



**Global Health
EDCTP3**

GOVERNING BOARD OF THE GLOBAL HEALTH EDCTP3 JOINT UNDERTAKING

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Annual Work Programme 2023

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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 diseases¹, 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 Africa², the Global Approach to Research & Innovation³ and the new EU Global Health Strategy⁴, 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.

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 trematodiasis, human African trypanosomiasis (sleeping sickness), leishmaniases, leprosy (Hansen disease), lymphatic filariasis, mycetoma, onchocerciasis (river blindness), rabies, schistosomiasis, soil-transmitted helminthiasis, 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.

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 IKAA's 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 EDCTP3 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 presence⁸. 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 services⁹ 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 contribution¹⁰	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