



GOVERNING BOARD OF THE GLOBAL HEALTH EDCTP3 JOINT UNDERTAKING

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Annual Work Programme 2022

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2. LIST OF ACRONYMS, DEFINITIONS AND ABBREVIATIONS

CA	Contractual Agent
CSA	Coordination and Support Action
EDCTP	European and Developing Countries Clinical Trials Partnership
Gates Foundation	Bill & Melinda Gates Foundation
GH EDCTP3	Global Health EDCTP3 Joint Undertaking
HIV	human immunodeficiency virus/acquired immunodeficiency syndrome
IHI	Innovative Health Initiative Joint Undertaking
IKAA	In-contributions to additional activities
OJ	Official Journal of the European Union
OLAF	European Anti-Fraud Office
PGI	Pathogen Genomics Initiative
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
TA	Temporary Agent
TB	Tuberculosis
tGHN	the Global Health Network

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, including (re-)emerging diseases, particularly those affecting sub-Saharan Africa. 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, in particular Sustainable Development Goal 3, and the joint communication from the Commission entitled 'Towards a Comprehensive Strategy with Africa', 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 is a partnership between the EU and the EDCTP Association, whose members are several European and African countries.

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 sub-Saharan Africa. 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.

Sub-Saharan Africa 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 alarming rise of antimicrobial resistance is compromising available treatments and undermining multiple branches of medicine that rely on effective therapies for infection control. Changing patterns of disease, driven by the climate crisis and environmental degradation, exacerbate these challenges.

Combating infectious diseases is central to achieving Sustainable Development Goal 3 (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.

GH EDCTP3 is inscribed in the European Union comprehensive strategy with Africa. 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 sub-Saharan Africa countries. The GH EDCTP3 builds on and will extend the platforms created by EDCTP.

The GH EDCTP3 focuses on the major infectious disease threats facing sub-Saharan Africa, namely HIV, TB, malaria, lower respiratory tract infections, diarrhoeal diseases, neglected infectious diseases¹ and emerging and re-emerging infections, with special reference to antimicrobial resistance, and the impact of the climate crisis on infectious diseases.

The first GH EDCTP3 work programme 2022 addresses several key aspects of the Strategic Research and Innovation Agenda (SRIA – GB Dec. N° 04/2022).²

The focus and goals of GH EDCTP3 of bringing health technologies to patients and health systems is reflected in the 2022 topic on *Promoting implementation of research results into policy and practice*. The objective to strengthen capacity in sub-Saharan Africa for epidemic preparedness is addressed by the topic on *Implementing adaptive platform trials*. This topic also supports building capacity for more efficient testing of interventions in clinical trials.

Strategic engagement including collaboration with Contributing partners (e.g. foundations or industry) is a key aspect of GH EDCTP3, leveraging investments from different type of partners and bringing together the unique strengths of the partners. Through the 2022 work programme a first such collaboration is implemented with the Bill & Melinda Gates Foundation (Gates Foundation) for a joint programme on genomic epidemiology for surveillance and control of infectious diseases. This collaboration brings together investments from the Gates Foundation in pathogen genomic sequencing in Africa through their support of the Africa pathogen genomics initiative (PGI) and in global health research and innovation through the Global Health Network (tGHN) with funding from GH EDCTP3 for genomic epidemiology projects.

Within the GH EDCTP3, the research capacity building in sub-Saharan Africa is addressed specifically through Coordination and Support Actions. The 2022 topic on *Creating a sustainable clinical trial network for infectious diseases in sub-Saharan Africa* will ensure the coordination between clinical trial and laboratory networks in sub-Saharan Africa and effectively contribute to better preparedness and a rapid response in the case of an epidemic or pandemic. The 2022 topic on *Strengthening regulatory capacity for supporting conduct of clinical trials* will support and develop the technical expertise needed to reinforce regulatory systems in sub-Saharan Africa countries, essential for conducting clinical trials.

Support for an Africa office complements the investment under this first GH EDCTP3 work programme. The Africa office will contribute to implementing the GH EDCTP3 programme through informing sub-Saharan Africa countries about the funding opportunities and the application process, promoting exchanges between funded networks and fellows.

All projects planned for this work programme support South-South and South-North networking. Furthermore, it is expected that the GH EDCTP3 work programme take account of the upcoming AU-EU Innovation Agenda and particularly of proposed actions in the area of public health. Activities and achievements should be promoted under this Agenda accordingly, aiming to effectively translate the results into tangible outcomes, where possible.

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 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/info/sites/default/files/research_and_innovation/research_by_area/documents/ec_rtd_edctp3-sria-2022.pdf

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 2022.

The key focus for the year 2022 is to ensure that the call for proposals can be launched, the received applications evaluated and the budget available can be committed. The imperative to implement the budget led to the choice of opening all topics in the 2022 work programme as single-stage calls.

Beyond 2022, a strategy meeting will be organised periodically with the newly appointed Scientific Committee where the priorities to be addressed and the scope of the calls for 2023 and subsequent years will be discussed. The best use of single-stage and two-stage calls will also need to be discussed and considered for the design of future work programmes.

A mechanism will be developed to ensure involvement of the Scientific Committee in the discussions with prospective contributing partners.

A workshop is planned for Q2 or Q3/2022 to bring together a range of funders supporting fellowships in sub-Saharan Africa. Building on the significant investment in this area under EDCTP2, the goal of this workshop

will be to identify the niche for GH EDCTP3 to fund fellowships in sub-Saharan Africa for the coming years. Resource efficiency will have to be a key consideration.

A streamlined reporting for the contributions of the EDCTP Association, which is the GH EDCTP3 member other than the Union, is to be developed during 2022. This concerns the in-kind contributions to additional activities (IKAA) reporting and the management of financial contributions. The reporting of contributions from Contributing partners will also be developed.

The first grants under the programme will be awarded by the end of the year 2022/beginning of the year 2023. To achieve this, the scientific and ethical evaluations of the submitted proposals will have to be carried out, followed by grant agreement preparation and advance payments to the successful consortia. Good interaction with and among the supported grants from the start of the programme is essential to achieve the ambitious objectives of GH EDCTP3.

Communication activities will have to be developed and implemented to allow GH EDCTP3 to attract the broadest possible range of relevant applicants to its calls and involve partners at all levels to achieve its goals.

The new legal obligation to ensure affordable access is translated into contractual obligations for relevant grants. Introducing this new obligation for projects needs to be appropriately accompanied to bring concrete benefit for patients and health systems in sub-Saharan Africa and Europe.

The Stakeholders Group is to be constituted during the year. Productive interactions with the group need to be developed so it can provide relevant input on the scientific, strategic and technological priorities to be addressed by GH EDCTP3 and enable concrete synergies between GH EDCTP3 and adjacent sectors or any sector with which synergies will be considered of added value.

All activities developed and implemented should allow for a smooth transition from GH EDCTP3 being run under responsibility of the European Commission to the Joint Undertaking, which should achieve autonomy in Q2/2023.

4. WORK PROGRAMME 2022

4.1 Executive Summary

This is the first work programme under the GH EDCTP3 . The topics are based on the Strategic Research and Innovation Agenda adopted by the Governing Board.³

The work programme includes three topics for Research and Innovation Actions (RIA) and two topics for Coordination and Support Actions (CSA).

The first RIA topic, *GH-EDCTP3-2022-CALL1-01-01: Promoting implementation of research results into policy and practice*, will contribute to the objective of increasing the uptake of new or improved health technologies for tackling infectious diseases. It aims at supporting exploitation of research results into policy and practice by funding registration and/or post-registration studies of health technologies (such as pragmatic effectiveness studies) that address diseases within the scope of GH EDCTP3 to demonstrate the clinical effectiveness in relevant patient populations.

³ https://ec.europa.eu/info/sites/default/files/research_and_innovation/research_by_area/documents/ec_rtd_edctp3-sria-2022.pdf

The second RIA topic, *GH-EDCTP3-2022-01-02: Implementing adaptive platform trials*, aims to support a number of multi-country adaptive platform trials on novel treatments with the operational capability to rapidly adapt to evaluate treatment approaches of infectious diseases outbreaks with epidemic or pandemic potential, thereby tackling the GH EDCTP3 objective of strengthening the capacity in sub-Saharan Africa for epidemic preparedness.

The third RIA topic, *GH-EDCTP3-2022-CALL1-01-03: Genomic epidemiology for surveillance and control of poverty-related and emerging/re-emerging infections in sub-Saharan Africa*, is part of a topic developed in collaboration with the Gates Foundation. In this topic the Gates Foundation joins the GH EDCTP3 programme as a Contributing Partner to leverage the genomic sequencing capacity being built in Africa to support epidemiology and surveillance of endemic and epidemic pathogens.

The first CSA topic of this work programme, *GH-EDCTP3-2022-CALL1-01-04: Creating a sustainable clinical trial network for infectious diseases in sub-Saharan Africa*, will support an efficient coordination and collaboration mechanism between clinical trial and laboratory networks in sub-Saharan Africa, thus contributing to the GH EDCTP3 objective of strengthening capacity in sub-Saharan Africa for epidemic preparedness.

The second CSA topic, *GH-EDCTP3-2022-CALL1-01-05: Strengthening regulatory capacity for supporting conduct of clinical trials*, will support and develop the technical expertise needed to reinforce regulatory systems in sub-Saharan Africa countries, essential for conducting clinical trials, thus contributing to the GH EDCTP3 objective of strengthening research capacity and national health research systems in sub-Saharan Africa for tackling infectious diseases. The work programme also includes:

- a topic to support the EDCTP Africa Office with the objective to enhance the GH EDCTP3 activities and involvement in the African region and which will be awarded as an *action not subject to calls for proposals*;
- a topic for an agreement with identified beneficiaries, which will provide the matching contribution from the Gates Foundation to the *GH-EDCTP3-2022-CALL1-01-03* topic as part of the collaboration of this Contributing partner with GH EDCTP3;
- and the necessary budget for the experts evaluating proposals and carrying out other work for GH EDCTP3.

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 sub-Saharan Africa	# of calls launched; # projects funded; € invested in RIA
To strengthen research and innovation capacity and the national health research systems in sub-Saharan Africa 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 sub-Saharan Africa 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

Overall, there is a risk of delay in the implementation of the 2022 work programme and budget execution due to the set-up of the new partnership. There is also a risk of delayed autonomy due to the lengthy process for recruiting the permanent Executive Director or due to lack of qualified staff, in case the build-up of the Secretariat proceeds more slowly than anticipated.

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 sub-Saharan Africa. 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 (sub-Saharan Africa) and in the Union.

The GH EDCTP3 will work towards achieving scientific priorities related to implementation of clinical trials in order to develop health technologies to control and treat infectious diseases, as well as enhancing research

and innovation coordination, supporting the training of sub-Saharan Africa 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 sub-Saharan Africa, stronger research and innovation capacity in sub-Saharan Africa, 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 sub-Saharan Africa and an increased health security in sub-Saharan Africa and globally.

4.2.3 Calls for proposals

Described in Annex 1 to the 2022 work programme

4.3 Support to operations of the Global Health EDCTP3 Joint Undertaking

4.3.1 Communication, dissemination and exploitation

Communication activities in 2022 focus on the launch of the programme and call for proposals. As no grants are currently ongoing, no dissemination and exploitation activities for such grants are envisaged.

The launch of the programme will be communicated through a launch event that will take place on 10 May in Paris in hybrid format. Speakers and panel discussants will be present in person, in front of a small audience. A wider audience is invited to join through live web-streaming.

The launch of the call for Expressions of Interest for joining the GH EDCTP3 Scientific Committee was communicated in January and February 2022 and attracted a good list of candidates, out of which the high-calibre GH EDCTP3 Scientific Committee was constituted, following selection by the Governing Board.

The launch of the call for Expressions of Interest for joining the GH EDCTP3 Stakeholders Group was communicated in March and April 2022.

Once the Work Programme is published and the 2022 calls for proposals are made public, several communication activities will be planned to ensure that a broad range of relevant stakeholders learn about such calls. An info-day session to give further details on the calls for proposals will be held in May/June 2022.

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 sub-Saharan Africa and in Europe.

A temporary website has been launched on the DG Research & Innovation web presence⁴. Work is ongoing for launching a permanent website for GH EDCTP3.

⁴ https://ec.europa.eu/info/research-and-innovation/research-area/health-research-and-innovation/edctp_en

Building on the EDCTP logo, in collaboration between the EDCTP Association and the European Commission, a logo was designed and adopted for GH EDCTP3. During 2022, a corporate design will be developed for the new organisation with the help of external contractors.

4.3.2 Procurement and contracts

A number of contracts need to be prepared and signed during the first year of operation of GH EDCTP3 to build the Secretariat and prepare for GH EDCTP3 to achieve autonomy in Q2/2023.

A first set of such contracts concerns Service-Level Agreements (SLA) with departments of the European Commission, which provide corporate solutions for certain business processes. This concern, for example, applications and services related to human resources, budget and accounting services, IT and the use of the applications for the proposal submission and evaluation, as well as the grant management system of Horizon Europe.

SLAs will also be signed with other Joint Undertakings established under the same legal basis as GH EDCTP3. This will concern especially the back-office arrangements as foreseen under Article 13 of the 2021/2085 Council Regulation. To explore options for the back-office arrangements, through a SLA with the Europe's Rail Joint Undertaking, a contract with Deloitte consultants will be implemented.

Additional synergies will be 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 space in the White Atrium Building in Brussels, currently used by IHI. Office equipment and some of the existing IT infrastructure will be procured for GH EDCTP3 through a SLA with IHI. This arrangement is considered beneficial for GH EDCTP3 for a number of reasons:

- Excellent office space that is very well located and equipped;
- Space for 20 desks, which should be sufficient to serve the needs of GH EDCTP3 for some time, also in view of flexible working arrangements;
- It is resource efficient to do one Service-Level Agreement with IHI to rent space, procure desks, chairs, lamps, coffee kitchen including coffee machine etc. instead of having to run public procurements for all these items separately;
- Access to meeting rooms in a conference centre through a joint arrangement for all the Joint Undertakings located in the same office building;
- Joint security for the building, joint internet access including a secured IT-connection to the European Commission (so called S-Testa line), which is required for access to the accounting system of the European Commission;
- The co-location with several other Joint Undertakings will facilitate the implementation of the common back-office arrangements;
- The co-location with the Innovative Health Initiative Joint Undertaking will allow for synergies on issues of concern for both of these Joint Undertakings active in the area of health research funding (e.g. ethics review, expertise in following clinical trial projects);
- Co-location will also facilitate joint research programmes, for example in the area of healthcare IT or diagnostics.

One of the meeting rooms in the space to be rented, as well as one of the large meeting rooms in the joint conference centre, are already equipped for hybrid meetings. It will be assessed which additional video-conference equipment for online/hybrid meetings will be needed.

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

For the development of a corporate design, an external contractor will be sought. This contract should then also provide graphic design services for the ongoing communication activities of GH EDCTP3 in the coming years. Contracts will also be concluded for website hosting and design.

For organising events, contracts (ideally existing framework contracts) will be used for event organisation, catering and supporting travel of participants.

4.3.3 Other support operations

As already mentioned under the procurement and contracts section, the GH EDCTP3 being established will use existing arrangements amongst the legacy Joint Undertakings, such as in the areas of IT, HR etc. This will be phased in, in preparation of autonomy planned for Q2/2023.

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.

4.3.4 Human resources

4.3.4.1 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. This includes the interim Executive Director appointed by the Commission on 22 December 2021.

The key task in 2022 is to recruit the GH EDCTP3 staff based on the posts available in the staff establishment plan. A total of 23 posts (16 Temporary Agents and 6 Contractual Agents) is available for 2022.

The Governing Board has approved the text of the vacancy notice for the post of the Executive Director and this is currently being prepared for publication by the European Commission. The recruitment will follow the process for senior management recruitments at the European institutions. A short list of candidates – approved by the European Commission – will be presented to the Governing Board to select the Executive Director.

The recruitment of other staff will be done in collaboration with the Human Resources and Security department of the European Commission. All positions will be widely published. Where relevant it is foreseen to open the positions for nationals of countries in sub-Saharan Africa that are member of the EDCTP Association and have committed to the GH EDCTP3 programme.

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.

During the build-up of the organisation, the information available through the network of follow-up of legal decisions relevant to HR is being checked.

4.3.4.2 Strategy for achieving efficiency gains and synergies

As mentioned before, options for the back-office arrangements, as foreseen under Article 13 of the 2021/2085 Council Regulation are being explored, through a SLA with the Europe's Rail Joint Undertaking, a contract with Deloitte consultants will be implemented.

In the way GH EDCTP3 is being set up, the best possible efficiency of the organisation is being considered. Synergies within the organisation and with other Joint Undertakings, and – where relevant – with Commission services as well as outside partners are explored.

This concerns for example the co-location in the office space of the IHI JU. This is made possible by the new flexible working arrangements approved by the European Commission in March 2022 and which allow IHI to liberate office space that can be rented by GH EDCTP3. This then will lead to 'automatic synergies' for the use of office equipment, the basic IT service provision, and all elements of infrastructure, that would have to be organised, if GH EDCTP3 were located in its own offices elsewhere.

This synergy as regards infrastructure will continue to be sought when the set of JUs established in Brussels explore the office location post-2024 (the current rental contract runs out then). The search for office space post-2024 includes the option to remain in the current location.

GH EDCTP3 is fully involved in the discussions about jointly organising the provision of the Accounting Officer function, after the Budget department of the European Commission ceases to provide this service to the Joint Undertakings in December 2022.

For the year 2022 this is not yet relevant for GH EDCTP3, due to the direct management of the implementation of GH EDCTP by the European Commission, but the accounting officer function must be in place for the end of 2022, so that the planning for autonomy in Q2/2023 can proceed.

4.3.4.3 Staff establishment plan

Function group and grade	2021				2022		2023	
	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	0.3	0	0	0	1	0	1
AD12	0	0	0	0	0	2	0	2
AD11	0	0	0	0	0	1	0	1
AD8	0	0.3	0	0	0	3	0	5
AD7	0	1.3	0	0	0	4	0	4
AD6	0	0.3	0	0	0	3	0	5
AD5	0	0.3	0	0	0	1	0	1
Total AD	0	2.7	0	0	0	15	0	19
AST5	0	0	0	0	0	0	0	1
AST4	0	0.3	0	0	0	1	0	1
AST3	0	0	0	0	0	1	0	1
Total AST	0	0.3	0	0	0	2	0	3
Total AD+AST	0	3	0	0	0	17	0	22
Total staff (incl. CA)	0	3.3	0	0	0	23	0	30

Contract Agents	FTE corresponding to the authorised budget 2021	Executed FTE as of 31-12-2021	Headcount as of 31/12/2021	FTE corresponding to the authorised budget 2022	FTE corresponding to the authorised budget 2023
FGIV	0.3	0	0	3	4
FGIII	0	0	0	3	4
Total	0.3	0	0	6	8

4.4 Governance activities

The constitution of the Governing Board on 12 January 2022 with adoption of its Rules of Procedure and the GH EDCTP3 Strategic Research and Innovation Agenda formally established the organisation. Further important decisions and activities at the level of the Governing Board in 2022 include: the adoption of the vacancy notice for the Executive Director post; the adoption of this Work Programme 2022 at the meeting of the 3 May; and the adoption of the Work Programme 2023 at the meeting of November/December 2022.

The selection criteria and process for both the Scientific Committee and the Stakeholders Group were have already been adopted by the Governing Board. The Scientific Committee members were selected and the Scientific Advisory body for GH EDCTP3 was constituted with its first meeting on 18 March. At its first meeting the Scientific Committee gave input on the scientific priorities to be addressed and the scope of the calls for proposals and was consulted on the IKA plan. Thus, essential pre-requisites for adopting this work programme were fulfilled.

The necessary input from the Scientific Committee on priorities to be addressed and scope of calls for preparation of the work programme 2023 will be organised in June/July and the committee will again be consulted on the IKA plan, as soon as a draft will be available.

The call for Expressions of Interest for the Stakeholders Group is open until 20 April. Subsequently, selection of members will be carried out. Due to resource constraint it will only be possible to organise a meeting of this group later in the year.

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 and depending on available resources will be taken forward during the year.

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

For the year 2022, 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 Q2/2023. 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

The budget for the 2022 work programme draws on appropriations available for 2021 and 2022. With the approval of the legal basis for GH EDCTP3 on 19 November 2021 and entry into force with publication on 30 November 2021 as well as constitution of the Governing Board only on 12 January 2022, it was not possible to implement any of the 2021 budget during that year.

STATEMENT OF REVENUE												
Title Chapter	For Information: from 2021 Appropriations				For information: from 2022 Appropriations				Financial Year 2022			
	Estimated Commitment Appropriations	In %	Estimated Payment Appropriations	In %	Estimated Commitment Appropriations	In %	Estimated Payment Appropriations	In %	Estimated Commitment Appropriations	In %	Estimated Payment Appropriations	In %
EU contribution (excl. EFTA and third countries contribution)	33,336,000	100%	0		68,135,000	97.6%	3,735,000⁵	99.6%	101,471,000	98.4%	4,071,000⁶	98.7%
of which (fresh C1) Administrative (Title 1&2)	336,000	1%	0		2,135,000	3.1%	2,135,000 ⁷	56.4%	2,471,000	2.4%	2,471,000 ⁸	59.9%
of which Operational (Title 3)	33,000,000	99%			66,000,000	94.5%	1,600,000	42.2%	99,000,000	96.0%	1,600,000	38.8%
EFTA and third countries contribution	0	0%			1,682,935	2.4%	52,735	1.4%	1,682,935	1.6%	52,735	1.3%
of which Administrative EFTA(Title 1&2)	0	0%			52,735	0.1%	52,735	1.4%	52,735	0.1%	52,735	1.3%
of which Operational EFTA (Title 3)	0	0%			1,630,200	2.3%	0		1,630,200	1.6%	0	0%
Financial Members other than the Union contribution ⁹	0				0		0		0		0	

⁵ To be reinforced by 336,000 Euro, as concerns fresh C1 administrative payment appropriations

⁶ Currently available are 3,735,000 Euro, to be reinforced, as concerns fresh C1 administrative payment appropriations

⁷ To be reinforced by 336,000 Euro

⁸ Currently available are 2,135,000 Euro, to be reinforced

⁹ According to Article 102 of the 2021/2085 Council Regulation, the European Union covers the entire administrative expenditure for GH EDCTP3

Of which Operational (Title 3)												
Financial Contributing partners contribution												
Interest generated												
Unused appropriations from previous years												
Of which administrative												
Of which operational												
TOTAL ESTIMATED REVENUE	33,336,000	100%	0	69,817,935	100%	3,787,735¹⁰	100%	103,153,935	100%	4,123,735¹¹	100%	

¹⁰ To be reinforced by 336,000 Euro, as concerns fresh C1 administrative payment appropriations

¹¹ Currently available are 3,787,735 Euro, to be reinforced

STATEMENT OF EXPENDITURE FINANCIAL YEAR 2022						
Title Chapter	For information Budget coming from 2021 appropriations		For information Budget coming from 2022 appropriations		Financial year 2022	
	Estimated Commitment Appropriations	Estimated Payment Appropriations	Estimated Commitment Appropriations	Estimated Payment Appropriations	Total Estimated Commitment Appropriations	Total Estimated Payment Appropriations
2-Staff expenditure						
Salaries & allowances	208.624	208.624	1.309.054	1.309.054	1.517.678	1.517.678
- Of which establishment plan posts	199.274	199.274	1.132.806	1.132.806	1.332.080	1.332.080
- Of which external personnel	9.350	9.350	176.248	176.248	185.598	185.598
Expenditure relating to Staff recruitment		0	60.000	60.000	60.000	60.000
Mission expenses	12.376	12.376	20.000	20.000	32.376	32.376
Socio-medical infrastructure		0	15.000	15.000	15.000	15.000
Training		0	24.149	24.149	24.149	24.149
External Services		0	10.000	10.000	10.000	10.000
Receptions, events and representation		0	1.500	1.500	1.500	1.500
Social welfare					0	0
Other Staff related expenditure					0	0
Total Staff	221.000	221.000	1.439.703	1.439.703	1.660.703	1.660.703
2-Infrastructure and operating expenditure						
Rental of buildings and associated costs	26.210	26.210	70.000	70.000	96.210	96.210
Information, communication technology and data processing	43.508	43.508	170.000	170.000	213.508	213.508
Movable property and associated costs	202	202	70.000	70.000	70.202	70.202

Current administrative expenditure	5.121	5.121	35.000	35.000	40.121	40.121
Postage / Telecommunications	1.532	1.532	16.032	16.032	17.564	17.564
Meeting expenses	1.129	1.129	160.000	160.000	161.129	161.129
Running costs in connection with operational activities	5.645	5.645	55.000	55.000	60.645	60.645
Information and publishing	14.758	14.758	72.000	72.000	86.758	86.758
Studies	16.895	16.895	100.000	100.000	116.895	116.895
Other infrastructure and operating expenditure		0	0	0	0	0
Total Infrastructure and operating	115.000	115.000	748.032	748.032	863.032	863.032
TOTAL ADMINISTRATIVE (1+2)	336.000	336.000	2.187.735	2.187.735	2.523.735	2.523.735
3-Operational expenditure						
TOTAL OPERATIONAL (3)	33.000.000	0	67.630.200	1.600.000	100.630.200	1.600.000
ESTIMATED TOTAL EXPENDITURE	33.336.000	336.000	69.817.934	3.787.734	103.153.934	4.123.734

6. ANNEXES

6.1 Calls for proposals 2022

The calls for proposals and topic descriptions are annexed in 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).