Global Health
EDCTP3

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Work Programme 2025

Global Health EDCTP3 Joint Undertaking

Annex to Governing Board decision No. GH-EDCTP3-GB/34/2024.

The Work Programme 2025 of the Global Health EDCTP3 Joint Undertaking was adopted by the Governing Board on 13 December 2024.

In accordance with Council Regulation (EU) 2021/2085 and with Article 33 of the Financial Rules of the Global Health EDCTP3 Joint Undertaking.

The Work Programme is made publicly available after its adoption by the Governing Board.

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List of acronyms

Acronym/Abbreviation	Full title/Definition
AAP	Additional Activities Plan
Africa CDC	Africa Centres for Disease Control and Prevention
AMR	Antimicrobial Resistance
ARIPO	African Regional Intellectual Property Organisation
AU	African Union
AUDA-NEPAD	African Union Development Agency-New Partnership for Africa's Development
AVAREF	African Vaccine Regulatory Forum
BCG	Bacille Calmette-Guérin vaccine
BOA	Back-office arrangements
CA	Contractual Agent
CAAR	Consolidated Annual Activity Report
CBO	Community Based Organisations
CHMP	Committee for Medicinal Products for Human Use
COVID-19	Coronavirus disease 2019
CSA	Coordination and Support Action
CSO	Civil Society Organisations
CTIS	Clinical Trials Information System
DALYs	Disability-adjusted life years
DDs	Diarrhoeal Diseases
DG	Directorate-General
DG BUDG	Directorate-General for Budget
DG RTD	Directorate-General for Research and Innovation
DNDi	Drugs for Neglected Diseases initiative
DPO	Data Protection Officer
ECA	European Court of Auditors
ED	Executive Director
EDCTP	European & Developing Countries Clinical Trials Partnership
EDCTP AO	EDCTP Africa Office
EMA	European Medicines Agency
EU	European Union
FAIR	Findable, Accessible, Interoperable, Reusable
FR	Financial Regulation
FWC	Framework Contract
GB	Governing Board
GF	Gates Foundation
Global Health EDCTP3 JU	Global Health EDCTP 3 Joint Undertaking
HIV/AIDS	Human immunodeficiency virus/acquired immunodeficiency syndrome
HR	Human resources
IHI	Innovative Health Initiative Joint Undertaking

Acronym/Abbreviation	Full title/Definition
JU	Joint Undertaking
IAC	Internal Audit Capability
IAS	Internal Audit Service
ICAM	Internal Control and Audit Manager
ICF	Internal Control Framework
ICP	Internal Control Principles
IT	Information and communication technology
IKAA	In-kind contributions to additional activities
IKOP	In-kind contributions to operational activities
IPC	Infection Prevention and Control
LMICs	Low and Middle Income Countries
MAV+	Manufacturing and Access to Vaccines, medicines and health products
M&E	Monitoring & Evaluation
MMVC	Multi-Stage Malaria Vaccine Consortium
MoU	Memorandum of Understanding
Mtb	Mycobacterium tuberculosis
NCDs	Noncommunicable diseases
NIDs	Neglected Infectious Diseases
NPHIs	National Public Health Institutes
NTDs	Neglected Tropical Diseases
OAPI	African Intellectual Property Organisation
OJ	Official Journal of the European Union
PPMT	Public procurement management tool
REA	Research Executive Agency
RIA	Research and Innovation Action
R&D	Research and Development
R&I	Research and Innovation
SARS-CoV2	Severe acute respiratory syndrome coronavirus 2
SBA	Single Basic Act
SC	Scientific Committee
SDGs	Sustainable Development Goals
SG	Stakeholders Group
SIAP	Strategic Internal Audit Plan
SLA	Service-level agreement
SRIA	Strategic Research and Innovation Agenda
SSA	Sub-Saharan Africa
STIs	Sexually Transmitted Infections
TA	Temporary Agent
TB	Tuberculosis
TEI-MAV+	Team Europe Initiative on Manufacturing and Access to Vaccines, medicines and health products
TFEU	Treaty on the Functioning of the European Union

Acronym/Abbreviation	Full title/Definition
TTG	Time to Grant
TTI	Time to Inform
TTP	Time to Pay
UN	United Nations
UNGA	United Nations General Assembly
WASH	Water, Sanitation and Hygiene
WHO	World Health Organization
WHO-AFRO	World Health Organization African Region Office
WP	Work Programme

1. Introduction

1.1 Mission statement of the Global Health EDCTP3 Joint Undertaking

The Global Health EDCTP3 Joint Undertaking (Global Health EDCTP3) exists to accelerate the clinical development, evaluation, and implementation of new or improved health technologies for the identification, treatment and prevention of poverty-related and neglected infectious diseases[1], including (re-)emerging diseases, particularly those affecting sub-Saharan Africa (SSA). In addition, Global Health EDCTP3 funds activities for research capacity building in Africa, supporting networking and researchers' careers and strengthening national health research systems. Furthermore, the partnership facilitates alignment of public and private funders around a common Strategic Research and Innovation Agenda (SRIA).

In the context of the Commission's priorities of contributing to the United Nations Sustainable Development Goals (SDGs), in particular Sustainable Development Goal 3, the Comprehensive Strategy with Africa[2], the Global Approach to Research & Innovation[3], the AU-EU Innovation Agenda[4], and the new EU Global Health Strategy[5], the EU is committed to ensuring healthy lives and promoting well-being for all, to building an even stronger partnership between the two continents and to supporting the development of research and innovation capacities within Africa.

Global Health EDCTP3 builds on the first and second European & Developing Countries Clinical Trials Partnership (EDCTP) programmes. This new joint undertaking (JU) is a partnership between the European Commission, representing the European Union (EU), and the EDCTP Association, currently representing 15 European and 30 African countries. The partnership aims to reduce the individual, social, and economic burden of poverty-related and neglected infectious diseases and strengthen research capacities to prepare and respond to emerging and re-emerging infectious diseases in SSA and across the world.

1.2 Background and link with the Strategic Research and Innovation Agenda

Global Health EDCTP3, which is the EU–Africa global health partnership, represents the third EDCTP programme. Its SRIA supports international collaborations accelerating the clinical evaluation and implementation of interventions against poverty-related infectious diseases, including the neglected ones affecting SSA. By building research capacity, it also enhances the ability of SSA countries to identify and respond to key infectious disease health challenges.

Infectious diseases remain a major cause of death, disability, and ill health in SSA[6]. Diseases such as human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS), malaria, tuberculosis

1 WHO's list of neglected tropical diseases covers a diverse group of 20 diseases caused by different pathogens that have diverse manifestations, life cycles, and methods of transmission. The Global Health EDCTP3's remit will cover the following diseases from this list: 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, and yaws. The Global Health EDCTP3's remit will not cover chromoblastomycosis and other deep mycoses, scabies and other ectoparasites, and snakebite envenoming.

2 https://ec.europa.eu/commission/presscorner/detail/en/fs_20_374

3 https://ec.europa.eu/commission/presscorner/detail/en/ip_21_2465

4 https://research-and-innovation.ec.europa.eu/document/download/c9c4eb8e-df0f-41e7-a322-891786fef29b_en?filename=ec_rtd_au-eu-innovation-agenda-final-version.pdf

5 https://ec.europa.eu/commission/presscorner/detail/en/ip_22_7153

6 Keddy, Karen H et al. The continuing challenge of infectious diseases. The Lancet Infectious Diseases, Volume 24, Issue 8, 800 - 801.

(TB), respiratory infections, diarrhoeal diseases, and a panoply of neglected infectious diseases (NIDs) have a devastating impact on individuals and communities and delay national economic development[7].

SSA is also at risk of emerging and re-emerging infections, such as Mpox, Ebola, Marburg, Lassa fever, Yellow fever and, most recently, SARS-CoV-2, which imperil global health security[8]. The alarming rise of antimicrobial resistance (AMR) is compromising available treatments and undermining multiple branches of medicine that rely on effective therapies for infection control. A high level of AMR burden for several bacterial pathogens and pathogen–drug combinations has been reported present in the WHO African region showing a higher AMR related mortality in lower resource settings[9]. Changing patterns of disease, driven by the climate crisis and environmental degradation, exacerbate these challenges.

Combatting infectious diseases is central to achieving SDG3, to ensure healthy lives and promote well-being for all at all ages. Furthermore, preventing and treating infections supports progress towards multiple other SDGs, by reducing the economic burden on countries, enhancing child development, promoting gender equity and the interests of populations with major unmet medical needs, and ensuring that healthier populations contribute to greater productivity and national prosperity.

Despite some progress, the Global Action Plan for Healthy Lives and Well-being for All, launched at the United Nations General Assembly (UNGA) in September 2019, noted that extra efforts would be required if health-related SDGs were to be met by 2030. It identified research and development (R&D) as a key accelerator of progress and emphasised the importance of global collaboration and alignment.

For infectious diseases predominantly affecting low- and middle-income countries (LMICs), limited commercial incentives exist to encourage the substantial investment required to develop and evaluate new vaccines, diagnostics, and treatments. Innovative models of collaboration to develop and evaluate new medicinal products are therefore required across public and private sectors, national governments, and regional and global agencies.

As a strategic partner, the EU seeks to enhance cooperation with Africa to promote actions targeted to finding solutions to challenges that are global in nature, yet often negatively impact Africa hardest, such as infectious diseases. The Comprehensive Strategy with Africa, the Global Approach to Research & Innovation and the AU-EU Innovation Agenda are the EU's most recent policy initiatives that prioritise research and innovation as a key dimension of sustainable development. Moreover, the new EU Global Health Strategy offers a framework for EU health policies leading up to 2030, setting policy priorities and guiding principles to shape global health, including by tackling infectious diseases, and recognises Global Health EDCTP3 as a key initiative for supporting the implementation of the strategy[10].

Initially set up in 2003, EDCTP has established itself as the focal point of clinical research cooperation for infectious diseases between the EU, European and SSA countries. The Global Health EDCTP3 work programmes for years 2022, 2023 and 2024 addressed several key aspects of the SRIA (GB Decision N° GH-EDTP3-GB/04/2022)[11].

Global Health EDCTP3 continues to build on and extend the platforms created by the EDCTP Association under the first and second EDCTP programmes, which contribute to the above-mentioned

[7] Ismahene Y. Infectious Diseases, Trade, and Economic Growth: a Panel Analysis of Developed and Developing Countries. J Knowl Econ. 2022;13(3):2547–83. doi: 10.1007/s13132-021-00811-z. Epub 2021 Jul 21.

[8] Moyo E, et al. Emerging infectious disease outbreaks in Sub-Saharan Africa: Learning from the past and present to be better prepared for future outbreaks. Front Public Health. 2023 May 9;11:1049986.

[9] Reference: Lancet Global Health, VOLUME 12, ISSUE 2 E201-E216, FEBRUARY 2024.

[10] EU Global Health Strategy: better health for all in a changing world

[11] The Global Health EDCTP3 Joint Undertaking Strategic Research and Innovation Agenda

policies. This work programme sets out the activities to be carried out in 2025, building on the activities supported so far and focuses on the following topics:

- Development of vaccines for reducing the disease burden of Tuberculosis in SSA.
- Research on existing Malaria therapeutics and clinical development of new antimalarial candidates.
- Accelerating the development of prophylactic vaccines against Neglected Tropical Diseases (NTDs) or otherwise referred to as Neglected Infectious Diseases (NIDs) in SSA.
- Tackling Diarrhoeal Diseases in the context of Climate and Health.
- Strengthening preparedness and response capacity in SSA, at the individual level through capacity building in epidemiology, biostatistics and modelling, and at the institutional level through the strengthening of the existing Networks of Excellence.
- Novel or emerging transformative innovations in global health.

It is also foreseen to directly reach out to the research and innovation community without launching a call for proposals in case of a public health emergency and for now EUR 1 million is set aside for this activity. This amount may be increased through contributions from the EDCTP Association or contributing partners, or by transferring funding from other topics, depending on the type and magnitude of public health emergency, and need for launching actions.

In addition, Global Health EDCTP3 supports an Africa Office to facilitate implementation of the Global Health EDCTP3 programme in SSA through a grant to identified beneficiary according to Financial Regulation Article 198(e) and Article 24(3) (a) of the Horizon Europe Regulation. The EDCTP Association Africa Office is the identified beneficiary to serve in this role.

All topics planned for this work programme support South-South and South-North networking. This is reflected in the obligation to have at least one partner from EU member states or countries associated to Horizon Europe and at least one partner from SSA countries that are members of the EDCTP Association.

1.3 Strategy for the implementation of the programme

To maximise the impact of the partnership, Global Health EDCTP3 focuses on strategically critical areas of unmet public health needs. Mechanisms are established to identify emerging priorities and opportunities. Global Health EDCTP3 issues annual calls for proposals that reflect specific current research needs for target diseases and research capacity development. Prioritisation is indicated in the SRIA and takes account of the following criteria:

- **State of the product development landscape:** For each disease area, the current state of clinical development of interventions for prevention (including vaccination), diagnosis, and treatment will be analysed.
- **Priority infections:** Priority setting is informed by analyses of disease burden, changing patterns of disease, contribution of a weakened immune system, extent of unmet medical needs, and the potential impact on a disease as a public health problem.
- **Disease burden and treatment/prevention priorities:** These analyses identify key knowledge gaps and need for new evidence.
- **Emerging opportunities of translational bottlenecks:** Global Health EDCTP3 focuses on points in the translational and implementation pathway that delay the clinical development and uptake of novel interventions, supporting effectiveness studies, pharmacovigilance, and product-focused implementation research as required.
- **Strategic engagement:** Committed to early engagement with the World Health Organization (WHO) and other strategically important international and African partners, Global Health EDCTP3

ensures global alignment of its policies and priorities and promote coordinated responses to evidence gaps and capacity-building needs.
- **Strategic portfolio:** Global Health EDCTP3 aims to develop and sustain a strategic portfolio across disease areas, types of intervention, and types of study. It balances short-term and long-term priorities and funding across targeted diseases, with a view to supporting research that is most likely to produce significant reductions in disease burden and overall mortality. In some areas, a portfolio approach is considered in prioritising and selecting different intervention candidates for funding.

Priority setting aims to balance the need for an over-arching framework to guide the work of Global Health EDCTP3 with the flexibility to respond to emerging opportunities and health challenges. This annual programme includes details of the specific calls for proposals for the year 2025.

On the side of launching calls for proposals, the focus for the year 2025 is to expand on the investments made in previous years, including the 2023 and 2024 work programmes, based on the programme's criteria for prioritisation of funding. The strategy process for developing the 2025 work programme was launched with discussions and a meeting of the Scientific Committee and the same approach is taken for developing the 2025 work programme. With the Stakeholders Group fully operational, their input has been sought at topic level given that members can apply to proposals, with no detailed information on the topics given. Dedicated consultations on specific areas are held in different formats, as appropriate. Outreach to prospective contributing partners is a continuous effort and this will be pursued in a portfolio approach.

Building on the initial topics for training networks and academia/industry fellowships under the 2023 and 2024 work programmes respectively, strategic planning of the training activities for the coming years should take place during the year, with involvement of the EDCTP Africa Office.

1.4 Contributions from the EDCTP Association and contributing partners

The EDCTP Association continues to plan for significant contributions through in-kind contributions to additional activities (IKAA) in 2025. The IT tools for planning and reporting of IKAA are now in place and have been utilised for the submission of the plans and reporting of incurred costs for years 2022-2024. The subsequent IKAA plans and reporting are expected to be submitted through the tools as well, and in accordance with the IKAA plan 2025 annexed to this Work Programme (Annex 4.2). The guidance for the certification was prepared during 2024. An IKAA certification model is therefore expected to be used for the first year in 2025 and tested with the EDCTP Association and its member countries accordingly.

Close interaction with the EDCTP Association will be maintained in 2025 to ensure timely planning of future IKAA activities, reporting and certification of the IKAA.

In 2025, contributions from contributing partners are foreseen in certain topics as described in Annex 4.1. Furthermore, discussions with various other contributing partners are at different stages of maturity and are planned to be concluded in time for contributions for the work programme 2026.

1.5 Preparing grant agreements – reporting from ongoing grants

All grant agreements for 2022 calls and single-stage calls of 2023 are signed. The grant agreements from the two-stage 2023 calls for proposals are being prepared for signature, working towards meeting the defined Time-To-Grant (TTG) deadline of 03 December 2024.

Following the outbreak of Mpox in the Democratic Republic of Congo (DRC), a call for proposals on Mpox was launched in May 2024. The grant agreements of the five main projects have been signed less than 2 months after the invitation letter was sent to the beneficiaries. On 13 August 2024, Africa CDC declared the mpox outbreak a Public Health Emergency of Continental Security (PHECS) and on 14 August 2024, the World Health Organization (WHO) declared a Public Health Emergency of International Concern (PHEIC). In parallel, the UK Department for Health and Social Care (DHSC) confirmed additional funding to support the four projects on the reserve list, which were invited to grant agreement preparation on 02 September 2024 and grant agreements are concluded.

The grant agreement preparation of the two-stage calls of 2024 will start at the end of 2024 and will be concluded in 2025. There will be only limited reporting from ongoing grants in 2024 and the related activities of checking the scientific and financial reports will become more substantial as of 2025.

2. Work Programme 2025

2.1 Message from the Executive Director and Executive Summary 2025

2.1.1 Message from the Executive Director

Dear colleagues, partners and friends,

I am delighted to present to you the Global Health EDCTP3 Work Programme 2025, the largest and most ambitious since the creation of the Joint Undertaking.

This fourth work programme is the result of our long-lasting and fruitful collaboration with the European Commission, the EDCTP Association and other strategic partners and I trust it reflects our shared goal of bringing new health solutions to sub-Saharan African populations and ensuring health security globally.

This work programme is also a statement of our commitment to continue supporting the priority areas set out in the SRIA and outlined in the AU-EU Innovation Agenda and in the EU Global Health Strategy, while adapting and responding to the needs of the ever-evolving global health agenda.

In 2025, Global Health EDCTP3 intends to launch four calls for proposals with a total indicative budget of EUR 214 million. This is our largest annual call budget so far and it reflects our ambition to become the leading research partnership on infectious diseases, addressing both specific disease areas and overarching global health challenges.

Our calls in 2025 will support a range of research and innovation actions (RIA) aimed at developing novel vaccines and therapeutics for tuberculosis, malaria and neglected tropical diseases. Additionally, coordination and support actions (CSA) strengthening the enabling environment for conducting clinical research in Africa will be funded at the individual level through fellowships in public health with emphasis on the areas of biostatistics, epidemiology, and modelling, as well as at the institutional level through regional networks of excellence for preparedness and response to outbreaks. The rapidly growing climate and health challenge will be addressed in a dedicated topic focused on tackling diarrhoeal diseases. On top, we aim to foster novel and emerging transformative innovations in global health developing interventions serving underserved populations or making them more affordable and accessible.

We will also explore new approaches and ways of collaboration to promote greater efficiency in 2025. We are considering running a pilot on lump sum contributions in the grant agreements for two call topics and will introduce more flexible ways of working with contributing partners in an effort to facilitate increased engagement with Global Health EDCTP3 and forge new and stronger partnerships.

2025 will also be a year of reunion. From 15 to 20 June, Global Health EDCTP3 and the EDCTP Association will jointly organise the Twelfth EDCTP Forum in Kigali, Rwanda, to be hosted by the Ministry of Health of Rwanda and the Rwanda Biomedical Centre. Over 1 000 delegates are expected to attend this biennial event under the theme 'Better health through global research partnerships'. The main Forum programme will include plenary sessions, parallel sessions, exhibition of posters, symposia, workshops, and various opportunities for discussion and collaboration. I warmly invite you to attend and hope to see many of you in Kigali!

The publication of this fourth work programme coincides with my first anniversary as Executive Director of Global Health EDCTP3. It has been an exciting and enriching year, and I am deeply grateful to the Programme Office team in Brussels for setting and running smoothly the operations of the Joint Undertaking, in addition to all colleagues and partners involved in our Governing Board, Scientific

Committee and Stakeholders Group for their invaluable contributions to the preparation of our Work Programme 2025.

I am convinced of the added value of Global Health EDCTP3 as a novel EU body with an International collaboration dimension, and I look forward to working with you through the exciting new activities, collaborations and partnerships that will materialise as a result of this work programme.

Dr Michael Makanga
Global Health EDCTP3 Executive Director

2.1.2 Executive Summary 2025

This is the fourth work programme under Global Health EDCTP3. The topics are based on the SRIA adopted by the Governing Board[12]. Under the work programme 2025 four calls for proposals are expected to be launched:

1. A two-stage call covering 3 topics for Research and Innovation Actions (RIA);
2. A two- stage call covering 1 topic for Coordination and Support Actions (CSA);
3. A two-stage call covering 1 topic for Coordination and Support Actions (CSA); and
4. A two-stage call covering 2 topics for Research and Innovation Actions (RIA).

With the following indicative budget:

Call	Budget (in million EUR)
Horizon-JU-GH-EDCTP3-2025-01-two-stage	122.7
Horizon-JU-GH-EDCTP3-2025-02-two-stage	6.7
Horizon-JU-GH-EDCTP3-2025-03-two-stage	40
Horizon-JU-GH-EDCTP3-2025-04-two-stage	44.6
Total	**214**

The work programme also foresees other actions, including: (a) a Grant to identified beneficiaries: Support for an Africa Office for EUR 3 million (b) expenditure related to experts carrying out monitoring of running actions for the Global Health EDCTP3 JU for EUR 1 million, (c) preparation and organisation of the EDCTP Forum for a maximum of EUR 1.1 million and (d) funding to be mobilised in case of a public health emergency for EUR 1 million.

The total operational budget 2025 covering those activities corresponds to **EUR 220.1 million** as detailed in section 3 of this document.

In the context of the Work Programme and Calls 2025, the JU is considering running a pilot of grant agreements under two topics, taking the form of lump sum actions as defined in the Decision of 7 July 2021 authorising the use of lump sum contributions under the Horizon Europe Programme – the Framework Programme for Research and Innovation (2021-2027) – and in actions under the Research and Training Programme of the European Atomic Energy Community (2021-2025). This decision is

[12] The Global Health EDCTP3 Joint Undertaking Strategic Research and Innovation Agenda

available on the Funding and Tenders Portal, in the reference documents section for Horizon Europe, under 'Simplified costs decisions' or through this link: ls-decision_he_en.pdf (europa.eu).

2.2 Operational activities of Global Health EDCTP3 for 2025

2.2.1 Objectives, indicators and risks

Global Health EDCTP3 JU Objectives	Indicators
To advance development and use of new or improved health technologies for tackling infectious diseases by supporting the conduct of the clinical trials, in SSA	# of calls launched # projects funded € invested in RIA
To strengthen research and innovation capacity and the national health research systems in SSA for tackling infectious diseases	# of calls launched # projects funded € invested in CSA
To facilitate better alignment of Member States, associated countries and sub-Saharan countries around a common Strategic Research and Innovation Agenda in the field of global health to increase the cost-effectiveness of European public investment	# of in-kind contributions to additional activities (IKAA) included in annual work plan € invested by countries on IKAA
To strengthen capacity in SSA for epidemic preparedness through effective and rapid research response to develop essential diagnostics, vaccines and therapeutics for early detection and control of emerging diseases of epidemic potential	# of calls launched # projects funded € invested in RIA & CSA
To promote productive and sustainable networking and partnerships in the area of global health research building North–South and South–South relationships with multiple private and public-sector organisations	# of joint calls with Contributing partners # projects funded by Contributing partners € invested by Contributing partners

Risks
Risk management is a proactive process for identifying and assessing any event that could pose a threat to the achievement of the Global Health EDCTP3 objectives and determining how the corresponding risks should be managed. Therefore, risks management is an integral element of the strategic planning and monitoring cycle.

In order to control the risks identified, the Programme Office ensures their monitoring and continuous reviewing, considering the corresponding mitigating measures identified and taking further actions where necessary to ensure controls remain effective. Relevant Global Health EDCTP3 financial needs and the budget for 2025 have also been appropriately estimated. The staff is regularly informed on the objectives, activities and new planning.

2.2.2 Scientific priorities, challenges and expected impacts

Despite much progress, infections such as HIV, TB, malaria, respiratory infections, diarrhoeal diseases, and other poverty-related and neglected infectious diseases, are still responsible for a high burden of disease in SSA[13]. Besides their impact on individuals, infectious diseases impose a high economic burden on countries, impeding national development. The COVID-19 pandemic has shown that new infectious threats may appear and that, with the increased connectivity of different regions in the world, can spread rapidly and significantly impact the world. Developing health technologies for the identification, treatment and prevention of poverty-related and neglected infectious diseases is therefore crucial to control these diseases, as well as to fight them once they have spread, protecting the health of citizens in the countries expected to be disproportionally affected (such as SSA) and in the European Union.

Global Health EDCTP3 works towards achieving scientific priorities related to implementation of clinical research to develop health technologies to prevent, detect and treat infectious diseases, as well as enhancing research and innovation coordination, supporting the training of SSA researchers and building strategic partnerships.

These investments will result in specific outputs and results, such as an increased number of new or improved health technologies and better use in SSA, stronger research and innovation capacity in SSA, an increased cost-effectiveness of European public investment and strengthened sustainable global health networks.

The long-term impacts of Global Health EDCTP3 are expected to reduce the socio-economic burden of infectious diseases in SSA and increase health security in SSA and globally.

2.2.3 Calls for proposals 2025 and other actions not subject to call for proposals

Described in Annex 4.1 to the Work Programme 2025.

2.2.4 Monitoring, Evaluation, and Impact Assessment

To support the Monitoring & Evaluation (M&E) activities of Global Health EDCTP3, a full-time M&E Officer was appointed in September 2024. This role is focused on developing and implementing the M&E framework that will track progress towards JU objectives using technically sound indicators and robust data. The M&E framework will consist of the following key components:

1. **Programme Logic:** This will visually map how Global Health EDCTP3 plans to achieve its objectives, detailing the relationships between activities, outputs, outcomes, and impact. It will also specify the external conditions (assumptions) necessary for these links to function. The Programme Logic will serve as the backbone of the M&E system by specifying which results are expected and when they should occur, guiding the progress tracking accordingly.
2. **Indicator List:** This list will measure the completion of activities and achievement of results at various levels (outputs, outcomes, impact) as outlined in the Programme Logic. It will include indicators mandated by Horizon Europe, following Annex V of Regulation 2021/695 and Article 171 of Council Regulation 2021/2085. The list will also integrate indicators jointly used across JUs, as well as indicators already in use within Global Health EDCTP3 JU. New indicators will be added as needed, to address any gaps.

[13] The state of health in the WHO African Region: an analysis of the status of health, health services and health systems in the context of the Sustainable Development Goals. Brazzaville: WHO Regional Oce for Africa; 2018. Licence: CC BY-NC-SA 3.0 IGO.

3. **M&E Plan:** The plan will define data collection methods for each indicator, assign roles and responsibilities, set measurement frequencies, and outline reporting procedures.
4. **Interactive Dashboard:** A tool will be developed to allow users to combine and filter indicator data by various subgroups.

The Programme logic, indicator list and M&E plan will be finalised in Q2 2025 and used for reporting in the 2024 Annual Activity Report. Development of the dashboard will begin in Q3 2025 following an AGILE approach, with a first version ready by Q4 2025.

2.3 Support to operations of the Global Health EDCTP3 Joint Undertaking

2.3.1 Back-office arrangements (BOA)

According to Article 13 of Council Regulation 2021/2085 establishing the Joint Undertakings under Horizon Europe[14], the JUs under Horizon Europe shall achieve synergies via the establishment of back-office arrangements operating in some identified areas. The Council Regulation also underlines that these synergies should be implemented where screening of resources has proved to be efficient and cost effective, while respecting the autonomy and the responsibility of each Authorising Officer.

The back-office arrangements "*shall be provided by one or more selected joint undertakings to all others. Interrelated arrangements shall be kept within the same joint undertaking to the extent appropriate for efficient and effective implementation of the tasks concerned in order to ensure a coherent organisational structure*".

Accounting
The Accounting Officer function for the JUs established under Horizon 2020 was provided in a fully centralised manner by the Budget department of the European Commission (DG BUDG). Due to resource constraints, the service is no longer provided since 1 December 2022 and a new solution had to be found for the JUs established under Horizon Europe.

Thus, the accounting function was the first area where back-office arrangements have been implemented. Global Health EDCTP3 signed the service-level agreement (SLA) to join the accounting function provided under the lead of the Europe's Rail JU. The accounting officer in the back-office arrangement for accounting was nominated by the Governing Board in preparation for financial autonomy and will prepare the accounts of Global Health EDCTP3. An accounting correspondent in Global Health EDCTP3 is also nominated to interact closely with the accounting officer.

A procurement was concluded in 2023 to provide accounting services via an external contractor for the annual audit of the JU's statutory accounts, as well as consulting services related to accounting and financial management. The services of these companies will be used in 2025 and onwards to support the annual audit of the JU's accounts and for in-house work on the annual accounts and the financial management of the JU.

[14] Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014

Human resources (HR)
Article 13 of the Council Regulation 2021/2085 establishing the Joint Undertakings under Horizon Europe[15] identifies human resources (HR) support among the areas where common back-office arrangements can be set up. The HR domain is a sensitive area for all JUs, where confidentiality is a key building block of effective HR policies and for staff management, considering the strategic objectives to be achieved. It is therefore welcome that the legislator focuses on the support area of HR where synergies can be achieved without impacting HR policies that must remain under the remit of the JU and ultimately under the responsibility of each Executive Director as appointing authority.

For what concerns the HR domain, the JUs explore synergies in different areas, such as:

- **Recruitment**: establishment of common recruitment procedures, mapping of procedures, sharing of the recruitment IT tool, etc.
- **Legal framework**: common HR strategies, shared networks of confidential counsellors, etc.
- **Digitalisation**: harmonisation of IT tools, shared practices, possibly obtaining a single contract for all JUs, etc.

These synergies aim to achieve a better harmonisation among the JUs, exploiting best practices, achieving efficiency gains and economy of scale.

Since the back-office arrangement for HR is implemented and from 2023, Global Health EDCTP3 carried out the recruitment for the budget officer position jointly with the Clean Hydrogen JU. It is expected that this practice of creating joint reserve lists will continue in 2025. Also, JUs open reserve lists to each other. Again, already since 2023, Global Health EDCTP3 benefited from getting access to a reserve list from other JUs and provided access to some of its reserve lists. More strategic use of joint recruitments for common functions will be pursued in 2025.

Procurement
Centralised administrative procurement capability and process to maximise open tenders for award of inter-JUs framework contracts and middle value negotiated procedures with focus on the critical joint administrative procurement is being set up. In accordance with the Council Regulation and the back-office arrangements, Global Health EDCTP3 will continue to develop synergies and efficiencies in procurement related activities with other JUs. In this regard, a Service Level Agreement for Procurement Services ("BOA Procurement") has been signed between Global Health EDCTP3 and other JUs, and a joint bi-annual procurement plan has been drafted for endorsement by the end of 2024. In particular, common procurements in the areas of Data Protection and Communication activities (new framework contract (FWC) for organisation of events, digital publications and newsletters, etc.) have been carried out in 2024 and are expected to be finalised in 2025. For more information on the BOA procurement activities please see below section 2.3.3).

Information and communication technologies (IT)
The goal is to achieve economies of scale such as the purchase of joint licenses to the extent that this will be possible in each individual case. The deployment of IT solutions will be synchronised and experiences across JUs will be leveraged. The goal is to arrive at a flexible solution by appropriately managing quotas and ceilings in joint procurements. The IT management and administrative follow-up will be simplified.

[15] Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014

The back-office arrangements should also lead to improved business continuity with effective back up and overcoming redundancies. The back-office arrangements can also provide the framework for building a common and standardised approach/method for reporting on common Horizon Europe KPIs, as well as leveraging common tools for database management and data visualisation (e.g., PowerBI).

The back-office ICT working arrangements will be settled in the form of an SLA that is expected to be finalised by the end of 2024, which shall formalise and clarify the mandate(s), roles and responsibilities, as well as establish criteria for repartition of costs. Even if the BOA for IT hasn't been formalised yet, the JUs are already collaborating in many distinctive areas and continued to monitor common IT strategy in 2025. Following the signature of the SLA, the BOA IT should be fully implemented from 2025 and onwards.

2.3.2 Communication, dissemination and exploitation

In 2025, all communication activities will be implemented in alignment with the newly launched Global Health EDCTP3 communication and brand strategies and will focus on the promotion of the 2025 calls for proposals, the promotion of activities and results from grants signed under work programmes 2022-2024, the promotion of other activities carried out by Global Health EDCTP3, such as contributions to events and meetings or the activities of the members of the JU, and the organisation of the Twelfth EDCTP Forum.

With the launch of the 2025 calls, coordinated communication activities will be undertaken to ensure that a broad range of relevant stakeholders learn about the new funding opportunities. Info-day sessions to give details on the calls for proposals will be organised and social media activities will be launched. These events and activities will focus on both scientific content and administrative aspects, so that applicants have a good understanding of the specific requirements and conditions of the Global Health EDCTP3 calls. This is done to ensure that Global Health EDCTP3 attracts the broadest possible range of relevant applicants and involves partners at all levels to achieve its goals. In this context, to also reach Franco/Lusophone countries, it is planned to organise info day sessions in French. For providing information in Portuguese, collaboration with the Portuguese member of the EDCTP Association will be sought.

Particular attention will be paid to have good understanding amongst applicants and grantees about the legal obligation to ensure affordable access and how this is translated into contractual obligations for relevant grants and reports, as applicable, as well as the role of scientific project leaders, a novelty under Global Health EDCTP3 compared to EDCTP2. In order to reach out to regional stakeholders, and especially potential applicants in SSA countries, the EDCTP Africa Office will support the activities undertaken by Global Health EDCTP3.

As strategic discussions and actions are carried out with contributing partners, for example, these will be supported by relevant communication activities.

The Twelfth EDCTP Forum will take place in Kigali, Rwanda from 15-20 June 2025. About 1,000 participants are expected to attend the event, including representatives from research institutions and universities, the larger scientific community, health care providers, governments, regional bodies, regulators, civil society, and public and private research and development partners. Global Health EDCTP3 will actively promote the event and opportunities for participation, such as sponsorship and the submission of scientific abstracts, applications for scientific symposia, and prize nominations through its communication channels. A dedicated website will be created for the event.

As relevant and appropriate, Global Health EDCTP3 will contribute to exploiting and disseminating results from its predecessor programmes. This can occur by selecting follow-on grants that build on results from previous EDCTP programmes, where applicable, and/or by collaborating with the EDCTP Association Secretariat on the organisation of events, workshops and presenting on the results and impact of the EDCTP programmes at conferences and meetings. Synergies in exploitation and dissemination are particularly relevant in the reach-out to countries in SSA and in Europe.

Throughout 2025, work will continue to further enhance and maintain the new Global Health EDCTP website, especially when it comes to building a robust projects area.

Moreover, the key activities and results of Global Health EDCTP3 will be promoted via the monthly newsletter and on social media, especially LinkedIn where Global Health EDCTP3 has more than 11,000 followers.

2.3.3 Procurement and contracts

The Governing Board adopted its decision GB/10/2023 on 3 August 2023 approving the principle of back-office arrangements between joint undertakings on procurement. Prior to that, the interim Executive Director had signed an SLA with several other JUs setting out the frame and conditions for this arrangement, as mentioned in the section 2.3.1 above. Clean Aviation JU acts as the lead JU in this context, coordinating the back-office arrangement and providing services to other JUs. Its Executive Director is responsible for the organisation, oversight and coordination including reporting. It is supported for this purpose by the Europe's Rail and EuroHPC JUs. This arrangement enables the JUs to carry out common procurement procedures. Such synergies imply that Global Health EDCTP3 may save substantial human resources as its staff in charge of procurement may often rely on a common procedure led by the Clean Aviation JU instead of launching its own. In addition, financial savings are also expected given that the contracts to be awarded relate to larger needs, which are pooled between JUs. This arrangement has already proved efficient, and it is expected that it will be used for most of the procurement needs of Global Health EDCTP3 in the future.

The IT and procurement management tool PPMT that has been developed by the Joint Research Centre will be the main tool to be used in procurement procedures in 2025.

For instance, SLAs are in place with DG Human Resources for several services (such as medical service). Within the frame of the SLA, more detailed arrangements have been put in place for the use of the human resources management system (SYSPER), etc.

Furthermore, an agreement with the paymaster office of the European Commission (PMO) has been signed in relation to experts and their payment and with DG DIGIT for the provision of IT support services and the participation of the JU in the ICT framework contracts. An SLA with the Secretariat General for the provision of HAN service (archiving) has been also concluded and an SLA has also been concluded with DG BUDG regarding the use of the ABAC system and treasury services.

In 2025, Global Health EDCTP3 will generally also seek to join existing framework contracts or common procedures managed by the European Commission or EU agencies, as it did since Its financial autonomy in 2024. No major procurement activities of Global Health EDCTP3 on its own are planned at this point for 2025.

2.3.4 Information Technology

With regards to Information Technology, the main objectives of Global Health EDCTP3 in 2025 are to:

- Fine-tune the Global Health EDCTP3 IT infrastructure and finalise any remaining items of the IT autonomy from the European Commission.
- Strengthen further the collaboration with the other JUs through the back-office arrangements on IT.
- Define the data architecture and support the Monitoring and Evaluation framework from a technical IT perspective.
- Take the necessary steps to implement the new EU cybersecurity regulation.
- Adopt the JU's specific IT Strategy for IT hardware and Software purchase, assets management, M365 assets implementation with digitalisation and process simplification, and Cybersecurity.
- Setting up the network infrastructure and moving to the new Global Health EDCTP3 premises.

Following the year 2024 and IT autonomy, several pre-conditions have been fulfilled in order to implement the JU IT autonomy, like setting up new website https://www.global-health-edctp3.europa.eu/ and email addresses @global-health-edctp3.europa.eu and obtaining from DG DIGIT new EU Login(s) for the staff. As such, by end of 2024 the JU would proceed to setup new laptops with the new accounts and handover them to the staff, as well as migrate existing staff roles in corporate IT systems like HAN/ARES for document management, SyGMa/Compass & eExperts for managing grants, HR systems, ABAC, etc. To allow digital signature of contracts with the external world, digital certificates will need to be purchased and set up. The confirmation of successful IT migration, final tests and back-up plan would be implemented by end-of-Q1 2025, when it is expected to release all EC IT equipment back to DG DIGIT services.

In alignment with the practices of the other JUs, Global Health EDCTP3 will be part of the implementation of the next-generation secured network with the European Commission (also known as S-Testa) and from a connectivity perspective the JU will continue to on-board telecommunication services and integrate them with Microsoft 365 in 2025.

In the broader context of the back-office arrangements on IT, Global Health EDCTP3 will collaborate with the other JUs in the fields of shared IT infrastructure, inter-JU IT governance, IT framework contracts, tools and services and Security and compliance management.

To ensure safe and FAIR (findable, accessible, interoperable, reusable) collection of data and results of projects funded by Global Health EDCTP3, the JU will define a data architecture and start the implementation of a data warehouse. The new data warehouse will allow user-friendly retrieval of information for the staff, to communicate and disseminate information easily and with transparency. Additionally, various possibilities for tracking of publications funded by Global Health EDCTP3 and related analyses will be further investigated.

In order to foster collaboration and information sharing among staff, as well as easy access to data, reporting and systems, a private secured Intranet will be created.

The replacement of the corporate accounting system ABAC with SUMMA is expected to occur either in 2026 or 2027 and the JU will need to prepare the necessary steps to ensure a smooth transition to SUMMA. However, by 1 January 2025, the SUMMA Business Partner module (replacing the ABAC LEF/BAF monitoring for the vendor and customer accounts) will be implemented. IT and financial colleagues have been trained accordingly in 2024 for smooth implementation from 2025 and onwards.

In 2025, the JU will also move to its new premises located on the second floor of the White Atrium building. In this respect, IT hardware preparation and set up is expected to start as of December 2024. The JU will set-up new offices for all its staff, new meeting rooms for internal use and external stakeholders, including a new Board room. With most of the meetings with external participants being

conducted via teleconference, the JU office new meeting rooms will therefore be equipped with the necessary video-conference equipment.

Global Health EDCTP3 will continue working to align with the corporate requirements in terms of cybersecurity and data protection. In addition to the BOA IT common JU's IT strategy, Global Health EDCTP3 is planning to develop its own strategy for aspects specific to its Information Systems Internal management in 2025.

Further, the JU will take the necessary steps to implement effective record management, covering both electronic and physical records. The record management implementation will contribute to meet our transparency and accountability obligations as well as ensure evidence of the Global Health EDCTP3 activities and retention of its legacy.

2.3.5 Data protection and access to documents

Regarding data protection, Global Health EDCTP3 will continue its work towards finalising the setting up its data protection framework to ensure compliance with Regulation No 2018/1725 laying down data protection obligations for the EU institutions and bodies when processing personal data. Global Health EDCTP3 is liaising with the relevant services of the European Data Protection Supervisor and contributing to the activities of the inter-institutional data protection networks to raise awareness among the staff and stakeholders.

The role of the Data Protection Officer (DPO) is exercised by a Legal Officer of Global Health EDCTP3, assisted by an external contractor. Global Health EDCTP3, as a controller, maintains a record of processing activities under its responsibility in a register and makes this register publicly accessible. In addition, Global Health EDCTP3 takes appropriate measures to provide transparent information, communication and modalities for the exercise of the rights of the data subject. A collection of privacy notices is available in the JU's website. More information is available on the Global Health EDCTP3 JU data protection and legal notices pages[16]. In accordance with the Council Regulation and the back-office arrangements, Global Health EDCTP3 will continue to develop synergies and efficiencies in data protection related activities with other Joint Undertakings, as in 2024, regarding the development of an on-line central register (FWC lead by Europe's Rail JU in which Global Health EDCTP3 participates) and the support by external contractors on data protection services (FWC lead by SESAR JU in which Global Health EDCT3 participates).

Regarding access to documents, Global Health EDCTP3 will address any requests for access to documents according to Regulation No 1049/2001, in a spirit of openness and transparency, in order to bring its activities and outputs closer to the public by giving the opportunity to the public to monitor its work.

2.3.6 Other support operations

As already mentioned above, Global Health EDCTP3 will use existing arrangements amongst the JUs established under Horizon Europe, such as in the areas of IT, HR and procurement. Additional areas for collaboration through back-office arrangements will be explored.

Global Health EDCTP3 will continue to use the Horizon Europe corporate IT tools for encoding work programme call topics for publication to submission of proposals through evaluation, grant preparation and grant management and follow-up (eGrants suite of online tools). The reimbursement of evaluation

16 https://globalhealth-edctp3.eu/legal-notice-and-privacy

experts will continue to be handled by the Research Executive Agency (REA) as part of the use of the Horizon Europe IT tools. Some training may be required in view of the planned migration to SUMMA, which will impact also on the tool for selecting and contracting evaluation experts.

It is planned to use the AGM tool of the Paymasters Office of the European Commission to reimburse ad-hoc experts by the beginning of 2025. The use of the tool is already covered by the SLA in place.

In addition to collaborating through back-office arrangements as explained above, the JUs also work together informally at all levels of the organisations: Executive Directors, Heads of Unit of Administration and Finance, IT Officers, HR Officers, Scientific Project Officers, etc.

As several other JUs, Global Health EDCTP3 will continue to participate into the EU Agencies Network (EUAN) which provides support and information sharing on relevant matters, such as HR.

Global Health EDCTP3 will move to its new premises located on the second floor of the White Atrium building, on the basis of a new rental contract directly signed with the owner of the building, starting from 1 October 2024. Works are planned for setting up the new offices between October and December 2024. These new offices will fully accommodate the needs of the Programme Office in terms of staff number and meeting facilities.

2.3.7 Human resources (HR)

2.3.7.1 HR Management

The objective of the Global Health EDCTP3 JU's HR function is to enable the organisation to achieve its overall goals, through the optimisation of its resources. Specifically, HR focuses on attracting, developing, motivating, and retaining talent, while ensuring compliance with the Staff Regulations and HR Implementing Rules.

Key achievements in 2024
In 2024, 12 statutory staff members joined Global Health EDCTP3. The management team was completed by the recruitment and onboarding of the Head of Administration and Finance, the Head of Operations and the Strategic Partnerships and Communications Team Leader, ensuring the JU's stability, direction, and the capacity to achieve strategic goals. The use of 4 temporary resources (Interim staff) was necessary to provide administrative support in different organisational areas: Finance, Operations and Communications.

HR IT tools, including the Systal and Sysper modules which will allow the JU to improve the selection process, were onboarded.

The first learning and development framework was adopted, covering the initial staff training and development needs specific to Global Health EDCTP3.

The first performance management cycle, in which individual performance and development goals are defined, monitored and evaluated was carried out with the organisation of the first annual objectives, appraisal and annual reclassification exercises.

Organising a first JU team building allowed the JU to strengthen relationships, work on a common work vision and values, improve communication, and boost morale among the management team and staff.

Key objectives for 2025

By the end of 2025, Global Health EDCTP3 will have achieved the targeted level of staffing and completed the implementation of HR policies and processes, in order to fulfil its mandate.

In view of the above-mentioned objectives, the HR staff will focus on the following activities:

1. **Talent Acquisition and Recruitment** will continue to be a key element as Global Health EDCTP3 will continue to grow. The JU will identify profiles for which new reserve lists will be established and will conduct recruitment procedures accordingly.
2. Implement a **multiannual strategic plan for HR**, which will address important strategic choices regarding staffing needs and the internal division of responsibilities. The plan will be implemented in 2025 and beyond, and will be reviewed periodically to ensure alignment with Global Health EDCTP3 operational goals.
3. Continue to adopt relevant **HR policies and implementing rules** (e.g. prevention of harassment) to further develop the legal framework applicable to staff.
4. Boost **organisational development**: Global Health EDCTP3 will develop a corporate culture that is in line with its operational objectives and commonly agreed vision and values, and an internal organisation that fosters efficiency, effectiveness and collaboration.
5. **Staff Development and Training:** HR will roll out the learning and development programme for 2025, offering training opportunities to help staff fully develop their potential and contribute at their best. To further tailor the training available to Global Health EDCTP3, the HR team will carry-out a training needs analysis at the beginning of 2025 and further develop targeted courses and workshops.
6. **Monitoring and reporting:** In order to ensure a smooth management of HR activities, Global Health EDCTP3 will investigate the possibility of either developing internal HR reporting tools or acquiring existing tools in the market or from other JUs or EU Institutions.
7. **Employee Engagement and Retention:** the first staff engagement survey will be launched early 2025 to assess overall satisfaction working at Global Health EDCTP3. The objective will be to create a positive work environment that fosters employee satisfaction, motivation, and loyalty, preventing turnover rates. Measures to ensure staff wellbeing and non-discrimination will be implemented.
8. To optimise the working relationship between employees and employer, HR will actively continue to engage with the staff committee.

2.3.7.2 Strategy for achieving efficiency gains, synergies through back office arrangements

According to Council Regulation (EU) 2021/2085, JUs shall achieve synergies via the establishment of back-office arrangements operating in some identified areas.

Article 13 identifies Human Resources Support among the areas where common BOA can be set up. In that respect, CBE JU expressed its willingness to be the lead JU for the BOA HR with IHI JU as back-up JU.

The BOA HR will implement actions in three main areas of HR Support: recruitment, HR legal framework and HR digitalisation. Its objective is to maximise synergies among the JU's, harmonise procedures by valorising best practices, ensure coherent HR support services, achieve efficiencies and economies of scale, increase the negotiation power of JU's operating under the SBA towards contractors and service providers.

The JUs established under Council Regulation (EU) 2021/2085 will contribute to BOA HR Support together with EuroHPC and SESARJU that will participate on specific initiatives in line with their internal priorities and according to their own specificities.

Scope of the BOA HR support
In line with the proposal of an enhanced coordination of the Network of JUs' HR officers, the conclusion of a Service Level Agreement (SLA) among the JU's has been deemed necessary since a clear commitment to the execution of the BOA HR Annual Work Plans must be made by the JUs under the coordination of the Lead JU.

The actual implementation of the BOA HR which started in 2024 and will continue in 2025 focuses on three predefined areas of HR support:

Recruitment

- **Alignment and harmonisation of the JUs' recruitment processes:** The JUs will finalise the work started in 2024 on the best practices by establishing a common selection process based on the existing relevant legal framework. This common selection process will then be applied across all JUs when launching a selection procedure. This project will include for example the creation of common templates, scoring guides, platforms and tools that will provide a consolidated ground for individual and common selection procedures and recruitments.
- **Organisation of joint selection procedures:** In order to increase efficiency gains the JUs will organise as much as possible joint selection procedures for common profiles with same grades. This practice is already in place but will continue in 2025.
- **Establishment and sharing of reserve lists/ job profiles library:** The JUs will continue to share their reserve lists to shorten their recruitment processes and time-to-recruit and will start to work on the harmonisation of job profiles.

HR legal framework
The JUs share a common legal framework in the HR domain, therefore, additional synergies can be achieved by enhancing the existing collaboration in this area. The focus in 2025 will be on:

- **Inter-JU network of Confidential Counsellors (CCs):** currently the JUs share a common network of confidential counsellors and regularly organise joint calls for expression of interest to expand the network. Training, information campaigns and joint actions are also organised to promote the JUs' staff well-being and raise awareness on psychological and sexual harassment and to prevent interpersonal conflicts. A new inter-JU call for expression of interest will be launched in order to replace the Confidential Counsellors who will depart due to the end of their mandates. New training sessions will be provided both to the Confidential Counsellors but also to staff members on this matter. In the context of the HR BOA, the JUs will also promote the visibility of mediation services by organising an information campaign for all JU staff;
- **Collaboration with the EU Agencies Network (EUAN) and the European Commission:** the JUs will continue to attend EUAN meetings including possible ad-hoc participation of the HR Officers to different working groups. The JUs will continue to liaise with DG HR /PMO about common HR matters and seek advice for specific topics;
- **Inter JUs' HR Officers network:** The JUs' HR Officers will continue to meet bi-weekly to share best practices and also provide support to the newly established JUs. To this purpose, a common

collaborative platform was created (Teams) to facilitate the interactions between HR Officers, the exchange of information and documents.

HR digitalisation
In 2025, the JUs will continue to move towards a digitalisation of HR processes and will work on the harmonisation of their IT systems in the HR area.

The inter-JU HR Officers will continue to share good practices in the use of their IT systems and will continue to actively take part in the HR Transformation programme led by the European Commission, notably by contributing to the projects of the second wave (2024-2025).

The JUs will implement the actions defined in the 2025 BOA HR Annual Work Plan and more specifically the following projects:

- Alignment and harmonisation of practice for selection and recruitment procedures
- Develop an inter JU Competency Framework;
- Identify the common recruitments for 2025 and shared reserve lists;
- Continuation of the 2024 actions.

2.3.7.3 Staff establishment plan

Function group and grade	2024				2025-2027*	
	Authorised budget 2024		Actually filled at 31/12/2024		Authorised budget*	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts
AD14	0	1	0	1	0	1
AD12	0	2	0	2	0	2
AD11	0	1	0	1	0	1
AD8	0	7	0	3	0	7
AD7	0	4	0	4	0	4
AD6	0	7	0	7	0	7
AD5	0	1	0	1	0	1
Total AD	**0**	**23**	**0**	**19**	**0**	**23**
AST5	0	1	0	1	0	1
AST4	0	1	0	1	0	1
AST3	0	1	0	1	0	1
Total AST	**0**	**3**	**0**	**3**	**0**	**3**
Total AD+AST	0	26	0	22	0	26
Total staff (incl. CA)	0	**34**	0	**29**	0	**34**

Contract Agents	FTE corresponding to the authorised budget 2024	Headcount at 31/12/2024	FTE corresponding to the authorised budget 2025 -2027*
FGIV	4	4	4
FGIII	4	3	4
Total	**8**	**7**	**8**

**Adjustments to the staffing level may be decided by Corporate Management Board after considering the budgetary top-ups by third country credits and other aspects.*

2.4 Governance activities

Following the successful establishment of Global Health EDCTP3, its governance, advisory and consultation bodies have also been set up and are fully operational.

According to the relevant provisions of the Council Regulation establishing the JUs under Horizon Europe, the bodies of Global Health EDCTP3 are:

- Governing Board
- Executive Director
- Scientific Committee
- Stakeholders Group.

2.4.1 Governing Board

The Governing Board is the decision-making body of Global Health EDCTP3. It has the overall responsibility for the strategic orientation, coherence with the relevant European Union objectives and policies and operations of the JU and supervises the implementation of its activities.

The Governing Board of Global Health EDCTP3 is composed of six representatives of the European Commission on behalf of the European Union and six representatives of the EDCTP Association on behalf of the African and European countries participating in the programme. It shall hold ordinary meetings at least twice a year, whereas extraordinary meetings may be convened at the request of the Chairperson, the Executive Director, the European Commission or the EDCTP Association. The meetings of the Governing Board are convened by the Chairperson. The agenda of the meetings and the decisions taken are made publicly available on the website of Global Health EDCTP3.

In 2025, it is foreseen that the Governing Board will hold three meetings, focusing on the strategic priorities and implementation of the activities of Global Health EDCTP3.

Further important decisions may be adopted via written procedures which are launched by the Executive Director on behalf of the Chairperson of the Governing Board.

2.4.2 Executive Director

The Executive Director is the chief executive responsible for the day-to-day management of the JU. The Executive Director is the legal representative of Global Health EDCTP3 and is accountable to the Governing Board. He is supported in his activities by the Programme Office staff of the JU.

The initial mandate of the current Executive Director, Dr Michael Makanga, started in 2023 for a period of four years until 15 November 2027.

2.4.3 Scientific Committee

The Scientific Committee is the scientific advisory body of Global Health EDCTP3.

During 2025, the Scientific Committee will continue its important work of providing input on the scientific priorities to be addressed and the scope of the calls for proposals. The Scientific Committee is also consulted on the additional activities plan (AAP).

In line with the Council Regulation establishing the JUs under Horizon Europe, the Chairperson shall prepare a report after each meeting of the Scientific Committee and submit it to the Governing Board.

For 2025, three meetings of the Scientific Committee are planned.

2.4.4 Stakeholders Group

The Stakeholders Group of Global Health EDCTP3 will actively provide input on the scientific, strategic and the technological priorities to be addressed by the JU as laid down in the SRIA taking into account the progress and needs of the Global Health and adjacent sectors.

As foreseen in the Council Regulation 2021/2085 establishing the JUs under Horizon Europe, the Executive Director may advise the Governing Board to consult the Stakeholders Group on specific issues. Where such consultation takes place, a report shall be submitted to the Governing Board after the relevant discussion within the Stakeholders Group and will be published on the website of the JU.

During 2025, three meetings for the Stakeholders Group are planned.

When the occasion arises, a joint meeting of the Scientific Committee and the Stakeholders Group may be held.

2.5 Strategy and plans for the organisational management and internal control systems

The Global Health EDCTP3 Internal Control Framework (ICF) was adopted by the Governing Board in August 2023 (Decision GH-EDCTP3-GB/11/2023). The Global Health EDCTP3 Internal Control Framework is based on the framework adopted by the European Commission that consists of five internal control components and 17 principles based on the COSO 2013 Internal Control-Integrated Framework.

The priority objective for 2025 remains to implement and maintain an effective internal control system so that reasonable assurance can be given that resources assigned to the activities are used according to the principle of sound financial management and control procedures in place give the necessary guarantees concerning the legality and regularity of transactions.

In Q1 2025, Global Health EDCTP3 will perform the annual self-assessment exercise to understand if all principles are present and functioning. The results of the ICF self-assessment will be presented in the Global Health EDCTP3 2024 Consolidated Annual Activity Report (CAAR).

2.5.1 Financial procedures

The Global Health EDCTP3 Financial Rules were adopted by the Governing Board by decision GH-EDCTP3-GB/22/2022. The workflows in place follow the financial rules, as adopted via the GB Decision abovementioned. The financial circuits are established to standardise the mandatory steps of the processing of financial transactions and to clarify who are the different actors and their responsibilities (administrative and operational expenditure). The financial circuits were adopted by the interim Executive Director by decision GH-EDCTP3-ED/21/2023. After the financial autonomy, the financial circuits were updated on 4 July 2024 by decision GH-EDCTP3-ED/18/2024.

Financial procedures in the JU are also based on the controls embedded in Commission tools. In Horizon Europe, reporting and validation of costs (including evaluation experts) is implemented using the European Commission IT tools (SyGMa, COMPASS, ECS). In accounting, the controls are implemented using the accounting system ABAC.

2.5.2 Ex-ante and ex-post controls

The purpose of **ex-ante controls** is to ascertain that the expenditure is in order and complies with the provisions applicable and the principle of sound financial management has been applied. Monitoring will be ensured through indicators such as time to pay and budget implementation amongst others.

Ex-ante controls for Horizon Europe programme are implemented using the tools and methods developed by the European Commission.

Ex-post controls are an important tool to support management's assurance on the achievement of the financial management and internal control objectives.

Ex-post controls of operational expenditure will continue to be implemented in line with the Audit Strategy of Horizon Europe which is an integral part of the overall Horizon Europe Control Framework. The Common Audit Service of the Common Implementation Centre of the Research & Innovation Directorate of the European Commission carries out all audits for Global Health EDCTP3 (internally or outsourced to external firms) for Horizon Europe. At this stage, no ex-post audits for Global Health EDCTP3 have yet been identified.

During 2025, the JU will continue to work with the Research and Innovation (R&I) family to implement the control strategy (ex-ante and ex-post) for the Horizon Europe programme.

2.5.3 Risk Assessment and Management

The risk assessment methodology aims to identify the main risks in achieving the objectives of the JU, analyse them and determine action plans on how they should be managed. All risks are captured in the Global Health EDCTP3 Risk Register, which provides for an evaluation of the risk level and description of the mitigating activities.

The annual risk assessment exercise took place between September and October 2024. The most significant risks were included in the risk register of Global Health EDCTP3. An action plan has been put in place and will be monitored and followed up during the year 2025. The JU will continue to run an annual risk assessment exercise in 2025.

2.5.4 Anti-fraud initiatives

The R&I family has established a common implementation approach for the prevention and detection of fraud in the framework programmes. Global Health EDCTP3 alongside other entities implementing Research and Innovation Programmes share participants and face similar fraud patterns, making therefore the common approach more effective and efficient to coordinate anti-fraud activities. The Common Anti-Fraud Strategy in the research and innovation family was revised in 2023 and endorsed by the Horizon Europe Executive Committee on 22 December 2023. Global Health EDCTP3 adopted by analogy the Anti-Fraud strategy of the R&I family on 15 March 2024 (GH-EDCTP3-GB/09/2024).

In 2025, a specific Global Health EDCTP3 anti-fraud strategy will be adopted, covering also areas that are not related to grant management: such as, fraud risks related to procurement, expert management.

Further actions have been planned, such as:

- Awareness raising amongst staff on anti-fraud measures;
- Participation to meetings organised by DG RTD and common trainings organised for the JUs (in cooperation with the Common Audit Service).

2.5.5 Audits

Internal audits are carried out by the Internal Audit Service of the European Commission (IAS) in liaison with the Internal Control and Audit Manager. The IAS will commence in Q4 of 2024 a risk assessment to establish the strategic internal audit plan for Global Health EDCTP3. Therefore, the main activity for the year will focus on coordinating and supporting IAS audit work on risk assessment.

External audits are carried by the European Court of Auditors (ECA). The ECA will audit and issue opinions on the legality and regularity of the underlying transactions, revenue, and reliability of accounts. In line with Articles 70(6) and 71 of the EU Financial Regulation[17], the audit of the reliability of the accounts of the JUs is outsourced to independent audit firms and ECA reviews the quality of the work done by these external firms and obtains sufficient assurance so that they can rely on their work in formulating ECA audit opinions on the reliability of the JUs annual accounts for the specific year. In this regard, the annual accounts are audited by an external audit company (contracted through Europe's Rail Joint Undertaking framework contract on statutory audit services).

In 2025, the key activities will focus on:

- Providing the necessary information and support for ECA audit in 2024 and 2025 accounts.
- Following up and implementing any audit observations identified during the ECA annual audit on Global Health EDCTP3 for the financial year 2023.
- Supporting the ECA team in their field or remote missions for the Global Health EDCTP3 projects selected (on a sample basis) for an ex-post financial review.
- Liaising with the external audit company that will audit the 2024 annual accounts, as required by the Financial Rules of Global Health EDCTP3.

The **Internal Audit Capability** of Global Health EDCTP3 is performed by the Internal Control and Audit Manager. The objective established for the Internal Audit Capability is to provide the Executive Director with assurance as to the effectiveness and efficiency of risk management, control and governance process in the JU.

[17] Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council of 23 September 2024 on the financial rules applicable to the general budget of the Union (recast).

3. Budget 2025

3.1 Global Health EDCTP3 Budget 2025

In accordance with the General Annexes of the Horizon Europe Work Programme 2023-2024, regarding budget flexibility, the budgets set out in the calls and topics are indicative. Unless otherwise stated, final budgets may change following evaluation. In addition, the final figures may change by up to 20% compared to the total budget indicated in each individual part of the Work Programme. Changes within these limits will not be considered substantial within the meaning of Article 110(5) of Regulation (EU, Euratom) No 2024/2509.
Budget 2025 covers both administrative and operational requirements of the year.
It is noted that the budget of the JU shall be adapted to consider the amount of the EU contribution as laid down in the budget of the Union.

Revenue
The **Administrative budget** is financed by fresh appropriations under Horizon Europe. According to Article 102 of the Council Regulation 2021/2085, the European Union covers the entire administrative expenditure for the Global Health EDCTP3 JU.

The **Operational budget** breakdown is as follows:

- Horizon Europe operational contributions are financed by fresh appropriations of the EU. An additional amount of EUR 36.7 million from the EU funding is foreseen following the UK association to Horizon Europe.
- A contribution of EUR 3.3 million is expected as contribution from Members other than the EU on the work programme 2025.
- Reactivation of unused commitment appropriations from 2023 and 2024 amounting to EUR 5.1 million are included in the initial budget.

Expenditure

Title 1 - Staff
Title 1 represents 66% of the total 2025 administrative budget. The principal allocation of this cost are the salaries and allowances for staff and external personnel (contract agents, interims and trainees) as presented in the establishment plan.

In addition, missions' cost is composed of an estimated amount of EUR 120,000 for the annual mission budget (which has increased compared to 2024 considering the ramp up phase of the JU's activities) and of an addition of EUR 87,000 estimated for the staff of the JU who will attend the 12th EDCTP Forum in Kigali (Rwanda) in mid-June 2025, and actively contribute to its organisation and implementation. This amount will mainly cover the booking of flight tickets and accommodation during the days of the event.

On top of that, Title 1 also includes training for staff and other staff related expenditure such as different SLAs signed with the EC (DG HR and PMO services among others), recruitment costs, European schools and other events and activities.

Title 2 - Infrastructure and operating expenditure
Title 2 represents the remaining 34% of the administrative budget for 2025.

It covers, amongst others, the rental and building costs of the new premises on the second floor at the White Atrium building. It is to be mentioned that there is an important decrease of costs associated to building and furniture equipment in 2025 compared to 2024. This is due to the fact that the majority of

equipment purchase and works for the new premises have been budgeted, and with contracts signed, in 2024. Similarly, IT costs will slightly decrease as no significant additional needs are identified in 2025 as most of the equipment was purchased in previous years.

In particular, the important increase in information and communication costs is due to different activities planned such as strategic partnerships (sponsorship, participation and organisation of meetings and events) and support for graphic design, web and promotion of the EDCTP Forum among other actions. Moreover, current administrative expenditure (office supplies, library, translation services, etc.) and telecommunication and postage costs (telephony, videoconferencing, internet, fixed lines, postal services) will increase compared to the previous year. This is due to the fact that the JU is expected to run with full staff in 2025.

Meeting expenses (caterings and other costs) for the organisation of the Governing Board, Scientific Committee and Stakeholders Group will increase substantially, although the most significant impact will be linked to the organisation of the EDCTP Forum in Kigali.

Running costs in connection with operational activities will also include the reimbursement of experts, such as transportation and accommodation.

Service contracts generally cover contracting with third parties outside the European Commission's environment.

Finally, other infrastructure and operating expenditure will include different services covered under the SLAs signed with the EC departments (DG DIGIT, BUDG, etc.) and other joint undertakings or executive agencies.

Title 3 - Operational costs
Please refer to point *"3.4 Detailed overview of operational budget 2025"*

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3.2 Statement of revenue

STATEMENT OF REVENUE					
Budget line	Title Chapter	Adopted Budget - Financial Year 2025			
		Estimated Commitment Appropriations	In %	Estimated Payment Appropriations	In %
1	**EU contribution (excl. EFTA and third countries contribution)**	**176 882 121**	**78,0%**	**102 945 130**	**85,2%**
10	*of which Administrative (Title 1&2)*	6 579 100	2,9%	6 579 100	5,4%
11	*of which Operational (Title 3)*	170 303 021	75,1%	96 366 030	79,8%
2	**EFTA and third countries contribution**	**41 578 258**	**18,3%**	**2 830 991**	**2,3%**
20	*of which Administrative (Title 1&2)*	180 925	0,1%	180 925	0,1%
21	*of which Operational (Title 3)*	41 397 333	18,2%	2 650 066	2,2%
3	**Financial contribution from members other than the Union***	**3 300 000**	**1,5%**	**15 000 000**	**12,4%**
31	*Of which Operational (Title 3)*	3 300 000	1,5%	15 000 000	12,4%
4	**Contributing Partners financial contribution**	-	-	-	-
5	**Interest generated**	-	-	-	-
6	**Recoveries**	-	-	-	-
7	**Other****	**p.m.**	-	**p.m.**	-
8	**Unused appropriations from previous years**	**5 112 494**	**2,3%**	-	-
80	*of which Administrative (Title 1&2)*	-	0,0%	-	-
81	*of which Operational (Title 3)*	5 112 494	2,3%	-	-
TOTAL ESTIMATED REVENUE		**226 872 873**	**100%**	**120 776 121**	**100%**

*** According to Article 102 of the Council Regulation 2021/2085, the European Union covers the entire administrative expenditure for the Global Health EDCTP3 Joint Undertaking.**

**** No assigned revenue are expected to be collected in 2025 by the time of the initial budget submitted for adoption to the GB.**

3.3 Statement of expenditure

STATEMENT OF EXPENDITURE			
Budget line	Title Chapter	Adopted Budget - Financial Year 2025	
		Estimated Commitment Appropriations	Estimated Payment Appropriations
TITLE 1 - Staff expenditure			
11	Salaries & allowances	3 858 000	3 858 000
110	*of which establishment plan posts*	*3 094 000*	*3 094 000*
111	*of which external personnel*	*764 000*	*764 000*
120	Expenditure relating to staff recruitment	-	-
130	Mission expenses	207 025	207 025
140	Socio-medical infrastructure	-	-
150	Training	60 000	60 000
160	External Services	-	-
170	Receptions, events and representation	-	-
180	Social welfare	-	-
190	Other staff related expenditure	305 000	305 000
Total Staff		**4 430 025**	**4 430 025**
TITLE 2 - Infrastructure and operating expenditure			
200	Rental of buildings and associated costs	376 000	376 000
210	Information, communication technology and data processing	450 000	450 000
220	Office equipment (movable property and associated costs)	200 000	200 000
230	Current administrative expenditure	40 000	40 000
240	Postage / Telecommunications	40 000	40 000
250	Meeting expenses	200 000	200 000
260	Running costs in connection with operational activities	120 000	120 000
270	Information and publishing	400 000	400 000
280	Service contracts	200 000	200 000
290	Other infrastructure and operating expenditure	304 000	304 000
Total infrastructure and operating		**2 330 000**	**2 330 000**
TOTAL ADMINISTRATIVE (1+2)		**6 760 025**	**6 760 025**
TITLE 3 - Operational expenditure			
300	Grants	218 012 848	111 916 096
310	***Experts costs****	*1 000 000*	*1 000 000*
320	Other operational costs	1 100 000	1 100 000
TOTAL OPERATIONAL (3)		**220 112 848**	**114 016 096**
TITLE 4 - Unused appropriations			
400	Unused administrative appropriations	-	-
410	Unused operational appropriations	-	-
TOTAL UNUSED (4)		-	-
TOTAL ESTIMATED EXPENDITURE		**226 872 873**	**120 776 121**

*** This budget line has a type II co-delegation RTD>REA and the inscription of the appropriations for both CA and PA is also done on a budget line in ABAC that remains at the European Commission side.**

3.4 Detailed overview of operational budget 2025

Year 2025	Type of action and topics	Value of the actions
Multi-annual Call for Proposals	**Call 1 - RIA**	**122,7**
	TB Vaccines	*45,9*
	Malaria Therapeutics	*30,9*
	NTD Vaccines	*45,9*
	Call 2 - CSA	**6,7**
	Fellowships	*6,7*
	Call 3 - CSA	**40**
	Preparedness - NoE and Epidemics networks	*40*
	Call 4 - RIA	**44,6**
	Diarrhoeal Diseases in Climate and Health	*30,6*
	Transformative Innovations in global health	*14*
Operational Experts costs	Including through REA	**1,0**
Other operational costs	Including Public Health Emergency (PHE), Call Africa Office (IBA), and EDCTP Forum 2025 preparations	**5,1**
Total		**220,1**

Further information about the multi-annual call for proposals is available in the Annex 4.1.

It is to be noted that "*Other operational costs"* include EUR 1 million for a possible allocation to public health emergency action, similarly to what was activated in 2024 with the Mpox outbreak, and as described in the Annex 4.1.

Moreover, another EUR 3 million will be allocated for the Africa Office Grant (IBA) and EUR 1.1 million will be allocated in 2025 in "*Other operational costs"* among which operational activities associated to the organisation of the EDCTP Forum 2025.

4. Annexes

Global Health
EDCTP3

Co-funded by
the European Union

Annex 4.1: Calls for proposals 2025 and other actions not subject to calls for proposals

4.1.1 Indicative operational budget 2025

Call	Budget (in million EUR)
Horizon-JU-GH-EDCTP3-2025-01-two-stage	122.7
Horizon-JU-GH-EDCTP3-2025-02-two-stage	6.7
Horizon-JU-GH-EDCTP3-2025-03-two-stage	40
Horizon-JU-GH-EDCTP3-2025-04-two-stage	44.6
Other Actions - WP 2025 emergency funding call	1
Other Actions - HORIZON-JU-GH-EDCTP3-2025-05-AFRICA-01-IBA: Support for an Africa office	3
Experts	1
EDCTP Forum 2025 preparations	1.1
Total	**220.10**

4.1.2 Calls for proposals 2025

This is the fourth work programme under Global Health EDCTP3. The topics are based on the SRIA adopted by the Governing Board[18]. The Global Health EDCTP3 programme is implemented under the framework of the EU global health strategy[19] adopted in November 2022, the EU-AU summit deliverables[20] and the AU-EU innovation agenda launched in July 2023[21] and will play a key role in achieving the objectives of these strategies and initiatives.

Under this year's work programme, **four calls for proposals** are launched:

- HORIZON-JU-GH-EDCTP3-2025-01-two-stage covering 3 topics for Research and Innovation Actions (RIA)
- HORIZON-JU-GH-EDCTP3-2025-02-two-stage covering 1 topic for Coordination and Support Actions (CSA)
- HORIZON-JU-GH-EDCTP3-2025-03-two-stage covering 1 topic for Coordination and Support Actions (CSA)
- HORIZON-JU-GH-EDCTP3-2025-04-two-stage covering 2 topics Research and Innovation Actions (RIA).

The work programme also foresees other actions, including: (a) expenditure related to experts carrying out monitoring of running actions for Global Health EDCTP3, and (b) funding to be mobilised in case of a public health emergency.

With the work programme 2025 we extend the range of topics addressed under Global Health EDCTP3, building on the EDCTP2 programme and Global Health EDCTP3 activities launched between 2022 to 2024. The work programme 2025 addresses several objectives within the scope of

18 The Global Health EDCTP3 Joint Undertaking Strategic Research and Innovation Agenda
19 https://ec.europa.eu/commission/presscorner/detail/en/ip_22_7153
20 Sixth European Union - African Union Summit: A Joint Vision for 2030 - Consilium (europa.eu)
21 The AU-EU Innovation Agenda

Global Health EDCTP3: this ranges from the development of medicines and vaccines on key targeted infectious diseases such as TB, Malaria and NTDs to cross-disease and multi-disciplinary interventions through developing solutions for diarrhoeal diseases in the context of climate and health, as well as novel and emerging transformative innovations in global health. Additionally, a strong capacity building and preparedness component is integrated to the work programme 2025, through the scale-up of the EDCTP-Africa CDC calls to train biostatisticians, epidemiologists and modellers, as well as through the reshaping of the EDCTP established regional networks of excellence and consortia for epidemic preparedness, which also includes support to senior researchers. Furthermore, support to the EDCTP Africa office will be sustained.

For all topics in the work programme, where relevant, the support to African scientists from junior researchers to senior researchers in clinical research that embraces hands-on-training and mutual bi-directional learning during implementation of research projects should be promoted to assist them in sustaining and/or advancing their scientific careers. These scientists should be selected keeping gender and regional balance in mind.

The support through topics targeting a particular disease area as defined in the work programme 2025 complements support provided through broader topics under the previous work programmes of Global Health EDCTP3[22].

4.1.2.1 Conditions to the calls and call management rules

A. For Clinical studies

For RIA and, **in case relevant based on the topic text also for CSA** in the context of this work programme, a clinical study covers clinical studies/trials/investigations/cohorts and is defined as any systematic prospective or retrospective collection and analysis of health data obtained from individual patients or healthy persons to address scientific questions related to the understanding, prevention, diagnosis, monitoring or treatment of a disease, mental illness, or physical condition. It includes, but it is not limited to clinical studies, as defined by Regulation 536/2014 (on medicinal products), clinical investigation and clinical evaluation as defined by Regulation 2017/745 (on medical devices), performance study and performance evaluation as defined by Regulation 2017/746 (on *in vitro* diagnostic medical devices)[23].

For full proposals of two-stage proposals, the use of the “Information on clinical studies” template is recommended:
https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/temp-form/af/information-on-clinical-studies_he_en.docx

Yet, **three mandatory deliverables** below should be included in the single-stage proposals or full proposals of two-stage proposals involving clinical studies, to the extent relevant depending on the stage of the study:

1. **Study initiation package (before enrolment of the first study participant) including**

[22] Tuberculosis, emerging infectious diseases as well as HIV/AIDS, Malaria and neglected infectious diseases have all been addressed through projects funded from previous calls.

[23] https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/temp-form/af/information-on-clinical-studies_he_en.docx

- Registration number of the clinical study in a registry meeting WHO Registry criteria[24];
- Final version of study protocol as approved by the regulator(s) / ethics committee(s);
- Regulatory and ethics (if applicable, institutional) approvals required for the enrolment of the **first study participant.** (In case of **multicentre clinical studies**, submission of approvals for the first clinical site is sufficient.)

2. Midterm recruitment report

This report is due when 50% of the study population is recruited. The report shall include an overview of the number of recruited participants by clinical sites, any problems in recruitment and, if applicable, a detailed description of implemented and planned measures to compensate for any incurred delays.

3. Report on the status of posting results

Irrespective of the successful completion of the clinical study, summary results must be posted in the applicable registry/ies (where the study was registered) even if the timing of posting of results falls outside of the grant period. The report is to be scheduled for the time results posting is expected or for the last months of the project, whichever comes earlier.

- Studies must be registered in a registry meeting WHO Registry criteria[25] before recruitment of the first subject. From 31 January 2023, all initial clinical trial applications in the European Union must be submitted via the Clinical Trials Information System (CTIS). CTIS is now the single-entry point for sponsors and regulators of clinical trials for the submission and assessment of clinical trial data. All ongoing clinical trials in EU must be transitioned to CTIS by 30 January 2025.[26]
- The applicants should ensure that the sample size of the clinical studies is relevant to obtain meaningful results.

B. For all topics

- FAIR data principles and open access of publications are required in line with the Model Grant Agreement[27]. In the context of this work programme, FAIR data are data which meet principles of findability, accessibility, interoperability, and reusability. Data can include exploitation of information and data from European data infrastructures and programmes such as Copernicus, European Space Agency, and the GEO initiative. For further details, see the FAIR principles website[28], the FAIR cookbook[29] and the guides for researchers on how to make your data FAIR[30]. Data quality and integration as well as issues of cybersecurity and data protection must be addressed. Use of explainable and transparent artificial intelligence tools[31] in all research is encouraged where appropriate.
- The proposals should put emphasis on ethically involving vulnerable groups, including participants from less-resourced, underserved, or hard-to-reach communities in SSA. Applicants are also

24 https://www.who.int/clinical-trials-registry-platform/network/registry-criteria
25 https://www.who.int/clinical-trials-registry-platform/network/registry-criteria
26 https://www.ema.europa.eu/en/news/use-clinical-trials-information-system-becomes-mandatory-newclinical-trial-applications-eu
27 unit-mga_he_en.pdf (europa.eu)
28 https://www.go-fair.org/fair-principles/
29 https://faircookbook.elixir-europe.org/content/home.html
30 https://www.openaire.eu/how-to-make-your-data-fair
31 See: European strategic research agenda in artificial intelligence: https://www.elise-ai.eu/work/agendaand-programs

encouraged to provide methodologies for translating research findings into public health practice and policy guidelines. They are welcome to draw on any relevant lessons from the COVID-19 development strategies. As relevant, the proposals should involve all stakeholders, most notably policy makers, public health authorities, health care professionals and end-users. The applicants must ensure strong community engagement. International cooperation is encouraged, and the proposed research is expected to be multidisciplinary.

- Proposals are expected to come from research consortia with a strong representation of institutions and researchers from SSA countries, including involvement of Franco/Lusophone countries where possible and relevant. Proposals are to foster inclusive equitable partnerships also considering institutions or organisations from countries with high burden of disease and relatively lower research capacities, to the extent possible.
- Where relevant, it will be important for proposals to consider and support the existing and emerging partnerships between the EU/Team Europe (EU institutions, Member States and EU Financing Institutions) and the African Union (AU) and their key agencies, notably the Team Europe Initiatives on Manufacturing and Access to Vaccines, Medicines and Health Technologies (MAV+)[32], Sustainable Health Security[33], Public Health Capacity[34], Digital Health[35] and align with the Africa CDC Strategic Plan 2023-2027[36] and the African Medicines Agency. Moreover, collaborations with the African Regional Intellectual Property Organisation[37] (ARIPO) and the African Intellectual Property Organisation (OAPI)[38] should also be fostered as well as strengthened promoting the development and assessment of innovative tools.
- It will also be important that the projects arising from this call will contribute to the implementation of the short-term and medium-term actions of the AU-EU Innovation Agenda[39] in the area of Public Health and the EU global health strategy[40].
- As part of the evaluation of the criterion “Excellence”, proposals for RIA actions must clearly demonstrate their added value beyond the state of the art within their respective areas complementing existing research and funding and building on past programmes and projects financed by the EDCTP Association and/or other funders, in line with Article 100 of the Council Regulation 2021/2085[41].
- Proposals must comply with all ethics requirements arising out of the research, in line with Article 112 of the Council Regulation 2021/2085. Proposals evaluated above threshold and considered for funding will undergo an ethics screening carried out by independent ethics experts. The ethics appraisal process focuses on the compliance with ethical rules and standards, relevant European legislation, international conventions and declarations, national authorisations and ethics approvals, proportionality of the research methods, and the applicants' awareness of the ethical aspects and social impact of their planned research.

32 Team Europe Initiative on manufacturing and access to vaccines, medicines and health technologies in Africa (europa.eu)
33 Sustainable Health Security - Africa | Capacity4dev (europa.eu)
34 Public Health Capacity - Africa | Capacity4dev (europa.eu)
35 Digital Health - Africa | Capacity4dev (europa.eu)
36 Africa CDC Strategic Plan 2023 – 2027 – Africa CDC
37 African Regional Intellectual Property Organization (ARIPO)
38 African Intellectual Property Organization (OAPI)
39 https://research-and-innovation.ec.europa.eu/system/files/2023-07/ec_rtd_au-eu-innovation-agenda-final-version.pdf
40 https://ec.europa.eu/commission/presscorner/detail/en/ip_22_7153
41 Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014. *OJ L 427, 30.11.2021, p. 17–119;* https://eur-lex.europa.eu/eli/reg/2021/2085

- Finally, the proposals should take into consideration the potential impact of clinical research activities on climate change and must take appropriate measures to minimise any potential negative effects.

Of note, despite blind evaluation being mentioned in the standard application form for stage 1 proposals, available in the Funding and Tenders Portal (at the stage of adoption of this Work Programme), please note that this call is not part of the 'blind evaluation pilot', therefore no anonymisation is required for stage 1 proposals of the two-stage calls.

Information sharing regarding the proposals and the evaluation results

Applicants should be aware that the following information regarding their proposals may be shared with the members of the JU Committee of the EDCTP Association:

- Following eligibility check of the applications: aggregated country level data; number of applicants, funding requested, organisation type;

- Regarding project information following Grant Agreement (GA) signature: signature date of the GA; number, acronym, title, and duration of projects; role, country, legal name, PIC, legal type, URL, total cost, requested JU contribution, FC received, FC given, and IKOP of participants;

- For successful proposals, following Global Health EDCTP3 Governing Board decision on the call evaluation results: number; acronym; title; duration; role; country; legal name; PIC; legal type; total cost; requested JU contribution;
- Under specific conditions and following Global Health EDCTP3 Governing Board approval of the request of EDCTP Association, for proposals on the reserve list and unsuccessful proposals: number; acronym; title; duration; role; country; legal name; PIC; legal type; total cost; requested JU contribution.

4.1.2.2 Budget for Calls for Proposals

Indicative budget per call and topic

HORIZON-JU-GH-EDCTP3-2025-01-two-stage	Type of Action	Indicative JU Budget (in million EUR)	Expected JU contribution per project(in million EUR)	Number of projects expected to be funded
HORIZON-JU-GH-EDCTP3-2025-01-TB-01-two-stage	RIA	45.9	15.3	3
HORIZON-JU-GH-EDCTP3-2025-01-MALARIA-02-two-stage	RIA	30.9	10.3	3
HORIZON-JU-GH-EDCTP3-2025-01-NTD-03-two-stage	RIA	45.9	15.3	3
Overall indicative budget		**122.7**		

HORIZON-JU-GH-EDCTP3-2025-02-two-stage	Type of Action	Indicative JU Budget (in million EUR)	Expected JU contribution per project (in million EUR)	Number of projects expected to be funded
HORIZON-JU-GH-EDCTP3-2025-02-FELLOWSHIP-01-two-stage	CSA	6.7	1.34 *(to support 10 fellows)*	5
Overall indicative budget		**6.7**		

HORIZON-JU-GH-EDCTP3-2025-03-two-stage	Type of Action	Indicative JU Budget (in million EUR)	Expected JU contribution per project (in million EUR)	Number of projects expected to be funded
HORIZON-JU-GH-EDCTP3-2025-03-NETWORKS-01-two-stage	CSA	40	10	4
Overall indicative budget		**40**		

HORIZON-JU-GH-EDCTP3-2025-04-two-stage	Type of Action	Indicative JU Budget (in million EUR)	Expected JU contribution per project (in million EUR)	Number of projects expected to be funded
HORIZON-JU-GH-EDCTP3-2025-04-CH-01-two-stage	RIA	30.6	5,1	6
HORIZON-JU-GH-EDCTP3-2025-04-ACCESS-02-two-stage	RIA	14	1,4 to 2,33	6-10
Overall indicative budget		**44.6**		

4.1.2.3 General Conditions related to this Work Programme

For call management, Global Health EDCTP3 will utilise the EC eGrants IT systems available under the EU Funding & Tenders Portal. Unless specified otherwise, the sections of the General Annexes to the Horizon Europe Work Programme[42] apply *mutatis mutandis* to the calls for proposals covered by this Global Health EDCTP3 work programme.

General conditions related to Global Health EDCTP3 JU calls with indication of specific conditions	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B except for the specific conditions for the Global Health EDCTP3 JU funding as regards entities eligible for funding and consortium composition, the specific rule for countries where the coordinator may be established and the obligation to designate a scientific project leader as below.
Financial and operational capacity and exclusion criteria	The criteria are described in General Annex C.
Award criteria	The criteria are described in General Annex D. Also, for topics 1 and 2 under the call **Horizon-JU-GH-EDCTP3-2025-01-two-stage, topic HORIZON-JU-GH-EDCTP3-2025-02-FELLOWSHIP-01-two-stage** and **topic HORIZON-JU-GH-EDCTP3-2025-03-NETWORKS-01-two-stage,** additional aspects on award criteria apply. The scores and weighting section for single stage evaluations as well as second stage of two-stage evaluations, for both Research and Innovation Actions (RIA) and Coordination and Support Actions (CSA) are set out below.
Documents	The documents are described in General Annex E.
Procedure	The procedure is described in General Annex F.
Legal and financial set-up of the Grant Agreements	The rules are described in General Annex G and specific conditions regarding application of the right to object apply as described below. For the topics under the call **Horizon-JU-GH-EDCTP3-2025-01-two-stage,** specific conditions regarding affordable access apply. **For the topic HORIZON-JU-GH-EDCTP3-2025-02-FELLOWSHIP-01-two-stage,** specific conditions regarding financial support to third parties as well as use of lump sum contributions [as defined in the Decision of 7 July 2021 authorising the use of lump sum contributions under the

[42] wp-13-general-annexes_horizon-2023-2024_en.pdf (europa.eu)

	Horizon Europe Programme – the Framework Programme for Research and Innovation (2021-2027)][43] apply. **For the topic HORIZON-JU-GH-EDCTP3-2025-03-NETWORKS-01-two-stage,** specific conditions regarding the use of lump sum contributions (as defined in the Decision of 7 July 2021 authorising the use of lump sum contributions under the Horizon Europe Programme – the Framework Programme for Research and Innovation (2021-2027))[44] apply. **For the topic HORIZON-JU-GH-EDCTP3-2025-04-CH-01-two-stage** specific conditions regarding affordable access apply. **For the topic HORIZON-JU-GH-EDCTP3-2025-04-ACCESS-02-two-stage,** specific conditions regarding affordable access apply. The conditions are spelled out under the respective topics as relevant.

4.1.2.4 Specific Conditions to Global Health EDCTP3

Specific conditions replacing the relevant sections in General Annex B to the Horizon Europe Work Programmes

A. Entities eligible for funding

This section applies to both Research and Innovation Actions (RIA) and Coordination and Support Actions (CSA).

To become a beneficiary, legal entities must be eligible for funding. To be eligible for funding, applicants must be established in one of the following countries:

- The Member States of the European Union, including their outermost regions: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden;
- The Overseas Countries and Territories (OCTs) linked to the Member States: Aruba (NL), Bonaire (NL), Curação (NL), French Polynesia (FR), French Southern and Antarctic Territories (FR), Greenland (DK), New Caledonia (FR), Saba (NL), Saint Barthélemy (FR), Sint Eustatius (NL), Sint Maarten (NL), St. Pierre and Miquelon (FR), Wallis and Futuna Islands (FR);

[43] This decision is available on the Funding and Tenders Portal, in the reference documents section for Horizon Europe, under 'Simplified costs decisions' or through this link: ls-decision_he_en.pdf (europa.eu)

[44] This decision is available on the Funding and Tenders Portal, in the reference documents section for Horizon Europe, under 'Simplified costs decisions' or through this link: ls-decision_he_en.pdf (europa.eu)

- Countries associated to Horizon Europe[45]: Albania, Armenia, Bosnia and Herzegovina, Canada, Faroe Islands, Georgia, Iceland, Israel, Kosovo[46], Moldova, Montenegro, New Zealand (associated to Pillar II 'Global Challenges and European Industrial Competitiveness' as from the Work Programmes 2023 onwards, including for the institutionalised European partnerships), North Macedonia, Norway, Serbia, Tunisia, Turkey, Ukraine, United Kingdom;
- Until association agreements start producing legal effects either through provisional application or their entry into force, transitional arrangements apply. The transitional arrangements apply, at the time of the adoption of this Work Programme, with regard to the following countries and legal entities established in these countries, with which association negotiations are being processed or where association is imminent): Morocco.
- The following countries which are constituent states of the EDCTP Association[47]: Benin, Burkina Faso, Cameroon, Côte d'Ivoire, Democratic Republic of the Congo, Ethiopia, Eswatini, Gabon, The Gambia, Ghana, Guinea-Bissau, Guinea-Conakry, Kenya, Liberia, Malawi, Mali, Mozambique, Namibia, Niger, Nigeria, Republic of the Congo, Rwanda, Senegal, Sierra Leone, Somalia, South Africa, Tanzania, Uganda, Zambia, Zimbabwe.

Legal entities which are established in countries not listed above will be eligible for funding if provided for in the specific call/topic conditions, or if their participation is considered essential for implementing the action by the granting authority.

Entities established in low- and middle-income countries that are not members of the EDCTP Association and listed in the Horizon Europe List of Participating Countries on the Funding & Tenders Portal [48] are not eligible for funding unless the specific country in which the entity is established, is associated to Horizon Europe or if the participation of the entity is considered essential for implementing the action by the granting authority.

B. Consortium composition

Unless otherwise provided for in the specific call conditions, for all actions, due to the policy objectives of Global Health EDCTP3, legal entities forming a consortium are eligible to participate in actions under the programme provided that the consortium includes as beneficiaries:

- At least three legal entities independent from each other and each established in a different country, where legal entities are eligible to receive funding;
- At least one independent legal entity established in a Member State, or in an associated country to Horizon Europe that is a member of the EDCTP Association; and
- At least one independent legal entity established in a sub-Saharan African country that is a member of the EDCTP Association.

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45 The list is correct at the time of adoption of this work programme. Please see the Horizon Europe List of Participating Countries on the Funding & Tenders Portal for up-to-date information on the current list and on the position for Associated Countries: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/list-3rd-country-participation_horizon-euratom_en.pdf

46 This designation is without prejudice to positions on status and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence.

47 The list is correct at the time of adoption of this work programme. For an update, please check the EDCTP Association website www.edctp.org

48 Horizon Europe List of Participating Countries on the Funding & Tenders Portal https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/list-3rd-country-participation_horizon-euratom_en.pdf

This condition applies to both Research and Innovation Actions (RIA) and Coordination and Support Actions (CSA).

For the two CSA topics, i.e. topic HORIZON-JU-GH-EDCTP3-2025-02-FELLOWSHIP-01-two-stage and topic HORIZON-JU-GH-EDCTP3-2025-03-NETWORKS-01-two-stage - according to which the EDCTP Association is obligatorily part of the consortium as coordinator, the EDCTP Association must not be counted as one of the three independent legal entities necessary to ensure the eligibility of the consortium composition.

Specific cases:

Affiliated entities — Affiliated entities are eligible for funding if they are established in one of the countries listed above, or in a country identified in the specific call/topic conditions.

Associated partners — Entities not eligible for funding and therefore not able to participate as beneficiaries or affiliated entities (i.e. entities which participate in the action without signing the grant agreement, and without the right to charge costs or claim contributions) are allowed, subject to any conditions regarding associated partners set out in the specific call conditions.

International organisations – International European research organisations are eligible to receive funding. Other international organisations are not eligible to receive funding unless their participation is considered essential for implementing the action by the granting authority. International organisations with headquarters in a Member State or associated country are eligible to receive funding when provided for in the specific call conditions.

Specific rules regarding legal entities that may be the coordinator of an indirect action

In accordance with Article 110(2) of the Council Regulation 2021/2085 establishing the Joint Undertakings under Horizon Europe[49], where entities established in a third country without an agreement to protect the financial interests of the Union participate with funding in an indirect action, the coordinator of the indirect action must be established in a Member State or associated country, or South Africa.

Scientific project leader

If the coordinator is not established in a country in SSA (*please see previous paragraph*), the designation of a scientific project leader established in a SSA country member of the EDCTP Association with the roles as described below is mandatory. A work package on 'scientific project leadership' must be included in the proposals and budget needs to be provided for this activity. The scientific project leader oversees the project scientific governance and leadership. For this purpose, proposals must include a work package where the details of scientific project leadership are laid down. The scientific project leader should indicatively perform the following tasks:

- During the call for proposals and selection process, coordinate meetings on and drafting of the full project proposal.

[49] Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014. *OJ L 427, 30.11.2021, p. 17–119;* Regulation - 2021/2085 - EN - EUR-Lex (europa.eu).

- Work with the coordinator and other beneficiaries on the drafting and negotiation of the consortium agreement and other legal agreements among the beneficiaries.
- Act as the key contact point for the Global Health EDCTP3 JU regarding all scientific action governance issues, steer and provide oversight in the development of the scientific actions, without prejudice to the tasks entrusted directly to the coordinator as per the Model Grant Agreement.
- Support and collaborate with the coordinator on its monitoring activities and the adoption of appropriate internal measures, to ensure that beneficiaries are fulfilling their obligations regarding budget, timeline, deliverables, and scientific quality.
- Review the action's deliverables and reports before their submission by the coordinator.
- Lead the work packages(s) related to the tasks of scientific project leadership.

Annex 1 to the grant agreement and the consortium agreement should address the relationship of the scientific project leader with the coordinator regarding their respective tasks, for example sharing of the information received from or sent to Global Health EDCTP3 on all issues of interest for the proper scientific management of the action.

C. Specific conditions related to Scores and weighting

Replacing the scores and weighting section in General Annex D to the Horizon Europe Work Programmes as regards second stage of two-stage evaluations, for both Research and Innovation Actions (RIA) and Coordination and Support Actions (CSA)

Evaluation scores will be awarded for the criteria, and not for the different aspects listed in the table. For full applications, each criterion will be scored out of 5. The threshold for individual criteria 1 (Excellence) and 2 (Impact) will be 4 and for criterion 3 (Quality and Efficiency of the implementation) will be 3. The overall threshold, applying to the sum of the three individual scores, will be 12.

Proposals that pass the individual threshold and the overall threshold will be considered for funding, within the limits of the available call budget. Other proposals will be rejected.

Nota bene, for the first stage of the two-stage evaluation of both RIAs and CSAs, the scores and weighting as indicated in Annex D of the General Annexes of the Horizon Europe work programme 2023/2025 apply.

D. JU right to object to transfer/exclusive licensing

Global Health EDCTP3 may, up to 4 years after the end of the action, object to a transfer of ownership or to the exclusive licensing of results, as set out in the specific provision of Annex 5 of the Model Grant Agreement. In addition, in accordance with Article 24(3) of Council Regulation 2021/2085 establishing the Joint Undertakings under Horizon Europe[50] and the Model Grant Agreement, the right to object applies also to participants that have not received funding from the JU.

[50] Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014; OJ L 427, 30.11.2021, p. 17.

4.1.2.5 General presentation of the 2025 calls for proposals

During 2025, Global Health EDCTP3 will launch four two-stage open and competitive calls for proposals. These are planned as indicated in the table below.

Topics under Call	Type of Action	Call opening	Submission deadline short proposal	Submission deadline full proposal
HORIZON-JU-GH-EDCTP3-2025-01-two-stage (3 topics)	RIA	January 2025	March 2025	September 2025
HORIZON-JU-GH-EDCTP3-2025-02-two-stage (1 topic)	CSA	January 2025	March 2025	September 2025
HORIZON-JU-GH-EDCTP3-2025-03-two-stage (1 topic)	CSA	January 2025	March 2025	September 2025
HORIZON-JU-GH-EDCTP3-2025-04-two-stage (2 topics)	RIA	January 2025	March 2025	September 2025

Conditions for these four calls

Expected Impact:

Activities funded under the 2025 Work Programme calls for proposals of the Global Health EDCTP3 JU should contribute to:

- Reduce the individual, social, and economic burdens of infectious diseases in SSA through the development and uptake of new or improved interventions.
- Increase health security in SSA and globally by reducing the risk of outbreaks and pandemics and enhancing national and regional capacity to address antimicrobial resistance.
- Progressing towards the achievement of SDG3 ‘Ensure healthy lives and promote well-being for all at all ages’ in SSA countries.
- Enable the implementation of the short- and medium-term actions foreseen by the AU EU Innovation Agenda (adopted in July 2023) in the area of public health and the EU Global Health Strategy (November 2022).
- Improve equitable access to a full range of essential health services from health promotion to disease prevention and affordable quality treatment, rehabilitation and palliative care to fight communicable diseases.
- Expand partnerships based on equal footing, co-ownership, mutual interest and strategic priorities.
- Provide evidence for informed health policies and guidelines within public health systems in SSA and at international level.
- Enhance sustainable global scientific collaboration in health research and international cooperation across SSA.

Proposals are invited against the following topics:

HORIZON-JU-GH-EDCTP3-2025-01-TB-01-two-stage: Global collaboration action for the development of vaccines for reducing the disease burden of Tuberculosis in sub-Saharan Africa

Background

Tuberculosis (TB) is a preventable and usually curable disease. Yet in 2022, TB was the world's second leading cause of death from a single infectious agent, after coronavirus disease (COVID-19), and caused almost twice as many deaths as HIV/AIDS. More than 10 million people continue to fall ill with TB every year. Moreover, adolescents and adults account for over 80% of the TB burden and are the main source of transmission, including to children.

The main health care intervention available to reduce the risk of TB infection progressing to active TB disease, is TB preventive treatment. Other preventive interventions include vaccination of children with the bacille Calmette-Guérin (BCG) vaccine, which can confer protection, especially from severe forms of TB in children. Whereas TB vaccination is the most cost-effective and efficient approach in tackling this challenge, no new vaccines for prevention of all forms of TB have been licensed for over 100 years. BCG offers inconsistent protection against TB in adolescents and adults. Several TB vaccines are currently in clinical development, including some in phase III.

As part of the 2023 United Nations (UN) Declaration on TB, world leaders adopted a historical declaration with ambitious commitments to universal access to TB services in both high and low burden countries, with time-bound targets of reaching, with health services, at least 90% of people with or at risk of TB between 2023 and 2027, to increased investments in the TB response (including for research and innovation), and to fast-tracking the development and availability of new tools to prevent, diagnose and treat TB, particularly new TB vaccines. This includes USD 5 billion by 2027 for TB research and innovation, especially to high-burden countries. The Global Fund to Fight AIDS, TB and Malaria remains the main international donor (USD 9,2 billion for the three epidemics) and the Gates foundation the main contributor from the non-governmental sector. Among others, the other main funders include: Biofabri, company X, EDCTP, European Commission, Germany Federal Ministry of Education and Research, Global Affairs Canada, Indian Council of Medical Research, Innovative Health Initiative, L'Initiative, Novo Nordisk Foundation, Open Philanthropy, Otsuka Pharmaceutical, Oxford Immunotec, Unitaid, US Agency for International Development, US Centres for Disease Control and Prevention, US National Institutes of Health and Wellcome Trust.

This investment will build on and complement the previous EDCTP2 investments which involved at least two TB vaccine candidates in late-stage clinical development and played a pivotal role in the development of the Global TB Vaccine R&D roadmap. This call for proposals is part of the implementation of this roadmap that prioritises diversifying the TB vaccines pipeline and accelerating clinical development of vaccine candidates with an end-to-end approach to maximise public health impact.

Expected Outcome

This topic aims at supporting activities that contribute to one or several of the expected impacts for this call. To that end, proposals submitted under this topic should aim for delivering results that are

directed, tailored towards and contributing to at least two of the following expected outcomes, with the first being mandatory:

- Obtain evidence of immunogenicity, efficacy, safety or clinical utility on vaccine candidates under development and licensed vaccine(s).
- Generate clinical data on TB prophylactic vaccines serving adolescents and adults, and including where appropriate pregnant and lactating women, new-borns, children, other vulnerable and neglected populations, and people with co-infections and co-morbidities at risk in SSA.
- Contribute to the data package related to immunisation/vaccination enabling public health authorities and policy makers to recommend on vaccination strategies, publish updated or new evidence-based clinical guidelines and best practices or design tailor-made TB policies targeting SSA.

Scope

The objective of the topic is to progress the development of vaccine candidates under development and licensed TB vaccines, especially targeting the population in low-middle countries, particularly in SSA.

Proposals should carry out early and/or late-stage clinical studies to evaluate the safety, immunogenicity, efficacy and/or clinical utility on vaccine candidates under development and licensed vaccines in SSA. Proposals are to generate clinical data on TB prophylactic vaccines in adults and adolescents, and including where appropriate, pregnant and lactating women, new-borns, children, other vulnerable and neglected populations, and people with co-infections and co-morbidities at risk in SSA when relevant. A comparative arm with BCG and an assessment of overall health outcomes may be included when appropriate.

Implementation research is not in the scope of this topic.

Proposals submitted against this topic are expected to leverage financial and/or in-kind contribution from contributing partners. Proposals should define the activities of their project in its entirety, including details of the component(s) for which Global Health EDCTP3 funding is requested and the component(s) that are to be financed by contributing partners. Proposals should carefully consider WHO's Product Profile Characteristics and/or Evidence Considerations for Vaccine Policy framework. Applicants need to concisely describe any prior relevant research findings and explain how the proposal builds on available data (including data generated in scope of earlier EDCTP programmes if available). Full details of the development milestones, including specific go/no-go criteria for the implementation of the proposed clinical trial(s) must be included, as well as specific plans for the subsequent regulatory approval process, which should aim at obtaining relevant market authorisation. and an access strategy that will allow patients in low-resource settings to access the final product.

The applicants are encouraged to consider new adaptive trial designs and lessons learnt from COVID-19 potentially allowing for shorter development timelines.

Proposals should engage communities and relevant stakeholders, most notably (local) key opinion leaders, researchers or clinical Investigators, health care professionals, policy makers, public health authorities and end-users. Applicants should provide methodologies for translating research findings into public health practice and policy guidelines.

Where possible, collaboration and coordination with the Team Europe Initiative on Manufacturing and Access to Vaccines, medicines and health products (TEI-MAV+) or similar African initiatives is encouraged. The applicants could show, for example, willingness to enter into technology transfer agreements with their counterparts - including the provision of patents, technical knowledge and know-how -, or early engagement with regulators or with African manufacturers to support the translation into affordable products adapted to the regional market.

Applicants are reminded of the expectation that proposals should come from research consortia with a strong representation of institutions and researchers from sub-Saharan African countries, including active participation of Franco/Lusophone countries, if possible. Collaboration with other international research groups with relevant experience is very much encouraged. Applicants are also reminded of the expectation of reaching out to institutions/organisations in countries with high disease burden but with relatively lower research capacities.

Expected impact

The actions funded under this topic should contribute to increased international cooperation among researchers and funders, catalyse research synergies, and leverage resources and investments in order to achieve the reduction of disease burden in SSA through the development of vaccines.

Proposals are expected to include the effective in-kind and/or financial contribution of contributing partners, in order to produce meaningful and significant effects enhancing the impact of the related research activities.

Applicant consortium

The contributions from contributing partners should correspond to the amounts they have committed in the letter of endorsement requesting to become a contributing partner (Article 9 Council Regulation (EU) 2021/2085). Their contributions can consist of financial contributions and/or in-kind contributions. Applicant contributing partners must submit the endorsement letter for approval by the Global Health EDCTP3 Governing Board before the deadline for submission of the second-stage applications. It is recommended that the draft letter is submitted to the Global Health EDCTP3 Programme Office sufficiently ahead of deadline for submission of proposals to allow the review[51].

In case of in-kind contribution (even combined with financial contribution), contributing partners become a part of the applicant consortium and participate in the project, as appropriate i.e. as beneficiaries or affiliated entities in the meaning of Article 8 of the Horizon Europe model grant agreement.

Specific conditions to the topic	
Expected JU contribution per project	Global Health EDCTP3 estimates that a JU contribution of up to EUR 15.3 million per project to be matched by an equal or greater financial and/or in-kind contribution from contributing partners, would allow the outcomes of this topic to be addressed appropriately. Nonetheless,

[51] The Global Health Programme Office will ask the applicant contributing partner to revise the letter in case it significantly departs from the template letter published on the Global Health EDCTP3 JU website or is missing any compulsory elements. The preliminary assessment by the Programme Office does not consider the merits of the application. The final decision as to acceptance or rejection of a new contributing partner rests with the Global Health EDCTP3 JU Governing Board.

	this does not preclude submission and selection of a proposal requesting different amounts.
Indicative budget	The total indicative JU budget for the topic is EUR 45.9 million.
Type of Action	Research and Innovation Action (RIA)
Award criteria	Additionally to the aspects of award criteria included in General Annex D, the following aspects are taken into consideration during the evaluation of second-stage proposals: For the 'impact' criterion: Production of meaningful and significant effects enhancing the impact of the relevant research activities via the inclusion of effective in-kind and/or financial contribution of contributing partners. For the 'quality and efficiency of the implementation' criterion: Leveraging of financial and/or in-kind contributions from contributing partners that are equal or greater than the requested JU contribution, in order to ensure the necessary resources and effort for the action.
Legal and financial set-up of the Grant Agreements - Standard deliverables	Implementing the provision on affordable access as defined in Article 114 of the Council Regulation 2021/2085 establishing[52], grants awarded under this topic will have to include in their Plan for the exploitation and dissemination of results including communication activities to be submitted during the project as a deliverable also the following: **Access plan** Participants must include in their Plan for the exploitation and dissemination of results an appropriate and proportionate access plan that demonstrates their strategies to ensure that the products and services that they develop based or partly based on the results of clinical studies undertaken by their project are affordable, available and accessible to the public (market and end-users) at fair and reasonable conditions. This covers registration targets, plans to meet demand, flexible approaches to IP, engagement with regulators and manufacturers where relevant and other strategies that reflect ability to pay and ensures that economic barriers to access are low. In addition, participants should add, if relevant, as part of the plan, an outline on how to achieve the optimal use of an intervention including, for example, how to avoid irrational use, overuse or abuse (e.g. antimicrobials). Additionally to any updates during the project, a final version of the Plan for the exploitation and dissemination of results including the above access plan, must also be submitted with the final report of the project.

[52] Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014; OJ L 427, 30.11.2021, p. 17.

Legal and financial set-up of the Grant Agreements - Additional exploitation obligations	Also in line with Article 114 of the Council Regulation 2021/2085, participants will be subject to the following additional exploitation obligations: 1. Participants must – up to four years after the end of the action (see Data Sheet, Point 1) – use their best efforts to ensure that resulting health technologies and services will be broadly available and accessible, as soon as possible and at fair and reasonable conditions. In this respect, if, despite a participants' best efforts, the results are not exploited within one year after the end of the action, participants must (unless otherwise agreed in writing with the granting authority) use the Horizon Results Platform to find interested parties to exploit the results. 2. In case the participants cannot fulfil the preceding obligation, the participants must (if requested by the granting authority) grant non-exclusive licences - under fair and reasonable conditions - to their results to legal entities that commit to rapidly and broadly exploiting the resulting health technologies and services and ensure that they are broadly available and accessible, as soon as possible and at fair and reasonable conditions. 3. In case of transfer of the ownership or licensing of results, participants must pass on such additional exploitation obligations to the legal entities exploiting the results. 4. For up to four years after the action (see Data Sheet, Point 1), the funding body must be informed every year about the status of the development of the product and any other exploitation of the results through an annual report that is due on each anniversary of the end of the grant agreement.
Other requirements	For all projects under this topic, if the coordinator is not from a country in SSA, the designation of a scientific project leader with the roles as described in the introduction is mandatory. A work package on 'scientific project leadership' must be included in the proposals and budget needs to be provided for this activity.

HORIZON-JU-GH-EDCTP3-2025-01-MALARIA-02-two-stage: Global collaboration action for research on existing Malaria therapeutics and clinical development of new antimalarial candidates

Background

In the past two decades, significant progress has been made in the fight against malaria. However, malaria remains a major burden with enormous socio-economic impact, on individual, family, community, and national levels in many parts of sub-Saharan Africa. In 2022, the WHO African Region accounted for about 93.6% of cases and 95.4% of deaths globally; 78.1% of all deaths in the WHO African region were among children aged under 5 years in 2022, compared with 90.7% in 2000. Between 2019 and 2020, estimated malaria cases increased from 218 million to 230 million, and deaths from 552,000 to 604,000.

Despite recent progress made towards malaria control including implementation of the Malaria RTS,S and R21 vaccines, serious bottlenecks remain in providing compelling regional effectiveness data in the context of combined medical interventions and full access to preventive interventions, diagnostic testing, and treatment and further efforts are required to ensure these vaccines are well integrated in multi-tool strategies to prevent and control the disease. The greatest burden of disease affects children, pregnant women, and immune-compromised individuals of all age groups.

Several antimalarial drugs have been developed, but the ever-present potential for emergence of resistance underscores the need for new highly efficacious drugs with adequate safety profiles. In addition, new antimalarial drugs with different modes of action are needed for malaria chemoprevention in the most vulnerable populations.

In this context, Global Health EDCTP3 aims to invest in Malaria therapeutics and strategically pivot the major investments made by funding of the earlier EDCTP programmes in this field. Recommendations from the JU advisory bodies and results of the literature review included the need for novel treatment strategies to address the resistance against Artemisinin-based combination, R&D for malaria therapeutics in the light of emerging resistance and generation of evidence on. In addition, the need for preparatory studies to design and conduct clinical trials focusing on complimentary tools for maximum impact (vaccines, treatments, prophylaxis, vector control) was also highlighted.

Expected Outcome

This topic aims at supporting activities that contribute to one or several of the expected impacts for this call. Proposals submitted under this topic should aim for delivering results that are directed, tailored towards and contributing to at least two of the following expected outcomes:

- Generate clinical data progressing development of new or improved antimalarial treatment regimen combatting drug resistance.
- Progress new drug(s) and/or drug combinations towards registration for treatment of malaria in SSA.
- Generate clinical data on special populations, including pregnant women, neo-nates, infants, children, adolescents and immune-compromised individuals living in high transmission regions.
- Generation of evidence on resistance to current treatments including combined therapies, as secondary outcome.

Scope

Proposals submitted under this topic are expected to advance the clinical development of existing and new antimalarial candidates.

The development of prophylactic vaccines and monoclonal antibodies is not in scope for this topic.

Proposals should carry out early and/or late-stage clinical studies to evaluate the safety, efficacy and effectiveness of new combinations of currently approved or novel therapeutic candidates targeting individuals in SSA. Proposals are to generate clinical data targeting children, pregnant women, and immune-compromised individuals or adolescents living in high transmission regions as relevant. Interventions may target both *P. Falciparum* and/ or *P. Vivax*. Promising transmission blocking agents may be included as part of combination therapies.

To this end, proposals submitted under this call topic should address at least two of the following, with the first being mandatory:

- Clinical trials from Phase 2a onwards, to progress the development of new combinations of currently approved or novel therapeutic candidates.
- Long term effectiveness studies through aligned primary endpoints where possible.
- Generation of pharmacovigilance data on currently registered therapeutics or candidates in late-stage efficacy trials.
- Evidence on resistance to current treatments including combined therapies as secondary outcome.

Proposals submitted against this topic are expected to leverage financial and/or in-kind contribution from contributing partners. Proposals should define the activities of their project in its entirety, including details of the component(s) for which Global Health EDCTP3 funding is requested and the component(s) that are to be financed by contributing partners.

Where possible, collaboration and coordination with the Team Europe Initiative on Manufacturing and Access to Vaccines, medicines and health products (TEI-MAV+) or similar African initiatives is encouraged. Applicants could show, for example, willingness to enter into technology transfer agreements with African counterparts - including the provision of patents, technical knowledge and know-how -, or early engagement with regulators or with African manufacturers to support the translation into affordable products adapted to the regional market.

Applicants are reminded of the expectation that proposals should come from research consortia with a strong representation of institutions and researchers from SSA countries, including involvement of Franco/Lusophone countries, if possible. Applicants are also reminded of the expectation of reaching out to organisations in countries with relatively lower research capacities.

Proposals should clearly describe the desired target product profile. Applicants need to concisely describe any prior relevant research findings and explain how the proposal builds on available data (including data generated in scope of earlier EDCTP programmes if available). Full details of the development milestones, including specific go/no-go criteria for the implementation of the proposed

clinical trial(s) must be included, as well as specific plans for the subsequent regulatory approval process, which should aim at obtaining relevant market authorisation and an access strategy that will allow patients in low-resource settings to access the final product.

Proposals should engage communities and relevant stakeholders, most notably (local) key opinion leaders, researchers, health care professionals, policy makers, public health authorities and end-users. Applicants should provide methodologies for translating research findings into public health practice and policy guidelines.

Collaboration with other international research groups with relevant experience is very much encouraged.

Expected impact

The action funded under this call for proposals should contribute to increased international cooperation among researchers and funders, catalyse research synergies, and leverage resources and investments in order to achieve rapid advances in the development of new or improved anti-malarial drugs or drug combinations. The action should have the potential to achieve maximum impact in the field and to make a significant contribution to the objectives of the Global Health EDCTP3 programme, and in particular:

- Contribute towards combatting drug resistance through development of new or improved antimalarial products.
- Lead to the advancement of new drugs and/or drug combinations, with the aim of registration of new drug(s) and/or drug combinations for treatment and prevention of malaria in SSA and globally.
- Contribute to the reduction of malaria mortality and morbidity in SSA, particularly in pregnant women, infants and children and thus contribute to achieving SDG 3 ‘Ensure healthy lives and promote well-being for all at all ages’.

Proposals are expected to include the effective in-kind and/or financial contribution of contributing partners, in order to produce meaningful and significant effects enhancing the impact of the related research activities.

Applicant consortium

The contributions from contributing partners should correspond to the amounts they have committed in the letter of endorsement requesting to become a contributing partner (Article 9 Council Regulation (EU) 2021/2085). Their contributions can consist of financial contributions and/or in-kind contributions. Applicant contributing partners must submit the endorsement letter for approval by the Global Health EDCTP3 Governing Board before the deadline for submission of the second-stage applications. It is recommended that the draft letter is submitted to the Global Health EDCTP3 Programme Office sufficiently ahead of deadline for submission of proposals to allow the review[53].

In case of in-kind contribution (even combined with financial contribution), contributing partners become a part of the applicant consortium and participate in the project, as appropriate i.e. as

[53]The Global Health Programme Office will ask the applicant contributing partner to revise the letter in case it significantly departs from the template letter published on the Global Health EDCTP3 JU website or is missing any compulsory elements. The preliminary assessment by the Programme Office does not consider the merits of the application. The final decision as to acceptance or rejection of a new contributing partner rests with the Global Health EDCTP3 JU Governing Board.

beneficiaries or Affiliated entities in the meaning of Article 8 of the Horizon Europe model grant agreement.

Specific conditions to the topic	
Expected JU contribution per project	Global Health EDCTP3 estimates that a JU contribution of up to EUR 10.3 million per project to be matched by an equal or greater financial and/or in-kind contribution from other contributing partners, would allow the outcomes of this topic to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
Indicative budget	The total indicative JU budget for the topic is EUR 30.9 million.
Type of Action	Research and Innovation Action (RIA)
Award criteria	Additionally to the aspects of award criteria included in General Annex D, the following aspects must be taken also into consideration during the evaluation of second-stage proposals: For the 'impact' criterion: Production of meaningful and significant effects enhancing the impact of the relevant research activities via the inclusion of effective in-kind and/or financial contribution of contributing partners. For the 'quality and efficiency of implementation' criterion: Leveraging of financial and/or in-kind contributions from contributing partners that are equal or greater than the requested JU contribution, in order to ensure the necessary resources and effort for the action.
Legal and financial set-up of the Grant Agreements - Standard deliverables	Implementing the provision on affordable access as defined in Article 114 of the Council Regulation 2021/2085 establishing[54], grants awarded under this topic will have to include in their Plan for the exploitation and dissemination of results including communication activities to be submitted during the project as a deliverable also the following: **Access plan** Participants must include in their Plan for the exploitation and dissemination of results an appropriate and proportionate access plan that demonstrates their strategies to ensure that the products and services that they develop based or partly based on the results of clinical studies undertaken by their project are affordable, available and accessible to the public (market and end-users) at fair and reasonable conditions. This covers registration targets, plans to meet demand, flexible approaches to IP, engagement with regulators and manufacturers where relevant and other strategies that reflect ability to pay and ensures that economic barriers to access are low. In addition, participants should add, if relevant, as part of the plan, an outline on how to achieve the optimal use of an intervention

[54] Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014; OJ L 427, 30.11.2021, p. 17.

	including, for example, how to avoid irrational use, overuse or abuse (e.g. antimicrobials). Additionally to any updates during the project, a final version of the Plan for the exploitation and dissemination of results including the above access plan, must also be submitted with the final report of the project.
Legal and financial set-up of the Grant Agreements - Additional exploitation obligations	Also in line with Article 114 of the Council Regulation 2021/2085, participants will be subject to the following additional exploitation obligations: 1. Participants must – up to four years after the end of the action (see Data Sheet, Point 1) – use their best efforts to ensure that resulting health technologies and services will be broadly available and accessible, as soon as possible and at fair and reasonable conditions. In this respect, if, despite a participants' best efforts, the results are not exploited within one year after the end of the action, participants must (unless otherwise agreed in writing with the granting authority) use the Horizon Results Platform to find interested parties to exploit the results. 2. In case the participants cannot fulfil the preceding obligation, the participants must (if requested by the granting authority) grant non-exclusive licences - under fair and reasonable conditions - to their results to legal entities that commit to rapidly and broadly exploiting the resulting health technologies and services and ensure that they are broadly available and accessible, as soon as possible and at fair and reasonable conditions. 3. In case of transfer of the ownership or licensing of results, participants must pass on such additional exploitation obligations to the legal entities exploiting the results. 4. For up to four years after the action (see Data Sheet, Point 1), the funding body must be informed every year about the status of the development of the product and any other exploitation of the results through an annual report that is due on each anniversary of the end of the grant agreement.
Other requirements	For all projects under this topic, if the coordinator is not from a country in SSA, the designation of a scientific project leader with the roles as described in the introduction is mandatory. A work package on 'scientific project leadership' must be included in the proposals and budget needs to be provided for this activity. Contributing partners (if any) may have access to and be involved in the assessment of the deliverables and reports of projects they co-fund.

HORIZON-JU-GH-EDCTP3-2025-01-NTD-03-two-stage: Accelerating the development of prophylactic vaccines against Neglected Tropical Diseases (NTDs) in sub-Saharan Africa

Background

Neglected Tropical Diseases (NTDs) represent a challenge to public health, particularly in the African continent, where their prevalence is intertwined with socio-economic disparities. In January 2021, the WHO published the report "Ending the neglect to attain the sustainable development goals: a roadmap for neglected tropical diseases 2021-2030" followed by 2024 WHO Global report which is the second in a series of global reports describing progress towards the 2030 targets set in the road map for neglected tropical diseases 2021–2030. The road map sets global targets and milestones to prevent, control, eliminate or eradicate 20 diseases and disease groups as well as cross-cutting targets aligned with the Sustainable Development Goals. Three foundational pillars will support global efforts to achieve the targets: accelerate programmatic action (pillar 1), intensify cross-cutting approaches (pillar 2) and change operating models and culture to facilitate country ownership (pillar 3). The overarching global targets described in this report, in line with the SDGs and the WHO's 13th General Programme of Work are to ensure 90% fewer people requiring interventions against NTDs, 75% fewer NTD-related DALYs and 100 countries achieving elimination of at least one NTD and eradication of two NTDs (Dracunculiasis and Yaws).

The 2023 Annual WHO African region report[55] mentions: "Nineteen countries in the WHO African Region have successfully eliminated at least one NTD, with Togo notably eliminating four: Guinea worm disease, lymphatic filariasis, human African trypanosomiasis (HAT) (gambiense), and trachoma".

As progress is made on the therapeutics front with tangible impact from EDCTP2 investments, it has been increasingly evident that vaccine development represents a very valuable solution. Today, Dengue, Chikungunya and Rabies are the only NTDs that can be prevented through vaccination, but cost and availability still limit their more widespread use. Moreover, the development of NTD vaccines, including those for schistosomiasis, leishmaniasis, leprosy, hookworm, and Chagas disease are led by nonprofit product development partnerships with a need for more funds to address translational activities.

In this context, the Global Health EDCTP3 programme is aiming to contribute significantly to the fight against NTDs and alleviate the disease burden in Africa aligning with SDGs and fostering improved health outcomes for the most vulnerable populations. It aims to unite the collective intersectoral efforts of researchers, policymakers, and healthcare practitioners, ensuring inclusivity for all.

Expected Outcome

This topic aims at supporting activities that contribute to one or several of the expected impacts for this call. Proposals submitted under this topic should aim for delivering results that are directed, tailored towards and contributing to following one of the expected outcomes:

55 ENDISA NTD report_Final (who.int)

- Generate data on novel or existing vaccines (Phase II/Phase III trials) to make progress towards prevention, control and elimination of NTDs in SSA (note: in case of no or limited vaccine candidates in development, early development is encouraged (Phase I onwards).
- Improve the understanding of barriers for progression of new or improved vaccines against NTDs through the R&D pipeline.
- Generate clinical data including pregnant and lactating women, new-borns, children, adolescents, other vulnerable and neglected populations, and people with co-infections and co-morbidities at risk in SSA as relevant.

Scope

The objective of the topic is to progress the development of prophylactic vaccines against NTDs in sub-Saharan Africa.

Proposals should carry out early and/or late-stage clinical studies to evaluate the safety, immunogenicity, efficacy in Africa in NTDs. The **NTDs in scope** of Global health EDCTP3 are: 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, and yaws. **NTDs out of scope** are: Chagas, chromoblastomycosis and other deep mycoses, scabies and other ectoparasites, and snakebite envenoming. Proposals should identify clearly which NTD(s) they are targeting.

Research on development of integrated preventive measures across NTDs is strongly encouraged.

Combined approaches embracing vector control and vaccine development targeting the host/reservoir in the context of One Health are applicable. However, implementation research is out of scope for this topic.

Proposals are to generate clinical data on prophylactic vaccines in the general population and/or, when relevant, include pregnant and lactating women, new-borns, children, adolescents, other vulnerable and neglected populations, and people with co-infections and co-morbidities at risk in SSA. Relevant determining characteristics (sex, gender, age, socio-economic status, etc.) are to be considered. Where possible, collaboration and coordination with the Team Europe Initiative on Manufacturing and Access to Vaccines, medicines and health products (TEI-MAV+) or similar African initiatives is encouraged. The applicants could show, for example, willingness to enter into technology transfer agreements with African counterparts - including the provision of patents, technical knowledge and know-how, or early engagement with regulators or with African manufacturers to support the translation into affordable products adapted to the regional market.

Proposals should clearly describe the desired target product profile. Applicants need to concisely describe any prior relevant research findings and explain how the proposal builds on available data (including data generated in scope of earlier EDCTP programmes if available). Full details of the development milestones, including specific go/no-go criteria for the implementation of the proposed clinical trial(s) must be included, as well as specific plans for the subsequent regulatory approval process, which should aim at obtaining relevant market authorisation and an access strategy that will allow patients in low-resource settings to access the final product.

The applicants are encouraged to consider new adaptive trial designs and lessons learnt from COVID-19 potentially allowing for shorter development timelines.

Proposals should engage communities and relevant stakeholders, most notably (local) key opinion leaders, researchers, health care professionals, policy makers, public health authorities and end-users. Applicants should provide methodologies for translating research findings into public health practice and policy guidelines and, if relevant, market exploration plans.

Applicants are reminded of the expectation that proposals should come from research consortia with a strong representation of institutions and researchers from sub-Saharan African countries, including involvement of Franco/Lusophone countries, if possible. Collaboration with other international research groups with relevant experience is very much encouraged. Applicants are also reminded of the expectation of reaching out to organisations in countries with relatively lower research capacities.

All projects funded under this topic are strongly encouraged to participate in networking and joint activities, such as external conferences, workshops or symposiums for an exchange of knowledge, and best practices with external collaborators.

The purpose of this topic is to fund a varied portfolio of projects tackling different diseases. The granting authority will therefore base its funding decision relevant to this topic on the ranking of the proposals taking into account diversity of the respective diseases targeted in the proposals that are graded above the threshold.

Specific conditions to this topic	
Expected JU contribution per project	Global Health EDCTP3 estimates that a JU contribution of up to EUR 15.3 million per project would allow the outcomes of this topic to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
Indicative budget	The total indicative JU budget for the topic is EUR 45.9 million.
Type of Action	Research and Innovation Action (RIA)
Procedure	Additionally to General Annex F, the following is taken into consideration for the evaluation procedure and ranking: The purpose of this topic is to fund a varied portfolio of projects tackling different diseases. The granting authority will therefore base its funding decision relevant to this topic on the ranking of the proposals taking into account diversity of the respective diseases targeted in the proposals that are graded above the threshold. It may therefore fund in priority proposals that are ranked lower than others, if they target another relevant disease that is not tackled yet among the higher ranked proposals.

Legal and financial set-up of the Grant Agreements - Standard deliverables	Implementing the provision on affordable access as defined in Article 114 of the Council Regulation 2021/2085 establishing[56], grants awarded under this topic will have to include in their Plan for the exploitation and dissemination of results including communication activities to be submitted during the project as a deliverable also the following: **Access plan** Participants must include in their Plan for the exploitation and dissemination of results an appropriate and proportionate access plan that demonstrates their strategies to ensure that the products and services that they develop based or partly based on the results of clinical studies undertaken by their project are affordable, available and accessible to the public (market and end-users) at fair and reasonable conditions. This covers registration targets, plans to meet demand, flexible approaches to IP, engagement with regulators and manufacturers where relevant and other strategies that reflect ability to pay and ensures that economic barriers to access are low. In addition, participants should add, if relevant, as part of the plan, an outline on how to achieve the optimal use of an intervention including, for example, how to avoid irrational use, overuse or abuse (e.g. antimicrobials). Additionally to any updates during the project, a final version of the Plan for the exploitation and dissemination of results including the above access plan, must also be submitted with the final report of the project.
Legal and financial set-up of the Grant Agreements - Additional exploitation obligations	Also in line with Article 114 of the Council Regulation 2021/2085, participants will be subject to the following additional exploitation obligations: 1. Participants must – up to four years after the end of the action (see Data Sheet, Point 1) – use their best efforts to ensure that resulting health technologies and services will be broadly available and accessible, as soon as possible and at fair and reasonable conditions. In this respect, if, despite a participants' best efforts, the results are not exploited within one year after the end of the action, participants must (unless otherwise agreed in writing with the granting authority) use the Horizon Results Platform to find interested parties to exploit the results. 2. In case the participants cannot fulfil the preceding obligation, the participants must (if requested by the granting authority) grant non-exclusive licences - under fair and reasonable conditions - to their results to legal entities that commit to rapidly and broadly exploiting the resulting health technologies and services and

[56] Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014; OJ L 427, 30.11.2021, p. 17.

	ensure that they are broadly available and accessible, as soon as possible and at fair and reasonable conditions. 3. In case of transfer of the ownership or licensing of results, participants must pass on such additional exploitation obligations to the legal entities exploiting the results. 4. For up to four years after the action (see Data Sheet, Point 1), the funding body must be informed every year about the status of the development of the product and any other exploitation of the results through an annual report that is due on each anniversary of the end of the grant agreement.
Other requirements	For all projects under this topic, if the coordinator is not from a country in SSA, the designation of a scientific project leader with the roles as described in the introduction is mandatory. A work package on 'scientific project leadership' must be included in the proposals and budget needs to be provided for this activity.

HORIZON-JU-GH-EDCTP3-2025-02-FELLOWSHIP-01-two-stage: Global Health EDCTP3 and contributing partners funded Strategic Training Hubs for Fellowships in Public Health covering Biostatistics, Epidemiology and Modelling

Background

Capacity building and strengthening of the research environment is at the core of Global Health EDCTP3 objectives and in line with the implementation of the EU Global Health Strategy's Guiding Principles 6 and 7 to "address workforce imbalances and foster skills" and "strengthen capacities for prevention, preparedness and response and early detection of health threats globally".

The Africa CDC Framework for Public Health Workforce Development 2020-2025 aims to strengthen the capacity of 1) field epidemiologists, 2) laboratory leadership and medical laboratory training, 3) public health informatics, as well as 4) specific knowledge and skills such as surveillance, AMR monitoring and management, laboratory quality assurance as well as surveillance and response. The 2023-2027 Africa CDC Strategic Plan stresses the acute shortage of critical public health workforce with only 1 900 field epidemiologists out of the 6,000 required and only 5,000 of the needed 25,000 frontline epidemiologists.

Following a pilot collaboration with Africa CDC for a joint fellowship call under EDCTP2, Global Health EDCTP3 is proposing to renew the joint call for fellowships[57]. After taking stock of the lessons learnt from the first programme, a funders partnership will support a joint call, 1) to increase the number of fellows trained and 2) to expand the breadth of skills offered and diversity hosting institutions involved. This renewed joint call will include epidemiology and biostatistics and infectious disease modelling.

Expected Outcome

Proposals submitted under this topic should aim for delivering results that contribute to at least three of the following expected outcomes:

- Increase the number of public experts: skilled epidemiologists, biostatisticians, and infectious diseases modellers in sub-Saharan Africa (SSA).
- Promote the career development and retention of skilled personnel in SSA.
- Strengthen SSA countries clinical human capital base in R&I.
- Enhance talent retention, knowledge circulation and uptake across the research and innovation landscape in SSA.
- Establish sustainable and mutually beneficial collaboration between national public health institutes, clinical research organisations and academia across SSA and Europe.

Scope

The objective of this topic is to establish an African cohort of epidemiologists, biostatisticians, mathematical modellers by supporting institutions in SSA and Europe that provide Master's training in

[57] Cooperation is based on the "Working Arrangement between the Africa CDC and the European Commission" signed in March 2024 and is foreseen to be further developed within a framework collaboration agreement between the Global Health EDCTP3 JU and Africa CDC (currently under preparation).

epidemiology and biostatistics or those that process public health data with advanced quantitative methods to inform policy, as part of the Africa CDC's framework for public health workforce development.

The Master's degree courses with practical field research experience must be robust and of the level of training for the epidemiology and biostatistics that is delivered within reasonable time for the required numbers and high-quality fit-for purpose personnel urgently needed in zones of outbreak/epidemic risks in SSA. Early- to mid-career researchers or data scientists (or similar) are the targeted level of training for the infectious disease modelling.

Proposals must demonstrate all of the following:

- A high-quality training programme as 1) Master's training in Epidemiology and/or Biostatistics (broader Master's in public health majoring in epidemiology or biostatistics are also applicable); or 2) specific training courses/seminars/workshops infectious disease mathematical modelling.
- The Master's programme must include a research and development component aligned with the scope of Global Health EDCTP3 and must be conducted in a country in SSA.
- An open, fair and transparent procedure for selecting the fellows coming from different geographical regions of SSA, based on quality and with appropriate gender balance.
- Robust mentorship and supervision mechanisms to support fellows through to timely successful course completion.
- The applicant must be an organisation with an established legal entity in SSA (the applicant legal entity).
- Proposals must be submitted by a consortium of institutions which must provide above mentioned trainings for up to 50 early- to mid-career researchers per consortium.
- Proposals should provide details on the methodology for linking clinical research aspects with the translation into healthcare practice and policy.
- The requested Global Health EDCTP3 contribution per action shall not exceed EUR 1.25 million.

The fellow must:

- Be resident of or be willing to relocate to a sub-Saharan African country, member of the EDCTP Association
- Not have been funded under a similar previous EDCTP or Global Health EDCTP3 fellowship scheme before.

In addition:

1) For the Master's degree training:

- Proposals should include institutions with a proven track record in the provision of high-quality Master's training with clear local and regional collaborations with National Public Health Institutes-NPHIs (or similar agencies), Ministries of Health and other academic institutions.
- The maximum fellowship duration shall be 24 months.
- Fellows for the Master training must be employed or have guaranteed employment by the applicant legal entity (the host organisation) where they intend to remain working for a minimum of two years after the expiration of the grant, therefore, applying trainees must provide evidence to demonstrate this through a letter of support from their home institution.

2) For proposals with modelling training:

Contributing partners, via the Global Health EDCTP3, will provide funding on modelling training, meeting the need for modellers to strengthen NPHIs core functions. The funding will support comprehensive short term training programmes, workshops and/or seminars to interested specialists to empower Africa-based researchers with relevant skills to conduct infectious disease modelling and enhance capacity to respond effectively to outbreaks and pandemics. Supported institutions will offer:

- Modelling training focusing on infectious diseases modelling;
- Workshops or seminars considering different skill levels of trainees to cover key aspects of infectious disease modelling, including but not limited to:

  i. Mathematical and statistical modelling techniques;
  ii. Scenario planning and model forecasting;
  iii. Integration of modelling output into public health policy and response strategies.

- Provide mentorship and support to facilitate the application of acquired skills in real world settings for key LMIC implementors.

Proposals submitted against this topic are expected to leverage financial and/or in-kind contribution from contributing partners. Proposals should define the activities of their project in its entirety, including details of the component(s) for which Global Health EDCTP3 funding is requested and the component(s) that are to be financed by contributing partners introduced by the applicant consortium.

In addition to these contributions leveraged by the applicants, Global Health EDCTP3 may involve other contributing partners that have expressed interest in supporting this topic with cash or in-kind contribution.

Proposals should describe how participating organisations are expected or plan to have access to large databases that will enable future fellows to work on and with robust data. Proposals are encouraged to include the use of Artificial Intelligence in the training when relevant.

FAIR data principles and open access of publications are required in line with the Model Grant Agreement[58].

Proposals should include consortia with strong representation from institutions and researchers across sub-Saharan African countries, demonstrating a broad regional distribution in the SSA region, including involvement of new institutions and Franco/Lusophone countries, and considering previous EDCTP 1 and 2 investments and the current Global Health EDCTP3 call. Applicants are also reminded of the expectation of reaching out to organisations in countries with high burden of disease with relatively lower research capacities, for which appropriate funding allocations should be proposed. Collaboration with other international research groups with relevant experience and participation in networking and joint activities, as relevant, is strongly encouraged.

Expected impact

[58] general-mga_horizon-euratom_en.pdf (europa.eu)

The actions funded under this topic should contribute to increased international cooperation among researchers and funders, catalyse research synergies, and leverage resources and investments in order to achieve the establishment of an African cohort of epidemiologists, biostatisticians, mathematical modellers by supporting institutions in sub-Saharan Africa and Europe that provide Master's training in epidemiology and biostatistics or those that process public health data with advanced quantitative methods to inform policy, as part of the Africa CDC's framework for public health workforce development. Proposals are expected to include the effective in-kind and/or financial contribution of contributing partners, in order to produce meaningful and significant effects enhancing the impact of the related research activities.

Applicant consortium

The contributions from contributing partners should correspond to the amounts they have committed in the letter of endorsement requesting to become a contributing partner (Article 9 Council Regulation (EU) 2021/2085). Their contributions can consist of financial contributions and/or in-kind contributions. Applicant contributing partners must submit the endorsement letter for approval by the Global Health EDCTP3 Governing Board before the deadline for submission of the second-stage applications. It is recommended that the draft letter is submitted to the Global Health EDCTP3 Programme Office sufficiently ahead of deadline for submission of proposals to allow the review[59].

In case of in-kind contribution (even combined with financial contribution), contributing partners become a part of the applicant consortium and participate in the project, as appropriate i.e. as beneficiaries or Affiliated entities in the meaning of Article 8 of the Horizon Europe model grant agreement.

Specific conditions to this topic	
Expected JU contribution per project	Global Health EDCTP3 estimates that a JU contribution of EUR 1.34 million to support 10 fellows per project, to be matched by an equal or greater financial and/or in-kind contribution from other contributing partners, would allow the outcomes of this topic to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts and number of fellows.
Indicative budget	The total indicative JU budget for the topic is EUR 6.7 million
Type of Action	Coordination and Support Action (CSA)
Admissibility and eligibility conditions	All proposals submitted under this topic must include the EDCTP Association as a coordinator at the second stage of the proposals' submission. This requirement is justified by the financial and administrative expertise of the EDCTP Association on project management and its technical expertise in SSA, which are relevant in the context of this lump sum Model Grant Agreement pilot. This is relevant namely regarding distribution of payments and quality of the reporting and deliverables. In addition, the EDCTP Association has a unique expertise in terms of African and European collaboration and wide knowledge of the research context in sub-Saharan Africa. The eligible costs of the EDCTP Association in the actions funded under this topic may not be reimbursed by the JU and may be used as a

[59] The Global Health Programme Office will ask the applicant contributing partner to revise the letter in case it significantly departs from the template letter published on the Global Health EDCTP3 JU website or is missing any compulsory elements. The preliminary assessment by the Programme Office does not consider the merits of the application. The final decision as to acceptance or rejection of a new contributing partner rests with the Global Health EDCTP3 JU Governing Board.

	basis for in-kind contributions to operational activities (IKOP). This in-kind contribution of the EDCTP Association will cover the coordination activities of the project. On the basis of the outcome of the first stage evaluation, the applicant consortia of the highest ranked short proposals (first stage) will be invited to contact the EDCTP Association in order to include it as coordinator in their full proposal (second stage) and obtain the estimated amount of the Association's contribution as well as any other relevant information. First stage applicants should nevertheless include an entity acting as coordinator to submit the proposal. The EDCTP Association must not be counted as one of the three independent legal entities necessary to ensure the eligibility of the consortium composition, as requested in the Call conditions, "*Specific conditions to Global Health EDCTP3 JU - B. Consortium composition".*
Award criteria	Additionally to the aspects of award criteria included in General Annex D, the following aspects are taken into consideration during the evaluation of second-stage proposals: For the 'impact' criterion: Production of meaningful and significant effects enhancing the impact of the relevant support and coordination activities via the inclusion of effective in-kind and/or financial contribution of contributing partners. For the 'quality and efficiency of the implementation' criterion: Leveraging of financial and/or in-kind contributions from contributing partners that are equal or greater than the requested JU contribution, in order to ensure the necessary resources and effort for the action.
Legal and financial set-up of the Grant Agreements	The rules are described in General Annex G. The following exceptions apply: Eligible costs will take the form of a lump sum as defined in the Decision of 7 July 2021 authorising the use of lump sum contributions under the Horizon Europe Programme – the Framework Programme for Research and Innovation (2021-2027) – and in actions under the Research and Training Programme of the European Atomic Energy Community (2021-2025). This decision is available on the Funding and Tenders Portal, in the reference documents section for Horizon Europe, under 'Simplified costs decisions' or through this link: ls-decision_he_en.pdf (europa.eu).
Legal and financial set-up of the Grant Agreements - Costs for providing financial support to third parties allowed	Beneficiaries may provide financial support to third parties. The support to third parties can only be provided in the form of grants. The maximum amount to be granted to each third party is EUR 90,000. This is justified since the main objective of these projects is to provide fellowship support. The support to third parties can only be provided in the form of grants. These grants are the fellowships to be awarded. The specific conditions regarding Global Health EDCTP3 JU fellowships laid down in Annex 5 to the Model Grant Agreement apply.

Other requirements	As the funding in these actions will also be provided by contributing partners introduced by Global Health EDCTP3, by applying under this topic, participants consent that the JU will share their project technical reports and deliverables with the contributing partners participating in the action, who may provide input to the JU for the assessment of the reports and deliverables. For all projects under this topic, the designation of a scientific project leader with the roles as described in the introduction is mandatory. A work package on 'scientific project leadership' must be included in the proposals and budget needs to be provided for this activity.

HORIZON-JU-GH-EDCTP3-2025-03-NETWORKS-01-two-stage: Global collaborative action for strengthening the Regional Networks of Excellence and Epidemic Preparedness Consortia

Background

The burden of recent outbreaks of Ebola Virus Disease (EVD), Mpox, Cholera along with the recent COVID-19 pandemic has been tremendous in terms of lives lost. Attempts were made during the epidemic to develop and evaluate vaccines, treatments, and diagnostics for EVD, but these were hampered by weak systems and capacity was not in place to carry out these activities on a very rapid timescale.

The earlier EDCTP Programmes have made important long-term investments towards the African clinical trials ecosystem through the regional networks of excellence, the epidemic preparedness and other related collaborative clinical research activities. The EDCTP consortia for Epidemic Preparedness were ready to carry out research response in several outbreaks across countries that were hosting the projects. It is vital that capacity is strengthened and further developed to undertake rapid evaluation of interventions in clinical trials when future outbreaks occur of emerging or re-emerging diseases. In parallel, strengthening surveillance systems to detect such outbreaks at an early stage, and strengthening laboratory systems to rapidly confirm diagnoses, are of high priority. Assembling background clinical and epidemiological data now on diseases that are currently prevalent and have epidemic potential, will facilitate the planning of clinical trials of new interventions, such as vaccines and treatments, as these are developed.

There are significant clinical research disparities and a very heterogeneous clinical research landscape for conducting clinical trials in sub-Saharan Africa (SSA) across African researchers, institutions, countries and sub-regions. Fostering research collaborations is a means of addressing this challenge through investing in a joint pathway towards a stronger and sustainable SSA clinical research landscape. It is important to invest in efforts that will enable effective management of infectious diseases with epidemic potential using evidence-based preventive methods, prompt laboratory diagnosis, timely treatment, protection of healthcare workers and at the same time ensuring geographical containment.

Alignment and coordination with key players in the field is important to ensure complementarity of investments. Building on EDCTP2 investments and in collaboration with key global health partners (GF, PEPFAR, CEPI, Africa CDC), Global Health EDCTP3 aims to strengthen the pre-established Networks of Excellence and Epidemic Preparedness Networks, through disease specific networks nodes (such as TB, HIV/AIDS, Malaria and NTDs depending on disease epidemiology and the networks' regional priorities), and horizontal functions weaved in the current health security architecture coordinated by the Africa CDC.

Expected Outcome

The purpose of this topic is to provide funding to restructured EDCTP Regional Networks tailored to the evolving regional clinical trials landscape and learnings from COVID-19, as well as other regional disease threats, towards achieving the pre-defined deliverables set out in this call.

Building on EDCTP2 investments, proposals under this topic should aim to deliver results that are directed, tailored towards, and contributing to the following expected outcomes. Proposals need to address all the following outcomes:

- Strengthening clinical research capacity in order to be able to conduct multi-country clinical trials to ICH-GCP standards and compliance with WHO Guidance for Best Practices for Clinical Trials[60].
- Enhancing collaboration and optimising the use of resources and infrastructures within the network.
- Offering training, mentorship and support to senior scientists to promote professional development and scientific leadership in clinical trials.
- Strengthening South-South, North-North and North-South collaborations between researchers and institutions.
- Encouraging and promoting networking and dialogue between researchers, communities and policy makers to maximise the impact of clinical research in Africa.
- Promote resource sharing and harmonisation.
- Establishing or strengthen partnerships with National Public Health Institutes.
- Establishing/strengthening/expanding multidisciplinary epidemiology networks, generating accelerated evidence for optimal management of patients and for guiding public health response to any severe infectious outbreak caused by pathogens within the scope of Global Health EDCTP3.

Scope

Proposals must address **three** of the following areas:

1. Expertise

- Strengthening expertise on clinical research in all disease areas in the scope of Global Health EDCTP3. Proposals aiming to strengthen expertise on HIV/AIDS clinical research are encouraged to align with activities supported by PEPFAR across SSA.
- Strengthening expertise and preparedness for research response to emerging and re-emerging diseases with epidemic potential. Proposals aiming to strengthen expertise and preparedness for research response to emerging and re-emerging diseases with epidemic potential are encouraged to align with activities supported by other funders.
- Supporting National Public Health Institutes in collaboration with Team Europe Initiative "Supporting Public Health Institutes in Africa" [61]. Strengthening/establishment, in conjunction with African CDC, of at least one ICH-GCP-compliant clinical trial site (compliant with WHO Guidance for Best Practices for Clinical Trials[62]) conducted and managed by appropriately qualified staff within the network.
- Pool of interdisciplinary experts organised in networks including at least one NPHI, able to provide accelerated evidence on infectious diseases.

60 Guidance for best practices for clinical trials (who.int)
61 Public Health Capacity - Africa | Capacity4dev
62 Guidance for best practices for clinical trials (who.int)

- Training of a specified number of clinical research associates, certified to monitor clinical trials and can be contracted by Global Health EDCTP3, other funders or clinical trial sponsors to monitor the progress and quality of clinical trials.
- Strengthening the ethics, regulatory, and pharmacovigilance capacities.

2. Training, mentorship and support to senior researchers

- Develop a comprehensive training and mentorship plan to support the career development of talented individuals through dedicated courses, short term staff exchange programmes, and active rotation process among sites for mentors/trainers and trainees.
- Support a specified number of senior researchers to conduct a research project leveraging the infrastructure, network and expertise supported through this call and EDCTP2 funding.

3. Partnerships

- Enhance South-South and North-South collaboration, and strengthen partnership with National Public Health Institutes and regional public health bodies.
- Propose a sustainability plan and networks that can be pivoted to respond to outbreaks within the respective sub-regions.
- Provide a coordination function to align with Africa CDC and other funders' strategies and activities to strengthen the African clinical trial ecosystem.

4. Infrastructure

- Upgrade at least one additional clinical laboratory, accredited to the GCLP standards.
- Develop/upgrade or expand a functioning data management service, which can be used by the network or contracted by external clinical trial sponsors.

Proposals submitted against this topic are expected to leverage financial and/or in-kind contribution from contributing partners. Proposals should define the activities of their project in its entirety, including details of the component(s) for which Global Health EDCTP3 funding is requested and the component(s) that are to be financed by contributing partners.

Proposals should include consortia with strong representation from institutions and researchers across sub-Saharan African countries, demonstrating a broad regional distribution in the SSA region, including involvement of new institutions and Franco/Lusophone countries, and considering previous EDCTP 1 and 2 investments and the current Global Health EDCTP3 call. Applicants are also reminded of the expectation of reaching out to organisations in countries with high burden of disease with relatively lower research capacities, for which appropriate funding allocations should be proposed. Collaboration with other international research groups with relevant experience and participation in networking and joint activities, as relevant, is strongly encouraged.

FAIR data principles and open access of publications are required in line with the Model Grant Agreement[63] when relevant.

[63] general-mga_horizon-euratom_en.pdf (europa.eu)

Expected impact

The actions funded under this topic should contribute to increased international cooperation among researchers and funders, catalyse research synergies, and leverage resources and investments in order to achieve the strengthening of the Regional Networks of Excellence and Epidemic Preparedness Consortia. Proposals are expected to leverage and include the effective in-kind and/or financial contribution of contributing partners, in order to produce meaningful and significant effects enhancing the impact of the related research activities.

Applicant consortium

The contributions from contributing partners should correspond to the amounts they have committed in the letter of endorsement requesting to become a contributing partner (Article 9 Council Regulation (EU) 2021/2085). Their contributions can consist of financial contributions and/or in-kind contributions. Applicant contributing partners must submit the endorsement letter for approval by the Global Health EDCTP3 Governing Board before the deadline for submission of the second-stage applications. It is recommended that the draft letter is submitted to the Global Health EDCTP3 Programme Office sufficiently ahead of deadline for submission of proposals to allow the review[64].

In case of in-kind contribution (even combined with financial contribution), contributing partners become a part of the applicant consortium and participate in the project, as appropriate i.e. as beneficiaries or affiliated entities in the meaning of Article 8 of the Horizon Europe model grant agreement.

Specific conditions for this topic	
Expected JU contribution per project	Global Health EDCTP3 estimates that a JU contribution of up to EUR 10 million per project to be matched by an equal or greater financial and/or in-kind contribution from other contributing partners, would allow the outcomes of this topic to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
Indicative budget	The total indicative JU budget for the topic is EUR 40 million.
Type of Action	Coordination and Support Action (CSA)
Admissibility and eligibility conditions	All proposals submitted under this topic must include the EDCTP Association as a coordinator already at the first stage of the proposals' submission. This requirement is justified by the financial and administrative expertise of the EDCTP Association on project management and its technical expertise in SSA, which are relevant in the context of this lump sum Model Grant Agreement pilot. This is relevant namely regarding distribution of payments and quality of the reporting and deliverables. In addition, the EDCTP Association has a unique expertise in terms of African and European collaboration and wide knowledge of the research context in sub-Saharan Africa. The coordinator is to ensure adequate coordination of the networks funded.

[64] The Global Health Programme Office will ask the applicant contributing partner to revise the letter in case it significantly departs from the template letter published on the Global Health EDCTP3 JU website or is missing any compulsory elements. The preliminary assessment by the Programme Office does not consider the merits of the application. The final decision as to acceptance or rejection of a new contributing partner rests with the Global Health EDCTP3 JU Governing Board.

	The eligible costs of the EDCTP Association in the actions funded under this topic may not be reimbursed by the JU and may be used as a basis for in-kind contributions to operational activities (IKOP). The in-kind contribution of the EDCTP Association will cover the coordination activities of the project. The applicant consortia should contact the EDCTP Association in order to include it as coordinator in their proposal and obtain the estimated amount of the Association's contribution as well as any other relevant information. The EDCTP Association will timely provide the information to all potential applicants. The EDCTP Association must not be counted as one of the three independent legal entities necessary to ensure the eligibility of the consortium composition, as requested in the Call conditions, "*Specific conditions to Global Health EDCTP3 JU - B. Consortium composition".*
Award criteria	Additionally to the aspects of award criteria included in General Annex D, the following aspects are taken into consideration during the evaluation of second-stage proposals: For the 'impact' criterion: Production of meaningful and significant effects enhancing the impact of the relevant support and coordination activities via the inclusion of effective in-kind and/or financial contribution of contributing partners. For the 'quality and efficiency of the implementation' criterion: Leveraging of financial and/or in-kind contributions from contributing partners that are equal or greater than the requested JU contribution, in order to ensure the necessary resources and effort for the action.
Legal and financial set-up of the Grant Agreements	The rules are described in General Annex G. The following exceptions apply: Eligible costs will take the form of a lump sum as defined in the Decision of 7 July 2021 authorising the use of lump sum contributions under the Horizon Europe Programme – the Framework Programme for Research and Innovation (2021-2027) – and in actions under the Research and Training Programme of the European Atomic Energy Community (2021-2025). This decision is available on the Funding and Tenders Portal, in the reference documents section for Horizon Europe, under 'Simplified costs decisions' or through this link: ls-decision_he_en.pdf (europa.eu
Other requirements	For all projects under this topic, the designation of a scientific project leader with the roles as described in the introduction is mandatory. A work package on 'scientific project leadership' must be included in the proposals and budget needs to be provided for this activity.

HORIZON-JU-GH-EDCTP3-2025-04-CH-01-two-stage: Global collaborative action tackling diarrhoeal diseases in the context of climate and health

Background

At the current 8-year mean heating of 1.14 degree Celsius pre-industrial levels, climate change is undeniably impacting health: over half of known human pathogenic diseases can be aggravated by climate change, 24% of all estimated global deaths are linked to the environment and WHO estimates that climate change, between 2030 and 2050, will cause approximately 250,000 additional deaths per year from malnutrition, malaria, diarrhoeal and heat stress alone. In addition to the health burden, unequal evidence base is also observed, with underdeveloped methods: only ~10% of peer-reviewed publications in 2022 were focusing on Africa and innovative tools integrating climate and health data for modelling are often skewed towards a specific disease and available in HICs. The need for integrated interdisciplinary approaches and the generation of impact evidence is lacking and will be instrumental to inform policy making and adaptation and mitigation options. Furthermore, disruptive and integrated innovations need to be incentivised to foster cross-sector collaboration.

This call focuses on diarrhoeal diseases (DDs) as part of the climate and health related diseases, majority of which are mostly transmitted through excreta-related infections. DDs are preventable and treatable but still represent the third leading cause of death in children 1–59 months of age. Globally, WHO reports nearly 1.7 billion cases of childhood diarrhoeal diseases every year (mostly in South-Asia and sub-Saharan Africa), leading to approximately 1.5 million deaths, of which over 400,000 children under 5 and over 50,000 children aged 5 to 9 years. Diarrhoea is also a leading cause of malnutrition in children under 5 years old. Repeated episodes of severe diarrhoea can lead to malnutrition, stunted growth and impaired cognitive development. DDs contribute to increased risk of death and ill health, diminished opportunities and reduced productivity over a lifetime for millions of people.

Increased temperatures, heavy rainfall or flooding have been associated to increased incidence of diarrhoeal diseases and have been shown to influence the transmission, geographical and seasonal ranges of diarrhoeal diseases. WHO reported projections estimating that climate change will lead to approximately 48,000 and 33,000 deaths per year in 2030 and 2050 respectively in children aged under 15 years. Context-specific evidence generation, vulnerability and adaptation assessments and adequate tools to combat diarrhoeal diseases are urgently needed in sub-Saharan Africa (SSA).

Expected Outcome

Within the scope of DDs of Global Health EDCTP3, this topic aims to reduce or manage the potential adverse consequences for DDs by contributing to at least two of the following expected outcomes, with the first being mandatory:

- Develop interventions to identify and control DDs through generating late-stage clinical data in sub-Saharan Africa.
- Implementation research combining interventions with current standard of care (including vaccines).
- Generate evidence to evaluate the populations and geographies of most vulnerable to DDs, understand the key underlying factors including those related to climate change, and understand the barriers to protect the people affected.

Scope

The scope of this call is anchored in the Global Health EDCTP3 SRIA.

The proposals are expected to generate late-stage clinical data evaluating safety, efficacy and clinical utility accelerating the development of novel or existing treatment against DDs or focus on late-stage development of novel or existing diagnostics to detect DDs. The scope limits to the following pathogens: rotavirus, shigella, cholera, enterotoxigenic E. coli, cryptosporidium, and norovirus. Solutions having the potential to reduce AMR are considered in scope. Other DD pathogens are out of scope of this call.

Where appropriate, proposals are encouraged to include implementation research combining interventions with current standard of care (including vaccines), as well as complementary research components that help to improve the understanding on how diarrhoeal diseases are currently influenced by climate and weather and may be further exacerbated by climate change (WHO Technical series on adapting to climate-sensitive health impacts: diarrhoeal diseases[65]).

Multidisciplinary approaches integrating adjacent sectors are strongly encouraged (i.e. nutrition, IPC/WASH). Proposals are to generate clinical data serving new-borns, children, people with co-infections and co-morbidities and other vulnerable and neglected populations at risk in SSA when relevant.

Applicants are expected to provide methodologies for translating research findings into public health/climate practice and policy guidelines.

When relevant, proposals should clearly describe the desired target product profile. Applicants need to concisely describe any prior relevant research findings and explain how the proposal builds on available data (including data generated in scope of earlier EDCTP programmes if available). Full details of the development milestones, including specific go/no-go criteria for the implementation of the proposed clinical trial(s) must be included, as well as specific plans for the subsequent regulatory approval process, which should aim at obtaining relevant market authorisation and an access strategy that will allow patients in low-resource settings to access the final product.

The applicants are encouraged to consider new adaptive trial designs and lessons learnt from COVID-19 potentially allowing for shorter development timelines.

Proposals should engage communities and relevant stakeholders, most notably (local) key opinion leaders, researchers, health care professionals, policy makers, public health authorities and end-users. Applicants should provide methodologies for translating research findings into public health practice and policy guidelines.

Applicants are reminded of the expectation that proposals should come from research consortia with a strong representation of institutions and researchers from sub-Saharan African countries, including involvement of Franco/Lusophone countries, if possible. Collaboration with other international research groups with relevant experience is very much encouraged. Applicants are also reminded of the expectation of reaching out to organisations in countries with relatively lower research capacities.

65 https://www.who.int/publications/i/item/9789240064591

All projects funded under this topic are strongly encouraged to participate in networking and joint activities, such as external conferences, workshops or symposiums for an exchange of knowledge, and best practices with external collaborators.

Specific conditions to this topic	
Expected JU contribution per project	Global Health EDCTP3 estimates that a JU contribution of around EUR 5.1 million per grant would allow the outcomes of this topic to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
Indicative budget	The total indicative JU budget for the topic is EUR 30.6 million.
Type of Action	Research and Innovation Action (RIA)
Legal and financial set-up of the Grant Agreements - Standard deliverables	Implementing the provision on affordable access as defined in Article 114 of the Council Regulation 2021/2085 establishing Implementing the provision on affordable access as defined in Article 114 of the Council Regulation 2021/2085 establishing[66], grants awarded under this topic will have to include in their Plan for the exploitation and dissemination of results including communication activities to be submitted during the project as a deliverable also the following: **Access plan** Participants must include in their Plan for the exploitation and dissemination of results an appropriate and proportionate access plan that demonstrates their strategies to ensure that the products and services that they develop based or partly based on the results of clinical studies undertaken by their project are affordable, available and accessible to the public (market and end-users) at fair and reasonable conditions. This covers registration targets, plans to meet demand, flexible approaches to IP, engagement with regulators and manufacturers where relevant and other strategies that reflect ability to pay and ensures that economic barriers to access are low. In addition, participants should add, if relevant, as part of the plan, an outline on how to achieve the optimal use of an intervention including, for example, how to avoid irrational use, overuse or abuse (e.g. antimicrobials). Additionally to any updates during the project, a final version of the Plan for the exploitation and dissemination of results including the above access plan, must also be submitted with the final report of the project.
Legal and financial set-up of the Grant Agreements - Additional exploitation obligations	Also in line with Article 114 of the Council Regulation 2021/2085, participants will be subject to the following additional exploitation obligations: 1. Participants must – up to four years after the end of the action (see Data Sheet, Point 1) – use their best efforts to ensure that resulting health technologies and services will be broadly

[66] Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014; OJ L 427, 30.11.2021, p. 17.

	available and accessible, as soon as possible and at fair and reasonable conditions. In this respect, if, despite a participants' best efforts, the results are not exploited within one year after the end of the action, participants must (unless otherwise agreed in writing with the granting authority) use the Horizon Results Platform to find interested parties to exploit the results. 2. In case the participants cannot fulfil the preceding obligation, the participants must (if requested by the granting authority) grant non-exclusive licences - under fair and reasonable conditions - to their results to legal entities that commit to rapidly and broadly exploiting the resulting health technologies and services and ensure that they are broadly available and accessible, as soon as possible and at fair and reasonable conditions. 3. In case of transfer of the ownership or licensing of results, participants must pass on such additional exploitation obligations to the legal entities exploiting the results. 4. For up to four years after the action (see Data Sheet, Point 1), the funding body must be informed every year about the status of the development of the product and any other exploitation of the results through an annual report that is due on each anniversary of the end of the grant agreement.
Other requirements	For all projects under this topic, if the coordinator is not from a country in SSA, the designation of a scientific project leader with the roles as described in the introduction is mandatory. A work package on 'scientific project leadership' must be included in the proposals and budget needs to be provided for this activity.

HORIZON-JU-GH-EDCTP3-2025-04-ACCESS-02-two-stage: Transformative Innovations in global health

Background

Novel and emerging transformative (disruptive) innovations[67] are a concept which applies to innovations that make products and services more accessible and affordable, thereby making them available to a larger population. These interventions or innovations should offer more accessible, cost-effective, and efficient solutions and be preferably beyond proof of concept. Funding under this topic will be aimed at encouraging research and innovations targeting those overlooked segments in R&D and products implementation delivering more patient-centric and context-specific delivery forms, improved functionality and new products and systems at a lower price or overall value-for-money advantage when combined with existing interventions.

Expected Outcome

This topic aims at supporting activities that contribute to one or several of the expected outcomes for this call. Proposals under this topic should aim to deliver results that are contributing to at least one of the following expected outcomes:

- Generate beyond proof-of-concept data with innovative ideas or inventions that will improve the uptake, adherence or implementation of preventative/treatment/diagnostic solutions.
- Progress an innovative approach that makes products and services (more) accessible and affordable to commercially unattractive markets or serves vulnerable populations in sub-Saharan Africa (SSA).
- Progress an innovative approach that addresses community-driven and trusted demand for new or repurposed tools, including those needed by hard-to-reach communities.
- Deliver innovative technologies which can generate accelerated cross-disease solutions, including communicable disease specific solutions.
- Repurpose or extend the use of an existing preventative/treatment/diagnostic intervention.

Scope

The objective of the topic is to progress a development which meets at least one of the below:

- Innovations in R&D or products implementation focusing on new or improvement of existing medicinal products and delivery systems of new or improved medical technologies within the health systems. This may include but not limited to use of new technologies.
- Development of a new intervention or improvements of an existing intervention for age-appropriate formulations or underserved populations. This may include but not limited to development of paediatric or geriatric formulations generating data for patients with co-morbidities.
- Development of tools to improve the affordability or accessibility of preventative/treatment/diagnostic solutions in SSA or specific vulnerable populations as relevant.

[67] Disruptive Technologies: Catching the Wave (hbr.org)

This may include but not limited to development of thermostable or humid resistant formulations, lower cost of goods, dose sparing approaches.

- Accelerate the development of delivery systems which will improve the efficacy or uptake of the preventative/treatment/diagnostic solutions in SSA. This may include but is not limited to assessing different route of administration ensuring easier access, new or improved devices or equipment ensuring higher efficacy or uptake, etc.
- Leverage existing data to repurpose and expand the use of the preventative/ treatment/ diagnostic intervention. This may include but is not limited to using well-established safety and pharmacological data from its use in one disease area into the infectious disease field in the scope of Global Health EDCTP3.

The scope includes infectious diseases in the scope of Global Health EDCTP3, including HIV/AIDS. Proposals are to generate beyond proof-of-concept data.

Out of scope: Infectious diseases not in the scope of Global Health EDCTP3, potential solutions tackling chronic diseases potentially caused by infections, and non-communicable diseases.

Applicants are invited to address the following in the proposals:

1. Proposals should clearly define the challenge or unmet need they are addressing. Applicants must provide a rationale explaining why this gap has not yet been successfully addressed and how their innovation will overcome these barriers. The proposal should highlight the unique value proposition and potential transformative impact of the innovation. Special attention should be paid to how the innovation serves vulnerable or underserved populations as relevant.
2. Proposals should present a comprehensive strategy for engaging communities and relevant stakeholders, most notably (local) key opinion leaders, researchers, health care professionals, policy makers, regulatory bodies, public health authorities, supply chain actors and end-users. Applicants should provide methodologies for translating research findings into public health practice and policy guidelines when relevant.
3. For innovations with a technological component, applicants should outline a clear roadmap for technology transfer, ensuring that the innovation can be scaled sustained by local or regional entities. The roadmap should include productisation pathways outlining how the innovation will transition from development to practical application. Proposals should also encourage local ownership by ensuring that the necessary skills and capacity building for long-term sustainability are embedded in the project.
4. Proposals should clearly describe the desired target product profile. Applicants need to concisely describe any prior relevant research findings and explain how the proposal builds on available data (including data generated in scope of earlier EDCTP programmes if available). Full details of the development milestones, including specific go/no-go criteria for the implementation of the proposed clinical trial(s) must be included, as well as specific plans for the subsequent regulatory approval process, which should aim at obtaining relevant market authorisation, and an access strategy that will allow patients in low-resource settings to access the final product.
5. Where relevant, proposals should demonstrate early engagement with regulatory bodies and manufacturers to facilitate the timely translation of innovations into affordable, regionally available products. Where possible, collaboration and coordination with the Team Europe Initiative on

Manufacturing and Access to Vaccines, medicines and health products (TEI-MAV+) or similar African initiative is encouraged. The applicants could show, for example, willingness to enter into technology transfer agreements with African counterparts - including the provision of patents, technical knowledge and know-how -, or early engagement with regulators or with African manufacturers to support the translation into affordable products adapted to the regional market.

Applicants are reminded of the expectation that proposals should come from research consortia with a strong representation of institutions and researchers from sub-Saharan African countries, including involvement of Franco/Lusophone countries, if possible. Collaboration with other international research groups with relevant experience is very much encouraged. Applicants are also reminded of the expectation of reaching out to institutions/organisations in countries with high disease burden but with relatively lower research capacities.

Specific conditions	
Expected JU contribution per project	Global Health EDCTP3 estimates that a JU contribution of between EUR 1.4 and EUR 2.33 million would allow the outcomes of this topic to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
Indicative budget	The total indicative JU budget for the topic is EUR 14 million.
Type of Action	Research and Innovation Action (RIA)
Legal and financial set-up of the Grant Agreements - Standard deliverables	Implementing the provision on affordable access as defined in Article 114 of the Council Regulation 2021/2085 establishing[68], grants awarded under this topic will have to include in their Plan for the exploitation and dissemination of results including communication activities to be submitted during the project as a deliverable also the following: **Access plan** Participants must include in their Plan for the exploitation and dissemination of results an appropriate and proportionate access plan that demonstrates their strategies to ensure that the products and services that they develop based or partly based on the results of clinical studies undertaken by their project are affordable, available and accessible to the public (market and end-users) at fair and reasonable conditions. This covers registration targets, plans to meet demand, flexible approaches to IP, engagement with regulators and manufacturers where relevant and other strategies that reflect ability to pay and ensures that economic barriers to access are low. In addition, participants should add, if relevant, as part of the plan, an outline on how to achieve the optimal use of an intervention including, for example, how to avoid irrational use, overuse or abuse (e.g. antimicrobials). Additionally to any updates during the project, a final version of the Plan for the exploitation and dissemination of results including the

[68] Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014; OJ L 427, 30.11.2021, p. 17.

	above access plan, must also be submitted with the final report of the project.
Legal and financial set-up of the Grant Agreements - Additional exploitation obligations	Also in line with Article 114 of the Council Regulation 2021/2085, participants will be subject to the following additional exploitation obligations: 1. Participants must – up to four years after the end of the action (see Data Sheet, Point 1) – use their best efforts to ensure that resulting health technologies and services will be broadly available and accessible, as soon as possible and at fair and reasonable conditions. In this respect, if, despite a participants' best efforts, the results are not exploited within one year after the end of the action, participants must (unless otherwise agreed in writing with the granting authority) use the Horizon Results Platform to find interested parties to exploit the results. 2. In case the participants cannot fulfil the preceding obligation, the participants must (if requested by the granting authority) grant non-exclusive licences - under fair and reasonable conditions - to their results to legal entities that commit to rapidly and broadly exploiting the resulting health technologies and services and ensure that they are broadly available and accessible, as soon as possible and at fair and reasonable conditions. 3. In case of transfer of the ownership or licensing of results, participants must pass on such additional exploitation obligations to the legal entities exploiting the results. 4. For up to four years after the action (see Data Sheet, Point 1), the funding body must be informed every year about the status of the development of the product and any other exploitation of the results through an annual report that is due on each anniversary of the end of the grant agreement.

4.1.3 Other actions not subject to call for proposals

4.1.3.1 Grant to identified beneficiary

HORIZON-JU-GH-EDCTP3-2025-05-AFRICA-01-IBA: Support for the Africa office of the EDCTP Association

Form of Funding: Grants not subject to calls for proposals

Type of Action: Grant to identified beneficiary according to Financial Regulation Article 198(e) and Article 24(3) (a) of the Horizon Europe Regulation - Coordination and Support Action

Global Health EDCTP3 will support an Africa office to facilitate implementation of the Global Health EDCTP3 programme in sub-Saharan Africa (SSA). The EDCTP Association Africa Office is the identified beneficiary to serve in this role.

Expected outcome

The proposal under this topic should aim at delivering results contributing to all of the following expected outcomes:

- Stronger infrastructure for clinical and implementation research in SSA.
- Increased clinical research capacity and scientific leadership in SSA, including the career promotion of women scientists.
- Enhanced ethics and regulatory capacities in SSA.
- Stronger international networks sharing clinical research good practice and new platforms for multicentre trials in SSA.
- Closer alignment of sub-Saharan Africa countries national research programmes and activities on infectious diseases.
- Stronger synergies among funders and other relevant organisations supporting clinical research in SSA.
- Increased common regulatory mechanisms across sub-Saharan African countries, with common regulatory reviews of new or improved health technologies.

Scope

Experience from EDCTP and EDCTP2 programmes has shown that, to increase EU-Africa collaboration and to build capacity to conduct clinical trials and implementation research according to ethical principles and regulatory international standards in SSA, the activities are more representative, genuine and efficacious if they are carried out from an African location. This applies also to enhancing scientific collaboration and international cooperation across SSA.

Accordingly, the proposal for the Africa Office should cover the following activities:

- Provide technical support for the design and implementation of Global Health EDCTP3 activities concerning networking and training on clinical research and regulatory and ethical issues in SSA.

- Organise workshops on proposal preparation and project and financial management trainings in the main (European) languages of SSA.
- Organise exchanges between the EDCTP Regional Networks of Excellence promoting synergies and collaborations.
- Organise the annual scientific meeting of EDCTP fellows in Africa.
- Promote the EDCTP alumni association and following up on career development of former fellows.
- Develop further links in Africa with industry, funders and other bodies working in the field to speed up the R&I process in SSA.
- Contribute to the Global Health EDCTP3 communication and outreach activities on the EDCTP achievements to increase visibility in Africa.
- Contribute to the organisation of the EDCTP Forum.
- Contribute to the implementation of the Memoranda of Understanding with relevant regional players in SSA (e.g. Africa CDC and WHO regional office for Africa).

Due to the objective of the topic to support an Africa office to facilitate implementation of the Global Health EDCTP3 programme in SSA, the consortium will be formed by only one legal entity, i.e. the European & Developing Countries Clinical Trials Partnership Association (EDCTP Association), which comprises the EDCTP Africa Office in Cape Town (South Africa) that manages the activities on clinical research capacity building, such as the regional networks and training activities, and the communication and outreach in SSA.

Expected impact

The proposal should facilitate productive and sustainable North–South and South–South networking and cooperation, building relationships to strengthen project-level and institutional collaborations in SSA. This support should result in an increased awareness of the Global Health EDCTP3 programme, a closer alignment of national research programmes and activities on infectious diseases R&I investments (at scientific, management and financial levels), and increased participation from industry and private foundations in the Global Health EDCTP3 programme to speed up the R&I process in SSA.

Legal entity

The European & Developing Countries Clinical Trials Partnership Association (EDCTP Association) - Anna van Saksenlaan 51- 2593 HW The Hague - The Netherlands

This legal entity comprises the EDCTP Africa Office in Cape Town (South Africa) that manages the activities on clinical research capacity building, such as the networking and training activities, and the communication and outreach in SSA.

Specific conditions	
Indicative timetable	Call opening: first quarter of 2025 Submission deadline proposal: first/second quarter of 2025
Indicative budget	The total indicative JU budget for the topic is EUR 3 million from the 2025 budget.
Type of Action	Coordination and Support Action (CSA)

Admissibility and eligibility conditions	Sole beneficiary: The European & Developing Countries Clinical Trials Partnership Association (EDCTP Association) - Anna van Saksenlaan 51- 2593 HW The Hague - The Netherlands This legal entity comprises the EDCTP Africa Office in Cape Town (South Africa) that manages the activities on clinical research capacity building, such as the regional networks and training activities, and the communication and outreach in SSA.
Legal and financial set-up of the Grant Agreements	The rules are described in General Annex G. The following exceptions apply: Eligible costs will take the form of a lump sum as defined in the Decision of 7 July 2021 authorising the use of lump sum contributions under the Horizon Europe Programme – the Framework Programme for Research and Innovation (2021-2027) – and in actions under the Research and Training Programme of the European Atomic Energy Community (2021-2025). This decision is available on the Funding and Tenders Portal, in the reference documents section for Horizon Europe, under 'Simplified costs decisions' or through this link: ls-decision_he_en.pdf (europa.eu).

4.1.3.2 External expertise, service level agreements and other actions

This action will support the use of appointed independent experts for the monitoring and evaluation of running actions (grant agreement, grant decision, public procurement actions, financial instruments) funded under Horizon Europe and include ethics checks, where appropriate, as well as compliance checks regarding the Gender Equality Plan eligibility criterion. It will also support Service Level Agreements and other actions related to the operational activities of the Joint Undertaking.

Form of Funding: Other budget implementation instruments

Type of Action: Expert contract action

Indicative timetable: 2025

Indicative budget: The total indicative JU budget is EUR 1 million from the 2025 budget.

4.1.3.3 EDCTP Forum 2025 preparations

The biennial EDCTP Forum provides an international platform for the presentation and discussion of clinical studies for everyone involved in combating poverty-related diseases and the appropriate capacity development and networking activities. The Forum has established itself as a valuable opportunity to develop and reinforce cooperation and synergy among the EDCTP Association stakeholders at various levels including scientific and policy. Scientists involved in EDCTP-funded projects are particularly encouraged to use this opportunity to share new developments and results from their projects. The Twelfth EDCTP Forum will take place in 2025 in Kigali, Rwanda.

This action will complement the procurement and payments already made in 2024 regarding the communication of the event, the rental of the venue and the catering services, supporting further the promotion and organisation of the Twelfth EDCTP Forum.

Expected impact: Providing a unique research communication platform for the 800-1,200 delegates expected to attend who work in the field of PRDs with the majority working in sub-Saharan Africa.

Form of Funding: Other budget implementation instruments

Type of action: Public Procurement – up to 5 service contracts.

Indicative timetable: The procurement process for the services will take place in the first quarter of 2025 with the objective of ensuring all procurements are made before the scheduled date of the Forum, which will be held from 15 to 20 June 2025. All procurements will be made in accordance with Global Health EDCTP3 procurement policies and procedures. Payments are expected to be made in the third and fourth quarters of 2025.

Indicative budget: EUR 1,100,000.

4.1.3.4 Mobilisation of research funds in case of Public Health Emergencies

Form of Funding: Grants not subject to calls for proposals according to Article 198(b) for the Financial Regulation or grants subject to a call for proposal

Type of Action: RIA or CSA

Expected outcome: Proposals should set out a credible pathway to contributing to one or several expected impacts of this Work Programme.

Project results are expected to contribute to the following expected outcome:

Allow the European Union and sub-Saharan African countries to respond to Public Health Emergencies.

Work in this area should allow a faster research response to outbreaks of epidemic or pandemic infectious diseases. This will allow the EU and sub-Saharan African member countries of the EDCTP Association to respond to public health emergencies.

In case of a public health emergency [69] (such as a public health emergency of international concern (PHEIC) according to the World Health Organization; a public health emergency under Regulation (EU) 2022/2371 [70]; or a public health emergency under applicable national frameworks and regulations), funding will be mobilised for:

[69] Should there be no Public Health Emergency in 2024, the indicative budget may be reallocated.

[70] Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (Text with EEA relevance) OJ L 314 6.12.2022, p. 26. (see https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R2371&qid=1673372768554)

- In line with Article 198 (b) of the EU Financial Regulation[71], funding will be raised to award grants without a call for proposals in exceptional and duly justified emergencies. At that time, the Funding & Tenders Portal will open a dedicated section where proposals can be submitted. This will be widely communicated, including on the Global Health EDCTP3 website and to the National Contact Points. The invitation to apply for funding will be open to all eligible entities or be limited to targeted entities, taking into account the need to achieve the underlying objectives in a quick and efficient manner considering the exceptional circumstances.

and/or

- The award of additional funding for ongoing grant agreements funded through EU Framework Programmes for Research and Innovation to cover additional activities specifically linked to the public health emergency, in exceptional and duly substantiated emergencies. Providing such additional funding to ongoing EU Framework Programmes for Research and Innovation grants that can support pertinent short- and mid-term research efforts to confront the public health emergency will save valuable time and allow addressing the situation with the appropriate urgency. Restricted calls for expression of interest or proposals will develop such additional activities or add additional partners to existing EU Framework Programmes for Research and Innovation actions.

It is expected that quality-controlled data are shared in accordance with the FAIR[72] principles. The use of harmonised protocols in collaboration with other actors is recommended for this purpose.

The general conditions, including admissibility conditions, eligibility conditions, award criteria, evaluation and award procedure, legal and financial set-up for grants, financial and operational capacity and exclusion, and procedure are provided in the introduction to this work programme and in parts A to G of the General Annexes to the Horizon Europe work programmes 2025.

The beneficiaries must comply with the public emergency related provisions listed in the General Annexes concerning the project implementation under - Intellectual Property Rights (IPR), background and results, access rights and rights of use (article 16 and Annex 5) for the duration of the Public Health Emergency, and under Communication, dissemination, open science and visibility (article 17 and Annex 5) during the entire duration of the action and for four years after the end of the action.

Specific conditions	
Indicative timetable	Will depend on the Public Health Emergency

[71] Article 198 (b) of the Financial Regulation 2024/2509 on the financial rules applicable to the general budget of the Union (recast) 'Grants may be awarded without a call for proposals only in the following cases: […] (b) in other exceptional and duly substantiated emergencies'.

[72] See the Horizon Europe programme guide available on the Funding & Tenders portal at https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/programme-guide_horizon_en.pdf

Indicative budget	The total indicative JU budget for this topic is EUR 1 million. This amount may be increased through contributions from the EDCTP Association or contributing partners, or by transferring funding from other topics, depending on the type and magnitude of public health emergency, and need for launching actions. Based on Article 110 of the Regulation 2021/2085, entities established in other states may be eligible for funding from Global Health EDCTP3 in the event of a call addressing a public health emergency.
Type of Action	RIA or CSA
Procedure	The following derogation to the evaluation procedure described in General Annexes F applies to open invitations to submit applications: In order to ensure a balanced portfolio covering responses to different aspects of the public health emergency, grants will be awarded to applications not only in order of ranking, but also to those projects that enhance the quality of the project portfolio through synergies between projects and avoidance of overlaps, provided that the applications attain all thresholds. The granting authority may therefore fund in priority proposals that are ranked lower than others, if they target another aspect of the public health emergency that is not tackled yet among the higher ranked proposals.
Legal and financial set-up of the Grant Agreements - Costs for providing financial support to third parties allowed	The action may also include justified derogations from the standard limits to financial support to third parties (maximum EUR 60,000 unless justified by the fact that the objective of the action would otherwise be impossible or overly difficult). Where applicable, the relevant grant agreement options will be applied.
Legal and financial set-up of the Grant Agreements - Standard deliverables	Implementing the provision on affordable access as defined in Article 114 of the Council Regulation 2021/2085 establishing[73], grants awarded under this topic will have to include in their Plan for the exploitation and dissemination of results including communication activities to be submitted during the project as a deliverable also the following: **Access plan** Participants must include in their Plan for the exploitation and dissemination of results an appropriate and proportionate access plan that demonstrates their strategies to ensure that the products and services that they develop based or partly based on the results of clinical studies undertaken by their project are affordable, available and accessible to the public (market and end-users) at fair and reasonable conditions. This covers registration targets, plans to meet demand, flexible approaches to IP, engagement with regulators and manufacturers where relevant and other strategies that reflect ability to pay and ensures that economic barriers to access are low. In

[73] Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014; OJ L 427, 30.11.2021, p. 17.

	addition, participants should add, if relevant, as part of the plan, an outline on how to achieve the optimal use of an intervention including, for example, how to avoid irrational use, overuse or abuse (e.g. antimicrobials). Additionally to any updates during the project, a final version of the Plan for the exploitation and dissemination of results including the above access plan, must also be submitted with the final report of the project.
Legal and financial set-up of the Grant Agreements - Additional exploitation obligations	Also in line with Article 114 of the Council Regulation 2021/2085, participants will be subject to the following additional exploitation obligations: 1. Participants must – up to four years after the end of the action (see Data Sheet, Point 1) – use their best efforts to ensure that resulting health technologies and services will be broadly available and accessible, as soon as possible and at fair and reasonable conditions. In this respect, if, despite a participants' best efforts, the results are not exploited within one year after the end of the action, participants must (unless otherwise agreed in writing with the granting authority) use the Horizon Results Platform to find interested parties to exploit the results. 2. In case the participants cannot fulfil the preceding obligation, the participants must (if requested by the granting authority) grant non-exclusive licences - under fair and reasonable conditions - to their results to legal entities that commit to rapidly and broadly exploiting the resulting health technologies and services and ensure that they are broadly available and accessible, as soon as possible and at fair and reasonable conditions. 3. In case of transfer of the ownership or licensing of results, participants must pass on such additional exploitation obligations to the legal entities exploiting the results. 4. For up to four years after the action (see Data Sheet, Point 1), the funding body must be informed every year about the status of the development of the product and any other exploitation of the results through an annual report that is due on each anniversary of the end of the grant agreement.

Global Health
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Annex 4.2
In-kind contributions to additional activities plan 2025

4.2 In-kind contributions to additional activities (IKAA) plan

IKAA to be initiated in year 2025 (EUR)							
by Specific objective							
Country	**Advance development and use of new or improved technologies**	**Facilitate better alignment of countries around a common Strategic Research and Innovation Agenda**	**Promote networking, building partnerships and strategic alliances**	**Strengthen capacity for epidemics preparedness**	**Strengthen research and innovation capacity**	**Strengthen research and innovation capacity**	**Total**
Belgium	3 027 776,10				280 912,50		3 308 688,60
Denmark	3 200 000,00						3 200 000,00
France	100 000,00			8 516 383,00	17 150 000,00	350 000,00	26 116 383,00
Germany	9 638 747,00		10 000 000,00		51 100 000,00		70 738 747,00
Mozambique			100 000,00				100 000,00
Niger	216 806,00				5 917,00		222 723,00
Norway	2 715 228,00	256 000,00					2 971 228,00
Portugal	730 000,00				260 000,00		990 000,00
South Africa				989 393,97			989 393,97
Spain	650 000,00						650 000,00
Uganda	26 036 848,00						26 036 848,00
United Kingdom	24 770 000,00						24 770 000,00
Total	**71 085 405,10**	**256 000,00**	**10 100 000,00**	**9 505 776,97**	**68 796 829,50**	**350 000,00**	**160 094 011,57**