Global Health EDCTP3

Annex to GB decision N° GH-EDCTP3-GB/18/2024

WORK PROGRAMME 2024

Consolidated version following amendment 1

adopted by the Governing Board

of Global Health EDCTP3 Joint Undertaking

on 27 June 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 will be made publicly available after its adoption by the Governing Board.

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1. INTRODUCTION

1.1 Mission statement of the Global Health EDCTP3 Joint Undertaking

The European and Developing Countries Clinical Trials Partnership (EDCTP) exists to accelerate the clinical development 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, the EDCTP 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.

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] and the new EU Global Health Strategy[4], 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.

The Global Health EDCTP3 Joint Undertaking (Global Health EDCTP3 JU) builds on the first and second European and Developing Countries Clinical Trials Partnership programmes. This new joint undertaking (JU) is a partnership between the EU and the EDCTP Association, whose members are several European and African countries. The partnership will deliver new solutions for reducing the burden of infectious diseases in SSA and strengthen research capacities to prepare and respond to re-emerging infectious diseases in this region and across the world.

1.2 Background and link with the Strategic Research and Innovation Agenda

Infectious diseases remain a major cause of death, disability, and ill health in SSA. Diseases such as human immunodeficiency virus/acquired immunodeficiency syndrome (HIV), 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 JU'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 JU'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://ec.europa.eu/commission/presscorner/detail/en/ip_22_7153

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

SSA is also at risk of emerging and re-emerging infections, such as Ebola, Marburg, Lassa fever, yellow fever and, most recently, SARS-CoV-2, which imperil global health security. The rise of antimicrobial resistance is compromising available treatments and undermining multiple branches of medicine that rely on effective therapies for infection control. Changing patterns of disease, driven by the climate crisis and environmental degradation, exacerbate these challenges.

Combating 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, and ensuring that healthier populations contribute to greater productivity and national prosperity.

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, but which often hit Africa hardest, such as infectious diseases. The Comprehensive Strategy with Africa and the Global Approach to Research & Innovation 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.

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 JU builds on and will extend the platforms created by EDCTP, contributing to the above-mentioned policies.

The Global Health EDCTP3 JU work programmes for years 2022 and 2023 addressed several key aspects of the Strategic Research and Innovation Agenda (SRIA – GB Decision N° GH-EDTP3-GB/04/2022)[5]. This work programme sets out the activities to be carried out in 2024, building on the activities supported so far. Broader topics are launched and thus a two-stage call process is used.

The focus and goals of the Global Health EDCTP3 JU of bringing health technologies to patients and health systems are addressed directly by six of the seven topics programmed for the 2024 work programme and indirectly by the remaining topic.

One of the call topics focuses on the development of novel, innovative HIV therapeutic interventions with improved efficacy, safety, adherence, and quality of life for HIV patients. The goal is reducing HIV-associated mortality and morbidity in sub-Saharan Africa, in particular for vulnerable HIV patients such as infants, children and those with co-morbidities.

[5] https://www.globalhealth-edctp3.eu/sites/default/files/2023-05/EDCTP3%20SRIA.pdf

Currently, two vaccines are recommended for malaria prevention, RTS'S and R21/Matrix-M. At the same time, more candidates are in the pipeline undergoing safety and/or efficacy trials. The aim of this topic is to support activities that are 1) generating additional data on safety and efficacy for the two recommended vaccines (RTS'S and R21/Matrix-M), and 2) generating evidence required for accelerating registration of new vaccine candidates. The topic is also expected to support projects that will lead to evidence-based recommendations on how to boost the sub-Saharan African manufacturing capacity and efficient supply chain for vaccines in general and malaria vaccines in particular.

The topic addressing neglected tropical diseases will contribute to the development of therapeutics towards registration and will advance integration of pharmaceutical interventions into national health systems, to make progress in the control and elimination of neglected tropical diseases (NTDs) in the scope of the Global Health EDCTP3 JU. The work should lead to improved understanding of barriers for progression of new therapeutics against NTDs through the R&D pipeline.

One of the call topics focuses on tackling Antimicrobial Resistance (AMR), specifically by conducting R&D on new and existing antimicrobials. AMR is one of the top 10 global public health threats facing humanity. Each year, at least 1.27 million people die of AMR, with Africa having the world's highest mortality rate from AMR infections.

A topic aims to address the burden of vector-borne diseases, which is highest in tropical and subtropical areas, disproportionately affecting the poorest populations. Focusing on vectors responsible for the transmission of one or more diseases within the scope of the Global Health EDCTP3 JU, projects supported under this topic should aim to deliver results that are contributing to the development and evaluation of new tools, technologies and approaches for vector control, aiming to reduce the burden of all those vector-borne diseases with no effective vaccines available and/or that cannot be effectively prevented with other well-established strategies.

Recent rapid advancements in digitalisation and unprecedented opportunities created by digital health, data or AI, promise to accelerate the achievement of the health-related SDGs and contribute to the implementation of the EU-AU summit declaration[6], the EU Global Health Strategy[7] and the Africa Centres for Disease Control and Prevention (Africa CDC) Digital Transformation Strategy[8].

The expected outcomes of the topic are to support:

1. Development of digital innovative solutions supporting clinical research through smart, highly innovative digital health technologies or concepts to accelerate the development of preventive, therapeutic or diagnostic interventions addressing poverty-related diseases in sub-Saharan Africa;

[6] https://www.consilium.europa.eu/media/54412/final_declaration-en.pdf
[7] https://ec.europa.eu/commission/presscorner/detail/en/ip_22_7153
[8] https://africacdc.org/download/digital-transformation-strategy/

2. Develop new digital technologies in public health interventions that can serve as drivers for the strengthening of health systems in sub-Saharan Africa. The proposed digital solutions should allow notably but not exclusively the improvement of development, production and access to health countermeasures, data and research evidence for better health outcomes and for the development and implementation of informed health policies and/or improved clinical guidelines in sub-Saharan Africa;
3. Contribution to the implementation of national and/or overarching regional digital health strategies.

Training activities are addressed through a collaboration with pharmaceutical companies. They will provide training on development of pharmaceutical interventions through classroom and online training activities. The companies also provide funding to support master-level training at academic institutions. The call will select one consortium of academic institutions that will incorporate the industry training in their training programme. Importantly, the fellows to be selected through an open and transparent procedure will be offered a return phase to pursue research. The return phase is also meant to ensure that there is no brain-drain from the African countries where the fellows come from.

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 by transferring funding from other topics, depending on the type of public health emergency and need for launching actions.

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, the Global Health EDCTP3 JU focuses on strategically critical areas of unmet medical need. Mechanisms are established to identify emerging priorities and opportunities. The Global Health EDCTP3 JU 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 will be 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 will identify key knowledge gaps and need for new evidence.
- **Emerging opportunities of translational bottlenecks**: The Global Health EDCTP3 JU will focus 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, the Global Health EDCTP3 JU will ensure global alignment of its policies and priorities and promote coordinated responses to evidence gaps and capacity-building needs.
- **Strategic portfolio**: The Global Health EDCTP3 JU will aim to develop and sustain a strategic portfolio across disease areas, types of intervention, and types of study. It will balance short-term and long-term priorities and funding across targeted diseases, with a view to supporting intervention research that is most likely to produce significant reductions in disease burden and overall mortality. In some areas, a portfolio approach will be used 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 the Global Health EDCTP3 JU 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 2024.

On the side of launching calls for proposals, the focus for the year 2024 is to expand on the investments made with the 2022 and 2023 work programme and implement a two-stage call. The strategy process for developing the 2024 work programme was launched with discussions and a meeting of the Scientific Committee and the same approach will be taken for developing the 2025 work programme. With the Stakeholders Group fully operational, their input will be sought early in the process of developing the 2025 work programme. Dedicated consultations on specific areas will also be 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 in the 2023 work programme and academia/industry fellowships under the 2024 work programme, strategic planning of the training activities for the coming years should take place during the year, with involvement of the EDCTP Africa Office.

Contributions from the EDCTP Association and contributing partners

The EDCTP Association continues to plan for significant contributions in-kind to additional activities (IKAA). The IT tools for planning and reporting of IKAA are now in place and will be fully rolled out during the year. Close interaction with the EDCTP Association will be maintained to ensure timely reporting and certification of the IKAA.

For the 2024, a second contribution from contributing partners (pharmaceutical companies) is foreseen. Discussions with various other contributing partners are at different stages of maturity and are planned to be concluded during the year for contributions to the work programme 2025.

Preparing grant agreements – reporting from ongoing grants

In 2024 the grants from the 2023 calls for proposals will be prepared, both from the single-stage call (earlier in the year) and from the two-stage call (as of conclusion of the evaluation towards the middle of the year). All grants from the 2022 call are concluded.

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 only as of 2025.

2. WORK PROGRAMME 2024

2.1 Executive Summary

This is the third work programme under the Global Health EDCTP3 JU. The topics are based on the Strategic Research and Innovation Agenda adopted by the Governing Board[9].

The work programme includes six topics for Research and Innovation Actions (RIA) under a two-stage call and one topic for a Coordination and Support Action (CSA) under a special two-stage call. For the academia/industry fellowship programme at stage one, a single outline proposal will be selected and will be merged with the pre-existing consortium of two companies. A joint full proposal will then be evaluated.

The other actions foresee mobilisation of research funds in case of public health emergencies without the launch of a call for proposals, as was already provided for under the 2023 work programme.

Call indicative topics and other actions not subject to Calls for proposals	Indicative call launch timing	Indicative budget (in EUR)	Call process
Developing novel, innovative HIV therapeutics for reducing the disease burden of HIV in sub-Saharan Africa – RIA	Q1 2024	22 000 000	Two-stage
Research on existing Malaria vaccines and development of new promising candidates – RIA	Q1 2024	30 000 000	Two-stage
Accelerating development of therapeutics and non-pharmaceutical interventions against neglected tropical diseases (NTDs) in sub-Saharan Africa – RIA	Q1 2024	22 000 000	Two-stage
Tackling Antimicrobial Resistance (AMR) through R&D in novel and existing antimicrobials – RIA	Q1 2024	24 000 000	Two-stage
New tools, technologies and approaches for vector control in sub-Saharan Africa – RIA	Q1 2024	18 432 135	Two-stage
Innovative digital health solutions for sub-Saharan Africa – RIA	Q1 2024	20 000 000	Two-stage
Global Health EDCTP3 academia/industry fellowship with return phase – CSA	Q1 2024	3 500 000	Two-stage

[9] https://www.globalhealth-edctp3.eu/sites/default/files/2023-05/EDCTP3%20SRIA.pdf

Call indicative topics and other actions not subject to Calls for proposals	Indicative call launch timing	Indicative budget (in EUR)	Call process
WP 2024 emergency funding call in response to the Mpox outbreak in the Democratic Republic of Congo (DRC)	Q2 2024	6 500 000	Single stage
Additional EU and EDCTP-Association members states contribution for call 2024	Q1 2024	64 054 482	Two stage
Total for Calls for proposals incl. other actions not subject to Calls for proposals		**210 486 617**	

The cost for external expertise, notably for the peer-review evaluation including ethics review will be covered under this part of the programme.

Total for Calls for proposals incl. other actions not subject to Calls for proposals		Indicative budget	
Cost for monitoring and evaluation experts		945 315	
Other actions (EDCTP Forum 2025 and Global Health EDCTP3 Prizes)		1 180 000	
Total operational expenditure		**212 611 932**	

2.2 Operational objectives

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 annual work plan € invested by countries on IKKA

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

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. Besides their impact on individuals, infectious diseases impose a high economic burden on countries, impeding national development. Moreover, the COVID-19 pandemic has revealed that new infectious threats may appear and that, with the increased connectivity of different regions in the world, these can spread rapidly all over the world. Developing health technologies is therefore crucial to limit the spread of such diseases, as well as to fight them once they have spread, protecting the health of citizens in the countries most concerned (SSA) and in the Union.

The Global Health EDCTP3 JU will work towards achieving scientific priorities related to implementation of clinical trials to develop health technologies to control 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 of them 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 expected impacts of the Global Health EDCTP3 JU are to achieve a reduced socio-economic burden of infectious diseases in SSA and an increased health security in SSA and globally.

2.2.3 Calls for proposals 2024 and other actions not subject to call for proposals

Described in Annex 1A to the 2024 work programme.

2.3 Support to operations of the Global Health EDCTP3 Joint Undertaking

2.3.1 Back-office arrangements

According to Article 13 of Council Regulation 2021/2085 establishing the joint undertakings under Horizon Europe, 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. The Global Health EDCTP3 JU 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 the Global Health EDCTP3 JU. An accounting correspondent in the Global Health EDCTP3 JU is also nominated to interact closely with the accounting officer.

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

Human resources (HR)

Article 13 of the Council Regulation 2021/2085 establishing the joint undertakings under Horizon Europe 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 will allow obtaining a better harmonisation among the JUs, exploiting best practices, achieving efficiency gains and economy of scale.

Already in 2023, the Global Health EDCTP3 JU carried out the recruitment for the budget officer position jointly with the Circular Biobased Europe JU. It is expected that this practice of creating joint reserve lists will continue in 2024. Also, joint undertakings open reserve lists to each other. Again, already in 2023, the Global Health EDCTP3 JU benefited from getting access to a reserve list from another JU and provided access to some of its reserve lists. More strategic use of joint recruitments for common functions will be pursued in 2024.

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. The back-office arrangement in this area was established through an SLA. A joint procurement for the building was carried out in 2023, as well as a joint procurement for accounting services and consulting services related to financial management and accounting. Furthermore, a service provider to support the data protection officers was selected in a joint procurement and common IT services were procured (see below). Further common procurements in the areas of corporate services, some communication support services, or list of law firms to use in case of need for legal representation, for example in case of litigation, are expected to be carried out in 2024. The areas that are taken forward are defined and agreed via joint public procurement planning.

The public procurement management tool (PPMT) that was developed by the DG Joint Research Centre will be used also by the JUs as part of the common back-office arrangements.

In addition, where relevant and appropriate, framework contracts of the European Commission are used to the extent possible. For example, the Global Health EDCTP3 JU recently expressed its interest in joining procurements launched by the European Commission's Research and Innovation

department for procuring event organising services and another procedure for acquiring services to provide training in use of the financial management tools (currently ABAC, in future SUMMA).

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.

The back-office arrangement 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 arrangements ICT working arrangements will be settled in the form of an SLA that is about to be finalised, which shall formalise and clarify the mandate(s), roles and responsibilities as well as establish criteria for repartition of costs.

2.3.2 Communication, dissemination and exploitation

Communication activities will focus on the calls for proposals for 2024, the grants signed under work programmes 2022 and 2023, and the promotion of other activities carried out by the Global Health EDCTP3 JU, such as contributions to events and meetings or the activities of the bodies of the JU.

With the launch of the 2024 calls, coordinated communication activities will be undertaken to ensure that a broad range of relevant stakeholders learn about such calls. 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 JU calls. This is done to ensure that Global Health EDCTP3 JU attracts the broadest possible range of relevant applicants to its calls and involves partners at all levels to achieve its goals.

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, as well as the role of scientific project leaders, a novelty under Global Health EDCTP3 JU compared to EDCTP2. In order to reach out to stakeholders and especially potential applicants in SSA countries, the EDCTP Africa Office will support the activities undertaken by the Global Health EDCTP3 JU. It is planned to organise info day sessions also in French. For providing information in Portuguese, collaboration with the Portuguese member of the EDCTP Association will be sought.

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

In 2024, preparations for the Twelfth EDCTP Forum will begin. This event is expected to be held in 2025 in Kigali and much of the organisational work will have to be carried out during the year 2024, including developing the general concept and idea and hiring contractors to support in the implementation of the event. The input from the Stakeholders Group will be sought extensively and other bodies and partners of the joint undertaking will also be consulted.

As relevant and appropriate, the Global Health EDCTP3 JU will contribute to exploiting results from the predecessor programme. This can occur by selecting follow-on grants that build on results from previous EDCTP programmes. It can also be achieved by working in collaboration with the EDCTP-Association Secretariat for organising events, workshops and presenting at conferences and meetings. Synergies in exploitation and dissemination are particularly relevant in the reach-out to countries in SSA and in Europe.

Other communication activities will include the up-to-date maintenance of the Global Health EDCTP3 JU website launched in 2023 and the social media channels.

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 joint undertakings setting out the frame and conditions for this arrangement. Clean Aviation Joint Undertaking acts as the lead joint undertaking in this context, coordinating the back-office arrangement and providing services to other joint undertakings. Its Executive Director is responsible for the organisation, oversight and coordination including reporting. It is supported for this purpose by the Europe' Rail and EuroHPC Joint Undertakings. This arrangement enables the joint undertakings to carry out common procurement procedures. Such synergies imply that the Global Health EDCTP3 JU may save substantial human resources as its staff in charge of procurement may often rely on a common procedure led by the Clean Aviation Joint Undertaking 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 joint undertakings. This arrangement has already proved efficient, and it is expected that it will be used for most of the procurement needs of the Global Health EDCTP3 JU in the future.

Under this approach, it is also planned to use the PPMT that has been developed by the Joint Research Centre.

The Global Health EDCTP3 JU will generally also seek to join existing framework contracts or common procedures managed by the European Commission or EU agencies, as it did in 2023.

No major procurement activities of the Global Health EDCTP3 JU on its own are planned at this point for 2024.

SLAs are in place with DG Human Resources for several services (such as medical service). Within the frame of the SLA, more detailed arrangements are being put in place, for example for the use of the human resources management system (SYSPER). 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) is planned to be concluded in Q1/2024. An SLA has also been concluded with DG BUDG regarding the use of the ABAC system and treasury services. The agreement between the Global Health EDCTP3 JU and the Innovative Health Initiative (IHI) JU to rent offices in the White Atrium Building in Brussels remains in force in 2024.

2.3.4 Information Technology

With regards to Information Technology, the main objectives of the Global Health EDCTP3 JU in 2024 are to:

- Achieve IT autonomy for the Global Health EDCTP3 JU from European Commission;
- Strengthen further the collaboration with the other JUs through the back-office arrangements on IT;
- Define the data architecture and start implementation of a data warehouse.

A number of pre-conditions must be fulfilled in order to implement the JU IT autonomy, like setting up new email addresses @globalhealth-edctp3.eu and obtaining from DG DIGIT new EU Login(s) for the staff. When all preconditions are met, 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. In order to allow digital signature of contracts with the external world, digital certificates will need to be purchased and set up.

The current website hosting contract will expire at the end of March 2024; in this sense the Global Health EDCTP3 JU will be looking into contracting a new hosting service that offers the required support and security updates.

In alignment with the practices of the other JUs, the Global Health EDCTP3 JU 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 on-board telecommunication services and integrate them with Microsoft 365.

In the broader context of the back-office arrangements on IT, the Global Health EDCTP3 JU 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 the Global Health EDCTP3 JU, 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 the Global Health EDCTP3 JU 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 has been postponed to 2025; the JU will need to prepare the necessary steps to ensure a smooth transition to SUMMA.

With most of the meetings with external participants being conducted via teleconference, the JU office meeting rooms will be equipped with the necessary video-conference equipment.

The Global Health EDCTP3 JU will continue working to align with the corporate requirements in terms of cybersecurity and data protection.

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 JU activities and retention of its legacy.

2.3.5 Data protection and access to documents

Regarding data protection, the Global Health EDCTP3 JU will continue its work towards 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. The Global Health EDCTP3 JU 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.

Regarding access to documents, the Global Health EDCTP3 JU 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, the Global Health EDCTP3 JU will use existing arrangements amongst the JUs established under Horizon Europe, such as in the areas of IT, HR, procurement. Additional areas for collaboration through back-office arrangements will be explored.

The Global Health EDCTP3 JU 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 experts will continue to be handled by the Research Executive Agency 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. 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 joint undertakings 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, the Global Health EDCTP3 JU is in the process of joining the EU agencies network (EUAN) which provides support and information sharing on relevant matters, such as HR.

The Global Health EDCTP3 JU currently rents offices from the IHI JU, which brings significant cost savings. During 2024 the move towards the new contract for renting office space in the White Atrium building needs to be prepared. Until the larger office space becomes available, interim solutions to acquire additional office space need to be found. The hybrid working arrangements with hot-desking provides for a flexible and cost-effective solution to procuring office space. Nevertheless, the current office footprint of just 329 m^2 is not sufficient for the growing needs of the JU.

2.3.7 Human resources (HR)

2.3.7.1 HR Management

The HR function will continue to be critical to the successful consolidation of the Global Health EDCTP3 JU as an autonomous JU during 2024.

Main HR ongoing objectives:

Recruitment:

In 2023, 16 staff members joined the Global Health EDCTP3 JU, amongst them the key functions during the setting-up phases: IT, Legal, HR, Budget, Governance, Communications Officers; Financial and Operations Assistants; Internal control and audit Manager.

The Governing Board appointed the Executive Director. The selected candidate was able to take function in November 2023, ensuring that the Global Health EDCTP3 JU could obtain its financial autonomy before the end of the year.

Three different vacancy notices were published in 2023. The Head of Administration and Finance, the Personal Assistant to the Executive Director and two Administrative Assistants. All are expected to take up duties before Q2.

Progress on recruiting and integrating staff is on track. The Executive Director will identify the profiles for which new reserve lists will be established. Further vacancies are expected to be published during the year, based on the posts available in the staff establishment plan. A total of 34 posts (26 Temporary Agents and 8 Contractual Agents) are available for 2024.

Key management roles at Head of Unit level will be filled in 2024: the selected candidate for Head of Unit Administration and Finance is expected to take up duties in Q1 and a Head of Scientific Operations is expected to be recruited.

It is expected that some administrative support through an interim position will continue to be needed at least for part of the year, while the assistant positions from vacancies launched in 2023 are being filled.

Legal framework and HR policies:

The main legal implementing rules to Staff Regulations, applicable to staff, were adopted. The Global Health EDCTP3 JU will continue to carefully monitor the implementing rules to the Staff Regulations that are being adopted by the European Commission.

The first Global Health EDCTP3 JU staff committee was successfully elected and established in the final months of 2023.

Specific HR policies were also adopted (e.g. policy on duration of contracts, renewal of contracts, recruitment policy). By the end of 2024, the HR policies will be completed, with focus on the following activities:

- Learning and development: the first learning and development framework will be adopted; covering the initial staff training and development needs specific to the Global Health EDCTP3 JU;
- Performance management: In 2024, the Global Health EDCTP3 JU will execute its first performance management cycle, in which individual goals for performance and development are defined, monitored and evaluated;
- Activities to ensure wellbeing of staff and non-discrimination will be implemented. The Global Health EDCTP3 JU will develop a culture that is in line with its operational objectives and agreed vision and values, and an internal organisation that fosters efficiency and collaboration.

HR IT tools, allowing autonomy in the selection process were onboarded in 2023. The Global Health EDCTP3 JU will investigate the possibility of acquiring more tools to facilitate its work.

The European Commission training catalogue is accessible to the Global Health EDCTP3 JU staff. Training needs for the staff concern in particular the use of the Horizon Europe IT tools, financial management and language training as appropriate. Some trainings are also procured separately.

Through an SLA with the European Commission medical and social services for staff are accessible. This concerns for example the medical examinations for newly recruited staff or seasonal vaccinations.

2.3.7.2 Strategy for achieving efficiency gains and synergies

As mentioned before, options for the back-office arrangements, as foreseen under Article 13 of the Council Regulation 2021/2085 establishing the joint undertaking under Horizon Europe are being put in place through SLAs with the different lead JUs.

Throughout the setting up of the Global Health EDCTP3 JU, the best possible efficiency of the organisation is being considered. Synergies within the organisation and with other JUs, and – where relevant – with Commission services as well as outside partners are explored.

This concerns for example the co-location in the office space of the IHI JU. This led to 'automatic synergies' for the use of office equipment, the basic IT service provision, and all elements of infrastructure, that otherwise would have had to be organised, if the Global Health EDCTP3 JU were in its own offices elsewhere.

This synergy as regards infrastructure will continue with the jointly procured office space for most of the JUs established in Brussels post-2024 (the current rental contract runs out in 2025). It is planned to remain in the same building, with some upgrades to the infrastructure foreseen.

Synergies on the side of the implementation of the programme will be sought in 2024. Working groups at Scientific Project Officer level were established in 2023 and are expected to provide concrete suggestions for joint work.

2.3.7.8 Staff establishment plan

Function group and grade	2023				2024		2025	
	Authorised budget		Actually filled at 31/12		Authorised budget		Authorised budget	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts
AD14	0	1	0	1	0	1	0	1
AD12	0	2	0	0	0	2	0	2
AD11	0	1	0	0	0	1	0	1
AD8	0	5	0	0	0	7	0	7
AD7	0	4	0	5	0	4	0	4
AD6	0	5	0	2	0	7	0	7
AD5	0	1	0	3	0	1	0	1
Total AD	0	19	0	0	0	23	0	23
AST5	0	1	0	0	0	1	0	1
AST4	0	1	0	0	0	1	0	1
AST3	0	1	0	0	0	1	0	1
Total AST	0	3	0	0	0	3	0	3
Total AD+AST	0	22	0	11	0	26	0	26
Total staff (incl. CA)	0	30	0	17	0	34	0	34

Contract Agents	FTE corresponding to the authorised budget 2023	Executed FTE at 31/12/2023	Headcount at 31/12/2023	FTE corresponding to the authorised budget 2024	FTE corresponding to the authorised budget 2025
FGIV	4	3.16	4	4	4
FGIII	4	1.79	2	4	4
Total	8	4.96	6	8	8

2.4 Governance activities

Following the successful setting up of the Global Health EDCTP3 Joint Undertaking, 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 joint undertakings under Horizon Europe, the bodies of the Global Health EDCTP3 JU are:

a) Governing Board
b) Executive Director
c) Scientific Committee
d) Stakeholders Group

Governing Board

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

The Governing Board of the Global Health EDCTP3 JU is composed of six representatives of the European Commission on behalf of the Union and six representatives of the EDCTP Association. 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 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 the Global Health EDCTP3 JU.

In 2024, it is foreseen that the Governing Board of the Global Health EDCTP3 JU will hold three meetings, one in Q2 where the main point will be the adoption of the consolidated annual activity report and the final annual accounts for 2023 and two in Q4 with main points the adoption of the award decision for the calls 2024 and the discussion about and then adoption of the work programme for 2025.

Key activities for 2024	
Adoption of the 2023 Annual Activity Report and Final Annual Accounts	Q2 2024
Award decision for calls 2024	Q4 2024
Adoption of the 2025 work programme	Q4 2024

Further important decisions such as amendments to the work programme, adoption of staff regulation implementing rules etc. may be adopted via written procedures which are launched by the Executive Director on behalf of the Chairperson of the Governing Board.

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 the Global Health EDCTP3 JU and is accountable to the Governing Board. He is supported in his activities by the staff of the joint undertaking.

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

Scientific Committee

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

During 2024, 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 IKAAs plan.

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

For 2024, three meetings of the Scientific Committee are planned.

Stakeholders Group

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

As foreseen in the Council Regulation 2021/2085 establishing the joint undertakings 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 joint undertaking.

During 2024, 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.

The host agreement with Belgium should be concluded in 2024.

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

The Global Health EDCTP3 JU Internal Control Framework (ICF) was adopted by the Governing Board in August 2023 (Decision GH-EDCTP3-GB/11/2023), whilst the operations of the JU were still covered by the organisational management and internal control system of the Research & Innovation Directorate-General of the European Commission until financial autonomy on 23 November 2023.

The priority objective 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 preparation for autonomy, an action plan on the ICF was prepared. The action plan was the result of a gap analysis performed on the 17 principles of the ICF of the Global Health EDCTP3 JU. The objective of the gap analysis was to understand and assess if all principles of the ICF were a) present and b) functioning. In the case that during the assessment there is a negative response this means a gap has been identified. Then, based on a gap analysis an action plan was prepared and validated by the interim Executive Director (Decision GH-EDCTP3-ED/22/2023). The timeframe for the actions to be implemented covers the period Q4 2023 to Q3 2024.

2.5.1 Financial procedures

The Global Health EDCTP3 JU 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 were adopted by the interim Executive Director by decision GH-EDCTP3-ED/21/2023.

In Horizon Europe, reporting and validation of costs (including evaluation experts) is implemented using the European Commission IT tools (SyGMa, COMPASS, EMI).

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.

In 2024, specific attention will be put to the following elements of ex-ante control:

- Project and financial webinar(s) for beneficiaries and projects to provide information on eligibility rules for Horizon Europe.

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 Horizon Europe Audit Strategy. The Common Audit Service of the Common Implementation Centre of the Research & Innovation department of the European Commission carries out all audits for the Global Health EDCTP3 JU (internally or outsourced to external firms) for Horizon Europe. At this stage, no ex-post audits for the Global Health EDCTP3 JU have yet been identified for 2024.

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 JU Risk Register, which provides for an evaluation of the risk level and description of the mitigating activities.

The first annual risk assessment exercise took place between September and October 2023. The most significant risks were included in the risk register of the Global Health EDCTP3 JU. An action plan has been put in place and will be monitored and followed up during the year 2024. The annual risk assessment exercise will be repeated in Q4/2024.

2.5.4 Anti-fraud initiatives

The Global Health EDCTP3 JU acknowledges that an anti-fraud strategy is based on the identification of the potential risks for the entity and the measures to manage those risks. In this regard, the JU has planned for adoption of a specific Global Health EDCTP3 JU anti-fraud strategy in 2024. Further actions have been planned, such as:

- Awareness raising amongst staff on anti-fraud measures;
- Participation to meetings organised by DG Research & Innovation 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 Internal Control and Audit Manager. In 2024, the IAS will commence risk assessment to establish the strategic internal audit plan for the Global Health EDCTP3 JU. 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 2024, the key activities will focus:

- Provide the necessary information and support for ECA audit on 2023 accounts;
- Liaise with the external audit company that will audit the 2023 annual accounts, as required by the Financial Rules of the Global Health EDCTP3 JU);
- Support the ECA team in their field or remote missions for Global Health EDCTP3 JU projects selected (on a sample basis) for an ex-post financial review, if any were to be launched in 2024.

The **Internal Audit Capability** of the Global Health EDCTP3 JU 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.

3. BUDGET 2024

In accordance with the General Annexes of the Horizon Europe Work Programme 2023-2024, with regard to 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 2018/1046.

Statement of revenue

STATEMENT OF REVENUE									
Budget line	Title Chapter	Original Budget - Financial Year 2024		Variances - Financial Year 2024		Adopted Amended Budget 1 (AMBU1) - Financial Year 2024			
		Estimated Commitment Appropriations	Estimated Payment Appropriations	Estimated Commitment Appropriations	Estimated Payment Appropriations	Estimated Commitment Appropriations	In %	Estimated Payment Appropriations	In %
1	**EU contribution (excl. EFTA and third countries contribution)**	**144 172 417**	**67 384 950**	**55 056 000**	**4 859 559**	**199 228 417**	**90,8%**	**72 244 509**	**96,6%**
10	*of which (fresh C1) Administrative (Title 1&2)*	6 490 427	6 490 427	-	-	6 490 427	3,0%	6 490 427	8,7%
11	*of which Operational (Title 3)*	137 681 990	60 894 523	55 056 000	4 859 559	192 737 990	87,9%	65 754 082	87,9%
2	**EFTA and third countries contribution**	**4 166 583**	**1 947 425**	**937 121**	**610 031**	**5 103 704**	**2,3%**	**2 557 456**	**3,4%**
20	*of which Administrative EFTA (Title 1&2)*	187 573	187 573	42 188	42 188	229 761	0,1%	229 761	0,3%
21	*of which Operational (Title 3)*	3 979 010	1 759 852	894 932	567 843	4 873 942	2,2%	2 327 695	3,1%
3	**Financial contribution members other than the Union***	-	-	**15 000 000**	-	**15 000 000**	**6,8%**	-	-
31	*Of which operational (Title 3)*	-	-	15 000 000	-	**15 000 000**	6,8%	-	-
4	Contributing Partners financial contribution	-	-	-	-	-	-	-	-
5	Interest generated	-	-	-	-	-	-	-	-
6	Recoveries	-	-	-	-	-	-	-	-
7	Other	-	-	-	-	-	-	-	-
8	Unused administrative appropriations from previous years	-	-	-	-	-	-	-	-
9	Unused operational appropriations from previous years	-	-	-	-	-	-	-	-
TOTAL ESTIMATED REVENUE		**148 339 000**	**69 332 375**	**70 993 120**	**5 469 590**	**219 332 120**	**100%**	**74 801 965**	**100%**

Statement of expenditure

STATEMENT OF EXPENDITURE							
Budget line	Title Chapter	Original Budget - Financial Year 2024		Variances - Financial Year 2024		Adopted Amended Budget 1 (AMBU1) - Financial Year 2024	
		Estimated Commitment Appropriations	Estimated Payment Appropriations	Estimated Commitment Appropriations	Estimated Payment Appropriations	Estimated Commitment Appropriations	Estimated Payment Appropriations
1 - Staff expenditure							
11	Salaries & allowances	3 701 016	3 701 016	-540 000	-540 000	3 161 016	3 161 016
110	*- Of which establishment plan posts*	*3 224 746*	*3 224 746*	*-540 000*	*-540 000*	*2 684 746*	*2 684 746*
111	*- Of which external personnel*	*476 270*	*476 270*	-	-	*476 270*	*476 270*
120	Expenditure relating to staff recruitment	105 684	105 684	-	-	105 684	105 684
130	Mission expenses	120 000	120 000	-	-	120 000	120 000
140	Socio-medical infrastructure	110 000	110 000	-	-	110 000	110 000
150	Training	40 000	40 000	20 000	20 000	60 000	60 000
160	External Services	260 000	260 000	-	-	260 000	260 000
170	Receptions, events and representation	4 000	4 000	20 000	20 000	24 000	24 000
180	Social welfare	-	-	-	-	-	-
190	Other staff related expenditure	-	-	-	-	-	-
Total Staff		4 340 700	4 340 700	-500 000	-500 000	3 840 700	3 840 700
2 - Infrastructure and operating expenditure							
200	Rental of buildings and associated costs	300 000	300 000	400 000	400 000	700 000	700 000
210	Information, communication technology and data processing	600 000	600 000	-	-	600 000	600 000
220	Office equipment (movable property and associated costs)	162 300	162 300	142 188	142 188	304 488	304 488
230	Current administrative expenditure	50 000	50 000	-	-	50 000	50 000
240	Postage / Telecommunications	35 000	35 000	-	-	35 000	35 000
250	Meeting expenses	150 000	150 000	-	-	150 000	150 000
260	Running costs in connection with operational activities	250 000	250 000	-	-	250 000	250 000
270	Information and publishing	410 000	410 000	-	-	410 000	410 000
280	Service contracts	380 000	380 000	-	-	380 000	380 000
290	Other infrastructure and operating expenditure	-	-	-	-	-	-
Total infrastructure and operating		2 337 300	2 337 300	542 188	542 188	2 879 488	2 879 488
TOTAL ADMINISTRATIVE (1+2)		6 678 000	6 678 000	42 188	42 188	6 720 188	6 720 188
3 - Operational expenditure							
300	Grants	140 932 135	61 702 048	69 554 482	4 434 414	210 486 617	66 136 462
310	*Experts costs**	*728 865*	*728 865*	*216 450*	*216 450*	*945 315*	*945 315*
320	Other operational costs	-	223 462	1 180 000	776 538	1 180 000	1 000 000
TOTAL OPERATIONAL (3)		141 661 000	62 654 375	70 950 932	5 427 402	212 611 932	68 081 777
TOTAL ESTIMATED EXPENDITURE		148 339 000	69 332 375	70 993 120	5 469 590	219 332 120	74 801 965

*** 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.**

4. ANNEXES

4.1 Calls for proposals 2024 and other actions not subject to call for proposals

4.1.1 Call for proposals 2024

This is the third work programme under the Global Health EDCTP3 Joint Undertaking (Global Health EDCTP3 JU). The topics are based on the Strategic Research and Innovation Agenda adopted by the Governing Board.[10] The Global Health EDCTP3 programme is implemented under the framework of the EU global health strategy[11] adopted in November 2022, the EU-AU summit deliverables[12] and the AU-EU innovation agenda launched in July 2023[13] and will play a key role in achieving the objectives of these strategies and initiatives.

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

- HORIZON-JU-GH-EDCTP3-2024-01-two-stage covering six topics for Research and Innovation Actions (RIA);
- HORIZON-JU-GH-EDCTP3-2024-02-two-stage covering one topic for Coordination and Support Actions (CSA).

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

With the 2024 work programme we extend the range of topics addressed under the Global Health EDCTP3 JU, building on the activities launched previously in 2022 and 2023. The work programme this year puts particular emphasis on supporting the development of interventions, ranging from pharmaceutical interventions (medicines and vaccines) and a possibly broad range of interventions for vector control to digital health tools. Training activities are addressed through a programme where academic training is to be followed by a return phase (HORIZON-JU-GH-EDCTP3-2024-02-01-two-stage). For all topics in the work programme, where relevant, the support to African scientists through degree training in clinical research and/or hands on training during implementation of research projects should be provided to assist them in advancing their scientific careers. These scientists should be selected keeping gender and regional balance in mind.

The work programme addresses a range of conditions within the scope of the objectives of Global Health EDCTP3 JU, including HIV/AIDS, Malaria, neglected tropical diseases and antimicrobial

[10] https://www.globalhealth-edctp3.eu/sites/default/files/2023-05/EDCTP3%20SRIA.pdf
[11] https://ec.europa.eu/commission/presscorner/detail/en/ip_22_7153
[12] Sixth European Union - African Union Summit: A Joint Vision for 2030 - Consilium (europa.eu)
[13] https://research-and-innovation.ec.europa.eu/system/files/2023-07/ec_rtd_au-eu-innovation-agenda-final-version.pdf

resistance (AMR). This support through topics targeted to a particular disease area complements support provided through broader topics under the previous work programmes of Global Health EDCTP3 JU[14].

Clinical studies

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).

Studies must be registered in a registry meeting WHO Registry criteria[15] before recruitment of the first subject. From 31 January 2023, all initial clinical trial applications in the European Union (EU) 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. This follows a one-year transition, during which sponsors could choose whether to apply for a new clinical trial in the EU/EEA in line with the Clinical Trials Directive or under the new Clinical Trials Regulation (CTR), which entered into application on 31 January 2022[16].

For stage-2 proposals, the use of the "Essential 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

Also, the three mandatory deliverables below should be included in the stage-2 proposals with 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:

    - Registration number of the clinical study in a registry meeting WHO Registry criteria[17]
    - Final version of study protocol as approved by the regulator(s) / ethics committee(s)

[14] Tuberculosis, emerging infectious diseases as well as HIV/AIDS, Malaria and neglected infectious diseases have all been addressed through projects funded from previous calls.
[15] https://www.who.int/clinical-trials-registry-platform/network/registry-criteria
[16] https://www.ema.europa.eu/en/news/use-clinical-trials-information-system-becomes-mandatory-newclinical-trial-applications-eu
[17] https://www.who.int/clinical-trials-registry-platform/network/registry-criteria

- 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.

FAIR data principles and open access of publications are required in line with the Model Grant Agreement[18]. 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[19], the FAIR cookbook[20] and the guides for researchers on how to make your data FAIR[21]. Data quality and integration as well as issues of cybersecurity and data protection must be addressed. Use of explainable and transparent artificial Intelligence tools[22] in all research is encouraged where appropriate.

The proposals should put emphasis on involving vulnerable groups, including participants from poorer, underserved, or hard-to-reach communities in SSA. Applicants are also 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 vaccination 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 sub-Saharan African countries, including involvement of Franco/Lusophone

[18] unit-mga_he_en.pdf (europa.eu)
[19] https://www.go-fair.org/fair-principles/
[20] https://faircookbook.elixir-europe.org/content/home.html
[21] https://www.openaire.eu/how-to-make-your-data-fair
[22] See: European strategic research agenda in artificial intelligence: https://www.elise-ai.eu/work/agendaand-programs

countries where possible and relevant. Whilst Horizon Europe primarily supports excellence in research, proposals are encouraged to involve organisations from countries with relatively lower research capacities.

Where relevant It will be important for proposals to consider and support the existing and emerging partnerships between the European Union (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 MAV+[23], Sustainable Health Security[24], Public Health Capacity[25], Digital Health[26] and align with the Africa CDC Strategic Plan 2023-2027[27] and the African Medicines Agency. Moreover, collaborations with the African Regional Intellectual Property Organisation[28] (ARIPO) and the African Intellectual Property Organisation (OAPI)[29] 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[30] in the area of Public Health and the EU global health strategy[31].

Proposals must clearly demonstrate their added value, beyond the state of the art within their respective areas complementing existing research and funding and building on success of past programmes and projects financed by the EDCTP Association and/or other funders, in line with Article 100 of the Council Regulation 2021/2085[32].

Proposals must comply with all ethics requirements arising out of the research, in line with Article 112 of the Council Regulation 2021/2085. In addition to the scientific evaluation, proposals 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.

[23] Team Europe Initiative on manufacturing and access to vaccines, medicines and health technologies in Africa (europa.eu)
[24] Sustainable Health Security - Africa | Capacity4dev (europa.eu)
[25] Public Health Capacity - Africa | Capacity4dev (europa.eu)
[26] Digital Health - Africa | Capacity4dev (europa.eu)
[27] Africa CDC Strategic Plan 2023 – 2027 – Africa CDC
[28] African Regional Intellectual Property Organization (ARIPO)
[29] African Intellectual Property Organization (OAPI)
[30] AU-EU Innovation Agenda: https://research-and-innovation.ec.europa.eu/system/files/2023-07/ec_rtd_au-eu-innovation-agenda-final-version.pdf
[31] https://ec.europa.eu/commission/presscorner/detail/en/ip_22_7153
[32] 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 consider the impact of climate change in the research as appropriate, for example as regards the ability to carry out the proposed activities. Also, proposals should address how the climate impact of the planned research can be minimised.

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.

4.1.1.1 BUDGET

Call	Budget (in million EUR)	Deadline
Horizon-JU-GH-EDCTP3-2024-01-two-stage	136,432	4 April (first stage)*
Horizon-JU-GH-EDCTP3-2024-02-two-stage	3,500	4 April (first stage)*
WP 2024 emergency funding call in response to the Mpox outbreak in the Democratic Republic of Congo (DRC)	6,500	June
Additional EU and EDCTP-Association members states contribution for call 2024	64,085	4 April (first stage)
Other actions	2,095	
Total	**212,612**	

*to be confirmed when call planning is finalised

4.1.1.2 General conditions related to this work programme

Unless specified otherwise, the sections of the General Annexes to the Horizon Europe work programme[33] apply *mutatis mutandis* to the Global Health EDCTP3 JU work programme.

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 issue of countries where the coordinator may be established and the obligation to designate a scientific project leader. Participation conditions related to Russia's illegal invasion of Ukraine are also set out 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. The scores and weighting section as regard Research and Innovation Actions (RIA) second stage of two-stage evaluations is 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 the application of the right to object is described below. For the topics under the call Horizon-JU-GH-EDCTP3-2024-01-two-stage, specific conditions regarding affordable access apply. For the topic under the call Horizon-JU-GH-EDCTP3- 2024-02-two-stage, specific conditions regarding financial support to third parties apply. The conditions are spelled out under the respective topics.

[33] https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/wp-call/2023-2024/wp-13-general-annexes_horizon-2023-2024_en.pdf

Replacing relevant sections in General Annex B to the Horizon Europe work programmes on eligibility (*"Entities eligible for funding"*)

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);
- Countries associated to Horizon Europe[34]: Albania, Armenia, Bosnia and Herzegovina, Faroe Islands, Georgia, Iceland, Israel, Kosovo[35], 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):

1. Canada

2. Morocco

- The following countries which are constituent states of the EDCTP Association[36]: Benin, Burkina Faso, Cameroon, Côte d'Ivoire, Democratic Republic of the Congo, Ethiopia, Gabon, The Gambia, Ghana, Guinea-Bissau, Guinea-Conakry, Kenya, Liberia, Malawi, Mali,

[34] 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

[35] 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.

[36] 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

Mozambique, Niger, Nigeria, Republic of the Congo, Rwanda, Senegal, Sierra Leone, Somalia, South Africa, Tanzania, Uganda, Zambia, Zimbabwe.

Consortium composition

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

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

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

Specific cases:

Affiliated entities — Affiliated entities (i.e. entities with a legal or capital link to a beneficiary[37] which participate in the action with similar rights and obligations to the beneficiaries, but which do not sign the grant agreement and therefore do not become beneficiaries themselves) are allowed, if they are eligible for participation and funding.

Associated partners — Entities not eligible for funding (and therefore not able to participate as beneficiaries) may participate as associated partners, unless specified otherwise 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.

[37] See Article 187 EU Financial Regulation 2018/1046.

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[38], 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 financial coordinator of the indirect action must be established in a Member State or associated country. Of the SSA countries members of the EDCTP Association, only South Africa concluded such an agreement at the moment[39].

Scientific project leader

If the coordinator is not established in a country in sub-Saharan Africa (SSA), 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;
- 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

[38] 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

[39] https://research-and-innovation.ec.europa.eu/strategy/strategy-2020-2024/europe-world/international-cooperation/south-africa_en

the information received from or sent to the Global Health EDCTP3 JU on all issues of interest for the proper scientific management of the action.

Replacing the *scores and weighting* section in General Annex D to the Horizon Europe work programmes as regards Research and Innovation Actions (RIA) second stage of two-stage evaluations.

Scores and weighting

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 criteria 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, the scores and weighting as indicated in Annex D of the General Annexes of the Horizon Europe work programme 2023/2024 apply. Furthermore, the scores and weighting for Coordination and Support Actions apply.

General Annex G to the Horizon Europe work programmes

The Global Health EDCTP3 JU 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[40] and the Model Grant Agreement, the right to object applies also to participants that have not received funding from the JU.

[40] 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

HORIZON-JU-GH-EDCTP3-2024-01-two-stage

CONDITIONS FOR THIS CALL

INDICATIVE BUDGET(S)

Topics under Call HORIZON-JU-GH-EDCTP3-2024-01-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
Opening: 18 January 2024 Deadline stage 1: 4 April 2024				
HORIZON-JU-GH-EDCTP3-2024-01-01-two-stage	RIA	22,000	5,50	4
HORIZON-JU-GH-EDCTP3-2024-01-02-two-stage	RIA	30,000	15,00	2
HORIZON-JU-GH-EDCTP3-2024-01-03-two-stage	RIA	22,000	5,00	4
HORIZON-JU-GH-EDCTP3-2024-01-04-two-stage	RIA	24,000	6,00	4
HORIZON-JU-GH-EDCTP3-2024-01-05-two-stage	RIA	18,432	6,14	3
HORIZON-JU-GH-EDCTP3-2024-01-06-two-stage	RIA	20,000	5,00	4
Overall indicative budget		**136,432**		

Expected Impacts:

Activities funded under the 2024 work programme of the Global Health EDCTP3 JU calls for proposals should contribute to:

- Reduce the individual, social, and economic burdens of infectious diseases in sub-Saharan Africa through the development and uptake of new or improved interventions, and
- Increase health security in sub-Saharan Africa 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 sub-Saharan African (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;
- Develop novel, innovative HIV therapeutics for reducing the disease burden of HIV in SSA
- Research on existing Malaria vaccines and development of new promising candidates
- Accelerating development and integration of therapeutics against neglected tropical diseases (NTDs) in SSA;
- Tackle Antimicrobial Resistance (AMR) through R&D in novel and existing antimicrobials
- Develop new tools, technologies and approaches for vector control in SSA;
- Develop innovative digital health solutions for SSA.
- Build appropriate local capacity.

Proposals are invited against the following topics:

HORIZON-JU-GH-EDCTP3-2024-01-01-two-stage: Developing novel, innovative HIV therapeutics for reducing the disease burden of HIV in sub-Saharan Africa

Specific conditions	
Expected EU contribution per project	The Global Health EDCTP3 JU estimates that a JU contribution of around EUR 5.5 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 budget for the topic is EUR 22 million.
Type of Action	Research and Innovation Actions
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 the Joint Undertakings under Horizon Europe[41], grants awarded under this topic will have to submit the following deliverables: 1. Stewardship plan Participants must prepare stewardship plans outlining how to achieve the optimal use of an intervention, including, for example, how to avoid irrational use, overuse or abuse of health technologies (e.g. antimicrobials). A draft plan must be submitted after half the duration of the project has elapsed and a final plan must be submitted with the final report. 2. Global access plan With the final report, participants must submit an appropriate and proportionate global access plan that covers registration targets, plans to meet demand, flexible approaches to IP and other strategies that reflect ability to pay and ensure that economic barriers to access are low.

[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

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 sub-Saharan Africa, 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.

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:

- Evidence of efficacy, safety and clinical utility for health care professionals and clinicians in sub-Saharan Africa about novel, targeted HIV therapeutics that improve treatment outcomes and quality of life;
- Innovative HIV therapeutics that have demonstrated meaningful advances over existing therapeutic interventions for patients living with HIV in terms of their ability to improve efficacy, safety, adherence, quality of life and reduce HIV-associated mortality and morbidity.
- Public health authorities and policy makers have information from comprehensive clinical trial data on the overall health effects of novel therapeutic HIV interventions, helping them to draft updated or new evidence-based clinical guidelines and best practices as well as design tailor-made HIV policies.

Background:

Over the last few decades, antiretroviral therapy has dramatically increased the life expectancy of HIV patients, turning HIV from a death sentence into a chronic illness. Nevertheless, there are currently around 39 million infected people around the globe and HIV remains a major cause of death, disability and ill-health. The HIV disease burden continues to be high in sub-Saharan Africa, in particular for children and adolescents, and those with co-morbidities. There is therefore a strong need to achieve the 2030 UNAIDS 95-95-95 target[42] (95% of people with HIV know their HIV status; 95% of people with diagnosed HIV infection receive antiretroviral therapy; 95% of people receiving antiretroviral therapy have effective viral suppression) and develop novel HIV therapeutics, novel clinical delivery modes for their administration and novel biomarkers for optimising treatment decisions.

Scope:

Accordingly, the proposed research must deliver on the following:

- Carry out advanced stage clinical trials of promising HIV therapeutic interventions, for example but not limited to broadly neutralising antibodies, long-acting antiretrovirals or gene therapy approaches.

It may additionally also include:

[42] Joint United Nations Programme on HIV/AIDS (UNAIDS). (2014). Fast-Track: ending the AIDS epidemic by 2030. https://www.unaids.org/sites/default/files/media_asset/JC2686_WAD2014report_en.pdf

- Creation and testing of novel clinical delivery routes for the administration of HIV therapeutic interventions that bring meaningful benefit for HIV patients in terms of safety, efficacy, adherence and quality of life;
- In the context of the planned clinical investigations, identification and validation of biomarkers for better optimisation and personalisation of HIV treatment decisions as well as more accurate predictors of progression towards AIDS.

Applicants need to concisely describe any prior research findings and explain how the proposal builds on these results.

Proposals must carry out late-stage clinical research. Implementation research is not in scope for this topic. The research to be conducted must be inclusive and involve vulnerable groups, in particular infants, children and adolescents. Applicants are further encouraged to involve populations with limited clinical trial data, as well as HIV patients with co-infections and co-morbidities, both of which are associated with polypharmacy and present a serious risk for drug-drug interactions. Sex and gender differences and the effects of age should be duly taken into account.

Proposals should engage all relevant stakeholders, most notably 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.

Where possible, collaboration and coordination with the Team Europe Initiative on Manufacturing and Access to Vaccines, medicines and health products (TEI-MAV+) 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 developing HIV therapeutics is very much encouraged. Applicants are also reminded of the expectation of reaching out to organisations in countries with relatively lower research capacities.

HORIZON-JU-GH-EDCTP3-2024-01-02-two-stage: Research on existing Malaria vaccines and development of new promising candidates

Specific conditions	
Expected EU contribution per project	The Global Health EDCTP3 JU estimates that a JU contribution of around EUR 15 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 budget for the topic is EUR 30 million.
Type of Action	Research and Innovation Actions
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[43], grants awarded under this topic will have to submit the following deliverables: 1. Stewardship plan Participants must prepare stewardship plans outlining how to achieve the optimal use of an intervention, including, for example, how to avoid irrational use, overuse or abuse of health technologies (e.g. antimicrobials). A draft plan must be submitted after half the duration of the project has elapsed and a final plan must be submitted with the final report. 2. Global access plan With the final report, participants must submit an appropriate and proportionate global access plan that covers registration targets, plans to meet demand, flexible approaches to IP and other strategies that reflect ability to pay and ensure that economic barriers to access are low.
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

[43] 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

	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 sub-Saharan Africa, 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.

Expected Outcome:

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

- Generating evidence required for accelerating registration of new vaccine candidates;
- Generating long-term safety and efficacy data on currently registered vaccines;
- Safety and efficacy results from other vaccines, especially those targeting all stages of plasmodium falciparum lifecycle, including promising candidates in phase 2a/b;
- Generating evidence-based recommendations on how to boost manufacturing capacity and build an efficient supply chain for vaccines in general, and malaria vaccines in particular sub-Saharan Africa.

Background:

Currently, two vaccines are recommended for malaria prevention, RTS'S and R21/Matrix-M. At the same time, more candidates are in the pipeline undergoing safety and/or efficacy trials. To maximise the impact of currently recommended malaria vaccines in the context of the global technical strategy for malaria 2016-2030, it is important for the Global Health EDCTP3 JU to capitalise on the 1) recommendation of RTS'S as the first malaria vaccine recommended for large scale, 2) latest WHO recommendation of R21/Matrix-M for malaria prevention in updated advice on immunization.

As a longstanding public health crisis, malaria requires a multidimensional approach, including more and better vaccine strategies. Therefore, further R&D on other promising candidates in the pipeline is required, and further research on cross-cutting issues is necessary, to ensure both pharmaceutical and non-pharmaceutical prevention strategies are part of future evidence-based malaria prevention and control measures. Cross-cutting issues may include social sciences and community engagement activities as part of vaccines studies in malaria endemic regions. Synergy between researchers and other relevant stakeholders is required to develop and strengthen vaccines manufacturing capacity and to build an efficient supply chain in sub-Saharan Africa.

Scope:

Proposals submitted under this topic are expected to advance knowledge on the safety, efficacy and effectiveness of currently recommended malaria vaccines or new malaria vaccines. To this end, proposals submitted under this call topic should address at least two of the following:

- Trials from Phase 2a should be considered, to ensure continuation of R&D on new generations of vaccines targeting all stages of plasmodium falciparum lifecycle;
- Long term effectiveness studies through aligned primary endpoints should be considered where possible;
- Collection, analysis and sharing of pharmacovigilance data on vaccines that are currently registered or candidates in late-stage efficacy trials.

Where possible, collaboration and coordination with the Team Europe Initiative on Manufacturing and Access to Vaccines, medicines and health products (TEI-MAV+) is encouraged. The proposers 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. Applicants are also reminded of the expectation of reaching out to organisations in countries with relatively lower research capacities.

HORIZON-JU-GH-EDCTP3-2024-01-03-two-stage: Accelerating development and integration of therapeutics against Neglected Tropical Diseases (NTDs) in sub-Saharan Africa

Specific conditions	
Expected EU contribution per project	The Global Health EDCTP3 JU estimates that a JU contribution of around EUR 5 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 budget for the topic is EUR 22 million.
Type of Action	Research and Innovation Actions
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[44], grants awarded under this topic will have to submit the following deliverables: 1. Stewardship plan Participants must prepare stewardship plans outlining how to achieve the optimal use of an intervention, including, for example, how to avoid irrational use, overuse or abuse of health technologies (e.g. antimicrobials). A draft plan must be submitted after half the duration of the project has elapsed and a final plan must be submitted with the final report. 2. Global access plan With the final report, participants must submit an appropriate and proportionate global access plan that covers registration targets, plans to meet demand, flexible approaches to IP and other strategies that reflect ability to pay and ensure that economic barriers to access are low.
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

[44] 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

	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 sub-Saharan Africa, 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.

Expected Outcome:

This topic aims at supporting activities that contribute to at least two of the expected impacts for this call. Proposals under this topic should aim at delivering results that are contributing to the following expected outcomes:

- Accelerate development of therapeutics towards registration to make progress in the control and elimination of NTDs in sub-Saharan Africa;
- Improve the understanding of barriers for progression of existing and new therapeutics against NTDs through the R&D pipeline;
- Generate evidence-based recommendations on how to better integrate research and innovation in efficient supply chains for NTDs;
- Gain a better understanding of different country or region-specific health and research needs, to ensure a better case management of patients with NTDs;

Background:

There is some progress in eliminating and eradicating NTDs as per WHO publication[45] in October 2023: *"nineteen countries in Africa have eliminated at least one NTD and there are currently 18 million fewer people requiring interventions against NTDs. Togo achieved a world first by eliminating four NTDs. Guinea worm disease (dracunculiasis) is on the verge of eradication; sleeping sickness (T. b. gambiense human African trypanosomiasis) has been eliminated as a public health problem in seven countries; and the number of reported Buruli ulcer cases decreased by 71% between 2010 and 2021".* However, diseases such as schistosomiasis, onchocerciasis, and other NTDs continue to affect hundreds of millions of people who are most often society's poorest, in sub-Saharan Africa. The WHO Global report provides information for 2021-2022 on regional progress in Africa NTDs[46].

Many of NTDs are vector-borne diseases (NTD vector control is in scope of topic HORIZON-JU-GH-EDCTP3-2024-01-05-two-stage of this call: new tools, technologies and approaches for vector control in sub-Saharan Africa) have animal reservoirs and are associated with complex life cycles. The epidemiology of NTDs is complex and multifactorial, often related to environmental conditions, that makes their public-health control challenging. Moreover, COVID-19 pandemic severely disrupted health systems, including conduct of clinical trials, supply chains for NTD therapeutics and health products and the implementation of prevention strategies. Thus, pharmaceutical interventions combined with interventions such as house improvements, improved access to safe water, sanitation and hygiene (WASH) are also critical in the prevention for the majority of the NTDs, especially[47] *for Trachoma, Soil-transmitted helminthiases (STHs), Schistosomiasis and Dracunculiasis.*

Scope:

The proposals submitted to this call topic are expected to address at least one of the following activities in scope:

- Conduct clinical trials on therapeutics for NTDs in the scope of the Global Health EDCTP3JU:

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. Global Health EDCTP's remit will not cover chromoblastomycosis and other deep mycoses, scabies and other ectoparasites, and snakebite envenoming.

    - For existing therapeutics for specific indications, there is need to conduct clinical trials of combination therapies against multiple diseases and applicability to vulnerable populations

[45] Ending the neglect: lessons from a decade of success in responding to Neglected tropical diseases in Africa
[46] Global report on neglected tropical diseases 2023 (who.int)
[47] Information on cross-cutting issues in NTDs | InfoNTD

  - For infections where therapeutics are lacking entirely, clinical trials will be required for the development of new interventions (early stage) or extension of indications (re-purposing)

- Implementation research of pharmaceutical interventions for several NTDs and, when possible, their mainstreaming into national health systems in combination with other control measures

Where possible, collaboration and coordination with the Team Europe Initiative on Manufacturing and health products (TEI-MAV+) is encouraged. The proposals 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.

Activities related to community engagement are encouraged in the context of developing new pharmaceutical interventions targeting NTDs.

Applicants need to concisely describe any prior research findings and explain how the proposal builds on these results.

The research to be conducted must involve vulnerable groups, including participants from poorer, underserved or hard-to-reach communities in sub-Saharan Africa. The full range of relevant determining characteristics (sex, gender, age, socio-economic status, etc.) needs to be considered.

Applicants are also encouraged to provide methodologies for translating research findings into public health practice and policy guidelines.

The proposals should involve all stakeholders, most notably policy makers, public health authorities, health care professionals and end-users. Activities related to community engagement are encouraged in the context of developing new pharmaceutical interventions targeting NTDs. International cooperation is encouraged, and the proposed implementation research for pharmaceutical interventions is expected to be multidisciplinary through the involvement of medical sciences, psychological sciences, social sciences and the humanities.

All projects funded under this topic are strongly encouraged to participate in networking and joint activities, as appropriate. These networking and joint activities could, for example, involve the participation in joint workshops, the exchange of knowledge, the development and adoption of best practices, or joint communication activities. The details of these joint activities will be defined during the grant agreement preparation phase.

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. Applicants are also reminded of the expectation of reaching out to organisations in countries with relatively lower research capacities.

HORIZON-JU-GH-EDCTP3-2024-01-04-two-stage: Tackling Antimicrobial Resistance (AMR) through R&D in novel and existing antimicrobials

Specific conditions	
Expected EU contribution per project	The Global Health EDCTP3 JU estimates that a JU contribution of around EUR 6 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 budget for the topic is EUR 24 million.
Type of Action	Research and Innovation Actions
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[48], grants awarded under this topic will have to submit the following deliverables: 1. Stewardship plan Participants must prepare stewardship plans outlining how to achieve the optimal use of an intervention, including, for example, how to avoid irrational use, overuse or abuse of health technologies (e.g. antimicrobials). A draft plan must be submitted after half the duration of the project has elapsed and a final plan must be submitted with the final report. 2. Global access plan With the final report, participants must submit an appropriate and proportionate global access plan that covers registration targets, plans to meet demand, flexible approaches to IP and other strategies that reflect ability to pay and ensure that economic barriers to access are low.
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

[48] 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

	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 sub-Saharan Africa, 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.

Expected Outcome:

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 at least two of these, with the first bullet point being compulsory:

- Improvement of the use of existing antimicrobials to reduce AMR and providing data contributing to their equitable access in sub-Saharan Africa, and/or the advancement of late-stage clinical R&D of novel antimicrobials with improved properties (efficacy, safety, resistance pattern, useability) in the clinical trials pipeline;
- Data about development and implementation of antimicrobial stewardship (AMS) processes to optimise the use of antimicrobial medicines in human health and reduce antimicrobial resistance (AMR), employing the One Health approach;
- Effective infection prevention control measures, sanitation and hygiene to reduce the need for and the use of antimicrobial medicines.

Background:

The WHO has declared that AMR is one of the top 10 global public health threats facing humanity. Each year, at least 1.27 million people die as a consequence of AMR, with Africa having the world's highest mortality rate from AMR infections, resulting in over 27 deaths per 100,000[49]. Without action, the death toll could rise even higher, to as many as 10 million deaths annually by 2050[50].

Tackling AMR requires multi-modal interventions, the collaboration of many disciplines and countries. According to the Organisation for Economic Co-operation and Development (OECD), measures to prevent infections such as vaccinations, promoting hand hygiene and better hygiene in health-care facilities more than halves the risk of death and decreases the health burden of AMR. Antimicrobial stewardship (AMS) could further reduce the burden of drug-resistant infection[51]. The WHO defines AMS as a coherent set of integrated actions which promote the responsible and appropriate use of antimicrobials to help improve patient outcomes across the continuum of care. Responsible and appropriate use of antimicrobials includes prescribing only when needed, selection of the optimal drug regime, drug dosing, route of administration and duration of treatment following proper and optimized diagnosis. These actions are complemented by the implementation of infection prevention and control (IPC), enhancing water, sanitation and hygiene (WASH), and optimizing vaccination coverage[52].

AMR is one of the Global Health issues which can hugely benefit from the employment of the One Health approach. The One Health approach is defined as a joint effort of various disciplines that come together to provide solutions for human, animal, and environmental health, including food safety[53];

[49] The Lancet AMR analysis: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02724-0/fulltext

[50] World Bank, Antimicrobial Resistance: https://www.worldbank.org/en/topic/health/brief/antimicrobial-resistance-amr and Global AMR R&D Hub and WHO, Incentivising the development of new antibacterial treatments 2023: https://globalamr.e-laborat.eu/incentivising-the-development-of-new-antibacterial-treatments-progress-report-by-the-global-amr-rd-hub-and-who/

[51] OECD, Stemming the Superbug Tide: https://www.oecd.org/els/stemming-the-superbug-tide-9789264307599-en.htm; Antimicrobial stewardship programmes in health-care facilities in low-and middle-income countries: a WHO practical toolkit: https://www.who.int/publications/i/item/9789241515481; A European One Health Action Plan against Antimicrobial Resistance (AMR): https://health.ec.europa.eu/antimicrobial-resistance/eu-action-antimicrobial-resistance_en#ref-2017-eu-one-health-action-plan-against-amr; Antimicrobial stewardship: can we add pharmacovigilance networks to the toolbox? https://link.springer.com/article/10.1007/s00228-020-03035-3

[52] WHO policy guidance on integrated antimicrobial stewardship activities: https://www.who.int/publications/i/item/9789240025530; WHO Global research agenda for antimicrobial resistance in human health: https://www.who.int/publications/m/item/global-research-agenda-for-antimicrobial-resistance-in-human-health; Global Action Plan on Antimicrobial resistance: https://www.who.int/publications/i/item/9789241509763

[53] Antimicrobial resistance: global report on surveillance: https://iris.who.int/handle/10665/112642; Council recommendation published in June 2023: https://www.consilium.europa.eu/en/press/press-releases/2023/06/13/tackling-antimicrobial-resistance-council-adopts-recommendation/#:~:text=Overall%2C%20the%20Council's%20recommendation%20seeks,become%20resistant%20to%20medical%20intervention

more information can also be found in the Global research priorities agenda for One Health AMR[54]. AMR transmission is a critical global problem affecting humans, the environment, and animals. Hence, proposals need to have the One Health approach at their centre[55].

Furthermore, the availability and access to existing antibiotics is also a challenge[56]. The Global Leaders Group on AMR recently established that the world faces a serious antibiotic pipeline and access crisis that requires innovative financing measures. In particular, efforts to ensure equitable access to antibiotics in LMICs that experience the highest burden of AMR, are needed.

Scope:

Proposals must address at least two of the following areas, with the delivery of the first bullet point being compulsory:

- Conduct R&D on the better use of existing antimicrobials to reduce AMR and provide data to contribute to their equitable access in SSA, and/or conduct late-stage clinical R&D on novel antimicrobials with improved properties (efficacy, safety, resistance pattern, useability) for infections within the scope of EDCTP3 to reduce AMR;
- Develop innovative antimicrobial stewardship strategies in human health on how to tackle AMR based on the One Health approach within the scope of EDCTP3 in SSA;
- Develop and implement cost effective, acceptable and feasible infection prevention and control (IPC) strategies, in reducing AMR in healthcare facilities and communities.

Only proposals focusing their research on existing and/or novel antimicrobials from phase 3 onwards will be eligible. Neither pre-clinical research nor early-stage clinical trials in the context of product development are within the scope of this call.

The inclusion of industry partners involved in the development and/or manufacturing of the antimicrobials in the consortium is strongly encouraged.

Where possible, collaboration and coordination with the Team Europe Initiative on Sustainable Health Security in Africa or Manufacturing and health products (TEI-MAV+) 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

[54] WHO Global One Health priority research agenda for antimicrobial resistance: https://iris.who.int/bitstream/handle/10665/370279/9789240075924-eng.pdf?sequence=1

[55] ILRI One Health Strategy: Stopping the global rise of high-impact zoonotic disease, foodborne disease and antimicrobial resistance: https://cgspace.cgiar.org/bitstream/handle/10568/125264/OneHealthStrategy.pdf?sequence=1&isAllowed=y

[56] Progress report by the Global AMR R&D Hub and WHO 2023: https://globalamr.e-laborat.eu/incentivising-the-development-of-new-antibacterial-treatments-progress-report-by-the-global-amr-rd-hub-and-who/;
The Global Response to AMR, Wellcome Trust: https://wellcome.org/sites/default/files/wellcome-global-response-amr-report.pdf

engagement with regulators or with African manufacturers to support the translation into affordable products adapted to the regional market.

Environmental aspects relating to antimicrobial resistance in the production of antimicrobials and the waste of antimicrobials should be considered.

For the purposes of this call, existing antimicrobials are classified as those already on the market, but impacted by AMR, and in need of improvement of their use to minimise AMR, whilst by novel antimicrobials we refer to those in the clinical trial development pipeline, but not yet on the market.

Proposals should assess the impact, contribution, utility, accessibility, equity and cost-effectiveness of proposed interventions on AMR across socioeconomic settings in SSA.

Sepsis is included in the scope of this call. According to the Berlin Declaration on Sepsis, calling upon the enforcement of the WHA70.7 resolution, sepsis should be tackled as part of actions against AMR to maximise efficiencies and reduce the burden of disease.[57]

Applicants are encouraged to work among international sectors and actors, including human and veterinary medicine, agriculture, finance and environment experts.

Applicants need to concisely describe any proven research evidence of previous findings and explain how the proposal builds on these results.

Proposals should present a sound assessment of the feasibility of the proposed work, in particular as regard to the proposed clinical interventions. Realistic plans for recruitment of subjects (as part of the clinical trial plan with projected dates) should be presented and documented by demonstrated success from previous studies. The proposals should justify the choice of populations to be enrolled into the interventions. Relevant determining characteristics (such as socio-economic status) also need to be considered.

Proposals must assure that the clinical trials are conducted in line with national and international standards of research, to comply with current legislation, good clinical practice, ethics, and safety-related issues, as well as good manufacturing practice, as relevant.

Proposals should describe how stakeholder views of the proposal's relevance and the study design have been incorporated into the work plan of the research proposal. Proposals should indicate explicitly the plans for good participatory practices for engaging stakeholders at every step of the research life cycle.

[57] 2023 Berlin Declaration on Sepsis: https://www.esaic.org/esa-news/the-2030-world-sepsis-declaration/#:~:text=The%20Berlin%20Declaration%20on%20Sepsis%20is%20an%20urgent%20call%20for,reinvigorated%20global%20action%20on%20sepsis

Proposals should provide details on the methodology for linking clinical research aspects with the translation into healthcare practice and policy.

For all proposed research activities, attention should be paid to critical social factors such as sex, gender, age, socio-economic factors, ethnicity/migration, and disability both in terms of the consortium composition and the selection of study participants. Vulnerable populations need to be included in the clinical study population, including children, pregnant women, people with co-infections and comorbidities, older people and people living in hard-to-reach communities (unless excluded for physiologic or metabolic reasons).

FAIR data principles and open access of publications are required.

All projects funded under this topic are strongly encouraged to participate in networking and joint activities, as appropriate.

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. Applicants are also reminded of the expectation of reaching out to organisations in countries with relatively lower research capacities.

HORIZON-JU-GH-EDCTP3-2024-01-05-two-stage: New tools, technologies and approaches for vector control in sub-Saharan Africa

Specific conditions	
Expected EU contribution per project	The Global Health EDCTP3 JU estimates that a JU contribution of around EUR 6.14 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 budget for the topic is EUR 18.432 million.
Type of Action	Research and Innovation Actions
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[58], grants awarded under this topic will have to submit the following deliverables: 1. Stewardship plan Participants must prepare stewardship plans outlining how to achieve the optimal use of an intervention, including, for example, how to avoid irrational use, overuse or abuse of health technologies (e.g. antimicrobials). A draft plan must be submitted after half the duration of the project has elapsed and a final plan must be submitted with the final report. 2. Global access plan With the final report, participants must submit an appropriate and proportionate global access plan that covers registration targets, plans to meet demand, flexible approaches to IP and other strategies that reflect ability to pay and ensure that economic barriers to access are low.
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

[58] 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

	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 sub-Saharan Africa, 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.

Expected Outcome:

Proposals under this topic should aim to deliver results that are directed, tailored towards, and contributing to the development and evaluation of tools, technologies and approaches for vector-borne diseases, including vector control and disease management technologies.

Background:

Vector-borne diseases[59] account for more than 17% of all infectious diseases, causing more than 700000 deaths annually. They are human illnesses caused by parasites, virus and bacteria that are transmitted by vectors, living organisms that can transmit infectious pathogens between humans or from animals to humans. Most vectors are bloodsucking insects, such as mosquitos and ticks.

[59] Vector-borne diseases (who.int) and Disease vectors (europa.eu)

The burden of vector-borne diseases is highest in tropical and subtropical areas, and they disproportionately affect the poorest populations. Continuing urbanization and climate change are driving the expansion of the geographic range in which many of these vectors can thrive. Increasing numbers of autochthonous cases have also been reported from European countries[2].

The "Global Vector Control Response (GVCR) 2017–2030", approved by the World Health Assembly in 2017, supports the implementation of approaches to vector control that will enable the achievement of disease-specific national and global goals and contribute to achievement of the Sustainable Development Goals and Universal Health Coverage.

Many of vector-borne diseases are preventable, through protective measure and community mobilisation. Vaccines can help prevent some vector-borne diseases, such as yellow fever, Japanese encephalitis, tick-borne encephalitis. Another crucial element in reducing the burden of vector-borne diseases is behavioural change. Access to water and sanitation is another very important factor in disease control and elimination. However, not all vector-borne diseases have effective vaccines available and/or can be effectively prevented.

Scope:

Within the scope of this topical area should be innovative interventions that target any vector-borne disease including transmission through mosquitos, ticks, flies, fleas, lice, aquatic snails, and bugs.

Proposals submitted to this call topic must focus on vectors responsible for the transmission of one or more diseases within the scope of the Global Health EDCTP3 JU (see Table 1). To that end, the following diseases are considered as relevant to this call topic:

Chikungunya, Dengue, Lymphatic filariasis, Rift Valley fever, Yellow Fever, Schistosomiasis, Onchocerciasis, Plague, Leishmaniasis, Crimean-Congo haemorrhagic fever, Sleeping sickness and malaria.

Table 1: Vector-Borne infectious diseases in the scope of the Global Health EDCTP3 JU

Vector		Disease caused	Type of pathogen	Global Health EDCTP3 scope category
Mosquito	*Aedes*	Chikungunya	Virus	NTDs
		Dengue	Virus	NTDs
		Lymphatic filariasis	Parasite	NTDs
		Rift Valley fever	Virus	EIDs
		Yellow Fever	Virus	EIDs
	Anopheles	Lymphatic filariasis	Parasite	NTDs
		Malaria	Parasite	PRDs
	Culex	Lymphatic filariasis	Parasite	NTDs
Aquatic snails		Schistosomiasis (bilharziasis)	Parasite	NTDs
Blackflies		Onchocerciasis (river blindness)	Parasite	NTDs
Fleas		Plague (transmitted from rats to humans)	Bacteria	EIDs
Sandflies		Leishmaniasis	Parasite	NTDs
Ticks		Crimean-Congo haemorrhagic fever	Virus	EIDs
Tsetse flies		Sleeping sickness (African trypanosomiasis)	Parasite	NTDs

Intervention could include novel or improved approaches of:

- Vector traps;
- Genetic manipulation;
- Sterilization agents;
- Reduced pathogen transmission by microorganisms;
- Insecticide-treated nets (ITN);
- Chemosensory interference, specifically spatial repellents, bait station and repel and lure strategies;
- Systemic insecticides and endectocides;
- Improvements in housing/urbanisation;
- Monitoring and surveillance tools.

Emphasis should be given to interventions at the community level and to the barriers of vector-control in the health system. Initiatives with linkage to climate change impact are welcome.

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. Applicants are also reminded of the expectation of reaching out to organisations in countries with relatively lower research capacities.

HORIZON-JU-GH-EDCTP3-2024-01-06-two-stage: Innovative digital health solutions for sub-Saharan Africa

Specific conditions	
Expected EU contribution per project	The Global Health EDCTP3 JU estimates that a JU contribution of around EUR 5 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 budget for the topic is EUR 20 million.
Type of Action	Research and Innovation Actions
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[60], grants awarded under this topic will have to submit the following deliverables: 1. Stewardship plan Participants must prepare stewardship plans outlining how to achieve the optimal use of an intervention, including, for example, how to avoid irrational use, overuse or abuse of health technologies. A draft plan must be submitted after half the duration of the project has elapsed and a final plan must be submitted with the final report. 2. Global access plan With the final report, participants must submit an appropriate and proportionate global access plan that covers registration targets, plans to meet demand, flexible approaches to IP and other strategies that reflect ability to pay and ensure that economic barriers to access are low.
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'

[60] 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

	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 sub-Saharan Africa, 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.

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 the following expected outcomes:

- Development, improvement and/or scaling-up of digital innovative solutions supporting clinical research through smart, highly innovative digital health technologies or concepts to accelerate the development of preventive, therapeutic or diagnostic interventions addressing poverty-related diseases in sub-Saharan Africa;
- Development, improvement and or Scale-up of digital technologies in public health interventions that can serve as drivers for the strengthening of health systems in sub-Saharan Africa. The proposed digital solutions should allow notably but not exclusively the improvement of development, production and access to health countermeasures, data and research evidence for better health outcomes and for the development and implementation of informed health policies and/or improved clinical guidelines in sub-Saharan Africa;

- Contribution to the implementation of national and/or overarching regional digital health strategies.

Background:

The recent rapid advancements in digitalisation and the unprecedented opportunities created by digital health, data or AI promise to accelerate the achievement of the health-related SDGs. The EU-AU summit declaration[61] identified digitalisation, health, scientific cooperation and technology sharing (through the AU-EU innovation Agenda) as key pillars of the joint EU-U commitments. Digital health and health research have a central role, both in the EU Global Health Strategy[62] and the Africa CDC's Digital Transformation Strategy. Whilst aligning with the WHO Global Strategy on Digital Health 2020-2025[63], this call will contribute to the implementation of the EU-AU summit commitments, including the EU-AU innovation agenda[64]; to the implementation of the EU Global Health Strategy and contribute to enabling the implementation of the Africa CDC's Strategic Plan 2023-2027, by enhancing and integrating digital and analytics approaches to public health in Africa.

Integration of digital health innovations in national and/or regional strategies and context will be instrumental to ensure long-term impact and sustainability.

Scope:

Proposals are expected to:

- Be anchored in the scope of Global Health EDCTP3 and national/regional digital health strategies;
- Target demonstrated highest medical needs in Sub-Saharan Africa;
- Tackle justified context-specific needs;
- Develop, improve or upscale solutions, with early-stage involvement of end users and health services implicated;
- Propose solutions which demonstrate seamless integration interoperability with key existing national, regional or global systems;
- Propose tools which are sustainable, accessible, open-source, evidence-based and which follow the standards of data protection and digital health global public goods[65] [66].

Propose a sound sustainability/integration strategy and prevent further fragmentation of the digital health ecosystem through a multiplication of pilots. Proposals of new tools must justify the need for

[61] https://www.consilium.europa.eu/media/54412/final_declaration-en.pdf
[62] EU Global Health Strategy - Guiding Principles 4 and 5: https://health.ec.europa.eu/system/files/2023-03/international_ghs-report-2022_en.pdf
[63] https://www.who.int/docs/default-source/documents/gs4dhdaa2a9f352b0445bafbc79ca799dce4d.pdf
[64] AU-EU Innovation Agenda: https://research-and-innovation.ec.europa.eu/system/files/2023-07/ec_rtd_au-eu-innovation-agenda-final-version.pdf
[65] Indicative standards (to be agreed which reference should be): https://digitalpublicgoods.net/standard/
[66] https://digitalpublicgoods.net/standard/

additional developments and the shortcomings of available solutions. Strong evidence is expected for the justification of proposed actions. Access to evidence for existing solutions must be demonstrated. Scoping studies/Evidence generation on the need for proposed solutions are encouraged in the initiation phase of projects.

Proposals could be related to one or more of the following areas:

- Scaling-up of digital innovations that have already yielded proven results, and their transferring to other countries where they have not yet been adopted;
- Digital systems used in the implementation of clinical research and patients management;
- Integration of digital health resources and data systems in sub-Saharan African countries with limited capacity, defining best practices, open standards, and quality-assured building blocks such as data harmonisation;
- Remote access to diagnostics capabilities and health professionals;
- Optimisation and adaptation of bioinformatics pipeline for next-generation-sequencing data and omics analyses in relation to the infectious diseases in scope;
- Systems biology applications to sustain health technology manufacturing, development, and optimisation;
- Systematic architectures and warehouses, at both national and provincial level, for clinical and epidemiological data collection, respecting the FAIR guidelines (Findable, Accessible, Interoperable, Reusable);
- Adaptation of image-based analysis tools and software for diagnostics systems of diseases in scope.

Where possible, collaboration and coordination with the Team Europe Initiative on Digital Health[67] is encouraged. 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. Applicants are also reminded of the expectation of reaching out to organisations in countries with relatively lower research capacities.

[67] Digital Health - Africa | Capacity4dev (europa.eu)

HORIZON-JU-GH-EDCTP3-2024-02-two-stage

CONDITIONS FOR THIS CALL

Topics under Call HORIZON-JU-GH-EDCTP3-2024-02-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
Opening: 18 January 2024 **Deadline stage 1: 4 April 2024**				
HORIZON-JU-GH-EDCTP3-2024-02-01-two-stage	CSA	3,50	3,50	1
Overall indicative budget		3,50		

Expected Impacts

Activities funded under the 2024 work programme of the Global Health EDCTP3 JU calls for proposals should contribute to:

- Achieve SDG3 'Ensure healthy lives and promote well-being for all at all ages' in sub-Saharan African (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;
- Enhance sustainable global scientific collaboration in health research and international cooperation across sub-Saharan Africa.
- Improve opportunities for training of researchers and healthcare professionals in sub-Saharan Africa.

Proposals are invited against the following topic:

HORIZON-JU-GH-EDCTP3-2024-02-01-two-stage: Global Health EDCTP3 JU training fellowship with return phase

Topic expected to be implemented with contributions from contributing partners from the pharmaceutical industry (to be confirmed at a later stage):

Specific conditions	
Expected JU contribution per project	The Global Health EDCTP3 JU estimates that a JU contribution of around EUR 3.5 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 budget for the topic is EUR 3,5 million.
Type of Action	Coordination and Support Action, one project will be funded following the second stage evaluation
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 maximum amount to be granted to each third party is EUR 300,000. The support to third parties can only be provided in the form of grants. These grants are the fellowships to be awarded. For multi-annual fellowships, the amount of up to EUR 300,000 is needed.

Expected Outcome:

Project results are expected to contribute to the following outcomes:

- Foster the culture of pharmaceutical innovation and entrepreneurship in sub-Saharan Africa;
- Increase the number of skilled clinical researchers and innovators in sub-Saharan Africa;
- Promote the career development and retention of skilled personnel in sub-Saharan Africa;
- Strengthen sub-Saharan African countries clinical human capital base in Research and Innovation (R&I);
- Enhance talent retention, knowledge circulation and uptake across the research and innovation landscape in sub-Saharan Africa;
- Establish sustainable and mutually beneficial collaboration between clinical research organisations, academia, and Industry Partners across sub-Saharan Africa and Europe.

Background:

Sub-Saharan Africa (SSA) has a disproportionally low number of skilled researchers and innovators working on interventions against infectious diseases that are highly prevalent in SSA. To establish a sustainable and robust ecosystem of clinical research and innovators in sub-Saharan Africa synergy between funders, academia, and industry is planned to advance relevant skills. This Global Health EDCTP3 training fellowship programme will target early and mid-career African global health scientists seeking international academic credentials and other professional enrichment.

By providing this funding for return-home R&D studies, after a period training enriched with industry mentorship, the fellowship programme will enable the alumnae fellows to position themselves as pivotal leaders in improving global health and R&D equity.

Where relevant, it will be important for proposals to consider and support the existing and emerging partnerships between the EU/Team Europe and the AU and their key agencies, notably the Team Europe Initiatives on MAV+, One Health, Public Health Institutes, and the collaboration with the Africa CDC and the AMA. Moreover, collaborations with the African Regional Intellectual Property Organization (ARIPO) and the African Intellectual Property Organisation (AIPO) 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 around Public Health.

Scope:

Proposals submitted to this topic should implement a master's level training programme in a discipline relevant for the Global Health EDCTP3 JU, providing transferable R&D skills, fostering innovation and entrepreneurship, incl. commercialisation of results, Intellectual Property Rights, communication, public engagement, and citizen science. The training provided by the academic institutions is expected to be complemented by training modules provided by pharmaceutical companies. It is expected that pharmaceutical companies will join the consortium as beneficiaries and/or associated partners at a later stage. The companies are expected to bring cash or in-kind contributions to the training programme for the fellows.

The training will address the research and development value chain from pre-clinical to clinical research including pharmaceuticals and vaccines.

Proposals must demonstrate all of the following:

- A high-quality training programme related to R&D on diseases in the scope of the Global Health EDCTP3 JU at master level in global health/clinical research;
- 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;

- Design of a programme where training for each fellow includes a **first phase (or outgoing phase)** of minimum 12 and maximum 24 months enrolment into an academic organization, and a **second phase (or return phase)** of at least 12 months in the country of origin of the fellow;
- A robust training and mentorship mechanisms to support the fellows through their first training phase and second home return phase;
- Linkages with other Global Health EDCTP3 JU actions should be foreseen as relevant (e.g. Global Health EDCTP3 Training Networks or Global Health EDCTP3 Genomic Epidemiology Networks).

Proposals should be made by institutions with a proven track record in the provision of high-quality research training and established regional and global collaborations. These may include research organisations, institutions of higher learning such as universities.

The proposals must explain how many fellows they plan to recruit, what the cost of the training in the first phase will be and how much funding will be provided to the fellows for the return phase.

Based on the described skills and curricula offered by the successful consortium, future fellows will apply to the available training opportunities in line with their own professional development plans.

Proposals should also clearly outline how future fellows will be mentored in the development and implementation of the second phase (return phase) at the home institution in SSA.

In-kind and financial contributions from private (profit and non-profit) entities, clinical research organisations and others interested in this scheme are encouraged. Financial contributions can be made with or without direct participation in the project implementation.

Especially, consortium members established in countries that are not eligible for the Global Health EDCTP3 JU funding, will have to cover the costs related to their tasks within the project without JU funding.

Financial contributions from third parties (e.g., foundations) interested in this scheme are encouraged to contribute to increase the budget, diversity, and impact.

4.1.2 Other actions not subject to call for proposals

4.1.2.1 External expertise

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.

Form of Funding: Other budget implementation instruments

Type of Action: Expert contract action

Indicative timetable: 2024

Indicative budget: EUR 945 315 from the 2024 budget.

4.1.2.2 Mobilisation of research funds in case of Public Health Emergencies

Expected outcome:

This topic aims at supporting activities that contribute to answering the most pressing questions raised by public health responders to the Mpox Public Health Emergency (PHE), as part of the efforts to manage and prevent the spread of the current epidemic. Proposals should result in new knowledge to manage and prevent future outbreaks and should strengthen the capacities of at-risk countries to respond to epidemics.

To that end, proposals submitted under this topic should aim at delivering results that are contributing to the following expected outcomes:

- Provide novel, critical and timely insights into the Mpox outbreak and/or potential avenues for its management or prevention, focusing on the most affected population, specifically children, pregnant women and immunosuppressed individuals.
- Be timely, with rapid activation, to enable early and valuable outcomes and results to be produced and/or to support access time-dependent resources.
- To contribute to the public health preparedness and response in the context of the ongoing Mpox epidemic.

Scope:

The Global Health EDCTP3 Work Programme 2024 foresees funding to be mobilised in case of a Public Health Emergency (PHE). This mechanism allows rapid mobilisation of research funding with or without a call for proposals in exceptional and duly substantiated emergencies. Global Health EDCTP3

considers a situation as an emergency if it is unforeseen and presents a serious and immediate risk to human health.

Following the Mpox outbreak in the Democratic Republic of Congo (DRC), first reported in 2023, the DRC Government, Africa CDC, World Health Organization (WHO) and partners have been closely monitoring it. From 1 January through 12 November 2023, a total of 12 569 suspected Mpox cases, including 581 suspected Mpox deaths (case fatality ratio: 4.6%), had been reported in 156 health zones from 22 out of 26 (85%) provinces of the DRC[68]. In 2024, and as of 29 March, 4 488 cases have been reported, of which 319 have been confirmed. A total of 279 deaths have been reported in the country in 2024 (CFR: 6.7%)[69].

On 13 April 2024, a High-Level Emergency Regional Meeting[70] was held in Kinshasa, to discuss the ongoing epidemic of Mpox in DRC and the potential risk of transmission to neighbouring countries and beyond. On the same day, the Ministry of Health (MoH) of DRC assessed the situation and considered the ongoing outbreak as a Public Health Emergency which requires a rapid and efficacious response. Aligning with this statement, the High-Level Meeting ended with a Communiqué (dated 13 April 2024) whereby twelve Ministers of Health and international partners called for a coordinated response to the outbreak and for the establishment of an Africa Taskforce for Mpox Coordination among Member States affected and at-risk of Mpox. These documents include a call to accelerate research and regulatory processes to enable access to vaccines, diagnostics and therapeutics for affected populations including children.

In the light of rising numbers of cases being reported in the DRC and the high public health risk, the Global Health EDCTP3 is activating the emergency funding mechanism to support research and innovation projects and activities as part of the Joint Undertaking's response to the emergency.

The Global Health EDCTP3 invites proposals for Research & Innovation Actions (RIA) to support research activities in DRC and neighbouring or affected countries, to manage and/or prevent the spread of the current Mpox outbreak.

Proposals should address one or more of the following areas:

1. **Vaccines research and development:**
   Trials should focus on both pre-exposure prophylaxis and post-exposure prophylaxis.

2. **Clinical trials for therapeutics:**
   Proposals should include trials on therapeutic products in the context of the Monitored Emergency Use of Unregistered Interventions (MEURI), such as tecovirimat (approved by the European Medicines Agency for use in the European Union) and other promising therapeutic

[68] https://www.who.int/emergencies/disease-outbreak-news/item/2023-DON493
[69] https://www.ecdc.europa.eu/en/news-events/outbreak-mpox-caused-monkeypox-virus-clade-i-democratic-republiccongo
[70] https://www.afro.who.int/media-centre/statements-commentaries/united-fight-against-mpox-africa

candidates. Research on pain management strategies should integrated in the proposed R&D efforts.

3. **Surveillance strategies, evaluation of rapid diagnostics and epidemiological studies:** Proposals should provide data on epidemiological characteristics such as geographical spread, viral genotype, and pathogenicity, clinical information on host susceptibility and host immune responses. This work is foreseen to use and evaluate available diagnostic tools to ensure improved surveillance.

Moreover, proposals should ensure:

- Focus on the most affected population, specifically children, pregnant women and immunosuppressed individuals.
- Alignment with the national priorities of the DRC and neighbouring countries as well as the African Taskforce for Mpox Coordination.
- Partnership with researchers and public health institutions in DRC and neighbouring countries.
- Strengthening of national and local research capacity.
- Coordination and collaboration with other research and/or humanitarian activities operational in the countries affected.
- Alignment with the Africa CDC Task Force recommendations for rapid activation of R&D activities to control the outbreak.
- Compliance with International Council on Harmonisation – Good Clinical Practice (ICH-GCP), regulatory and ethical standards.
- Commitment to open access and data sharing principles, including appropriate data management and governance plans.
- Demonstrate alignment/synergy with DRC national government health service delivery policy and plans, where appropriate.

Proposals should provide novel, critical and timely insights into the Mpox outbreak and/or potential avenues for its management or prevention, focusing on the most affected population, specifically children, pregnant women and immunosuppressed individuals.

Proposals must be timely, with rapid activation, to enable early and valuable outcomes to be established and/or to access time-dependent resources.

Proposals funded under this mechanism must share the relevant generated data within 30 days after generation with all parties that need and can use the findings to address the PHE.

Who should apply?

Under this mechanism, the invitation to apply for funding will be open to all eligible entities, and those based in affected countries are particularly encouraged to apply. To be eligible for assessment, proposals must be submitted by consortia that fulfil the eligibility criteria (See further under Eligibility).

Eligibility

The general conditions related to Work Programme 2024 (including Annex 1A, pages 7 to 12) apply.

In particular, a proposal/application will only be considered eligible if:

1. its content corresponds, wholly or in part, to the topic/contest description for which it is submitted;

2. it complies with the eligibility conditions set out below:

Legal entities forming a consortium are eligible to participate in actions under the programme provided that the consortium includes:

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

Indicative budget and Topic-Specific Conditions

Specific conditions

Specific conditions	
Indicative timetable	This Call will be open for a maximum period of 2 weeks.
Expected EU contribution per project	The Global Health EDCTP3 JU estimates that a JU contribution of around EUR 6,5 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. The total budget for this call may potentially attract additional funding from interested contributing partners.
Indicative budget	The total indicative budget for the topic is EUR 6,5 million.
Type of Action	Research and Innovation Actions.
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.
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). 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[71], grants that implement clinical studies awarded under this topic will have to submit the following deliverables: 1. Stewardship plan Participants must prepare stewardship plans outlining how to achieve the optimal use of an intervention, including, for example, how to avoid irrational use, overuse or abuse of health technologies (e.g. antimicrobials). A draft plan must be submitted after half the duration of the project has elapsed and a final plan must be submitted with the final report. 2. Global access plan With the final report, participants must submit an appropriate and proportionate global access plan that covers registration targets, plans to meet demand, flexible approaches to IP and other strategies that reflect ability to pay and ensure that economic barriers to access are low.
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

[71] 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

	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.

4.1.2.3 EDCTP Forum 2025 preparations in 2024

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.

It is expected that payments will be made in 2024 to cover expenses related to inspection and visit of potential venues; hire an EU and local events management company; and secure a venue and block bookings in local hotels. This action will support all eligible costs necessary to organise the Forum and collect and report on expected scientific and policy outputs.

Expected impact: The Forum is expected to draw 800-1200 delegates, the majority of whom are working in sub-Saharan Africa, and provide a unique research communication platform for those stakeholders working in the field of PRDs.

Form of Funding: Other budget implementation instruments

Type of action: Public Procurement – up to 20 service contracts.

Indicative timetable: The procurement process for some of the services will begin in the third quarter of 2024 with the objective of ensuring all procurements are made before the scheduled date of the Forum, which will be in the second quarter of 2025. All procurements will be made in accordance with the Global Health EDCTP3 JU procurement policies and procedures. First payments are expected to be made in the last quarter of 2024.

Indicative budget: EUR 1 000 000.

4.1.2.4 EDCTP Prizes in 2024

Prizes are financial contributions given as rewards following the publication of a contest (call). Prizes can take the form of "Inducement prizes" or "Recognition prizes". A 'recognition prize' is used to recognise past achievements and outstanding work after it has been performed, whereas an 'inducement prize' is used to spur investment in a given direction, by specifying a target prior to the performance of the work. The Global Health EDCTP3 prizes are recognition prizes funded under Horizon Europe. As per the EU Financial Regulation (Article 110(3)(d), only prizes with a unit value of EUR 1 000 000 or more must be included in the Annual Work Programme. Nevertheless, for transparency reasons, in 2024 the Global Health EDCTP3 is planning to issue and award seven prestigious international monetary prizes (EUR 180 000 in total) to recognise the achievements of outstanding researchers and research teams, especially from sub-Saharan Africa and Europe.

The seven prizes are:

Four Scientific Leadership Prizes:

The prize consists of a recognition trophy and a cash prize of EUR 15 000 for each of the four winners. The cash prize should be used to further the research programme of the winner and may support activities such as supporting study visits and training attachments to collaborating institutions, data collection for baseline studies, conference and meeting attendance, and other relevant research-related activities.

- Two Scientific Leadership Prizes (one woman and one man) for researchers residents of an EU Member State or a country associated with the Horizon Europe programme;
- Two Scientific Leadership Prizes (one woman and one man) for researchers residents of a SSA country which is a constituent state of the EDCTP Association.

Dr Pascoal Mocumbi Prize

The Dr Pascoal Mocumbi Prize aims to reward an individual in recognition of his/her outstanding achievements in advancing health research and capacity development in Africa with significant impact on the wellbeing of the African population. The prize consists of a recognition trophy and a cash prize of EUR 50 000.

The Outstanding Research Team Prize

This prize is awarded to outstanding research teams in sub-Saharan Africa and Europe working on HIV/AIDS, tuberculosis, malaria and neglected infectious diseases. The prize consists of a recognition trophy and a cash prize of EUR 50 000.

Outstanding Female Scientist prize.

The prize is awarded to female scientists who have made a significant scientific contribution and built measurable impactful research capacity through training and mentorship for the future generation of

researchers/scientists in Africa**.** The prize consists of a recognition trophy and a cash prize of EUR 20 000.

For all above prizes, the eligibility and award criteria as well as the deadline for submission of applications will be announced in a later stage.

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

The IKAA plan is annexed as a separate document (Annex 1).