

THE EUROPEAN & DEVELOPING COUNTRIES CLINICAL TRIALS PARTNERSHIP



WHAT IS EDCTP?

The European & Developing Countries Clinical Trials Partnership (EDCTP) is a **global health research and innovation (R&I) partnership** between the European Union (EU), and the EDCTP Association, which represents a number of EU Member States and African countries. Since 2003, its two consecutive programmes (EDCTP1 and EDCTP2) have pooled funding to accelerate the development of new or improved medical interventions for the identification, treatment, and prevention of poverty-related, and neglected infectious diseases.

THE BURDEN OF DISEASE

Poverty-related and neglected tropical diseases (PRNDs), including HIV & AIDS, malaria, tuberculosis (TB), and a variety of neglected conditions pose a disproportionately heavy burden on sub-Saharan Africa, and remain a major cause of death, ill-health and disability. PRNDs are diseases that typically face market failure, with little incentives for commercial organisations to invest in R&I. Chronic underfunding has resulted in a shortage of tools needed to tackle these diseases. **Innovative models of collaboration**, such as the EDCTP therefore play a crucial role in catalysing progress towards the 2030 Sustainable Development Goals.



AN INNOVATIVE PARTNERSHIP

By investing in research infrastructure and the development of the next generation of African researchers, the EDCTP has focused on **enhancing the capacity** of sub-Saharan African countries to conduct clinical studies, in particular **late-stage product development**. Through training and networking opportunities, the EDCTP has also strengthened ethical review and regulatory and legal frameworks for clinical research in sub-Saharan Africa, building health resilience across the continent and **strengthening global health security**.

TACKLING DIVERSITY GAPS

The EDCTP has been committed to fostering a more level playing field for individuals, institutions and countries in the field of clinical research, with a particular focus on **tackling geographical and gender imbalances**. The EDCTP has a Scientific Advisory Committee Working Group on Gender, and have implemented capacity building initiatives, fellowships and prizes to improve the representation of women across research, from clinical studies to ethical review. Between the first and second EDCTP programmes, the number of projects with a female research lead increased by 9% to 37%, 39% of EDCTP fellowships were held by women, up 12% and almost 40% of the members of expert review committees for EDCTP call evaluations are female.¹

CHAMPIONING WOMEN IN SCIENCE

Professor Francine Ntoumi is a Congolese parasitologist, specialising in malaria. A recipient of EDCTP funding, and coordinator of EDCTP-supported networks, Ntoumi has also served on the EDCTP Scientific Advisory Committee; playing a central role in the EDCTP's evolution. A passionate advocate, Ntoumi has worked tirelessly to promote gender equality in science and applauds the EDCTP's leading role in improving women's research careers, sharing that **"46% of postgraduate trainees on EDCTP2 projects across Africa are women**". This is very significant and offers hope that the future of health research in Africa will be more equal. There remains a lot to be done, however, and it will be crucial for the new partnership to strengthen intersectional efforts to support science by, and for women – key to tackling infectious diseases because of their disproportionate impact on women and girls".



ACCELERATING THE DEVELOPMENT OF NEW TOOLS TO TACKLE PRNDS



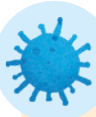
Advancing TB R&I

The EDCTP has played a central role in global TB R&I efforts, recognised as the second-largest funder of TB vaccine R&I, and the third-largest funder of TB research overall in 2020.^{2,3} The EDCTP also led the development of the TB vaccine roadmap,⁴ leading a global consultative process to identify key barriers to TB vaccine R&I; putting forward a set of priorities to guide the activities of all stakeholders involved in TB vaccine development and use.



First malaria vaccine

The WHO's endorsement of the RTS,S/AS01 vaccine was based on decades of research, including extensive testing across Africa. Many of the investigators and institutions that conducted studies on the vaccine received funding from the EDCTP for clinical research and capacity strengthening.⁷



A paediatric HIV drug

Thanks to the EDCTP-funded CHAPAS trials, a new child-friendly formulation combining antiretroviral drugs was developed, increasing children's access to treatment in Africa.⁵ The ongoing follow-up CHAPAS 4 study is evaluating new options for optimising second-line therapy for children living with HIV.⁶



New therapeutics for NTDs

The phase III trial of the paediatric schistosomiasis drug arpraziquantel, co-funded by the EDCTP confirmed a favourable efficacy and safety profile for use in children. With regulatory filing underway, a new, safe and affordable treatment for schistosomiasis could soon be available.⁸

DELIVERING ADDED VALUE TO EUROPE AND AFRICA

Fostering a new generation of African scientists

Requiring a minimum of one sub-Saharan African partner in each research consortium, and by supporting African researchers through its capacity development and fellowship programmes, the EDCTP is helping to tackle Africa's shortage of trained scientists.⁹



Boosting Europe's global competitiveness in R&I

The EU's global influence within the international research community has been significantly increased by the EDCTP. Over 90% of publications from projects funded by the EDCTP between 2003 and 2011 were published in high-impact journals.¹⁰



Accelerating access to safe medical interventions

The EDCTP has supported the strengthening of national pharmacovigilance systems across Africa, building capacities to detect and respond to possible adverse events, assuring the safety of new interventions and increasing uptake through maintaining public confidence.¹¹

Developing the skills of European researchers

By encouraging interdisciplinary approaches, and requiring multi-country collaboration, the EDCTP is supporting European researchers to build their skills in managing global collaborative projects, and enabling institutions to strengthen and diversify their expertise.¹²

Strengthening preparedness for disease outbreak

The EDCTP is working to enhance the capacity of African regions to carry out clinical research in emergency situations, and to detect, prepare for and respond to infectious disease outbreaks via two large consortia, ALERRT and PANDORA-ID-NET.¹³

Delivering on the EU's global commitments

Tackling poverty-related and neglected infectious diseases is central to delivering the Sustainable Development Goals, a firm commitment of the European Union.¹⁴

A NEW ERA FOR EDCTP

Building on the success of the EDCTP's initial programmes, its **third programme, the Global Health EDCTP3 Joint Undertaking (GH EDCTP3 JU)** will continue to drive forward and deliver new solutions to reduce the burden of infectious diseases in sub-Saharan Africa. The new programme will also mobilise opportunities to address the rising threat of antimicrobial resistance and climate-crisis-related infectious disease challenges.

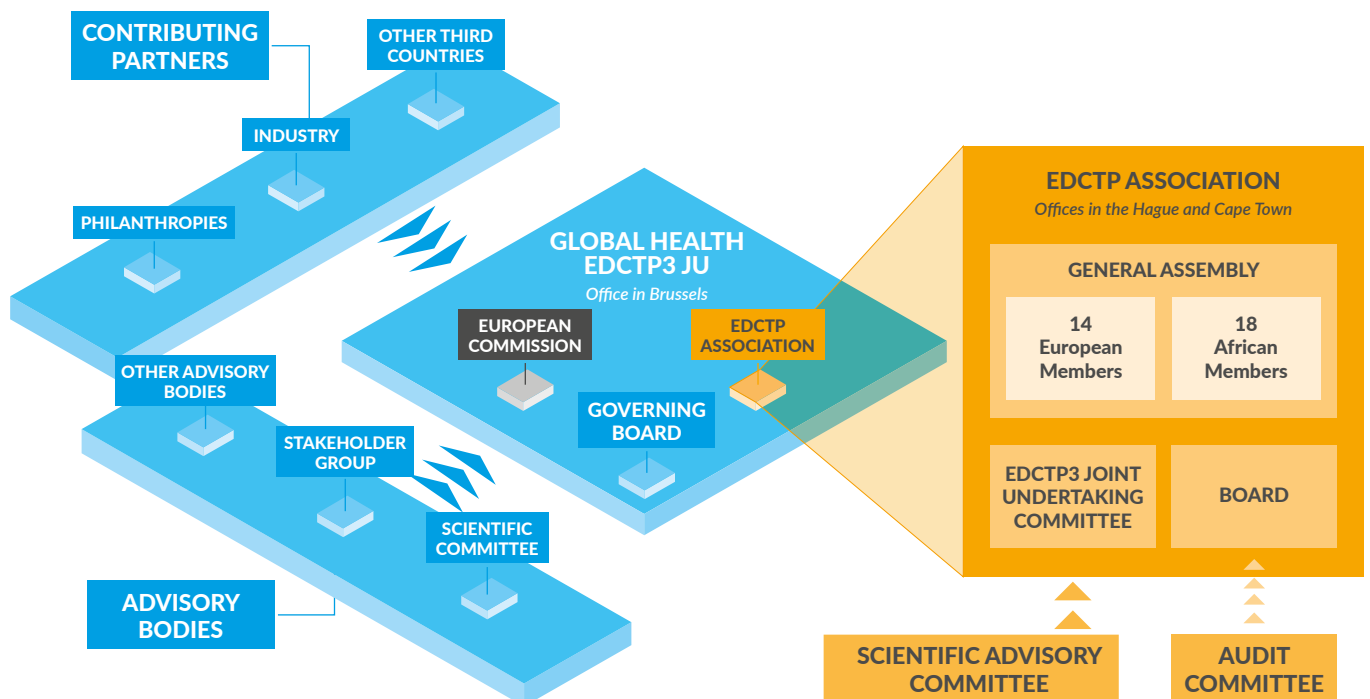
RESPONDING TO EVOLVING CHALLENGES

By 2030, the GH EDCTP3 JU aims to develop and deploy at least two new technologies tackling infectious diseases, and support at least 100 research institutes in 30 countries to develop additional health technologies, by:

- **Funding clinical trials** to accelerate the development and application of innovative technologies against diseases of poverty.
- **Building health research capacity** in Africa by strengthening clinical research capacity and developing the next generation of African science leaders.
- **Strengthening epidemic preparedness** by investing in clinical trial networks, data platforms and national ethics review and regulatory capacities.
- **Facilitating regional networking and promoting international cooperation** to strengthen health research systems and deliver universal health coverage.
- **Enhancing coordination**, alignment and, where appropriate integration of national research and development programmes in order to optimise investments in, and maximise the impact of infectious diseases R&I.

GOVERNANCE & FUNDING

A Governing Board, where both the EDCTP Association and the European Commission have equal votes, will lead the Partnership. The EDCTP Association currently has 14 European and 18 African member countries, each with equal voting rights in the General Assembly of the Association. The GH EDCTP3 JU will be advised by a Scientific Committee and a Stakeholders Group. Established as an Institutionalised Partnership under the EU's research framework programme Horizon Europe, the joint undertaking offers the possibility for the EU to match European and African participating states' contributions, as well as contributions from other public and private actors, including for example from industry, philanthropy, or non-EU, non-African countries.¹⁵





“ *The EDCTP has been a success story for EU–Africa research and innovation cooperation. Our partnership offers a renewed opportunity to deepen cooperation in tackling some of the world’s most devastating infectious diseases, essential in the face of converging threats such as climate change and emerging resistance. In developing new drugs, vaccines and diagnostics for key infectious diseases affecting sub-Saharan Africa, the partnership is accelerating economic and social transformation for the benefit of us all.* ”

Mariya Gabriel

Commissioner for Innovation, Research, Culture, Education and Youth

“ *A highly skilled workforce is necessary to strengthen healthcare systems in Africa, and for our collective health security. The Africa CDC and the EDCTP have worked closely over the last six years to accelerate action on this, including through a jointly funded programme to train highly skilled epidemiologists and biostatisticians in sub-Saharan Africa.* ”

Dr John Nkengasong

Director Africa CDC



WHAT CAN DECISION MAKERS AND THE EU DO TO MAXIMISE IMPACT?



Member countries should **increase their cash contributions** to support the partnership to fulfil its potential as a pooled funding mechanism.



Member countries should use the EDCTP as an **integration mechanism to build synergies and avoid overlaps** between different national global health R&I agendas.



The EU and member countries should **foster complementarities and collaboration with other global health instruments**, such as CEPI, HERA and others.



The EU and member countries should benefit from the EDCTP’s unique partnership model as a great **vehicle for science diplomacy and building sustainable collaborations** between Africa and Europe.



The governing bodies of the EDCTP3 need to **implement a strict open science agenda**, guaranteeing open access to research results, and promoting open access to research data, with strict criteria for derogations of open data requirements.¹⁶ The GH EDCTP3 JU also needs to ensure that research proposals include measures for ensuring **accessibility and affordability** of potential end products.¹⁷



The governing bodies of the EDCTP3 should **ensure a transparent and inclusive operation** of the partnership, e.g. by publishing relevant corporate documentation in a timely manner, and by organising meaningful consultations with all stakeholders.

1 EDCTP (2021) [Summary of achievements 2021](#)

2 Cobelens, F. et al. [Accelerating research and development of new vaccines against tuberculosis: a global roadmap](#). The Lancet. 2022

3 Treatment Action Group (2021) [Tuberculosis Research Funding Trends, 2005 – 2020](#)

4 DSW (2020) [EU support to global health research and innovation: a success story](#)

5 EDCTP website. [HIV treatment: CHAPAS Trials](#)

6 UCL website. [Children with HIV in Africa – Pharmacokinetics and Acceptability of Simple second-line antiretroviral regimens](#).

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

8 EDCTP website. [Completion of Phase III trial paediatric schistosomiasis drug apraziquantel](#)

9 EDCTP (2018) [The Added Value of EDCTP to Africa](#)

10 Breugelmanns JG, et al. Scientific impact increases when researchers publish in open access and international collaboration: A bibliometric analysis on poverty-related disease papers. PLoS One. 2018;13(9):e0203156

11 Ibid

12 EDCTP (2018) [The Added Value of EDCTP to Europe](#)

13 Ibid

14 Ibid

15 DSW (2020) [EDCTP Successor Technical Analysis](#)

16 DSW (2018) [Building on the Success of EDCTP](#)

17 Ibid