

# The African and European research partnership on infectious diseases

European Partnership

Co-funded by the European Union



# Who we are

**The European & Developing Countries Clinical Trials Partnership (EDCTP)** is a European Union (EU)-funded partnership between institutions mandated by the governments of 15 European and 29 African countries, and the European Commission.

Launched in 2003 and renewed in 2014 and 2021 with funding through to 2031, EDCTP has been the focal point for EU support for global health research in Africa, and a visible sign of the EU's commitment to the infectious disease-related objectives of the Millennium Development Goals and more recently the Sustainable Development Goals. Additionally, it contributes to the implementation of the EU Global Health Strategy and the African Union (AU)-EU Innovation agenda.

Through its evolution, EDCTP has been driven by the infectious disease priorities of sub-Saharan Africa and the need to develop African countries' capacity to collectively address these priorities into the future.

The first EDCTP programme - **EDCTP1** - ran as an Article 185 Initiative of the Treaty on the functioning of the EU from 2003–2015 and operated as a European Economic Interest Grouping (EEIG).

The second EDCTP programme - **EDCTP2** - was launched in 2014 as another Article 185 Initiative implemented by the EDCTP Association and will run until 2024.

The third EDCTP programme - **Global Health EDCTP3** – was established in 2021 as a Joint Undertaking, which is an Article 187 Initiative of the Treaty on the functioning of the EU, and will run until 2031.

## **OUR VISION**

Global Health EDCTP3's vision is to reduce the individual, social, and economic burden of povertyrelated infectious diseases, including neglected, emerging, and re-emerging infectious diseases, in sub-Saharan Africa.

## **OUR MISSION**

Global Health EDCTP3's mission is to reduce overall mortality and morbidity in sub-Saharan Africa by supporting global collaborative research, capacity strengthening, and international initiatives to accelerate the development, evaluation, and implementation of interventions to prevent, identify, treat and track infectious diseases and emerging/reemerging infections in the region.

## FUNDING OF THE PROGRAMME

Global Health EDCTP3 is a ten-year programme running from 2021 to 2031. The partnership aims for a €2 billion budget, having already secured €1.86 billion in pledges.

This includes a commitment of up to €910 million from the European Union (EU) to match the commitment of at least €550 million from the EDCTP Association members combined with an expected €400 million contribution from third parties.

The programme is implemented as part of the EU's Framework Programme for Research and Innovation, **Horizon Europe**.

# What **we do**

We fund **collaborative clinical research** on medical interventions and support the **strengthening of research capacities** in sub-Saharan African countries to conduct high quality clinical studies and to prepare for and respond to re-emerging infectious diseases. We do this by developing the health research infrastructure, investing in the development of the next generation of African researchers, and strengthening the ethical review, regulatory and legal frameworks for clinical research in sub-Saharan Africa.

The Global Health EDCTP3 programme encompasses **underserved populations** often excluded from clinical studies but with major unmet medical needs – including pregnant women, newborns, children, adolescents, other vulnerable populations, and people with coinfections and co-morbidities.

Global Health EDCTP3 also supports **productfocused implementation research** on the delivery and uptake of medical interventions, making our work directly relevant to health services in sub-Saharan African countries. This research provides new opportunities for partnerships with development organisations and other partners working on health systems, optimisation and integration of health services, and access to safe and effective medical interventions for the populations that need them most.



## **OUR OBJECTIVES**

Global Health EDCTP3 will contribute to the:

- Reduction of the socioeconomic burden of infectious diseases in sub-Saharan Africa by promoting the development and uptake of new or improved health technologies
- Increase of health security in sub-Saharan Africa and globally by strengthening research capacities for preparedness and response to control infectious diseases.



#### **Clinical research**

Advance the development and use of new or improved medical interventions for tackling infectious diseases by supporting the conduct of clinical trials in sub-Saharan Africa.



## **Capacity development**

Strengthen clinical research capacity and the national health research systems in sub-Saharan Africa for conducting clinical studies according to the highest ethical principles and regulatory standards.



## **Enhanced coordination**

Facilitate better alignment of countries around a common global health Strategic Research and Innovation Agenda.



## **Epidemic preparedness**

Strengthen capacity for epidemic preparedness in sub-Saharan Africa through effective and rapid research response.



## International cooperation

Promote networking and international cooperation on global health research through North-South, South-South and North-North collaboration, and develop strategic partnerships with multiple privateand public-sector organisations.

# What we fund

Global Health EDCTP3 supports all the elements required to develop and evaluate medical interventions against the key infectious diseases affecting sub-Saharan Africa, through clinical science, research capacity development, and networking (national and international).

## **TARGET DISEASES**

We support clinical research on HIV, tuberculosis (TB), malaria, neglected infectious diseases, diarrhoeal diseases, lower respiratory tract infections, and emerging and re-emerging infections relevant to sub-Saharan Africa.

Our scope also includes antimicrobial resistance (AMR), climate-crisis-provoked changes in infectious disease incidence, and co-infections and co-morbidities, including co-morbid non-communicable conditions associated with our target diseases or their treatment.

## **MEDICAL INTERVENTIONS**

We support clinical studies on medicinal products designed to detect, prevent or treat target diseases. These include novel drug treatments and formulations, new therapeutic regimens, microbicides, vaccines and diagnostics.

## **TYPE OF RESEARCH**

Interventional clinical studies make up the bulk of our portfolio. We support all phases of clinical evaluation (phases I-IV), with a particular emphasis on late-stage product development, including phase III and IV clinical trials, pharmacovigilance and post-licensing effectiveness studies (pragmatic trials, utility/impact studies), product-focused implementation research and field trials (diagnostic tests).

## **RESEARCH CAPACITY**

EDCTP makes an important contribution to the development of clinical research capacity in sub-Saharan Africa and strengthens the enabling environment for conducting clinical trials and other research activities. We support researchers at various career stages, from master's and PhD training through to fellowships. The EDCTP Alumni Network facilitates reflection on experiences, and fosters collaboration and networking among past and current fellows. EDCTP also supports activities strengthening the ethical, regulatory and legal framework for conducting trials.

## Neglected infectious diseases in the scope of Global Health EDCTP3\*:

- Buruli ulcer
- Dengue and chikungunya
- Dracunculiasis (guinea-worm disease)
- Echinococcosis
- Foodborne trematodiases
- Human African trypanosomiasis (sleeping sickness)
- Leishmaniases
- Leprosy (Hansen disease)

- Lymphatic filariasis
- Mycetoma, onchocerciasis (river blindness)
- Rabies, schistosomiasis
- Soil-transmitted helminthiases
- Taeniasis/cysticercosis
- Trachoma
- Yaws.

\* Based on the WHO list of neglected tropical diseases 2024; Chagas disease, chromoblastomycosis and other deep mycoses, noma, scabies and other ectoparasites, and snakebite envenoming are currently not in the Global Health EDCTP3 scope.



## **COMPETITIVE FUNDING**

Global Health EDCTP3 grants are awarded through competitive calls for proposals. The call topics are guided by the Global Health EDCTP3 **Strategic Research and Innovation Agenda**, based on research priorities identified in the Annual Research and Innovation Agenda, and included in the annual work programmes. Each work programme is developed following a comprehensive consultation process involving multiple stakeholders, including the Global Health EDCTP3 **Scientific Committee** and **Stakeholders Group** and the African and European **EDCTP Association** members. The annual work programmes are approved by the **Governing Board**, comprising representatives from the European Commission and the EDCTP Association.

All calls for proposals are published on the European Commission's Funding and Tender opportunities portal (https://ec.europa.eu/info/funding-tenders/ opportunities/portal). They are open to the participation of researchers globally provided they team up with European and sub-Saharan African partners. Only legal entities established in any EU Member States, countries associated to Horizon Europe, or any sub-Saharan African country which is a member of the EDCTP Association are eligible to receive funding.

Further information on the calls for proposals and related rules for participation can be found on the Global Health EDCTP3 website.

## Achievements since 2003

#### FUNDING OF RESEARCH & CAPACITY DEVELOPMENT

## €1.03 Bn

to support 692 grants since 2003 (€208 M EDCTP1; €824.30 M EDCTP2).

## €377 M

invested in 21 calls for proposals under Global Health EDCTP3 since 2022.

## >€257 M

EU net contribution in signed grant agreements and proposals approved for funding under Global Health EDCTP3.

#### BIOMEDICAL INTERVENTIONS

## 477

clinical studies supported (102 EDCTP1; 375 EDCTP2). Of these. 150 are phase II and III clinical studies of drugs and vaccines (52 EDCTP1; 98 EDCTP2).

## 58

studies targeted pregnant women and their children (9 EDCTP1; 49 EDCTP2).

## >2,000

peer-reviewed publications were generated (>700 EDCTP1; >1,300 EDCTP2).

### CLINICAL RESEARCH CAPACITY

## 121

grants supported to enhance ethics and regulatory capacity in sub-Saharan Africa (75 EDCTP1; 46 EDCTP2).

## 271

fellowship grants to researchers from sub-Saharan Africa (56 EDCTP1; 215 EDCTP2).

## >1,660

trainees supported from sub-Saharan African countries through EDCTP projects (460 EDCTP1; 1,202 EDCTP2).

#### EPIDEMIC PREPAREDNESS

## 3

emergency calls have been triggered to respond to the Ebola (EDCTP2, 2018), COVID-19 (EDCTP2, 2020) and Mpox (Global Health EDCTP3, April 2024) outbreaks/pandemics.

## 24

grants funded under Global Health EDCTP3 to strengthen preparedness capacity in sub-Saharan Africa.

## 2

epidemic preparedness networks - ALERRT and PANDORA-ID-NET - established for guiding the public health response to severe infectious outbreaks.

#### EUROPEAN COORDINATION AND PARTNERSHIPS

## €247 M

in cash contributions received from European member countries (€51 M EDCTP1; €196 M EDCTP2).

## €528 M

Leveraged in cash and in-kind support from partners (€73 M EDCTP1; €455 M EDCTP2).

## €33 M

leveraged from Global Health EDCTP3 contributing partners.

## GLOBAL HEALTH EDCTP3 INVESTMENTS PER DISEASE AREA\*



\*Indicative amounts based on signed grant agreements and planned budget. Values are not mutually exclusive.





EU countries and EDCTP Association member countries (as of September 2024) that are part of the Partnership and eligible to receive Global Health EDCTP3 funding

Horizon Europe associated countries eligible to receive Global Health EDCTP3 funding

Countries participating in Global Health EDCTP3-funded grants but not eligible to receive funding

Countries not participating and not eligible to receive Global Health EDCTP3 funding

### HIGHLIGHTS FROM GLOBAL HEALTH EDCTP3 PROJECTS

## ADDRESSING DISPARITIES IN CLINICAL TRIALS IN AFRICA

**CTCAN** connects researchers, regulators, and industry to accelerate impactful clinical research and high-quality clinical trials across the African continent. The network fosters coordination by defining priority diseases, offering a platform showcasing research sites and labs, streamlining regulations, and strengthening the role of new players through training.

#### PROTECTING PREGNANT WOMEN & NEWBORNS FROM MENINGITIS

**PROTECT** safeguards maternal and newborn health by tracking the effectiveness and safety of novel maternal vaccines. Drawing on the use of group B streptococcal and respiratory syncytial virus vaccines as models, it tackles key gaps in electronic health records to build and monitor pregnancy registries across multiple African countries.

#### PREVENTING MOTHER-TO-CHILD TRANSMISSION OF HIV

**PROMISE-ZERO** tackles the prevention of mother-to-child transmission of HIV. It assesses the (cost)-effectiveness of a novel clinical approach featuring near-patient testing and lamivudine administration to stop mother-to-child HIV infection through breastfeeding.



#### GENOMIC SURVEILLANCE IN WASTEWATER

**ODIN** strengthens sub-Saharan Africa's fight against infectious diseases through genomic surveillance in wastewater. Based on the management of extensive sets of genomic epidemiological data, the project is training experts and building local capacity, with the goal of establishing an overall system that allows to monitor outbreaks and antimicrobial resistance.

#### THERAPEUTIC TOOLS AGAINST EBOLA

**EBO-PEP** aims to increase the portfolio of therapeutic tools against Ebola by evaluating a post-exposure strategy (PEP) for communities and individuals exposed to the Ebola virus. Its multi-country Phase III trial evaluates the efficacy of monoclonal antibodies used in the context of multiple outbreaks. EBO-PEP will also advocate for PEP implementation in countries affected by the virus and train clinical researchers to boost knowledge on Ebola.

#### ELIMINATING WORM INFECTIONS IN AFRICA

eWHORM champions worm infections elimination in Africa. It assesses the efficacy of a new drug (oxfendazole) across four countries and trains healthcare professionals in these settings. An innovative approach based on an adaptative clinical trial platform paves the way to expand treatment options for patients infected with parasitic worms.



# Working in **partnership**

Partnerships lie at the heart of our activities. With the support of the EU over the past two decades, EDCTP has established itself as a key initiative for supporting the implementation of the **EU Global Health Strategy** and an important contributor to the Africa–EU Strategic Partnership. EDCTP has been recognised by the Advisory Group (AG) on R&I for Africa–Europe cooperation as "the most cited joint programme strengthening health research and health systems in Africa and the flagship EU-Africa partnership in health R&D cooperation, with large successful long–lasting research networks".

We operate as a true '**partnership of equals**' between North and South. African partners are involved at all levels, including priority setting, strategy development, implementation of plans, governance and leadership. This contributes to a sense of co-ownership and political commitment that increases the likelihood that research results influence policy and practice.

EDCTP-funded activities are underpinned by a strong commitment to networking within the research community, fostering productive relationships between European and African individuals, research groups and institutions. We engage with the governments of African and European countries, as well as countries associated to Horizon Europe, to promote and facilitate better alignment of research and development agendas within the scope of Global Health EDCTP3. We also work with a wide range of public and private partners, promoting synergies, collaboration and joint initiatives to attract additional investment, exploit opportunities for highquality clinical research, and maximise the impact of integrated approaches to research.

## Partner with us

We welcome opportunities to cooperate with likeminded organisations on areas of mutual interest. Our partners can contribute in cash or in-kind to various Global Health EDCTP3 activities. Visit our website for information about how to become a Contributing Partner.



#### GOVERNANCE

The **Governing Board** is the ultimate decision-making body of the Global Health EDCTP3 Joint Undertaking, which is the legal implementing structure for the Global Health EDCTP3 programme.

The Governing Board comprises two governing partners with equal votes: the **European Commission**, representing the European Union, and the **EDCTP Association**, representing the governments of European and sub-Saharan African countries participating in the programme.

The **Scientific Committee** and **Stakeholders Group** are the principal advisory bodies for Global Health EDCTP3. The implementation of the programme is ensured by a **Programme Office** based in Brussels, with the EDCTP Association's **Africa Office** representing EDCTP in Africa and executing programme operational activities best implemented from an African location through a Global Health EDCTP3 grant.

**Contributing Partners** engage with Global Health EDCTP3 on a case-by-case basis in a non-governance capacity.

## **EDCTP ASSOCIATION**

The EDCTP Association currently has 28 African and 15 European member countries, in addition to one African and one European Aspirant member. EDCTP Association members contribute directly and indirectly to Global Health EDCTP3.

National research activities within the scope of Global Health EDCTP3 that are independently funded and administered by participating states are an integral part of the programme. These so-called **In-Kind contributions to Additional Activities (IKAAs)** help to achieve our strategic objectives and are included as an annex to the annual work programmes and reported on annually.

The **General Assembly** of the EDCTP Association is composed of the institutions mandated by national governments representing the respective participating states. The European Commission, the African Union and the World Health Organization are observers.

More information on the governance and membership of the EDCTP Association can be found at <u>www.edctp.org</u>.

For more information about Global Health EDCTP3, please visit:

https://globalhealthedctp3.eu



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### **Global Health EDCTP3**

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Lab technician processing samples at the Universidade Eduardo Mondlane in Maputo, Mozambique, as part of the EMPIRICAL project funded by the EDCTP2 programme.

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