Global Health
EDCTP3

GOVERNING BOARD OF THE GLOBAL HEALTH EDCTP3 JOINT UNDERTAKING
Decision N°
GB 05/2023

Annual Work Programme 2023

Adopted on 03.04.2023

By written procedure the Governing Board of the Global Health EDCTP3 Joint Undertaking adopted this work programme including:

- The annual budget 2023;
- The staff establishment plan 2023;
- The content of the calls for proposals;
- The annual additional activities plan.

Done at Brussels, 03.04.2023

For the Governing Board of the Global Health EDCTP3 Joint Undertaking,

Henning Gädeke
Chairperson

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2. LIST OF ACRONYMS, DEFINITIONS AND ABBREVIATIONS

CA	Contractual agent
COVID-19	Coronavirus disease 2019
CSA	Coordination and support action
DG	Directorate-General
DG BUDG	Directorate-General for Budget
EDCTP	European and Developing Countries Clinical Trials Partnership
GH EDCTP3	Global Health EDCTP3 Joint Undertaking
HIV	Human immunodeficiency virus/acquired immunodeficiency syndrome
HR	Human resources
IHI	Innovative Health Initiative Joint Undertaking
JU	Joint undertaking
IT	Information and communication technology
IKAA	In-contributions to additional activities
OJ	Official Journal of the European Union
OLAF	European Anti-Fraud Office
POC	Point-of-care (diagnostic)
PRDs	Poverty-related diseases
RIA	Research and innovation action
SARS-CoV2	Severe acute respiratory syndrome coronavirus 2
SDG	Sustainable development goals
SLA	Service-level agreement
SRIA	Strategic research and innovation agenda
SSA	Sub-Saharan Africa
TA	Temporary agent
TB	Tuberculosis

3. INTRODUCTION

3.1 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 (GH EDCTP3) 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.

3.2 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 (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.

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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. Global Health EDCTP'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. Global Health EDCTP'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

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 GH EDCTP3 builds on and will extend the platforms created by EDCTP, contributing to the above-mentioned policies.

The first GH EDCTP3 work programme 2022 addressed several key aspects of the Strategic Research and Innovation Agenda (SRIA – GB Dec. N° 04/2022)[5].The second work programme sets out the activities to be carried out in 2023, building on the activities supported so far. Whilst in 2022 only topics for a single-stage call process were launched, this year five topics are open in a single-stage call and two topics are open in a two-stage call.

The focus and goals of GH EDCTP3 of bringing health technologies to patients and health systems was reflected in 2022 by a topic on *Promoting implementation of research results into policy and practice*. For the 2023 work programme, three topics address this main goal of the programme.

In the single-stage call, one of the topics will support clinical trials that had been launched with funding from the EDCTP2 programme and where implementation was slowed down significantly by the COVID-19 pandemic. The delays have also led to increased cost which cannot be fully covered by the original grants. A range of clinical trials addressing diseases such as HIV/AIDS, malaria, tuberculosis, neglected tropical diseases and different types of interventions from diagnostics, vaccines to medicines and evaluating morbidity will be supported.

A second call topic is on implementation research/real life assessment of existing interventions in women and children's health. Despite the progress made in other age groups, effective treatment and prevention of poverty-related diseases (PRDs) and other infectious diseases in mothers, newborns and children is often lacking and/or are sub-optimal. The frequent exclusion of pregnant women and children from clinical trials and the limited number of available products targeting these groups, are factors that contribute to the lowest health indicators in these vulnerable populations.

Moreover, failure to translate research findings into policy and practice prevents research from achieving maximum public health benefits. Concerted efforts are needed to increase access to potentially lifesaving, cost-effective interventions to prevent and treat infectious diseases in pregnant women, newborns and children and to enhance the use of existing interventions in these populations.

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5 https://ec.europa.eu/info/sites/default/files/research_and_innovation/research_by_area/documents/ec_rtd_edctp3-sria-2022.pdf

The last topic focusing on implementation research is on *Improving modes of delivery, deployment and uptake of vaccines through phase IV/implementation research* under the two-stage call. Despite offering strong protection against infectious diseases, global vaccination rates have been declining for a few years resulting in the re-emergence of preventable infectious diseases that were thought to be on the verge of elimination. This trend further worsened during the COVID-19 pandemic because of severe interruptions in public health services, restrictions of non-urgent medical care and diversion of limited health care resources, resulting in the cancellation or delays of routine vaccinations. Furthermore, there has been a significant erosion of trust in governments and public health institutions that coordinate and conduct such immunisation efforts. Novel logistical and clinical solutions for vaccine delivery and a better understanding of the behavioural barriers driving vaccine hesitancy in SSA are therefore of critical importance.

Accordingly, the proposed research is expected to deliver on phase IV/implementation research studies on the deployment and uptake of vaccines in SSA, examining operational aspects, access, coverage, vaccine acceptability/hesitancy, community engagement, real-life impact on overall health and cost-effectiveness.

Research on epidemic preparedness is addressed by the single-stage topic for research to rapidly evaluate interventions on Ebola outbreaks in SSA. Proposals submitted under this call topic are expected to advance knowledge on Ebola virus disease with the aim of contributing to an efficient patient management and public health response, as well as better epidemic preparedness in Africa. Special focus should be on improving understanding of the Sudan virus disease, in view of the recent outbreak in East Africa and the lack of available interventions for this viral strain. There are currently no licensed vaccines or therapeutics for the prevention and treatment of Sudan virus disease.[6]

As further support to emerging infectious diseases, the work programme also foresees a topic under other actions to rapidly mobilise funding in case of a public-health emergency without the need to launch a call for proposals. A nominal amount of EUR 1 million of funding is set aside for this topic. In case a public health emergency occurs, depending on the specific situation, additional funding will be mobilised.

Two areas previously not addressed are covered by topics under the 2023 work programme. The first concerns a two-stage call topic for advancing point-of-care (POC) diagnostics to the market. This includes all diseases in scope of Global Health EDCTP3, for example antimicrobial resistance and emerging diseases. POC diagnostic tests that are easy to use, affordable and can rapidly diagnose diseases will lead to timelier treatment and thereby reduce mortality, morbidity and transmission of diseases. POC diagnostic tests should improve the quality of healthcare for resource-poor communities in developing countries, where the burden of disease is the highest. A diagnostics gap for many diseases affecting SSA still exists and needs to be closed urgently to contribute to achieving the global and national disease elimination targets. Hence, proposals submitted under this topic should implement studies that lead to market authorisation of the relevant POC diagnostic test. This topic also contributes to addressing emerging infectious diseases.

Training activities are addressed for the first time under the GH EDCTP3 programme through a single-stage call topic on clinical research fellowships. The Global Health EDCTP3 Training Networks aim to

[6] https://www.who.int/emergencies/disease-outbreak-news/item/2022-DON410

train and develop skilled, innovative and resilient African researchers, scientists, clinicians and other public health professionals in the area of infectious disease research. The main objective is that infectious disease public health professionals can face current and future clinical research challenges, efficiently carry out clinical trials, implement research results, apply knowledge into products and services and/or analyse data to inform policy and practice for a better health for all in SSA. Through the training being offered to the fellows, important research questions with the framework of the Strategic Research and Innovation Agenda of Global Health EDCTP3 will be addressed.

Within the GH EDCTP3 work programme for 2023, research capacity building in SSA is also addressed through a Coordination and Support Action (CSA) topic under the single-stage call on strengthening ethics and regulatory capacity. The aim is to improve the functionality, recognition and performance of ethics committees and regulatory agencies in SSA countries.

Despite ongoing efforts by different partners and agencies, ethics and regulatory oversight in SSA countries requires prioritisation and ownership by these countries to ensure sustained strengthening with a long-term perspective. There is a need to better understand the challenges that these countries are facing. Coherent linkages between ethics and regulatory functions are also needed. Several initiatives have already established capacity development tools and structures that add value to the capacity development efforts of ethics and regulatory agencies in SSA and should be taken into consideration.

The projects funded under this call will support the SSA countries to establish and/or develop robust capacities for ethical review and national medicines regulatory systems. This scheme targets proposals with active involvement of national ethics committees and/or national regulatory agencies from SSA countries, and in particular from those countries with the highest infectious diseases burden.

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 each from EU member states or countries associated to Horizon Europe and from SSA countries that are members of the EDCTP Association.

3.3 Strategy for the implementation of the programme

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

- **State of the product development landscape**: For each disease area, the current state of clinical development of interventions for prevention (including vaccination), diagnosis, and treatment will be analysed.
- **Priority infections**: Priority setting 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**: GH EDCTP3 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 WHO and other strategically important international and African partners, GH EDCTP3 will ensure global alignment of its policies and priorities and promote coordinated responses to evidence gaps and capacity-building needs.
- **Strategic portfolio**: GH EDCTP3 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 GH EDCTP3 with the flexibility to respond to emerging opportunities and health challenges. This annual programme includes details of the specific calls for proposals for the year 2023.

On the side of launching calls for proposals, the focus for the year 2023 is to build on the investments made with the 2022 work programme and implement both a single- and a two-stage call. The strategy process for developing the 2023 work programme was launched with discussions and a meeting of the Scientific Committee and the same approach will be taken for developing the 2024 work programme. With the increase in the number of staff of the GH EDCTP3, it will be possible to organise consultations and meetings with relevant stakeholders. This concerns in particular the interactions with prospective contributing partners, where a portfolio approach will be developed.

Building on the first topic for training networks in the 2023 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. An update to the Horizon Europe Unit Model Grant Agreement to allow funding of individual fellowships by the GH EDCTP3 will be required. This process involves central services of the European Commission and has been initiated.

Contributions from the EDCTP Association and contributing partners

Good progress has been made on the processes for declaring and reporting in-kind contributions to additional activities (IKAA) and management of financial contributions. Further work will ensure that the practical aspects are clear to allow the EDCTP Association the first reporting of IKAAs from the year 2022 and to ensure that further contributions can be planned.

The partnership between the GH EDCTP3 and the Bill & Melinda Gates Foundation (a contributing partner) on genomic epidemiology research under the 2022 work programme was a first example of such type of collaboration. For this work programme, an approach for reporting contributions adapted to the specific example is in place. As the discussions with additional contribution partners take shape during the year, the modalities for reporting contributions will also have to be defined.

Preparing grant agreements

The first grant supported by GH EDCTP3 for financing the EDCTP Africa office for the period from 2023 through 2025 was signed shortly before the end of 2022. One of the most important activities during 2023 is the grant preparation for the 27 other projects deriving from the 2022 work programme. Good interaction with and among the supported grants from the start is essential to achieve the ambitious objectives of GH EDCTP3.

The communication activities are described under section 4.3.1. are linked to the strategy for implementation of the programme as described there.

4. WORK PROGRAMME 2023

4.1 Executive Summary

This is the second work programme under the GH EDCTP3. The topics are based on the Strategic Research and Innovation Agenda adopted by the Governing Board.[7]

The work programme includes four topics for Research and Innovation Actions (RIA) under a single-stage call and one topic for a CSA under this call. Two topics for RIA are launched under a two-stage call. The calls for proposals are complemented by other actions. The cost for external expertise, notably for the peer-review evaluation will be covered under this part of the programme.

The other actions also foresee mobilisation of research funds in case of public health emergencies without the launch of a call for proposals.

[7] https://ec.europa.eu/info/sites/default/files/research_and_innovation/research_by_area/documents/ec_rtd_edctp3-sria-2022.pdf

Work programme topic/action	Timing of launch	Budget (EUR)	
Clinical research fellowships (RIA)	Q2/2023	15 300 000	Single stage
Funding to successfully finalise clinical trials from EDCTP2, which have been negatively impacted by the COVID-19 pandemic (RIA)	Q2/2023	14 000 000	Single stage
Implementing research/real life assessments of existing interventions in women and children's health (RIA)	Q2/2023	26 000 000	Single stage
Research to rapidly evaluate interventions on Ebola outbreaks in Africa (RIA)	Q2/2023	11 000 000	Single stage
Strengthening ethics and regulatory capacity (CSA)	Q2/2023	8 000 000	Single stage
Improving modes of delivery, deployment and uptake of vaccines through phase IV/implementation research (RIA)	Q2/2023	30 000 000	Two-stage
Advancing point-of-care diagnostics to the market through comparative testing. This includes all diseases in scope of EDCTP3. For example, antimicrobial resistance and emerging diseases (RIA)	Q2/2023	26 000 000	Two-stage
External expertise	Q1-Q4/2023	597 312	Other actions
Raising research funds in the event of a public health emergency	Q1-Q4/2023	1 000 000	Other actions
Total		131 897 312	

4.2 Operational objectives

4.2.1 Objectives, indicators and risks

GH EDCTP3 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

The build-up of staff of the GH EDCTP3 Secretariat is making good progress, after delays in 2022. It should thus be possible to implement the programme overall in a satisfactory manner.

The process for recruiting the permanent Executive Director is still ongoing and it is not possible to ascertain that it will be concluded in the foreseen time frame (GB decision recruiting the Executive Director still in Q2). Having the Executive Director recruited – albeit she or he does not yet have had to start their function – is a pre-condition for GH EDCTP3 to achieve autonomy as now planned for the end of Q3. Any further delay on the Executive Director recruitment would push autonomy to Q1 or Q2/2024.

4.2.2 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. As well as 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 rapidly spread 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 GH EDCTP3 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 GH EDCTP3 are to achieve a reduced socio-economic burden of infectious diseases in SSA and an increased health security in SSA and globally.

4.2.3 Calls for proposals

Described in Annex 1 to the 2023 work programme

4.3 Support to operations of the Global Health EDCTP3 Joint Undertaking

4.3.1 Back-office arrangements

According to Article 13 of Council Regulation 2021/2085, 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 GH EDCTP3 signed the service-level agreement (SLA) to join the accounting function provided under the lead of the Europe's Rail JU. The practical implementation of being part of this arrangement will occur after autonomy is achieved.

Briefly, the arrangement is as follows: The Executive Director of the Lead JU is responsible for the organisation, oversight and coordination of the accounting services to the other JUs based on an annex of the specific SLA.

The Head of Administration and Finance or another officer with the necessary grade, skills and competencies of the Lead JU shall act as Accounting Coordinator of the back-office arrangement Accounting Officers. One of these individuals will be formally appointed as the Accounting Officer of the GH EDCTP3 by the Governing Board.

Human resources (HR)

Article 13 of the Council Regulation 2021/2085 identifies Human Resources 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 such as the coordination of the management of SYSPER, possibly obtaining a single contract for all JUs, joint recruitments, the harmonisation of job profiles and the establishment of common recruitment procedures. These synergies will allow obtaining a better harmonisation among the JUs, exploiting best practices, achieving efficiency gains and economy of scale. In this sense, at the end of 2022 the GH EDCTP3 JU launched a common recruitment procedure with Clean Hydrogen JU and will exploit further similar possibilities during 2023 and beyond.

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. This concerns for example IT, building management/corporate services, some communication support services, law firms list, data protection. 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.

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 avoid redundancies.

The back-office arrangement in this area will also provide the framework 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., Qlik, PowerBI).

4.3.2 Communication, dissemination and exploitation

Communication activities in 2023 focus on the calls for proposals for 2023, activities to promote the first grants signed under GH EDCTP3 under work programme 2022 and the Eleventh EDCTP Forum in November in Paris.

Communication activities around other key aspect will also be undertaken, such as the start of the activities of the Stakeholders Group, and the activities of the Scientific Committee.

With the launch of the 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.

The events will focus on both scientific content and administrative aspects, so that applicants have a good understanding of the specific requirements and conditions of the GH EDCTP3 calls. This is done to ensure that GH EDCTP3 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. This is key to bring concrete benefit for patients and health systems in SSA and Europe. To reach out to stakeholders and especially potential applicants in SSA countries, the EDCTP Africa office will support the activities undertaken by the GH EDCTP3.

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

A key event in 2023 will be the Eleventh EDCTP Forum taking place in November in Paris (France). The event is organised jointly by the EDCTP Secretariat and the GH EDCTP3 JU. The input from the Stakeholders Group will be sought, right from the start of this group with the first meeting to take place in Q1.

The transition of GH EDCTP3 from being run under responsibility of the European Commission to the achieving autonomy in Q3/2023 as well as the permanent Executive Director taking up her or his duties (Q3 or Q4) will be other important events to be communicated in 2023. It is expected that the financial autonomy of GH EDCTP3 JU and taking up duties of the Executive Director will occur close to the Eleventh EDCTP Forum. Synergies in communicating about the different events will be sought.

As relevant and appropriate, GH ETDCTP3 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 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.

A temporary website has been launched on the DG Research & Innovation web presence[8]. Work is ongoing for launching a permanent website for GH EDCTP3 and which will be running by end of Q1.

Building on the EDCTP logo, in collaboration between the EDCTP Association and the European Commission, a logo was designed and adopted for GH EDCTP3. In Q1 2023, the GH EDCTP3 corporate design will be finalised and adopted.

[8] https://ec.europa.eu/info/research-and-innovation/research-area/health-research-and-innovation/edctp_en

4.3.3 Procurement and contracts

Once the relevant paper for the back-office arrangements is accepted by Commission services, arrangements amongst the JUs established under Horizon Europe will be implemented to carry out procurements in a coordinated/synergistic manner and possibly centralising the majority if not all the procurements and contracting.

Under this approach, it is also planned to use the public procurement management tool (PPMT) that has been developed by DG Joint Research Centre and that is being rolled out.

Apart from the procurements related to IT equipment (*see IT section*), no major procurement activities are planned. The procurements that will be carried out will be largely in connection with some meetings and events (such as caterings for lunch/dinner, travels, etc.).

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) is also being negotiated to be signed as soon as possible.

During 2023, the GH EDCTP3 JU will seek to sign a similar SLA with DG DIGIT of the European Commission for the provision of IT support services and the participation of the JU in the ICT framework contracts. Further, an SLA with the Secretariat General for the provision of HAN services[9] is planned to be concluded during Q2.

A request for the use by the GH EDCTP3 of the European Commission accounting system ABAC has been granted. This system will be replaced by the new system SUMMA in Q4/2023 or Q1/2024. Due to the resources being dedicated to this major shift, DG BUDG has not yet agreed to offer treasury services. With support from the parent DG, the GH EDCTP3 tries to convince DG BUDG services that offering treasury services would be highly desirable.

The work leading up to autonomy in Q3 involves testing of using the ABAC system by the GH EDCTP3 and the necessary steps are planned in close cooperation with DG BUDG.

Additional synergies are being sought especially with the Innovative Health Initiative Joint Undertaking (IHI). A concrete example of this synergy is the agreement between GH EDCTP3 and IHI to rent offices in the White Atrium Building in Brussels, previously used by IHI. Office equipment and some of the existing IT infrastructure was procured for GH EDCTP3 through an SLA with IHI.

Contracts with external contractors (ideally existing framework contracts) will be used for event organisation, catering and supporting travel of participants.

4.3.4 Information Technology

As GH EDCTP3 is being built up, Information Technology (IT) equipment such as laptops, screens, docking stations will need to be procured.

[9] HERMES, ARES and NomCom– document management and archiving applications used by the European Commission

From IT infrastructure perspective a secured Wi-Fi network for the internal use of the JU will be put in place, as well as a secured IT-connection to the European Commission (so called S-Testa line - a pre-requirement to access the accounting and any other internal EC IT systems).

In line with the corporate collaboration and knowledge sharing principle, the Global Health EDCTP3 will foster the use of corporate IT platforms (i.e., M365, HAN system, Sharepoint, Sysper, etc).

GH EDCTP3 intends to align with the corporate requirements in terms of cybersecurity and data protection and in this sense, it will actively participate in the common JUs IT Group activities of 2023.Contracts will also be concluded for website hosting.

4.3.5 Other support operations

As already mentioned above, the GH EDCTP3 will use existing arrangements amongst the JUs established under Horizon Europe, such as in the areas of IT, HR etc. This will be phased in, in preparation of autonomy planned for Q3/2023.

During the period of implementation of GH EDCTP3 under responsibility of the Commission, other support operations such as internal control, record management, data protection, or access to documents are assured by the established processes at the European Commission and in particular in DG Research & Innovation.

In preparation for financial autonomy, all required functions inside GH EDCTP3 are being established.

4.3.6 Human resources

4.3.6.1 HR Management

The initial operation of GH EDCTP3 is assured by European Commission staff in the Combatting Diseases Unit of the People Directorate of DG Research & Innovation (RTD.D.1). This includes the interim Executive Director appointed by the Commission on 22 December 2021.

The key task in 2023 is to recruit the GH EDCTP3 staff based on the posts available in the staff establishment plan. A total of 30 posts (22 Temporary Agents and 8 Contractual Agents) is available for 2023.

The process for the recruitment of the Executive Director was kicked off in 2022 and the deadline for applications was 18 July. The selection procedure is ongoing and the outcome will be a short list of candidates approved by the European Commission. The Governing Board can then select the permanent Executive Director out of the short list. The selection needs to happen by the end of Q2 or early in Q3 to ensure that the GH EDCTP3 can go for autonomy in Q3 as planned. In case this timetable for recruiting the Executive Director cannot be met, autonomy will have to be postponed.

The recruitment of the staff of GH EDCTP3 started in 2022. It was delayed, with the first staff member arriving only on 16 October and two more staff members joining on 1 November. Thus, the work of the GH EDCTP3 was limited during 2022 due to the lack of human resources. The key activities had to be and were assured by European Commission staff, notably colleagues from unit RTD.D.1. Other services in the Research and Innovation department as well as other departments (such as DG Human Resources and Security) of the European Commission also supported the activities in various forms.

Eight different vacancy notices were published in 2022 and information was widely disseminated. One vacancy notice was launched in cooperation with the Clean Hydrogen Joint Undertaking. Large numbers of candidatures were received for all vacancies. Out of the established reserve lists, candidates were recruited (often more than 1 from one selection procedure) and staff are now progressively joining the GH EDCTP3 in the coming weeks and months. Selection procedures for three vacancies are ongoing and reserve lists should be finalised in Q1. Further vacancies are expected to be published during the year. Timing for some recruitment procedures will be arranged so that the future permanent Executive Director can hold the final interviews, for example for the position of his or her personal assistant.

To the strictly limited extent, recourse is taken to recruitments of interim staff from outside agencies. The framework contract of the European Commission is currently being used (before autonomy). One assistant is currently employed based on such a temporary posting and is expected to stay in place until autonomy of the GH EDCTP3 is achieved. It is planned to fill programme assistant positions until this point. In case this type of interim postings are required after autonomy, a framework contract in place for the JUs established under Horizon Europe will be used.

A key position still to be filled is that for the Human Resources Officer for which the vacancy notice has been launched before the end of 2022 and is expected to be finalised in Q1/2023. One of the first tasks for the newly recruited human resources manager will be to initiate the process for setting up the staff committee. A scheme to support staff in using public transport was put in place. Activities to ensure wellbeing of staff and non-discrimination will be implemented.

Staff have access to the training catalogue of the European institutions. The training needs will be appraised to see whether additional dedicated training should be offered. Apart from trainings on using relevant tools (such as the grant management IT-applications or the budget management applications), a focus will be put on trainings in the area of ethics and conflicts of interest. With the change from the ABAC accounting system to the SUMMA accounting system, relevant trainings will have to be followed by the staff concerned.

GH EDCTP3 will continue to carefully monitor the implementing rules to the Staff Regulations that are being adopted by the European Commission to check which ones to apply by analogy (either through decision of the Governing Board or automatically after 9 months), which ones to adapt for the needs of GH EDCTP3 (in consultation with the Human Resources and Security Department of the European Commission) and which ones not to apply.

The information available through the network of follow-up of legal decisions relevant to HR is being checked.

4.3.6.2 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 are being put in place through SLAs with the different lead JUs.

Throughout the setting up of GH EDCTP3, 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 IHI. 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 GH EDCTP3 were in its own offices elsewhere.

This synergy as regards infrastructure continues to be sought in the ongoing selection of office space for the JUs established in Brussels post-2024 (the current rental contract runs out in 2025). This search for office space post-2024 includes the option to remain in the current location.

Synergies on the side of the implementation of the programme will be identified in 2023. This requires staff resources for the interactions with other JUs or other parts of the Horizon Europe programme, which become available only during the year 2023.

4.3.6.3 Staff establishment plan

Function group and grade	2022				2023		2024	
	Authorised budget		Actually filled as of 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	0	0	1	0	1
AD12	0	2	0	0	0	2	0	2
AD11	0	1	0	0	0	1	0	1
AD8	0	3	0	0	0	5	0	7
AD7	0	4	0	0	0	4	0	4
AD6	0	3	0	0	0	5	0	7
AD5	0	1	0	0	0	1	0	1
Total AD	0	15	0	0	0	19	0	23
AST5	0	0	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	2	0	0	0	3	0	3
Total AD+AST	0	17	0	0	0	22	0	26
Total staff (incl. CA)	0	23	0	3	0	30	0	34

Contract Agents	FTE corresponding to the authorised budget 2022	Executed FTE as of 31-12-2022	Headcount as of 31/12/2022	FTE corresponding to the authorised budget 2023	FTE corresponding to the authorised budget 2024
FGIV	3	0.29	1	4	4
FGIII	3	0.33	2	4	4
Total	6	0.62	3	8	8

4.4 Governance activities

Three meetings of the Governing Board are planned for the year. At a first meeting in Q1 the work programme 2023 should be adopted. The key decision item for the second meeting of the Governing Board planned for late Q2/early Q3 will be the interview of the short-listed candidates for the position of the Executive Director and the selection of the successful candidate. At a final meeting towards the end of Q4, the work programme 2024 should be approved. It is also planned to organise a workshop of

the Governing Board on the margins of the EDCTP Forum, which will take place 7 through 10 November 2023. Furthermore, decisions of the Governing Board can be taken by written procedure.

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. A two-day meeting of the Scientific Committee is planned for 30/31 May to kick off the process for developing the work programme 2024. Holding a second meeting of the Scientific Committee within the frame of the EDCTP Forum will be explored.

The Scientific Committee requested that working groups be established. Decisions of the Governing Board for establishing these working groups will be taken.

The Stakeholders Group is the last of the bodies of the GH EDCTP3 that still need to be established. Response to the call for expressions of interest for members of this committee was not fully satisfactory. In a first round, the Governing Board adopted a list 10 members and the constituting meeting of the Stakeholders Group will take place in Q1/2023. After this meeting a second round of Expressions of Interest for members of the Stakeholders Group will be launched.

The Stakeholders Group will be asked in particular to provide input on the EDCTP Forum.

An administrative agreement concerning the privileges and immunities and other support to be provided by the host country Belgium should be prepared with the Belgian authorities. Contact has been established and a draft agreement has been received. Lack of resources in 2022 did not allow this to be concluded last year. The agreement should be finalised in 2023.

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

Until autonomy planned for Q3/2023 GH EDCTP3 is covered by the organisational management and internal control system of the Research & Innovation department of the European Commission. The task this year will be to build up the relevant structures and systems, in preparation for autonomy planned for Q3/2023. Due to resource constraints, this work can only start once competent staff will have been recruited. The pre-requisites for autonomy are:

- Internal control framework;
- Financial Circuits;
- Description of the governance structure;
- An internal control standard action plan developed;
- Development of anti-fraud measures, acceding to the interinstitutional Agreement of 25 May 1999 between the EP, the Council and the EC concerning internal investigations by the European Anti-fraud Office (OLAF) (OJ L 136, 31.5.1999, p. 15) and adopting an internal decision following the model annexed to the agreement;
- Insurance.

In addition, the structure and processes for managing the grants with appropriate ex-ante and ex-post controls will have to be developed.

5. BUDGET

STATEMENT OF REVENUE				
Title Chapter	Financial year 2023			
	Estimated Commitment Appropriations	In %	Estimated Payment Appropriations	In %
EU contribution (excl. EFTA and third countries contribution)	**133,693,568**	**97.2%**	**54,441,083**	**97.2%**
of which (fresh C1) Administrative (Title 1&2)	5,523,568	4.0%	5,523,568	9.9%
of which Operational (Title 3)	128,170,000	93.2%	48,917,515	87.3%
EFTA and third countries contribution	**3,863,744**	**2.8%**	**1,573,347**	**2.8%**
of which Administrative EFTA (Title 1&2)	159,631	0.1%	159,631	0.3%
of which Operational EFTA (Title 3)	3,704,113	2.7%	1,413,716	2.5%
Financial Members other than the Union contribution[10]	**0**		**0**	
Of which Operational (Title 3)	0		0	
Financial Contributing partners contribution	**0**		**0**	
Interest generated	**0**		**0**	
Unused appropriations from previous years	**0**		**0**	
Of which administrative	0		0	
Of which operational	0		0	
TOTAL ESTIMATED REVENUE	**137,557,312**	**100%**	**56,014,430**	**100%**

[10] According to Article 102 of the Council Regulation 2021/2085, the European Union covers the entire administrative expenditure for GH EDCTP3

STATEMENT OF EXPENDITURE		
Title Chapter	Financial year 2023	
	Estimated Commitment Appropriations	Estimated Payment Appropriations
1 - Staff expenditure		
Salaries & allowances	3,202,522	3,202,522
- Of which establishment plan posts	2,818,220	2,818,220
- Of which external personnel	384,302	384,302
Expenditure relating to Staff recruitment	132,920	132,920
Mission expenses	71,723	71,723
Socio-medical infrastructure	33,230	33,230
Training	53,498	53,498
External Services	22,153	22,153
Receptions, events and representation	3,323	3,323
Social welfare	0	0
Other Staff related expenditure	0	0
Total Staff	**3,519,369**	**3,519,369**
2 - Infrastructure and operating expenditure		
Rental of buildings and associated costs	220,000	220,000
Information, communication technology and data processing	531,248	531,248
Office equipment (movable property and associated costs)	161,142	161,142
Current administrative expenditure	92,094	92,094
Postage / Telecommunications	40,314	40,314
Meeting expenses	407,485	407,485
Running costs in connection with operational activities	139,204	139,204
Information and publishing	199,144	199,144
Service contracts	350,000	350,000
Other infrastructure and operating expenditure	0	0

Total Infrastructure and operating	2,140,631	2,140,631
TOTAL ADMINISTRATIVE (1+2)	5,660,000	5,660,000
3 - Operational expenditure		
TOTAL OPERATIONAL (3)[11]	131,897,312	50,354,430
TOTAL ESTIMATED EXPENDITURE	137,557,312	56,014,430

6. ANNEXES

6.1 Calls for proposals 2023

The calls for proposals and topic descriptions are annexed as a separate document (Annex 1).

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

The IKAA plan is annexed as a separate document (Annex 2).

[11] Including transfer of EUR 23,199 from administrative expenditure for both commitment and payment appropriations

Global Health
EDCTP3

Work programme 2023 Global Health EDCTP3
Call topics

This is the second work programme under the Global Health EDCTP3 Joint Undertaking (GH EDCTP3). The topics are based on the Strategic Research and Innovation Agenda adopted by the Governing Board.[1]

Under this work programme, two calls for proposals are launched:

- ***HORIZON-JU-GH-EDCTP3-2023-01*** covering four topics for Research and Innovation Actions (RIA) and one topic for Coordination and Support Actions (CSAs).
- ***HORIZON-JU-GH-EDCTP3-2023-02-two-stage*** covering two topics for Research and Innovation Actions (RIA).

The work programme also foresees other actions, including a) expenditure related to experts carrying out evaluations or other tasks for the GH EDCTP3, and b) funding to be mobilised in case of a public health emergency.

With the 2023 work programme we extend the range of topics addressed under the GH EDCTP3 JU, building on the activities launched in 2022. The work programme this year puts particular emphasis on capacity building and training. A topic calling for training networks is included (GH-EDCTP3-2023-01-01). Also, for the other topics in the work programme, where relevant, support of 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 balance in mind.

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).

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

[1] https://commission.europa.eu/system/files/2022-01/ec_rtd_edctp3-sria-2022.pdf

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.[2]

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[3], the FAIR cookbook[4] and the guides for researchers on how to make your data FAIR.[5]

Budget

Call	Budget (EUR million)	Deadline
HORIZON-JU-GH-EDCTP3-2023-01	74.30	29 June 2023
HORIZON-JU-GH-EDCTP3-2023-02-two-stage	56.00	28 September 2023 (first stage)
Other actions	1.597312	
	131.897312	

General conditions related to this work programme

Unless specified otherwise, the sections of the General Annexes to the Horizon Europe work programme[6] apply *mutatis mutandis* to the GH EDCTP3 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 GH EDCTP3 funding as regards Entities eligible for funding and Consortium composition, the specific issue of legal entities from which countries can be the coordinator 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.

2 https://www.ema.europa.eu/en/news/use-clinical-trials-information-system-becomes-mandatory-new-clinical-trial-applications-eu

3 https://www.go-fair.org/fair-principles/

4 https://faircookbook.elixir-europe.org/content/home.html

5 https://www.openaire.eu/how-to-make-your-data-fair

6 https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/wp-call/2021-2022/wp-13-general-annexes_horizon-2021-2022_en.pdf

Award criteria	The criteria are described in General Annex D.
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.

Replacing relevant sections in General Annex B to the Horizon Europe work programmes on Eligibility

Entities eligible to participate

Given the illegal invasion of Ukraine by Russia and the involvement of Belarus, the currently context does not allow the implementation of the actions foreseen in this programme with legal entities established in Russia, Belarus, or in non-government-controlled territories of Ukraine. Therefore, such legal entities are not eligible to participate in any capacity. This criterion also applies in cases where the action involves financial support given by grant beneficiaries to third parties established in Russia, Belarus or in non-government-controlled territories of Ukraine (in accordance with Article 204 of the Financial Regulation No 2018/1046).

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[7]; Albania, Armenia, Bosnia and Herzegovina, Faroe Islands, Georgia, Iceland, Israel, Kosovo[8], Moldova, Montenegro, North Macedonia, Norway, Serbia, Tunisia, Turkey, Ukraine. Considering the Union's interest to retain, in principle, relations with the countries associated to Horizon 2020, most third countries associated to Horizon 2020 are expected to be associated to Horizon Europe with an intention to secure uninterrupted continuity between Horizon 2020 and Horizon Europe. In addition, other third countries can also become associated to Horizon Europe during the programme. For the purposes of the eligibility conditions, applicants established in Horizon 2020 Associated Countries or in other third countries negotiating association to Horizon Europe will be treated as entities established in an Associated Country, if the Horizon Europe association agreement with the third country concerned applies at the time of signature of the grant

[7] 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

[8] 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.

agreement[9];

- The following low- and middle-income countries which are constituent states of the EDCTP Association[10]: Burkina Faso, Cameroon, Congo, Côte d'Ivoire, Democratic Republic of the Congo, Ethiopia, Gabon, The Gambia, Ghana, Guinea, Kenya, Liberia, Malawi, Mali, Mozambique, Niger, Nigeria, Rwanda, Senegal, South Africa, Tanzania, Uganda, Zambia, Zimbabwe.

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

Consortium composition

Unless otherwise provided for in the specific call conditions, for all actions, due to the policy objectives of the GH 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 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.

Specific cases:

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

Specific rules on which legal entities can be the coordinator of an indirect action

According to article 110 of the Council Regulation 2021/2085 establishing the Joint Undertakings under Horizon Europe[11], 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

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9 Association of New Zealand is expected to take effect during 2023.

10 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.

11 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*

the indirect action shall 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.[12]

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 GH EDCTP3 regarding all scientific action governance issues, steer and provide oversight in the development of the scientific actions, acting as the key contact point for the GH EDCTP3 JU for these matters including external communication, other than the ones entrusted directly to the coordinator as per the Model Grant Agreement;
- Support and collaborate with the coordinator on its monitoring activities and the adoption of appropriate internal measures, to ensure that beneficiaries are fulfilling their obligations regarding budget, timeline, deliverables, and scientific quality;
- Review the action's deliverables and reports before their submission by the coordinator;
- Lead the work packages(s) related to the tasks of scientific project leadership.

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

Replacing relevant section in General Annex D to the Horizon Europe work programmes
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.

General Annex G to the Horizon Europe work programmes

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

Annex 1 of the Global Health EDCTP3 work programme 2023: call topics

According to the Horizon Europe rules, and to protect Union interests, the right for the GH EDCTP3 to object to transfers of ownership of results or to grants of an exclusive licence regarding results should apply to participants. Therefore, the provisions set out in General Annex G to the Horizon Europe work programmes on the right to object apply generally. It should be noted that in accordance with the Council Regulation 2021/2085 establishing the Joint Undertakings under Horizon Europe[13] and the Model Grant Agreement, the right to object applies also to participants that have not received funding from the JU and for the periods set therein.

Expected impacts of the calls under the 2023 work programme of the Global Health EDCTP3 JU

Activities funded under the 2023 calls for proposals should contribute to:

- Achieve SDG3 'Ensure healthy lives and promote well-being for all at all ages' in sub-Saharan African countries;
- Enable the implementation of the short- and medium-term actions foreseen by the AU-EU Innovation Agenda[14] (expected to be adopted in June 2023) in the area of Public Health;
- Provide evidence for informed health policies and guidelines within public health systems in sub-Saharan Africa and at international level;
- Strengthen clinical research capability in sub-Saharan Africa to rapidly respond to emerging epidemics;
- Enable a regulatory environment that can ensure effective development, delivery, and uptake of new or improved safe health technologies guaranteeing that trials in sub-Saharan African countries meet international standards;
- Increase cost effectiveness of public investment through collaboration of funders of clinical trials in the area of infectious diseases in sub-Saharan Africa;
- Strengthen health systems to ensure uptake of effective health technologies and innovations;
- 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.

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13 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

14 Working document of the AU-EU Innovation Agenda available online at: https://research-and-innovation.ec.europa.eu/system/files/2022-02/final_au-eu_ia_14_february.pdf

HORIZON-JU-GH-EDCTP3-2023-01

Conditions for this call

Indicative budget(s)

Topics under Call HORIZON-JU-GH-EDCTP3-2023-01	Type of Action	Indicative GH EDCTP3 Budget (EUR million)	Expected GH EDCTP3 contribution per project (EUR million)	Number of projects expected to be funded
Opening: 10 May 2023 Deadline: 29 June 2023				
GH-EDCTP3-2023-01-01	RIA	15.30	5.00	3
GH-EDCTP3-2023-01-02	RIA	14.00	0.20 to 2.50	12
GH-EDCTP3-2023-01-03	RIA	26.00	4.00	6
GH-EDCTP3-2023-01-04	RIA	11.00	3.00	4
GH-EDCTP3-2023-01-05	CSA	8.00	1.00	8
Overall indicative budget		74.30		

The general conditions relating to this call are those applicable to the 2023 work programme of Global Health EDCTP3 outlined above.

Proposals are invited against the following topics:

HORIZON-JU-GH-EDCTP3-2023-01-01: Global Health EDCTP3 Training Networks - Clinical Research Fellowships

Specific conditions	
Expected EU contribution per project	GH EDCTP3 estimates that an EU contribution of around EUR 5.00 million would allow these outcomes 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 15.30 million.
Type of Action	Research and Innovation Actions
Legal and financial set-up of the Grant Agreements - Costs for providing financial support to third parties allowed	Beneficiaries may provide financial support to third parties. The support to third parties can only be provided in the form of grants. The maximum amount to be granted to each third party is EUR 300 000. This is justified since the main objective of these projects is to provide fellowship support. The relevant options of the Model Grant Agreement will apply.
Other requirements	For all projects under this topic, 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 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.

The Global Health EDCTP3 Training Networks aim to train and develop skilled, innovative, and resilient African researchers, scientists, clinicians, and other public health professionals working in the area of infectious disease research. The main objective is that these professionals can face current and future clinical research challenges, efficiently carry out clinical trials, mentor young scientists, implement research results, apply knowledge into development of products and services and/or analyse data to inform policy and practice for better health for all in sub-Saharan Africa (SSA). Through the training being offered to the fellows, important research questions within the framework of the Strategic Research and Innovation Agenda of Global Health EDCTP3[15] will be addressed.

The Global Health EDCTP3 Training Networks will strengthen the clinical research capacity and attractiveness of clinical research in SSA countries. They will equip health research professionals with the right combination of research-related competences and capabilities to enhance their career perspectives.

Expected Outcome:

Project results are expected to contribute to the following outcomes:

- Provide answers to research questions in the area of infectious disease clinical research of relevance for SSA and especially in the countries most severely affected by infectious diseases;
- Contribute to generate plausible solutions to improve uptake of innovations and new medical products;
- Increase the number of skilled infectious disease personnel working in SSA;
- Promote the career development and retention of skilled personnel in SSA;
- Strengthen the SSA countries' clinical human capital base in Research and Innovation (R&I);
- Enhance talent retention and knowledge circulation and uptake across the SSA R&I landscape;
- Improve the attractiveness of infectious disease clinical research careers in SSA;
- Contribute to the generation of a critical mass of clinicians and institutional clinical research capacity in SSA;
- Enhance clinical research capacity in poverty-related diseases, especially in the countries with the highest infectious disease burden;
- Enhance the application of One Health approaches across SSA;
- Strengthen the ability of SSA countries to prepare for and to manage epidemic disease outbreaks;
- Encourage cooperation between researchers and clinicians in SSA with Africa CDC[16], African Union Development Agency New Partnership for Africa's Development AUDA-NEPAD[17], World

[15] https://commission.europa.eu/system/files/2022-01/ec_rtd_edctp3-sria-2022.pdf

[16] African Union Africa CDC Centres for Disease Control and Prevention https://africacdc.org/

[17] https://www.nepad.org/

Health Organization African Region (WHO-Afro)[18], African Vaccine Regulatory Forum AVAREF[19] and other organisations relevant for R&I;

- Establish sustainable and mutually beneficial collaboration between clinical research organisations within SSA and Europe;
- Foster a culture of collaboration with Global Health EDCTP3 like-minded funders working in SSA;
- Foster a culture of open science, innovation, and entrepreneurship in SSA;
- Improve equity in research between the genders and across anglophone, francophone and lusophone sub-Saharan Africa.

Scope:

The Global Health EDCTP3 Training Networks will implement training programmes through consortia of clinical research institutions, academia, industry, businesses (including SMEs) and other socio-economic actors from different countries across SSA and Europe, with the objective to strengthen the health research systems of the SSA countries with the highest disease burden. Proposals should include training programmes for researchers, scientists, clinicians and/or other public health professionals in the area of infectious disease research, with practical field research experience. The individuals being trained will carry out ambitious and relevant clinical research projects on infectious diseases affecting SSA.

Global Health EDCTP3 Training Networks proposals should be submitted by a consortium of institutions which must provide training through research programmes to early- to mid-career researchers based in SSA. The fellows must commit to be in Africa for a minimum of two years after completing their training and provide evidence to demonstrate this through a letter of support from their host institution(s).

Proposals should include 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, national public health institutes or similar agencies, research councils, or other relevant institutions or government ministries. Proposals may also include industry, businesses (including SMEs) and other socio-economic actors.

These consortia should respond to well-identified needs on infectious disease research and innovation in SSA and describe the transfer of knowledge towards the countries with higher disease burden[20], ensuring that the benefit of the training goes to less-experienced institutions/countries. South-South collaboration is strongly encouraged, although North-South collaboration is not excluded. Where appropriate, the training programmes should expose the fellows to collaboration with national departments of health as well as with international and regional organisations[21].

The consortia should also offer transferable skills and competences relevant for innovation and fellows' long-term employability, including financial administration, communication, commercialisation of results, entrepreneurship, intellectual property rights, etc.

The maximum duration of a training programme of a Global Health EDCTP3 Training Network should be 54 months.

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18 https://www.afro.who.int/

19 https://www.afro.who.int/health-topics/immunization/avaref

20 https://www.who.int/data/gho/data/countries

21 International and regional organisations mentioned above

The training programme should include two levels of fellows to be trained by experienced researchers, where the higher level provides training and mentorship for the lower one:

- **Early-Stage Career Fellowships** to support researchers and other members of clinical research teams from SSA to acquire specific skills in clinical research through placements in pharmaceutical companies, contract research organisations (CROs), clinical or academic affiliated research organisations and/or product development partnerships (PDPs). This category covers both hands-on-training apprenticeship and Master and PhD training arrangements where the candidates can spend part of their training and supervision at a more established or complementary institution with skill sets, expertise and or competences not available at the fellows' host African institution(s).

  Target individuals should meet all the following criteria:

  1. Citizens or residents from a SSA country with a higher infectious disease burden than the country of the host organisation;
  2. Exceptionally, be citizens from non-SSA country willing to relocate to a SSA country with higher infectious disease burden;
  3. Preference to citizens or residents from a SSA low-income countries with lower clinical research capacity[22];
  4. Be either postgraduate MD, MSc, or PhD candidate, in an area relevant to infectious diseases or clinical staff with experience in infectious diseases employed for the last 12 months in an organisation with a registered legal entity in SSA;

  Duration of a single fellowship: between a minimum of 6 and a maximum of 36 months with the possibility of secondments up to a third of the single fellowship duration.

  Expected minimum number of Early-Stage Career fellowships per proposal: 4, expected maximum number of Early-Stage Career fellowships per proposal: 10.

- **Mid-Career Fellowships** to support researchers and key members of clinical research teams from SSA in their mid-career to develop their clinical research skills. The objective is to promote career development and retention of post-doctoral clinical researchers in SSA, to equip the fellows with the ability to establish themselves as independent researchers and with the skills to initiate and manage their own research at host organisations in the SSA countries with the highest disease burden.

  Target individuals should meet all the following criteria:

  1. Be citizens or residents from a SSA country with higher infectious disease burden;
  2. Exceptionally, be citizens from non-SSA country willing to relocate to a SSA country with higher infectious disease burden;
  3. Preference to citizens or residents from a SSA low-income country with lower clinical research capacity[20];
  4. MD/PhD related to infectious diseases or clinical research or a medical graduate with at least five years' relevant research experience;
  5. At least one publication in an international peer-reviewed journal.

  Duration of a single fellowship: between a minimum of 6 and a maximum of 24 months and can have secondments up to a third of the fellowship duration.

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[22] See Figure 4 – Scatter plot - severity/urgency of need vs relative research capacity – low-income countries at https://tdr.who.int/docs/librariesprovider10/essence/essence-mechanism-consultant-report-2020.pdf

Expected minimum number of Mid-Career fellowships per proposal: 2, expected maximum number of Mid-Career fellowships per proposal: 5.

The two training levels must be well integrated and designed to provide the required training support for the fellows. Training programmes should develop different training modules, including digital ones, addressing key transferable skills and competences common to all fields of clinical research, including research management and financial aspects, research collaboration and information-sharing, made possible by (digital) technologies (e.g. collaborative tools, opening access to publications and to other research outputs including data, FAIR data management, societal engagement and citizen science, etc.), and fostering the culture of Open Science, innovation and entrepreneurship as well as good scientific conduct such as research integrity.

Training programmes should have regular selection rounds following fixed deadlines or regular cut-off dates, allowing fair competition between candidates. The selection procedure for candidates must be open, transparent, and merit-based, in line with the Code of Conduct for the Recruitment of Researchers[23]. The vacancy notices should be widely advertised in SSA countries and include the gross salary to be offered to the fellows (not including employer's social contributions). The selection of the fellows should address gender and language/regional equity barriers.

Proposals must demonstrate the following:

- A high-quality training programme related to clinical research or implementation research on infectious diseases of importance in SSA, including One Health;
- 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, with an active open promotion of the vacancies specifically addressed to female candidates, as well as to candidates from French speaking and Portuguese speaking countries to ensure that candidates from these groups can be well represented;
- Robust mentorship mechanisms to support the fellows through their training period up to completion;
- A robust monitoring and evaluation mechanism used to assess the career progression of the fellows, the impact of the training programme in the region and compile lessons learnt that can be used to inform future training programmes;
- The training programme must be conducted in SSA, in collaboration with relevant local or regional organisations such as National Public Health Institutes (and/or similar agencies), Ministries of Health, Research Councils and other relevant institutions;
- Whenever relevant, training programmes should expose fellows to collaboration with regional and international organisations, e.g., Africa CDC, AUDA-NEPAD, WHO-Afro, AVAREF and/or other organisations relevant for R&I;
- Training programmes should be designed with different training modules addressing also key transferable skills and competences concerning clinical research management including communication, ethical, regulatory, administrative, and financial aspects;
- Training programmes should include individual fellows training packages so that the fellows can deliver on their individual expected results;

[23] https://euraxess.ec.europa.eu/jobs/charter

- Proposals should also include support for meetings and conferences for the trainees to participate in the annual networking meetings, conferences and forums organised by relevant African organisations such as Africa CDC, EDCTP, WHO-Afro, AUDA-NEPAD, and other relevant events;
- Linkages with other EDCTP actions should be foreseen (e.g., EDCTP Networks of Excellence[24] or Alumni Network[25]).
- Capacity to provide adequate training on skills and competences relevant for innovation, e.g., entrepreneurship, commercialisation of results, intellectual property rights, etc.

To strengthen the clinical research capacity in the SSA regions with the highest disease burden, expert evaluators will be asked to take the possibility/likelihood of the transfer of knowledge particularly into account when evaluating the 'impact' criterion of the proposal.

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

Contributions for recruited researchers and institutions per person-month

Monthly contributions are based on the Marie Skłodowska Curie schemes (MSCA) contributions. To the living allowance a country correction coefficient[26] for the recruited researcher will be applied to ensure equal treatment and purchasing power parity for all fellows. The mobility allowance will cover additional, private mobility-related costs (e.g., travel and accommodation costs), but not travel for professional or research purposes. A family allowance will contribute to mobility-related costs of researchers with family obligations which can be granted during the project.

Early-Stage Career (taken from the MCSA Work Programme 2023-2024 Doctoral Fellowships)

MSCA Doctoral Networks	Contributions for recruited researchers per person-month					Institutional unit contributions per person-month	
	Living allowance	Mobility allowance	Family allowance (if applicable)	Long-term leave allowance (if applicable)	Special needs allowance (if applicable)	Research, training, and networking contribution	Management and indirect contribution
	EUR 3 400	EUR 600	EUR 660	EUR 4 000 x % covered by the beneficiary	Requested unit x (1/number of months)	EUR 1 600	EUR 1 200

Mid-Term Development Career (taken from the MSCA Work Programme 2023-2024 Postdoctoral Fellowships)

[24] http://www.edctp.org/networks-excellence/

[25] http://www.edctp.org/our-work/fellowship-programme/edctp-alumni-network/

[26] https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/wp-call/2023-2024/wp-2-msca-actions_horizon-2023-2024_en.pdf

MSCA Postdoctoral Fellowships	Contributions for the recruited researcher per person-month					Institutional unit contributions per person-month	
	Living allowance	Mobility allowance	Family allowance (if applicable)	Long-term leave allowance (if applicable)	Special needs allowance (if applicable)	Research, training, and networking contribution	Management and indirect contribution
	EUR 5 080	EUR 600	EUR 660	EUR 5680 x % covered by the beneficiary	Requested unit x (1/number of months)	EUR 1 000	EUR 650

HORIZON-JU-GH-EDCTP3-2023-01-02: Funding to successfully finalise EDCTP2-funded clinical trials that were negatively impacted by the COVID-19 pandemic

Specific conditions	
Expected EU contribution per project	GH EDCTP3 estimates that an EU contribution of between EUR 0.25 and 2.5 million would allow these outcomes 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 14 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[27], grants awarded under this topic will have to submit the following deliverables: 1. Stewardship plan Beneficiaries 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, beneficiaries 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.

[27] 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 conditions	Only proposals addressing the clinical trials, listed by their registration number in a clinical trial registry in the topic description below, can be selected for funding.
Other requirements	For all projects under this topic, 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 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:

Project results are expected to contribute to the following outcomes:

- Clinical trials of medical technologies that were funded by EDCTP2 and whose activities were disrupted during the COVID-19 pandemic, can be concluded;
- Information about medical technologies can be used by health care professionals and health care systems.

Scope:

The following clinical trials – identified by their clinical trial registration numbers - are addressed by this topic:

ISRCTN[28] 61526229 PACTR[29]202010540737215	Assessing the safety and tolerability of artemether-lumefantrine+atovaquone-proguanil tri-therapy for malaria treatment in adults and adolescents in Gabon
ISRCTN 14750348 PACTR 202201797112873	A multicentre phase III trial to evaluate the safety, tolerability, and efficacy of a combination of three antimalaria drugs (artemether-lumefantrine+atovaquone-proguanil) versus two malaria drugs (artemether-lumefantrine) +placebo in African children aged 6-59months with an uncomplicated malaria infection
PACTR 202011812241529	Efficacy and safety of pyronaridine-artesunate (Pyramax) for the treatment of falciparum malaria in African pregnant women
NCT[30] 03876262 PACTR 202004639229710	Safety and Efficacy of Annual or Biannual Doses of Moxidectin or Ivermectin for Onchocerciasis
NCT 04311671 PACTR 202003567524647	Safety of a Single Dose of Moxidectin Compared With Ivermectin in Individuals Living in Onchocerciasis Endemic Areas
NL7294 (NTR7503) https://trialsearch.who.int/Trial2.aspx?TrialID=NTR7503	Integrated skin screening and SDR-PEP administration for leprosy prevention: comparing the effectiveness and feasibility of a community-based intervention to a health centre-based intervention in Ethiopia, Mozambique, and Tanzania (PEP4LEP)
PACTR 202011804563392	A cluster-randomised controlled Phase IV trial (cRCT) assessing the impact of a Vi-Polysaccharide conjugate vaccine in preventing typhoid infection in Asante Akim, Ghana (TyVEGHA)
NCT 05119426	Effectiveness of a Typhoid Conjugate Vaccine in DRC (TyVECO)
NCT 05047315	Evaluating a New Stool Based qPCR for Diagnosis of Tuberculosis in Children and People Living With HIV (Stool4TB)

[28] https://www.isrctn.com/

[29] Pan-African clinical trials registry https://pactr.samrc.ac.za/

[30] US National Library of Medicine clinical trial registry https://clinicaltrials.gov/

NCT 05048472	East Africa Point of Care Viral Load Study (EAPoC-VL)
NCT 05175794	Triage Test for All Oral DR-TB Regimen (TRiAD Study)
NCT 05317247	Cough Audio Classification as a TB Triage Test (CAGE-TB)
NCT 04145258	Intensified Tuberculosis Treatment to Reduce the Mortality of Patients With Tuberculous Meningitis (INTENSE-TBM)
NCT 04600167	Preventive Treatment Of Latent Tuberculosis Infection In People With Diabetes Mellitus (PROTID)
ISRCTN 77382043	Metformin treatment for diabetes prevention in Africa
NCT 04653948	Maternal, Neonatal and Infant Outcomes at Kawempe National Referral Hospital (PREPARE)
NCT 04732026	Serocorrelate of protection against GBS
NCT 04596878	Study of a Group B Streptococcus Vaccine in Pregnant Women Living With HIV and in Pregnant Women Who do Not Have HIV
PACTR202208844472053	Increasing the uptake of intermittent preventive treatment using sulfadoxine-pyrimethamine through seasonal malaria chemoprevention channel delivery
NCT05441410	Comparing Safety and Protective Efficacy of Vaccine Candidate PfSPZ-CVac and MVA ME-TRAP/ ChAd63 ME-TRAP in Adults (SPICY)
NCT04601714	Baseline Cohort Malaria Morbidity Study (BLOOMy)
PACTR201909810587438	Safety and efficacy of Dolutegravir and EFV400 for pregnant and breastfeeding women: a randomized non-inferiority clinical trial

This funding will ensure that essential clinical trials working to deliver answers of immediate public health relevance in SSA can be concluded. Focussing funding to projects previously supported under the EDCTP2 programme is justified by the advanced stage ongoing studies have reached. It is also justified by ethical issues, such as fully validating the willingness of trial participants to take part in the clinical investigations.

The proposals need to address all of the following:

- Demonstrate the work performed so far, such as number of recruited trial participants, follow-up status as well as analyses to be performed;

- Explain the impact of COVID-19-related delays and disruption in relation to the trial timing (start, recruitment, follow-up period);
- Clearly explain the additional work to be carried out, with a comprehensive plan and budget to conclude the planned studies in a tight timeframe;
- Proposals should present a sound assessment of the feasibility of the planned clinical investigations. Realistic plans for recruiting and following up trial subjects must be presented and corroborated by demonstrated success from previous studies and/or the current study;
- Whilst it is acknowledged that the projects build on previous studies, the proposals should briefly recall the justification of the choice of populations to be enrolled into the trials and explain how they relate to the larger population;
- It should also be explained how the full range of relevant determining characteristics (sex, gender, age, socio-economic status, etc.) is considered.

HORIZON-JU-GH-EDCTP3-2023- 01-03: Implementation research/real life assessment of existing interventions in women and children's health

Specific conditions	
Expected EU contribution per project	GH EDCTP3 estimates that an EU contribution of around EUR 4.00 million would allow these outcomes 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 26 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[31], grants awarded under this topic will have to submit the following deliverables: 1. Stewardship plan Beneficiaries 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, beneficiaries 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.

[31] 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 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 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. Proposals under this topic should aim for delivering results that are contributing to the following expected outcomes:

- Better understanding of the role of poverty-related diseases (PRDs), diarrhoeal diseases, bacterial infections (especially those where antimicrobial resistance is an issue), sepsis and lower respiratory tract infections in maternal, neonatal and child mortality and morbidity, as

well as the barriers for the uptake of health interventions against these diseases in sub-Saharan Africa (SSA).

- Evaluation of the real-life impact of existing interventions in women and children's health.
- Uptake of research findings on medical interventions (such as diagnostics, drugs, vaccines, and microbicides) of proven efficacy into clinical practice and routine care so that women and children in SSA can have access to safe health technologies for the management of PRDs.
- Widespread adoption of research findings into national, regional and/or international policy guidelines.
- Improved maternal, neonatal and child health in SSA.

Background & Scope:

According to the 2022 report of the World Health Organization, more than half of the world's maternal deaths occur in SSA, where the rate stands at 525 deaths per 100 000 live births and 27 neonatal deaths per 1000 live births[32]. Current trends show that by 2030 the region will still record 390 maternal deaths per 100 000 live births and 54 neonatal deaths per 1000 live births, very far from the targets set by the Sustainable Development Goals (SDGs). The factors contributing to maternal and child deaths are numerous.

In countries in SSA, infectious diseases remain the leading causes of morbidity and mortality, especially during pregnancy and childhood. Because of limited evidence on the contribution of these diseases to maternal and neonatal mortality, the importance of PRDs for maternal, foetal, and neonatal deaths is often poorly recognised. Despite the progress made in other age groups, effective treatment and prevention of PRDs and other diseases such as diarrhoeal diseases, bacterial infections (especially those where antimicrobial resistance is an issue), sepsis and lower respiratory tract infections in mothers, newborns and children is often lacking and/or lagging. The frequent exclusion of pregnant women and children from clinical trials and the limited number of available products targeting these groups, are factors that contribute to the lowest health indicators in these vulnerable populations. In addition, there is a need for critical appraisal of existing health interventions, which may have been introduced and used by healthcare systems without rigorous evaluation in clinical trials. It is thus important to understand whether such interventions lead to better overall health in these populations.

Moreover, failure to translate research findings into policy and practice prevents research from achieving maximum public health benefits. Despite substantial investment in clinical research in infectious diseases, including PRDs, exploitation, and use of results beyond research groups to date remains limited. Barriers to an efficient uptake of research findings include limited interaction between researchers, policymakers, patients' community and other stakeholders, lack of experience in exploiting research results beyond academia, limited health systems capacity, affordability issues, and differences between the research, programme planning and policymaking structures and actors.

Concerted efforts are needed to increase access to potentially lifesaving, cost-effective interventions to prevent and treat PRDs and other diseases such as diarrhoeal diseases, bacterial infections (especially those where antimicrobial resistance is an issue), sepsis and lower respiratory tract infections in pregnant women, newborns, and children to ensure solid evidence is produced for the recommended interventions and to enhance the use of existing interventions in these populations.

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[32] Africa's advances in maternal, infant mortality face setbacks: WHO report | WHO | Regional Office for Africa

Proposals should address the following activities:

- Carry out registration (phase III) and/or post-registration studies of health technologies that tackle infectious diseases affecting women and children to demonstrate clinical effectiveness;
- Demonstrate the cost-effectiveness of the health technologies being investigated in the relevant populations and communities;
- Identify the barriers to the uptake of the health technologies under investigation and address them in the proposed studies;
- Develop methods that can ensure translating clinical research results into healthcare policy and practice in a SSA setting. These methods should be broadly applicable to improve patients' quality of life beyond the specific health technology being investigated;
- Early involvement and regular interaction with policy- and decision-makers, including end-users, to ensure adoption of the health technology by health systems in SSA.

This call is restricted to the following diseases: HIV, malaria, tuberculosis, diarrhoeal diseases, bacterial infections (especially those where antimicrobial resistance is an issue), sepsis and lower respiratory tract infections.

The research carried out and the health technologies developed in the study should tackle infections affecting the health of pregnant women and children up to five years of age.

Neither pre-clinical research nor early-stage clinical trials in the context of product development are within the scope of this call.

Applicants need to concisely describe any proven research evidence of previous findings and explain how the proposal builds on these results. Building on results from projects supported under previous EDCTP programmes is encouraged.

Proposals should present a sound assessment of the feasibility of the proposed work, in particular as regards 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.

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

Proposals are expected to come from research consortia with a strong representation of institutions and researchers from African countries, including involvement of franco/lusophone countries where possible and relevant.

HORIZON-JU-GH-EDCTP3-2023- 01-04: Research to rapidly evaluate interventions on Ebola outbreaks in sub-Saharan Africa

Specific conditions	
Expected EU contribution per project	GH EDCTP3 estimates that an EU contribution of around 3.00 million would allow these outcomes 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 this topic is EUR 11.00 million
Type of Action	Research and Innovation Action
Legal and financial set-up of the Grant Agreements - Standard deliverables	Implementing the provision on affordable access as defined in Article 114 of the Council Regulation 2021/2085 establishing the Joint Undertakings under Horizon Europe33, grants awarded under this topic will have to submit the following deliverables: 1. Stewardship plan Beneficiaries 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, beneficiaries 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 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

[33] 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

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

- An increased portfolio of therapeutics and diagnostic tools are available to researchers to move along the clinical development phases to combat Ebola disease;
- An improved surveillance system to rapidly detect novel Ebola virus outbreaks in Africa;
- A better understanding of the social dynamics within communities affected by Ebola virus outbreaks and a better awareness from these communities when it comes to the implementation of public health measures such as social restrictions and/or medical interventions;

Scope:

Proposals submitted under this call topic are expected to advance knowledge on Ebola virus disease with the aim of contributing to an efficient patient management and public health response, as well as better epidemic preparedness in Africa. Special focus should be on improving our understanding of the Sudan virus disease, in view of the recent outbreak in East Africa and the lack of available interventions for this viral strain. There are currently no licensed vaccines or therapeutics for the prevention and treatment of Sudan virus disease[34].

Ebola is a severe disease, with high mortality risk, first identified in 1976 when two simultaneous outbreaks occurred in South Sudan and the Democratic Republic of the Congo. Ebola viruses are primarily transmitted to humans through close contact with blood, secretions, organs, or other bodily

[34] https://www.who.int/emergencies/disease-outbreak-news/item/2022-DON410

fluids of infected humans or animals, and contaminated surfaces and materials. Infected people generally present with fever, fatigue, muscle pain, headache, and sore throat, followed by vomiting, diarrhoea, rash, and/or symptoms of impaired kidney and liver function. The average Ebola case fatality rate is estimated around 50% with rates varying from 25% to 90% in past outbreaks. Ebola outbreaks have most commonly been caused by the Zaire and Sudan Ebola virus.

The scope of the proposals submitted under this call topic should include one or more of the following areas:

- Clinical development of therapeutics. This can include early phase testing of candidates for safety, validation of standardised animal models that adequately recapitulate the clinical hallmarks of human infection and illness to enable acceleration of regulatory pathways for vaccines and therapeutics, or platform trial designs or networks that can be pivoted to outbreaks where they occur. Best practices for the use and deployment of intervention tools, including storage and transport should be considered.
- Clinical development of point-of-care (POC) diagnostics, ensuring rapid evaluation of POC tools based on existing technologies to allow for fast case detection and better surveillance. It should be possible that the developed diagnostic tools can easily be taken up by health care systems and health care centres, also in rural settings.
- Social sciences research to improve risk communication activities, provide responses to social dynamics of Ebola virus outbreaks and increase acceptance of the public health response and medical countermeasures.

Promotion of close communication between clinical experts, patient communities, regulators, health care workers and policy makers is expected to increase the uptake of a developed intervention and improve outbreak response.

Interaction with relevant national public health institutes and regulatory authorities, African Medicines Agency, Africa Centres for Disease Control and Prevention, World Health Organization - Regional Office for Africa and/or other regional and international relevant organisations are expected to adequately address research needs.

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). Collaboration and coordination with existing outbreak response initiatives and ongoing Ebola research actions are highly encouraged to facilitate knowledge exchange, collaboration, synergies, and coordination of response activities. Community engagement should be supported.

Sex and gender aspects should be taken into account. All data should be disaggregated by sex, age, and other relevant variables, such as by measures of socioeconomic status (i.e., considering the socioeconomic gradient).

HORIZON-JU-GH-EDCTP3-2023-01-05: Strengthening ethics and regulatory capacity

Specific conditions	
Expected EU contribution per project	GH EDCTP3 estimates that an EU contribution of around EUR 1.00 million would allow these outcomes 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 8.00 million.
Type of Action	Coordination and Support Actions
Other requirements	For all projects under this topic, 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 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:

Projects funded under this Call for Proposals should contribute to the following outcomes:

- Stronger functionality, recognition, and performance of National Ethics Committees (NECs) and National Regulatory Agencies (NRAs) working in sub-Saharan Africa (SSA);
- Clinical trials authorised in these areas meet the appropriate standards;
- Improved efficiency regarding the process of clinical trial protocol authorisation for the development of new or improved health technologies;
- Improved efficiency of the NRAs concerning clinical trials oversight with alignment to continental initiatives of African Medicine Agency (AMA) and African Medicines Regulatory Harmonisation (AMRH);
- Better equipped health research systems to integrate new or improved health technologies;
- Sustainable health research strategies for both NECs and NRAs;
- Adoption of standardised training of both ethics committees and regulatory boards available in SSA through EDCTP partners;
- Generation of principles towards harmonised oversight for certification of clinical trial ethics and regulatory bodies in SSA countries;
- Creation of sustainable links and collaboration between NECs and NRAs and other important structures, such as clinical trial registries, research integrity offices and data access committees;
- Establishment of systematic reviews and data sharing in compliance with global requirements;
- Implementation of digital technologies to facilitate ethical and/or regulatory review processes.

Scope:

The aim of this call is to improve the functionality, recognition and performance of NECs and NRAs for carrying out clinical trials in SSA countries.

Despite ongoing efforts by different partners and agencies, ethics, and regulatory oversight in SSA countries requires prioritisation and ownership by these countries to ensure sustained strengthening with a long-term perspective. There is a need to better understand the challenges that these countries are facing. They include the varied levels of clinical trial activity, with no health research legislation in some of them; as well as the need of better quality control, certification and accreditation of ethics and regulatory bodies, adherence to common international standards and open data access. Coherent linkages between ethics and regulatory functions are needed, as well as linkages with clinical trial registration and more systematic research reviews. Furthermore, better systems and technologies, including more external expertise and digitalisation for processing research application review and handling of documentation and data, are required.

Several initiatives have already established capacity development tools and structures that add value to the capacity development efforts of ethics and regulatory agencies in SSA[35] and should be taken into consideration.

The projects funded under this call will support the SSA countries to establish and/or develop own robust capacities for ethics review and national medicines regulatory systems. This also includes support towards national and international collaboration in compliance with established international standards. This scheme targets proposals with active involvement of NECs and/or NRAs from SSA countries, and in particular with those countries with the highest infectious disease burden.

Proposals should address several of the following activities:

- Improvement of the efficiency of the functioning of NECs and NRAs through the introduction of innovative systems, reliance practices and/or technologies that would facilitate the various functions of these bodies with better quality outputs and improved timelines;
- Development of national health research legislation;
- Promotion of quality control systems and processes for NECs and NRAs, as well as certification and accreditation of the various bodies, as well as adherence to international standards;
- Promotion of international cooperation in ethics and regulatory activities through transfer of promising and successful innovative systems and/or technologies from other regions in Africa or other continents, fostering national and regional collaboration among these bodies;
- Creation of linkages between ethics and regulatory functions with other important structures, such as clinical trial registries, whilst simultaneously enforcing the sharing of data in compliance with global requirements;
- Promotion of the adoption and update of AVAREF, WHO and other international standards and best practices, by countries, groups of countries, or regional harmonisation initiatives;
- Support already established training centres to provide both innovative training, and mentorship to NECs and NRAs.
- Development or scale-up of innovative systems and technologies that support ethics and regulatory functions, training, networking and promotion of good practices and evidence-based adop-

[35] WHO AFRO, through AVAREF, has established a training course for ethics committees in both English and French. AUDA-NEPAD has established Regional Centres of Regulatory Excellence (RCOREs) designated with regulatory science expertise and training capabilities. Moreover, WHO has also developed standards for ranking maturity of regulatory boards as a measure to indicate advancement in capacity of these agencies.

tion of accreditation models from relevant internationally endorsed/peer-reviewed documented sources.

Proposals should clearly indicate the mismatch between the country disease burden, research activity and level of ethical review and regulatory oversight that justify the need for support in these areas.

Linkages of the proposal to relevant on-going initiatives and regional bodies is encouraged and should be demonstrated.[36] Plans to foster bi-lateral links between the European Medicines Agency (EMA) and the national ethics and regulatory authorities in the SSA countries of the participants are encouraged.

Each proposal should have at least two new technical staff members recruited to the NEC/NRA team to be trained and integrated in the new functions proposed in the action. The new staff members should have a well-defined function and objectives in the participating NEC and NRA with a systems approach. The new staff members should stay in the team for at least two years and participate in relevant networking and international events.

Particular attention should also be paid in the proposal for ensuring complementarity and coherence with other activities supported by the European Union and EU Member States in the countries involved. This concerns for example the EDCTP Regional Networks of Excellence[37] and the Team Europe initiative on Manufacturing and Access to Vaccines, Medicines, and Health Technologies (MAV+) in Africa[38] or other health Team Europe initiatives[39] of the Global Gateway investment package.

To strengthen the clinical research capacity in the SSA regions with the highest disease burden, the quality of the transfer of knowledge should be taken particularly into account when evaluating the criterion 'impact'.

Proposals should provide details on the steps to be taken to ensure gender balance and contribute to have representation from French speaking and Portuguese speaking SSA countries in the project team.

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36 These initiatives include: the African Medicines Agency (AMA), the Africa Vaccines Regulators Forum (AVAREF), the Regional Centres of Regulatory Excellence (RCORE) in Africa, the WHO-TDR-SIDCER initiative (Strategic Initiative for Developing Capacity in Ethical Review), the Pan African Clinical Trials Registry (PACTR), the African Medicines Regulatory Harmonisation (AMRH) and the Africa Centre for Disease Control and Prevention (ACDC) and WHO-AFRO.

37 EDCTP regional networks of excellence strengthen regional networking and provide platforms for research training and multicentre studies http://www.edctp.org/our-work/edctp-regional-networks-of-excellence/

38 The Team Europe initiative (TEI) on Manufacturing and Access to Vaccines, Medicines and Health Technologies (MAV+) https://ec.europa.eu/commission/presscorner/detail/en/ip_21_2594 directly funds the European Medicines Agency (EMA), African Medicine Agency AUDA-NEPAD (AMA) and the World Health Organization (WHO).

39 Team Europe Initiative with Africa on sustainable health security using a One Health approach https://europa.eu/capacity4dev/tei-jp-tracker/tei/sustainable%C2%A0health-security-africa

HORIZON-JU-GH-EDCTP3-2023-02-two-stage

Conditions for this call

Indicative budget(s)

Topics under Call HORIZON-JU-GH-EDCTP3-2023-02-two-stage	Type of Action	Indicative GH EDCTP3 Budget (EUR million)	Expected GH EDCTP3 contribution per project (EUR million)	Number of projects expected to be funded
Opening: 27 June 2023 Deadline stage 1: 28 September 2023				
GH-EDCTP3-2023-02-01-two-stage	RIA	30.00	5.00	6
GH-EDCTP3-2023-02-02-two-stage	RIA	26.00	5.00	5

HORIZON-JU-GH-EDCTP3-2023-02-01-two-stage: Improving modes of delivery, deployment, and uptake of vaccines through phase IV/implementation research

Specific conditions	
Expected EU contribution per project	GH EDCTP3 estimates that an EU contribution of around EUR 5 million would allow these outcomes 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 the Joint Undertakings under Horizon Europe[40], grants awarded under this topic will have to submit the following deliverables: 1. Stewardship plan Beneficiaries 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, beneficiaries must submit an appropriate and proportionate global access plan that covers registration targets, plans

[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

	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 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 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 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 all the following expected outcomes:

- Public health authorities and health care professionals in sub-Saharan Africa (SSA) have access to novel logistical and clinical solutions for vaccine delivery and have a better understanding of the behavioural barriers driving vaccine hesitancy, resulting in improved rates of vaccine deployment and uptake, particularly in poor and vulnerable communities.
- People in SSA have improved access, coverage, and trust in vaccines against all preventable infectious diseases within the scope of the Global Health EDCTP3[41]. Better tools as well as data on immunisation levels and the individual and public health benefit of immunization will drive vaccination even in hard-to-reach regions, thus helping to contribute towards the WHO Immunization Agenda 2030[42].
- Health professionals and especially clinicians as well as policy makers have access to comprehensive phase IV/implementation research results, making use of them to ensure widespread translation and adoption of research findings into national and international policy guidelines for better delivery, deployment, and uptake of vaccines in clinical practice in SSA.

Scope:

Despite offering strong protection against infectious diseases, global vaccination rates have been declining for a few years resulting in the re-emergence of preventable infectious diseases that were thought to be on the verge of elimination. This trend further worsened during the COVID-19 pandemic because of severe interruptions in public health services, restrictions of non-urgent medical care and diversion of limited health care resources, resulting in cancellation or delays of routine vaccinations. Underserved communities in SSA have been most affected, leaving them less protected against vaccine-preventable diseases. Under immunised individuals and zero-dose-children (not having received any vaccine) are also found in other communities. Furthermore, there has been a significant erosion of trust in governments and public health institutions that coordinate and conduct such immunisation efforts. Novel logistical and clinical solutions for vaccine delivery and a better understanding of the behavioural barriers driving vaccine hesitancy in SSA as well as better data to document beneficial vaccine effects on individual and public health are therefore of critical importance. Furthermore, there remain open questions on the use of vaccines, also in view of changing environments.

Accordingly, the proposed research is expected to deliver on the following:

- Carry out phase IV/implementation research studies on the deployment and uptake of registered vaccines[43] in SSA, examining operational aspects, access, coverage, vaccine acceptability/hesitancy, community engagement, real-life impact on overall health and cost-effectiveness;
- Develop and test novel logistical solutions for vaccination;
- As relevant, develop and test novel clinical solutions for vaccine delivery, including new delivery modes;

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41 Strategic Research and Innovation Agenda of the Global Health EDCTP3 Joint Undertaking: ec_rtd_edctp3-sria-2022.pdf (europa.eu)

42 Immunization Agenda 2030: A Global Strategy To Leave No One Behind (who.int)

43 It is recognized that the vaccines may not have a marketing authorization in the country or all the countries where the study is being carried out. Registered vaccines need to meet WHO-recommended standards of quality, safety and immunogenicity: Health products policy and standards (who.int)

- Gain a better understanding of different health care systems in sub-Saharan Africa as regards the factors driving structural inequalities in vaccine deliveries;
- Identify the social, economic, political, religious, cultural, and personal factors driving vaccine hesitancy in SSA and develop targeted solutions, as appropriate. Vaccine hesitancy should be considered in the context of the specificities of different types of vaccines and their perceived risks and benefits. It is further essential to investigate the factors that are undermining coverage in different countries, regions, or communities both in terms of vaccine types and doses received. In many cases, this means targeted collaborations with local leaders who can effectively address their communities' concerns and with caregivers who bring children to vaccination services. Applicants are also encouraged to develop evidence-based tools that can guide people towards informed vaccination decisions, delivering tailored information based on each user's concerns;

Applicants need to concisely describe any prior research findings and explain how the proposal builds on these results. Building on relevant results from projects supported under previous EDCTP programmes is encouraged.

The implementation research to be conducted must involve vulnerable groups, including participants from poorer, underserved, or hard-to-reach communities in SSA. 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. They are welcome to draw on any relevant lessons from the COVID-19 vaccination strategies.

Proposals are expected to come from research consortia with a strong representation of institutions and researchers from African countries, including involvement of franco/lusophone countries where possible and 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 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. Therefore, proposals are expected to include a budget for the attendance to regular joint meetings and may consider covering the costs of any other potential joint activities without the prerequisite to detail concrete joint activities at this stage. The details of these joint activities will be defined during the grant agreement preparation phase. In this regard, the Global Health EDCTP3 Joint Undertaking may take on the role of facilitator for networking and exchanges, including with relevant stakeholders, if appropriate.

HORIZON-JU-GH-EDCTP3-2023-02-02-two-stage: Advancing point-of-care diagnostics to the market

Specific conditions	
Expected EU contribution per project	GH EDCTP3 estimates that an EU contribution of 5.00 million would allow these outcomes 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 26 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[44], grants awarded under this topic will have to submit the following deliverables: 1. Stewardship plan Beneficiaries 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, beneficiaries 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 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

[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

	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 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 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:

Proposal under this topic should aim to deliver results that are directed, tailored towards, and contributing to all of the following expected outcomes:

- Health care providers and professionals have access to novel or improved point-of-care diagnostic (POC) devices that are suited to rapidly detect infectious diseases of relevance in sub-Saharan Africa (SSA) and within the scope of the Global Health EDCTP3 Scientific Research and Innovation Agenda.
- A diverse and robust pipeline of in vitro diagnostics is available, increasing options for clinical deployment, also in case of an infectious diseases outbreak with epidemic or pandemic potential, that can reach the most vulnerable populations.
- Health authorities and health care systems have access to health data and evidence to better develop and implement informed health policies and improved clinical surveillance of infectious diseases in SSA.

Scope:

POC diagnostic tests that are easy to use, affordable and can rapidly diagnose diseases will lead to more timely treatment and thereby reduce mortality, morbidity, and transmission of diseases. POC diagnostic tests should improve the quality of healthcare for resource-poor communities in developing countries, where the burden of disease is the highest. A diagnostics gap for many diseases affecting SSA still exists and needs to be closed urgently to contribute the global and national disease elimination targets.

Hence, proposals submitted under this topic should implement clinical studies that lead to market authorisation of the relevant POC diagnostic test. The POC diagnostic test device should be aimed at detection of diseases that currently lack POC diagnosis tests or where POC diagnostics are inadequate. Tests that can in the same specimen simultaneously and rapidly detect and thereby distinguish a wide range of diseases for improved clinical decision-making are encouraged (e.g., distinction between bacterial versus viral pathogens). The POC diagnostic tools are expected to be affordable and suitable for use in SSA countries. POC diagnostics for all diseases in scope of the current Global Health EDCTP3 programme[45], for example antimicrobial resistance and emerging diseases, are included in this call (exception is Ebola Virus disease, covered under topic HORIZON-JU-GH-EDCTP3-2023-01-04).

Proposals should address **all** of the following areas:

- Clinical performance studies in several sites across SSA of POC diagnostics that are of high technology readiness level to achieve regulatory approval and market launch (i.e., CE mark); post-market surveillance studies are excluded from this call and are covered by other initiatives such as the African Health Diagnostics Platform[46];
- Studies need to provide evidence-based practice for the POC diagnostic test especially in terms of the ability to decide on treatment options after diagnosis and improving disease outcome; the possibility of the POC diagnostic to be deployed in the field, its usability by primary care and community health care workers in resource-limited patient communities should be especially considered;
- Inclusion of a clear regulatory path to market to ensure future compliance with the legal requirements; early engagement with regulatory authorities is expected;
- Product development plans for translation from prototype to industrial design, to implementation and sustainability of the innovation should be provided, also including a plan for the process of "sample to result to the use of result & treatment option" and how to report data & results (e.g., via mobile health/portable technology);
- Where available and relevant, World Health Organization target product profiles for diagnostics need to be addressed;[47]
- Involvement of industry, notably of small and medium-sized enterprises (SMEs), especially African SMEs, is expected. Involvement of African SMEs is highly encouraged to contribute to developing the African industry and access to health products.[48]

Proposals submitted under this topic are encouraged to consider innovative diagnostics sampling methods or samples bringing a significant improvement, such as less invasive sampling methods and self-testing at home. The POC diagnostic should allow for easy storage, such as at room temperature. Consideration of environmental friendliness of diagnostic tests would be advantageous. Transmission and

[45] https://ec.europa.eu/info/sites/default/files/research_and_innovation/research_by_area/documents/ec_rtd_edctp3-sria-2022.pdf

[46] AHDP - AFRICAN HEALTH DIAGNOSTICS PLATFORM (eib.org)

[47] The list of target product profiles that have been developed by the World Health Organization can be accessed at: https://www.who.int/observatories/global-observatory-on-health-research-and-development/analyses-and-syntheses/target-product-profile/links-to-who-tpps-and-ppcs; please note that this list includes target product profiles for different types of healthcare interventions.

[48] The Team Europe initiative (TEI) on Manufacturing and Access to Vaccines, Medicines, and Health Technologies (MAV+) https://europa.eu/capacity4dev/tei-jp-tracker/tei/manufacturing-and-access-vaccines-medicines-and-health-technology-products-africa

economic modelling to examine the impact of the POC diagnostic assay on performance of long-term health outcomes and cost-effectiveness could be envisioned. Relevant partnerships with local and international organisation to create solutions for improved deployment of diagnostics for vulnerable populations in low-resource settings could be sought.

In addition, where relevant, the link between the diagnostic devices to relevant infectious disease surveillance strategies to inform public health authorities and advise public health policies should be made. This can include monitoring the impact of relevant POCs on the use of antibiotics.

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. Populations for POC diagnostic test development and evaluation of the POC diagnostic test performance and appropriateness should also include vulnerable populations, including children, pregnant women, people with co-infections and co-morbidities, older people, and people living in hard-to-reach communities. Rapid feedback from end-users through community engagement on the performance and acceptance of the technologies and their most effective use in endemic settings is expected.

Applicants need to concisely describe any prior research findings and explain how the proposal builds on these results. Building on relevant results from projects supported under previous EDCTP programmes is encouraged.

Proposals are expected to come from research consortia with a strong representation of institutions and researchers from African countries, including involvement of franco/lusophone countries where possible and relevant.

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. Therefore, proposals are expected to include a budget for the attendance to regular joint meetings and may consider covering the costs of any other potential joint activities without the prerequisite to detail concrete joint activities at this stage. The details of these joint activities will be defined during the grant agreement preparation phase. In this regard, the Global Health EDCTP3 Joint Undertaking may take on the role of facilitator for networking and exchanges, including with relevant stakeholders, if appropriate.

Other actions not subject to calls for proposals

1. External expertise

This action will support the use of appointed independent experts for peer-review evaluation of submitted proposals, monitoring of actions, for ethics checks, and for the evaluation of large actions annual work plans as well as for advising on the programme. A special allowance of EUR 450/day will be paid to the expert appointed in his/her personal capacity who acts independently and in the public interest.

Form of Funding: Other budget implementation instruments

Type of Action: Expert contract action

Indicative timetable: 2023

Indicative budget: EUR 597,312 from the 2023 budget.

2. Mobilisation of research funds in case of Public Health Emergencies

Expected Outcome:

Proposals should set out a credible pathway to contributing to one or several expected impacts of this work programme.

Project results are expected to contribute to the following expected outcome:
Allow the Union and sub-Saharan African (SSA) countries to respond to Public Health Emergencies.
Work in this area should allow a faster research response to outbreaks of epidemic or pandemic infectious diseases. This will allow the EU and SSA member countries of the EDCTP Association to respond to public health emergencies.

In case of a public health emergency[49] (such as a public health emergency of international concern (PHEIC) according to the World Health Organization; a public health emergency under Regulation (EU) 2022/2371[50]; or a public health emergency under applicable national frameworks and regulations), funding will be mobilised for:

- The award of grants without a call for proposals according to Article 195 (b) of the EU Financial Regulation[51] in exceptional and duly substantiated emergencies. At that time, the Funding & Tenders Portal will open a dedicated section where proposals can be submitted. This will be widely communicated, including on the Global Health EDCTP3 website and to the National Contact Points. The invitation to apply for funding will be open to all eligible entities or be

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49 Should there be no Public Health Emergency in 2023, the indicative budget may be reallocated.

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

51 Article 195 (b) of the Financial Regulation 2018/1046 'Grants may be awarded without a call for proposals only in the following cases: [...] (b) in other exceptional and duly substantiated emergencies'.

limited to targeted entities, considering the need to achieve the underlying objectives in a quick and efficient manner considering the exceptional circumstances;

and/or

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

It is expected that quality-controlled data are shared in accordance with the FAIR[52] principles. The use of harmonised protocols in collaboration with other actors is recommended for this purpose. The standard eligibility and admissibility criteria, evaluation criteria, thresholds, weighting for award criteria, maximum funding rate and conditions for providing financial support to third parties, are provided in the introduction to this work programme and the General Annexes. The beneficiaries must comply with the public emergency-related provisions listed in the General Annexes concerning the project implementation under - Intellectual Property Rights (IPR), background and results, access rights and rights of use (article 16 and Annex 5) for the duration of the Public Health Emergency; and under Communication, dissemination, open science and visibility (article 17 and Annex 5) during the entire duration of the action and for four years after the end of the action. The following derogations to the evaluation procedure described in General Annexes D and F apply to open invitations to submit applications: In order to ensure a balanced portfolio covering responses to different aspects of the public health emergency, grants will be awarded to applications not only in order of ranking, but also to those projects that enhance the quality of the project portfolio through synergies between projects and avoidance of overlaps, provided that the applications attain all thresholds. The action may also include justified derogations from the standard limits to financial support to third parties. Where applicable, the relevant grant agreement options will be applied.

Form of Funding: Grants not subject to calls for proposals

Type of Action: Grant awarded without call for proposals according to Financial Regulation Article 195 (b)

The general conditions, including admissibility conditions, eligibility conditions, award criteria, evaluation and award procedure, legal and financial set-up for grants, financial and operational capacity and exclusion, and procedure are provided in the introduction to this work programme and in parts A to G of the General Annexes to the Horizon Europe work programmes 2023-2024.

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

Specific conditions	
Indicative timetable	Will depend on the Public Health Emergency
Indicative budget	EUR 1.00 million from the 2023 budget
Type of Action	Will depend on the Public Health Emergency
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[53], grants that implement clinical studies awarded under this topic will have to submit the following deliverables: 1. Stewardship plan Beneficiaries 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, beneficiaries 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 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

[53] 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

	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.