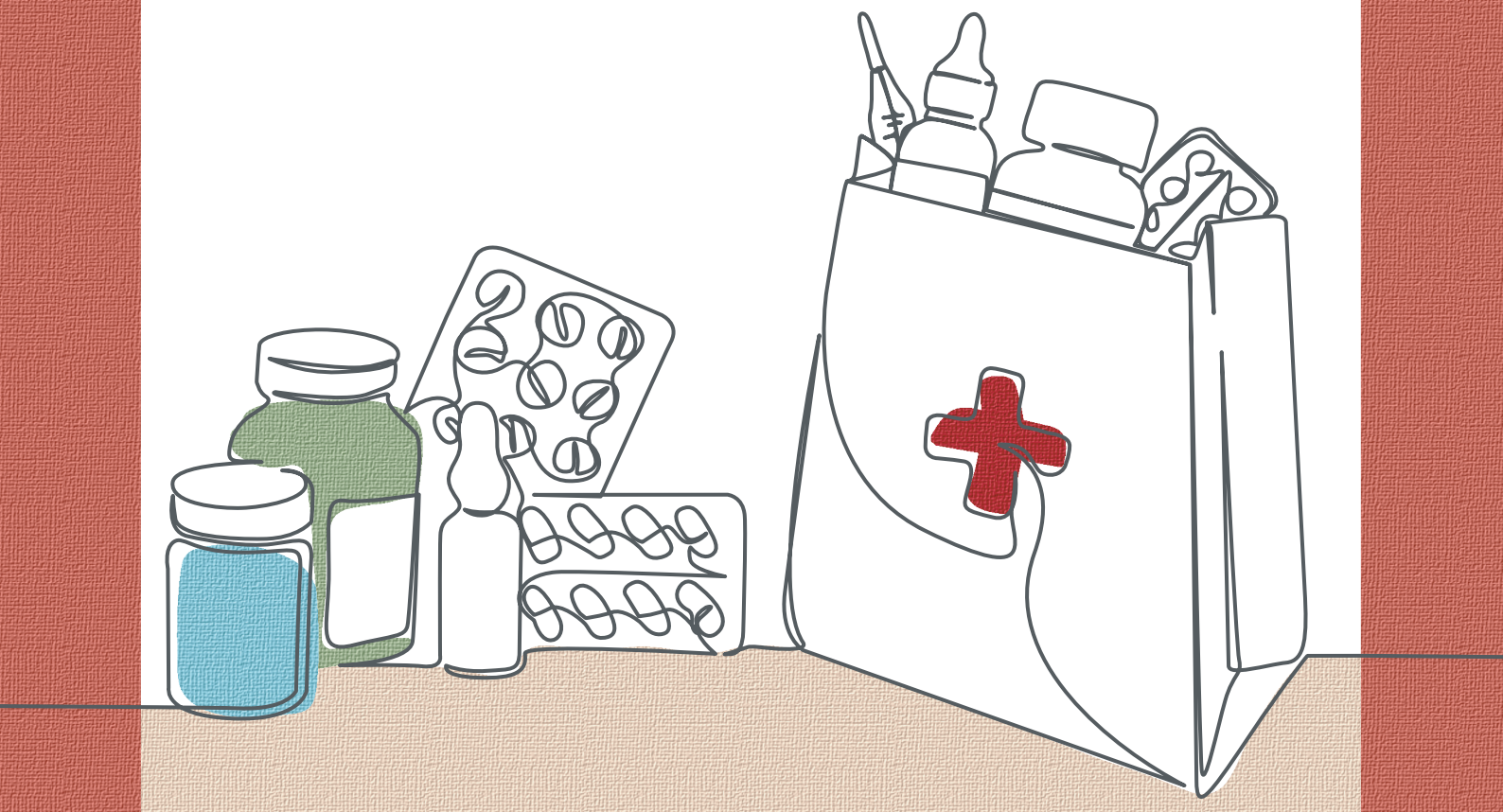
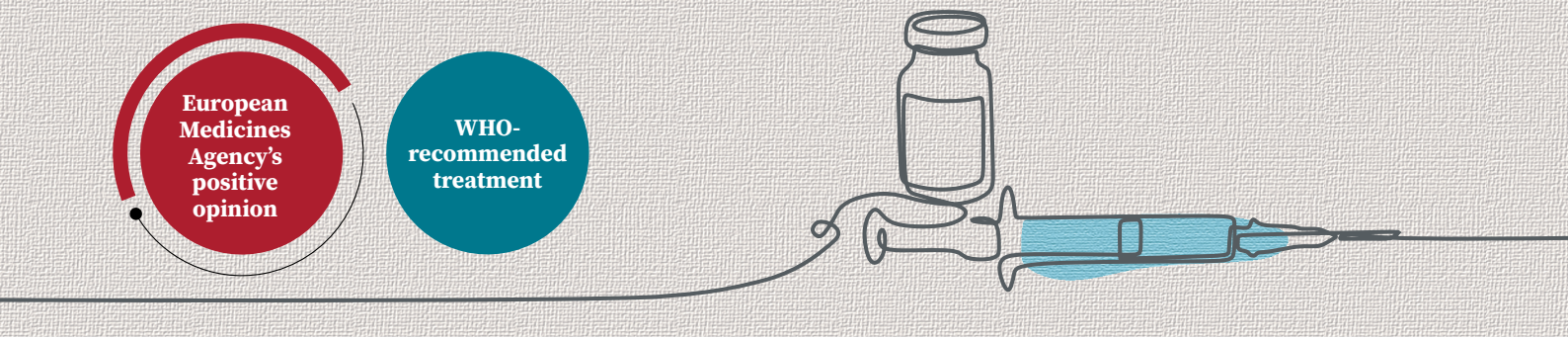




The first-ever malaria vaccines

What it is

RTS,S and R21/Matrix-M are the first vaccines against malaria and, more broadly, against any parasitic disease. Both vaccines stimulate an immune response that prevents malaria infection.

Why it matters

Global immunisation is among the most effective interventions to prevent infant mortality and severe disease. Each year, over 150 million children contract malaria, and around 500,000 die. These vaccines could prevent millions of illnesses and save thousands of children every year.

The story

Malaria is one of the deadliest diseases for children. EDCTP played a pivotal role in 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.[54]

Used along with other malaria control strategies, these two vaccines are safe, effective, and will significantly contribute to the reduction of mortality and morbidity due to malaria, especially in young children. As of August 2025, 21 African countries have introduced them into their national routine immunisation programmes, with many more ready to follow.[55]

These groundbreaking vaccines will save thousands of children's lives and protect millions from disease each year. In addition, they open the door to new technologies against other parasitic diseases and promise lasting improvements in quality of life, economic prospects, and social opportunities for millions of people.

Global Health EDCTP3 continues to support malaria vaccine research to boost vaccine effectiveness[56] and optimise vaccine deployment and use.[57]

The Lancet, Volume 397, Issue 10287, P1809–1818, May 15, 2021

54 Malaria Vaccines - EDCTP

55 Malaria vaccines (RTS,S and R21); https://www.gavi.org/types-support/vaccine-support/malaria

56 A Multi-stage Malaria Vaccine for Control and Elimination | PfVIMT | Project | Fact Sheet | HORIZON | CORDIS | European Commission

57 Building multidisciplinary evidence to support Integrating Malaria VACcine with Seasonal malaria chemoprevention in West Africa | IMVACS | Project | Fact Sheet | HORIZON | CORDIS | European Commission & Optimising a Deployable High Efficacy Multi-Stage Vaccine for Plasmodium falciparum Malaria: 2nd Generation Malaria Vaccine Consortium | MVC-2G | Project | Fact Sheet | HORIZON | CORDIS | European Commission

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.[58]

Implemented by the STOP Consortium, EDCTP co-funded[59] **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.[60] 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, t**he European Medicines Agency issued a positive opinion on this new medicine**,[61] paving the way for a WHO authorisation and its introduction in priority countries. [62]

Global Health EDCTP3 continues to support research on this treatment[63] in Kenya and Ghana, assessing its use in mass drug administration campaigns and its potential for treating other neglected diseases, such as lymphatic filariasis.

The Lancet Infectious Diseases, Vol. 25, P548–559, Issue 5, May 2025

58 Gebreyesus, T., Alemayehu, G., Asrat, B., & Mekonnen, Z. (2024). Efficacy of albendazole mass drug administration against soil-transmitted helminths in Ethiopia: Implications for emerging drug resistance. Infectious Diseases of Poverty, 13(1), 45. https://doi.org/10.1186/s40249-024-01176-6; Sisay, M., Mengistu, B., & Tadesse, D. (2024). Reduced albendazole efficacy against Trichuris trichiura: A systematic review and implications for treatment strategies. Scientific Reports, 14, 71308. https://doi.org/10.1038/s41598-024-71308-3; Wimmersberger, D., et al. (2018). Efficacy and safety of ivermectin against Trichuris trichiura in preschool-aged children: A randomized controlled dose-ranging trial. Clinical Infectious Diseases, 67(8), 1247–1254. http://doi.org/10.1093/cid/ciy246

59 New tablet shows promise for the control and elimination of intestinal worms - EDCTP

60 Home - STOP

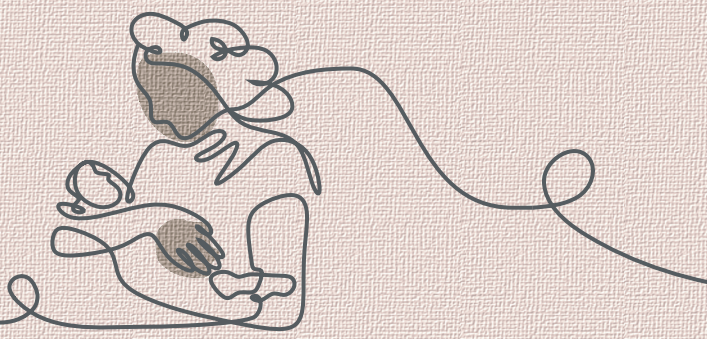
61 Ivermectin/Albendazole - opinion on medicine for use outside EU | European Medicines Agency (EMA)

62 ADOPT https://unlimithealth.org/research/adopt-programme/

63 Project - STOP2030

European Medicines Agency's positive opinion

WHO-recommended treatment



Groundbreaking innovations to protect children and pregnant women from malaria

What it is

Coartem® Baby and Pyramax®'s new formulations for children and pregnant women are safe and effective against malaria and better suited to their specific needs.

Why it matters

Malaria is life-threatening for unborn babies and children under five and a leading cause of child mortality in Africa. These safer and more acceptable medicines will better protect children from this threat.

The story

Each year, malaria affects more than 250 million people and causes over half a million deaths, the majority among children under five.[64] Since 2003, EDCTP has supported over 20 malaria research projects,[65] advancing **simpler and improved therapies for children with severe malaria[66] and for pregnant women.[67] Crucially, EDCTP has also contributed to:**

- **The approval of the antimalarial medicine Pyramax,[68]** including reconfirming its safety and efficacy for re-treatment.[69] It also enabled research on its safety in pregnant women,[70] and facilitated the development of a paediatric formulation [71].
- The update of the regulatory dossier for the antimalarial **Eurartesim,** supporting its use as a new treatment option for uncomplicated malaria.[72]
- **The approval of the first-ever malaria therapy for babies weighing less than 5 kg [73],** a priority population for which no approved medicine or vaccine currently existed. A new dissolvable medicine that can be mixed with breast milk, has a sweet cherry flavour to ease administration, and delivers precise dosing, improving safety and therapeutic effectiveness [74].

64 Malaria

65 Malaria - International partnerships against infectious diseases & Malaria treatment - EDCTP

66 Simplified artesunate regimen found efficacious in treating children with severe malaria - EDCTP

67 PREGACT: Safety and efficacy of four artemisinin-based combination treatments in African pregnant women with malaria - EDCTP

68 Pyramax - opinion on medicine for use outside EU | European Medicines Agency (EMA)

69 Re-treating malaria with Pyramax®: WANECAM study supports safety and efficacy - EDCTP

70 Pyramax ® label update: Now includes information for the treatment of pregnant women with malaria | Medicines for Malaria Venture

71 Pyramax® approved as antimalarial for treatment of multiple episodes of malaria - EDCTP

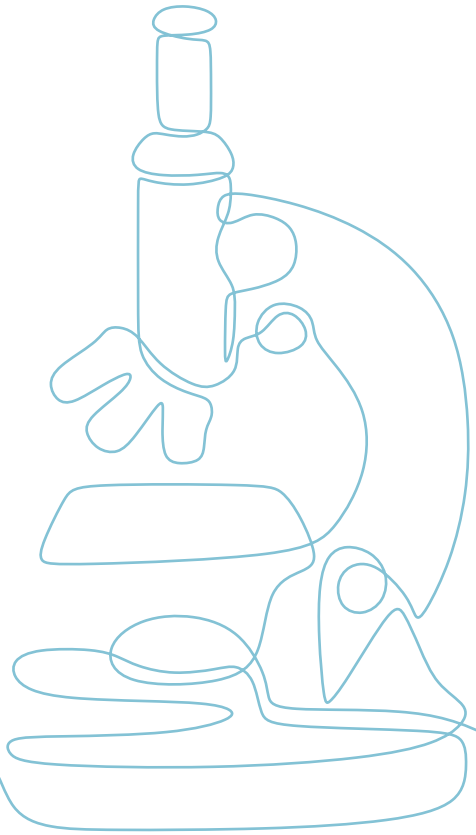
72 European Medicines Agency recommends new malaria treatment for approval | European Medicines Agency (EMA)

73 First malaria treatment for babies and young infants receives approval - EDCTP

74 First malaria treatment for babies and young infants receives approval - EDCTP

By advancing malaria treatments suitable for babies and other priority populations, 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.[75] **Global Health EDCTP3 continues to drive innovation against malaria, including supporting new formulations to address drug resistance,[76] protect pregnant women,[77] and improve vector-control tools.** [78]

The Lancet Infectious Diseases, Volume 16, Issue 2, P189–198, February 2016



75 Africa CDC Applauds First-Ever Malaria Treatment for Infants Under 5 kg – Africa CDC

76 https://www.edctp.org/news/wanecam-2-consortium-reports-positive-results-from-phase-2b-study-of-novel-treatment-for-children-with-malaria/

77 Home - SAFIRE - Safety of Antimalarials in FIRst trimEster

78 Delftia TsuruhatensTC1 Based-Intervention For Interrupting Malaria Transmission In Mosquitoes: A Novel Trial For Evaluating Alternative Tools For Control Of Vector-Borne Diseases | DEFEND | Project | Fact Sheet | HORIZON | CORDIS | European Commission & Effect of long-acting spatial repellents (LASR) vs indoor residual spraying (IRS) on malaria burden in western Kenya: a cluster-randomised trial | LASR | Project | Fact Sheet | HORIZON | CORDIS | European Commission

European Medicines Agency's positive opinion

WHO-recommended treatment

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 Paediatric 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)**.[79] 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 January 2025, the European Medicines Agency issued a positive scientific opinion,[80] paving the way for WHO approval and introduction in endemic countries.

In parallel, the ADOPT project,[81] co-funded by EDCTP and GHIT Fund, **is supporting the rollout of arpraziquantel in Africa, focusing on ensuring equitable and sustainable access to this critical medicine**.

Global Health EDCTP3 continues to support efforts to tackle schistosomiasis, including among women [82] and improving implementation strategies. [83] 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.

The Lancet Infectious Diseases, Vol. 23, Issue 7, P867–876, July 2023

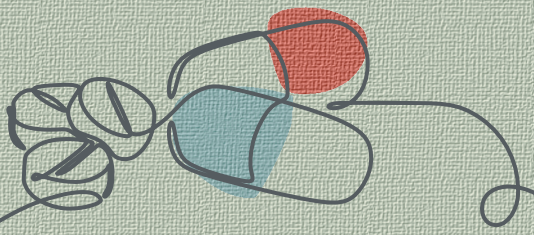
79 The Pediatric Praziquantel Consortium | Pediatric Praziquantel Consortium & Completion of Phase III trial paediatric schistosomiasis drug arpraziquantel - EDCTP

80 New treatment for young children with parasitic disease schistosomiasis | European Medicines Agency (EMA)

81 GHIT and EDCTP co-invest additional €7.8 million in access programme for treatment of schistosomiasis in preschool-aged children - EDCTP

82 (W)Initiative for womeN and GirlS affected by Female Genital Schistosomiasis | WINGS-4-FGS | Project | Fact Sheet | HORIZON | CORDIS | European Commission

83 Integrated Anthelmintic-Based control of Taenia solium cysticercosis/taeniasis, Soil-transmitted Helminthiasis and Schistosomiasis: safety, effectiveness and implementation strategies | 3SI-CONTROL | Project | Fact Sheet | HORIZON | CORDIS | European Commission



WHO-recommended treatment

European Medicines Agency's positive opinion

A patient-friendly medicine for sleeping sickness

What it is

Fexinidazole is the first all-oral treatment for sleeping sickness. Taken as simple pills over 10 days, it eliminates the need for hospitalisation and painful lumbar punctures, and has become the most widely used therapy for this disease.

Why it matters

Although sleeping sickness is nearing eradication, 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 this patient-friendly innovation essential.

The story

Human African trypanosomiasis, or sleeping sickness, is a deadly parasitic disease transmitted by tsetse flies. Although nearing eradication, the disease remains endemic in 36 African countries, placing millions of people at risk. **Existing treatments have been complex, toxic, and painful.**[84]

EDCTP has supported the HAT-r-ACC consortium,[85] enabling the development of **Fexinidazole Winthrop**, the first all-oral treatment for *T.b. rhodesiense sleeping sickness* [86]. This innovative medicine received a positive opinion from the European Medicines Agency in 2023, prompting the WHO to update its guidelines to recommend fexinidazole for the treatment of HAT caused by T.b.rhodesiense. In 2024, fexinidazole was registered for treating *T.b. rhodesiense* sleeping sickness in the Democratic Republic of the Congo, and approval for its use was granted in Malawi.

Developed by DND*i*, Sanofi, and partners,[87] **Fexinidazole represents a major advance in the treatment of sleeping sickness, including severe cases, with a simple, exclusively oral 10-day regimen**. Today, it accounts for approximately 70% of all sleeping sickness treatments, bringing the continent closer to eradication and offering a simpler, safer, and more effective therapy for affected populations. Global Health EDCTP3 continues to support research and innovation for enhanced interventions against sleeping sickness [88] to advance towards its eradication by 2030.

The Lancet Global Health, Volume 13, Issue 5, e910–e919, May 2025

84 Trypanosomiasis, human African (sleeping sickness) and ACOZI-KIDS: Start of clinical trial for simplified treatment of sleeping sickness in children - EDCTP

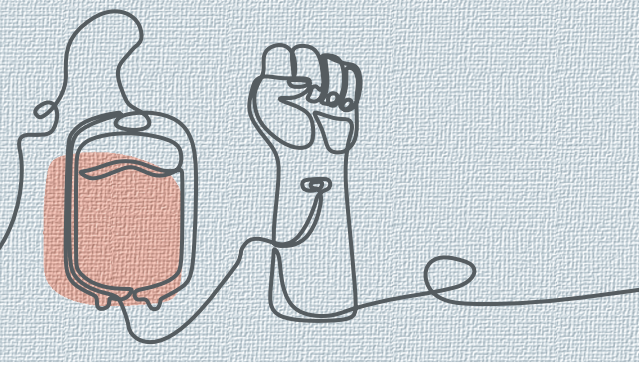
85 HAT-r-ACC - International partnerships against infectious diseases

86 https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(25)00016-6/fulltext

87 Fexinidazole for T.b. rhodesiense | DNDi & EMA gives positive opinion of Fexinidazole Winthrop as first oral treatment of acute form of sleeping sickness (rhodesiense) found in East and Southern Africa - EDCTP

88 The STROGHAT study protocol: An intervention ... | Open Research Europe

WHO-recommended treatment



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.[89] **Yet HIV remains incurable and intertwined with other severe conditions like tuberculosis, cryptococcosis, and cancer, as well as deep socioeconomic and mental health challenges.**[90] 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.[91] Even among ART-treated patients, cryptococcal mortality remains high; approximately 70% in low- and middle-income countries and 20–30% in high-income countries.[92] **Meningitis caused by cryptococcal disease accounts for roughly 15% of all AIDS-related deaths: close to 200,000 people each year.**

89 Global HIV Programme

90 Chronic comorbidities & coinfections among PLHIV. Global HIV Programme

91 Guidelines for diagnosing, preventing and managing cryptococcal disease among adults, adolescents and children living with HIV

92 Therapy for HIV-associated cryptococcal meningitis: a case report demonstrating a new treatment approach emphasizing updated treatment guidelines - PMC

Despite this, cryptococcal meningitis remains severely under-studied[93] 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.[94]

To address this, EDCTP funded the **AMBITION-cm trial**, the largest clinical study of cryptococcal meningitis in HIV patients to date.[95] 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.[96]** This regimen is now the WHO-recommended treatment for cryptococcal meningitis. Its efficacy[97] and cost-effectiveness[98] 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 HIV[99] and HIV-associated diseases**, including tuberculosis,[100] and focusing on priority populations such as children and pregnant women.[101]

NEJM, Volume 386, NO. 12, P1109–1120, March 2022

93 Filling the gap in funding for research on cryptococcal meningitis with HIV - eMagazine November 2021

94 Treatment of Cryptococcal Meningitis: How Have We Got Here and Where are We Going? | Drugs

95 AMBITION-cm - International partnerships against infectious diseases

96 Single dose of liposomal amphotericin B as effective in treating HIV-associated cryptococcal meningitis as current standard of care - EDCTP

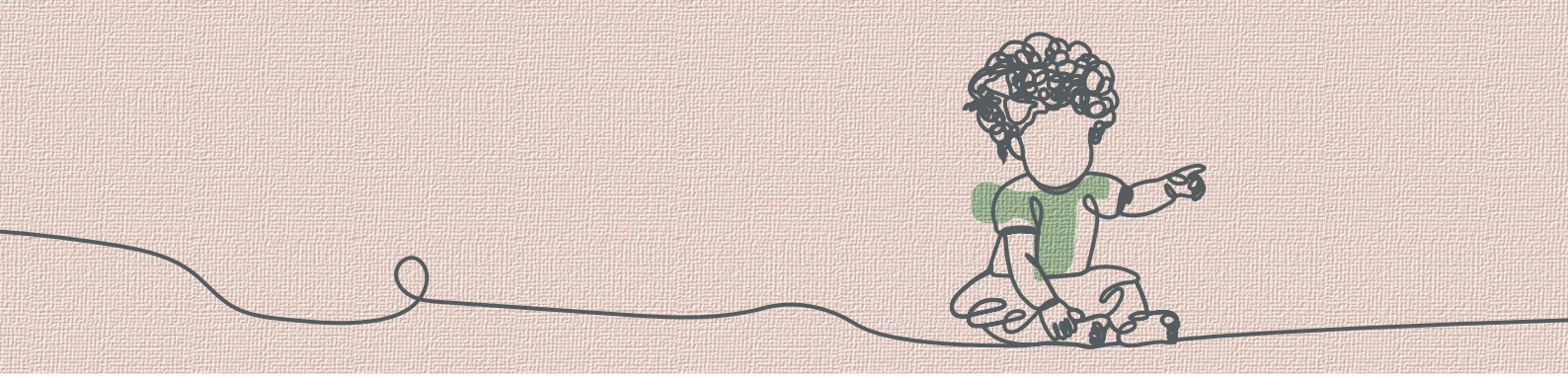
97 Implementation of Single High-dose Liposomal Amphotericin B Based Induction Therapy for Treatment of HIV-associated Cryptococcal Meningitis in Uganda: A Comparative Prospective Cohort Study | Clinical Infectious Diseases | Oxford Academic

98 Cost-effectiveness of single, high-dose, liposomal amphotericin regimen for HIV-associated cryptococcal meningitis in five countries in sub-Saharan Africa: an economic analysis of the AMBITION-cm trial

99 Developing novel, innovative HIV therapeutics for reducing the disease burden of HIV in sub-Saharan Africa | Programme | HORIZON | CORDIS | European Commission

100 Intensified tuberculosis treatment to reduce the high mortality of tuberculous meningitis in HIV-infected and uninfected patients | INTENSE-TBM-2 | Project | Fact Sheet | HORIZON | CORDIS | European Commission & Evaluating a new stool based qPCR for diagnosis of tuberculosis in children and people living with HIV | STOOL4TB | Project | Fact Sheet | HORIZON | CORDIS | European Commission

101 Drug Optimisation in LMICs of Pregnant HIV women and their Infants: temporary switch to CAB/RPV long acting injections | DOLPHIN-3 | Project | Fact Sheet | HORIZON | CORDIS | European Commission



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.[102] While antiretroviral therapy (ART) is recommended for all people with HIV, only half of the affected children receive treatment,[103] 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.[104] Although children in sub-Saharan Africa are most impacted, these barriers hinder access to HIV treatment and prevention for children globally.[105]

102 Global HIV Programme

103 HIV – Reported number of children receiving antiretroviral therapy

104 Challenges with pediatric antiretroviral therapy administration: Qualitative perspectives from caregivers and HIV providers in Kenya - PMC

105 Increasing Access to Antiretroviral Therapy for the Prevention and Treatment of HIV in Infants, Children, and Youth in the United States: Policy Statement | Pediatrics | American Academy of Pediatrics & Setback in the fight against pediatric HIV — Harvard Gazette

For more than 20 years, EDCTP has advanced HIV research to address these challenges.[106] Launched in 2005, the CHAPAS project[107] 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 options[108] and in July 2025, the CHAPAS-4 consortium announced[109] **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 care[110] while also advancing the development of improved HIV medicines for all.[111]

AIDS 22(5): p 557–565, March 12, 2008

106 World AIDS Day 2024: Supporting innovative research to end inequality - Global Health EDCTP3 JU & HIV & HIV-associated infections - EDCTP

107 HIV treatment: CHAPAS Trials - EDCTP

108 CHAPAS 4 - International partnerships against infectious diseases

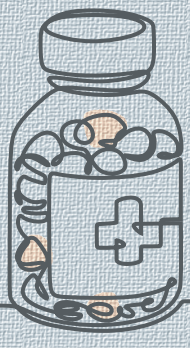
109 Revolutionary HIV treatment for children introduced by EDCTP-funded CHAPAS - Global Health EDCTP3 JU

110 CHAPAS-5: An Adaptive Platform Trial for Evaluation of Novel Treatment Regimens in ART-naive and Treatment-experienced Viraemic Children and Adolescents Living with HIV in Africa | CHAPAS-5 | Project | Fact Sheet | HORIZON | CORDIS | European Commission

111 Toxicity of dolutegravir and evaluation of doravirine for alternative 1st line antiretroviral treatment in people living with HIV | ELDORADO | Project | Fact Sheet | HORIZON | CORDIS | European Commission

European Medicines Agency's positive opinion

WHO-recommended treatment



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

What it is

Dihydroartemisinin-piperaquine (DHAPQ) is an artemisinin-based combination therapy (ACT) used to treat 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.

This combination provides a **simple** three-day 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.[112] When uncomplicated malaria is left untreated or inadequately treated, it can rapidly progress to severe disease and death.

DHAPQ helps address critical gaps in malaria treatment by providing a well-tolerated, easy-to-administer therapy that reduces both treatment failure and reinfection rates. It is suitable for children, who remain among the most vulnerable to malaria.

112 Our World in Data, Despite being preventable and treatable, malaria is the leading cause of child mortality in much of Sub-Saharan Africa

The story

For years, malaria treatment faced two major challenges: **drug resistance** and **complex dosing regimens** that made adherence difficult, especially for children. To overcome these, researchers developed DHAPQ as a fixed-dose combination, ensuring that patients receive the correct ratio of both drugs with each dose.

Supported by extensive clinical trials, DHAPQ demonstrated high efficacy and excellent tolerability, outperforming several other ACTs in preventing recurrent infections thanks to its **long post-treatment protection.**

The World Health Organization (WHO) now recommends DHAPQ among the ACTs for uncomplicated *Plasmodium falciparum* malaria. Countries such as Ghana have adopted it as a second-line therapy, where it continues to show efficacy rates above 90% in children under routine use.

Through **EDCTP funding**, researchers have been able to conduct **clinical trials focusing on safety, optimal dosing, and side effects**, particularly in vulnerable groups such as young children and people living with HIV.[113, 114] These studies generated essential data that have informed WHO recommendations and strengthened the evidence base for the safe and effective use of DHAPQ.[115]

Today, DHAPQ is widely used across Africa and Asia, is endorsed by the WHO, and is approved by the European Medicines Agency (EMA) under the trade name Eurartesim®. Its integration into national malaria control programmes and consistent clinical success mark it as a **cornerstone in the global fight against malaria.**

PLOS Medicine, 8(11): e1001119, November 8, 2011

113 EDCTP Association, Malaria treatment – The 4ABC study

114 EDCTP Association, IMPACT study

115 A Head-to-Head Comparison of Four Artemisinin-Based Combinations for Treating Uncomplicated Malaria in African Children: A Randomized Trial

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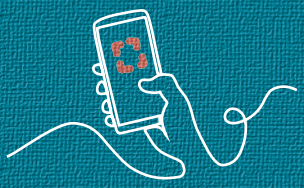

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