

GOVERNING BOARD OF THE GLOBAL HEALTH EDCTP3 JOINT UNDERTAKING Decision N° GB 21/2022

Annual Work Programme 2022

Adopted on 3 May



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2. LIST OF ACRONYMS, DEFINITIONS AND ABBREVIATIONS

СА	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
ІНІ	Innovative Health Initiative Joint Undertaking
ΙΚΑΑ	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
ТА	Temporary Agent
ТВ	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 isand 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 trematodiases, human African trypanosomiasis (sleeping sickness), leishmaniases, leprosy (Hansen disease), lymphatic filariasis, mycetoma, onchocerciasis (river blindness), rabies, schistosomiasis, soil-transmitted helminthiases, taeniasis/cysticercosis, trachoma, and yaws. Global Health EDCTP's remit will not cover chromoblastomycosis and other deep mycoses, scabies and other ectoparasites, and snakebite envenoming

² https://ec.europa.eu/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 <u>https://ec.europa.eu/info/sites/default/files/research_and_innovation/research_by_area/documents/ec_rtd_edctp3-sria-2022.pdf</u>



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

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 Undertaking4.3.1 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 ETDCTP3 will contribute to exploiting results from the predecessor programme. This can occur by selecting follow-on grants that build on results from previous EDCTP programmes. It can also be achieved by working in collaboration with the EDCTP Secretariat for organising events, workshops and presenting at conferences and meetings. Synergies in exploitation and dissemination are particularly relevant in the reach-out to countries in 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 <u>https://ec.europa.eu/info/research-and-innovation/research-area/health-research-and-innovation/edctp_en</u>



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.



Function		20	21		20	22	2023		
group and	Authorise	ed budget		illed as of /12	Authorised budget		Authorised budget		
grade	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	0	3.3	0	0	0	23	0	30	
(incl. CA)									

4.3.4.3 Staff establishment plan

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 IKAA 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 IKAA 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													
	-	For Information: from 2021 Appropriations					For information: from 2022 Appropriations				Financial Year 2022			
Title Chapter	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%	4,071,000 ⁶	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%	3,787,735 ¹⁰	100%	103,153,935	100%	4,123,735 ¹¹	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



	S	TATEMENT OF EX	PENDITURE FINA	NCIAL YEAR 2022	1	
	For info Budget comi	rmation ng from 2021 riations	For info Budget comi	rmation ng from 2022 riations	Financial year 2022	
Title Chapter	Estimated Commitment Appropriations	Estimated Payment Appropriations	Estimated Commitment Appropriation s	Estimated Payment Appropriations	Total Estimated Commitment Appropriations	Total Estimated Payment Appropriations
	1	2.	-Staff expenditure	9	•	
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-Infrastructu	re 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



EDCIPS						
Current administrative expenditure	5.121	5.121	35.000	35.000	40.121	40.121
Postage / Telecom- munications	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-Оре	erational expendi	ture		
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).



Work programme 2022 Global Health EDCTP3 Call topics

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

Under this work programme, two calls for proposals are launched, one covering the topics for submission of proposals and the second covering other actions:

- HORIZON-JU-GH-EDCTP3-2022-01 includes three topics for Research and Innovation Actions (RIA) and two topics for Coordination and Support Actions (CSAs). One of the RIA topics is part of a programme developed in collaboration with the Bill & Melinda Gates Foundation (BMGF), which joins the GH EDCTP3 programme as a Contributing Partner for the 2021/2022 work programme.
- HORIZON-JU-GH-EDCTP3-2022-02 includes a topic to support the EDCTP Africa Office, to be awarded as action not subject to calls for proposals; a topic for a grant to identified beneficiaries, which will provide the contribution from the Bill & Melinda Gates Foundation as part of a collaboration of this contributing partner with GH EDCTP3; and the budget for the experts evaluating proposals and carrying out other work for GH EDCTP3.

Call	Budget (EUR million)	Deadline
HORIZON-JU-GH-EDCTP3-2022-01	96.8800	30 August 2022
HORIZON-JU-GH-EDCTP3-2022-02	3.7502	30 August 2022

General conditions related to this work programme

Unless specified otherwise, the sections of the General Annexes to the Horizon Europe work programme² apply *mutatis mutandis* to the GH EDCTP3 work programme.

Admissibility conditions	The conditions are described in General Annex A.
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¹ <u>https://ec.europa.eu/info/sites/default/files/research_and_innovation/research_by_area/documents/ec_rtd_edctp3-sria-2022.pdf</u>

² <u>https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/wp-call/2021-2022/wp-13-general-annexes horizon-2021-2022 en.pdf</u>

Eligibility conditions	The conditions are described in General Annex B except for the specific conditions for GH EDCTP3 funding as regards <u>Entities</u> <u>eligible for funding</u> and <u>Consortium composition</u> described below. Participation conditions related to the illegal invasion in Ukraine by Russia are also set out below.
Financial and operational capacity and exclusion criteria	The criteria are described in General Annex C.
Award criteria	The criteria are described in General Annex D.
Documents	The documents are described in General Annex E.
Procedure	The procedure is described in General Annex F.
Legal and financial set-up of the Grant Agreements	The rules are described in General Annex G and the application of the right to object is described below.

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

Entities eligible to participate

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

Entities eligible for funding

To be eligible for funding, applicants must be eligible to participate and established in one of the eligible countries, i.e.

- The Member States of the European Union, including their outermost regions;
- The Oversees Countries and Territories (OCTs) linked to Member States³
- Eligible non-EU countries:
 - Countries associated to Horizon Europe⁴

³ Entities from Oversees Countries and Territories (OCT) are eligible for funding under the same conditions as entities from the Member State to which the OCT in question is linked. See the <u>Horizon Europe Programme Guide</u> for a complete list of OCTs.

⁴ See list of <u>associated countries and https://ec.europa.eu/info/research-and-innovation/strategy/strategy-2020-</u> 2024/europe-world/international-cooperation en

• Countries that are members of the EDCTP Association⁵

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

Specific cases:

Affiliated entities – Affiliated entities are eligible for funding if they are established in one of the countries listed above.

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

Consortium composition

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

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

<u>Replacing relevant section in General Annex D to the Horizon Europe work programmes</u> <u>Scores and weighting</u>

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

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

General Annex G to the Horizon Europe work programmes

According to the Horizon Europe rules, and in order to protect Union interests, the right for the Global Health EDCTP3 Joint Undertaking to object to transfers of ownership of results or to grants of an exclusive

⁵ See the <u>EDCTP website</u>

licence regarding results should apply to participants. Therefore, the provisions set out in General Annex G to the Horizon Europe work programmes on the right to object apply generally. It should be noted that in accordance with the Council Regulation 2021/2085 establishing the Joint Undertakings under Horizon Europe⁶ and the Model Grant Agreement, the right to object applies also to participants that have not received funding from the JU and for the periods set therein.

HORIZON-JU-GH-EDCTP3-2022-01

Conditions for this call

Indicative budget(s)

Topics under Call HORIZON-JU-GH-	Туре	Indicative	Expected	Number of
EDCTP3-2022-01	of	GH EDCTP3	GH EDCTP3	projects
	Action	Budget	contribution	expected
		(EUR million)	per project	to be
			(EUR	funded
			million)	
Ope	ening: 6 N	lay 2022		
Dead	line: 30 Au	ugust 2022		
GH-EDCTP3-2022-01-01	RIA	38.03	4.00	9
GH-EDCTP3-2022-01-02	RIA	30.85	6.00 to 8.00	5
GH-EDCTP3-2022-01-03	RIA	22.00	5.00	4
GH-EDCTP3-2022-01-04	CSA	1.00	1.00	1
GH-EDCTP3-2022-01-05	CSA	5.00	0.60	8
Overall indicative budget		96.85		

The general conditions relating to this call are those applicable to the 2021/2022 work programme of Global Health EDCTP3 outlined above.

Expected impacts of Call 1

Activities funded under this call for proposals should contribute to:

- Achieve SDG3 'Ensure healthy lives and promote well-being for all at all ages' in sub-Saharan African countries;
- Provide evidence for informed health policies and guidelines within public health systems in sub-Saharan Africa and at international level;
- Strengthen clinical research capability in sub-Saharan Africa to rapidly respond to emerging epidemics;

⁶ Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014; OJ L 427, 30.11.2021, p. 17

- Enable a regulatory environment that can ensure effective development, delivery, and uptake of new or improved safe health technologies guaranteeing that trials in sub-Saharan African countries meet international standards;
- Enable countries in sub-Saharan Africa to better understand pathogen epidemiology and support effective public health monitoring through integration of genomics and epidemiology;
- Increase cost effectiveness of public investment through collaboration of funders of clinical trials in the area of infectious diseases in sub-Saharan Africa;
- Strengthen health systems to ensure uptake of effective health technologies and innovations;
- Enhance sustainable global scientific collaboration in health research and international cooperation across sub-Saharan Africa.

Proposals are invited against the following topics:

HORIZON-JU-GH-EDCTP3-2022-CALL1-01-01: Promoting implementation of research results into policy and practice

Specific conditions	
<i>Expected EU contribution per project</i>	GH EDCTP3 estimates that an EU contribution of around EUR 4.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
Indicative budget	The total indicative budget for the topic is EUR 38.03 million.
Type of Action	Research and Innovation Actions
Legal and financial set-up of the Grant Agreements - Standard deliverables	 Implementing the provision on affordable access as defined in Article 114 of the 2021/2085 Council Regulation establishing the Joint Undertakings under Horizon Europe⁷, grants award under this topic will have to submit the following deliverables: 1. Stewardship plan Beneficiaries must prepare stewardship plans outlining how to achieve the optimal use of an intervention, including, for example, how to avoid irrational use, overuse or abuse of health technologies (e.g. antimicrobials). A draft plan must be submitted after half the duration
	of the project has elapsed and a final plan must be submitted with the final report.2. Global access plan
	With the final report, beneficiaries must submit an appropriate and proportionate global access plan that covers registration targets, plans to meet demand, flexible approaches to IP and other strategies that reflect ability to pay and ensure that economic barriers to access are low.

 ⁷ Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014; OJ L 427, 30.11.2021, p. 17

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

<u>Expected outcome</u>: This topic aims at supporting activities that contribute to one or several of the expected impacts for this call. To that end, proposals under this topic should aim for delivering results that are contributing to the following expected outcomes:

- Uptake of research results into clinical practice so that people in sub-Saharan Africa, particularly vulnerable populations, can have access to safe health technologies⁸ of proven efficacy for poverty-related diseases, including emerging and re-emerging infectious diseases and antimicrobial resistant infections;
- Operational and evaluation tools for successfully translating research results into clinical practice are validated and health systems in sub-Saharan Africa are improved;
- Widespread adoption of research results into national and international policy guidelines.

⁸ The definition of health technology is the application of organized knowledge and skills in the form of medicines, medical devices, vaccines, procedures and systems developed to solve a health problem and improve quality of life.

<u>Scope:</u> Failure to translate research findings into policy and practice prevents research from achieving maximum public health benefit. Despite substantial investment in clinical research in poverty-related diseases, including emerging and re-emerging infectious diseases and antimicrobial-resistant infections, exploitation and use of results beyond research groups to date remains limited. The barriers to an efficient uptake of research results include limited interaction between researchers, policymakers, patients' community and other stakeholders, lack of experience in exploiting research results beyond academia, limited health systems capacity, affordability issues, and structural and cultural differences between the realms of research, programme planning and policymaking.

Proposals should address the following activities:

- Carry out 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;
- Demonstrate the cost effectiveness of the health technologies being investigated in relevant communities;
- Identify barriers to uptake of the health technologies being investigated and address them in the studies to be carried out;
- Develop methods and evaluation tools that can ensure translating clinical research results into healthcare policy and practice. These methods should be broadly applicable to improve patients quality of life beyond the specific health technology being investigated;
- Early involvement and regular interaction with policy and decision makers as well as end-users to have the health technology adopted by health systems.

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

Proposals should present a sound assessment of the feasibility of the proposed work, especially as regards the planned clinical investigations. Realistic plans for recruiting trial subjects should be presented and corroborated by demonstrated success from previous studies. The proposals should justify the choice of populations to be enrolled into the trials and explain how they relate to the larger population. The full range of relevant determining characteristics (sex, gender, age, socio-economic status, etc.) needs also to be considered.

Proposals should describe how stakeholder views of the proposal's relevance and the study design have been incorporated in the co-creation process of planning the research proposal. Proposals should indicate explicit plans for good participatory practices for engaging stakeholders at every step of the research life cycle.

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

Applicants are welcome to draw on any relevant lessons from knowledge translation in response to the COVID-19 pandemic.

It is essential that proposals bring together clinical researchers with experience in implementation research, health policy experts and end users.

Specific conditions	
Expected EU contribution per project	GH EDCTP3 estimates that an EU contribution of between EUR 6.00 and 8.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
Indicative budget	The total indicative budget for the topic is EUR 30.85 million.
Type of Action	Research and Innovation Actions
Legal and financial set-up	Implementing the provision on affordable access as defined in Article 114
of the Grant Agreements -	of the 2021/2085 Council Regulation establishing the Joint Undertakings
Standard deliverables	under Horizon Europe ⁹ , grants award under this topic will have to submit the following deliverables:
	1. Stewardship plan
	Beneficiaries must prepare stewardship plans outlining how to achieve the optimal use of an intervention, including, for example, how to avoid irrational use, overuse or abuse of health technologies (e.g. antimicrobials). A draft plan must be submitted after half the duration of the project has elapsed and a final plan must be submitted with the final report.
	2. Global access plan
	With the final report, beneficiaries must submit an appropriate and proportionate global access plan that covers registration targets, plans to meet demand, flexible approaches to IP and other strategies that reflect ability to pay and ensure that economic barriers to access are low.
Legal and financial set-up of the Grant Agreements - Additional exploitation	Also in line with Article 114 of the 2021/2085 Council Regulation, participants will be subject to the following additional exploitation obligations:
obligations	 Participants must – up to four years after the end of the action (see Data Sheet, Point 1) – use their best efforts to ensure that resulting health technologies and services will be broadly available and accessible, as soon as possible and at fair and reasonable conditions. In this respect, if, despite a participants' best efforts, the results are not exploited within one year after the end of the action, participants must (unless otherwise agreed in writing with the granting authority) use the Horizon Results Platform to find interested parties to exploit the results.

HORIZON-JU-GH-EDCTP3-2022-CALL1-01-02: Implementing adaptive platform trials

 ⁹ Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe and repealing Regulations (EC) No 219/2007, (EU) No 557/2014, (EU) No 558/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014; OJ L 427, 30.11.2021, p. 17

2.	In case the participants cannot fulfil the preceding obligation, the participants must (if requested by the granting authority) grant non-exclusive licences - under fair and reasonable conditions - to their results to legal entities that commit to rapidly and broadly exploiting the resulting health technologies and services and ensure that they are broadly available and accessible, as soon as possible and at fair and reasonable conditions.
3.	In case of transfer of the ownership or licensing of results, participants must pass on such additional exploitation obligations to the legal entities exploiting the results.
4.	For up to four years after the action (see Data Sheet, Point 1), the funding body must be informed every year about the status of the development of the product and any other exploitation of the results through an annual report that is due on each anniversary of the end of the grant agreement.

<u>Expected outcome</u>: This topic aims at supporting activities that are contributing to one or several of the expected impacts for this call. To that end, proposals under this topic should aim for delivering results that are contributing to all the following expected outcomes:

- More clinicians and researchers in sub-Saharan Africa have the capacity to design, implement and maintain large-scale, multi-centre and multi-country adaptive platform trials allowing the simultaneous evaluation of multiple interventions in an adaptive manner;
- A number of large-scale, multi-centre and multi-country adaptive platform trials, investigating treatments and/or treatment regimens for infectious diseases are implemented in sub-Saharan Africa, having the operational capability to rapidly include treatment approaches for infectious diseases outbreaks with epidemic or pandemic potential;
- Health care providers and professionals in sub-Saharan Africa have a better understanding on how to treat and reduce the burden of infectious diseases within the scope of the GH EDCTP3 programme in this call topic;
- Trial sites across multiple institutions and countries belong to a coordinated network of clinical sites and facilities such as research laboratories with the capacity to deliver efficiently robust clinical evidence derived from a diverse population, through harmonized research methods, data collection and sharing and joint analysis;
- More clinical investigators and researchers at the earlier stages of their career (e.g. Master's, PhD candidates, or post-doctoral level), including increasing proportions of women scientists, are able to develop a scientific career in sub-Saharan Africa and establish themselves as scientific leaders in sub-Saharan Africa.

<u>Scope</u>: During the COVID-19 pandemic the research community has seen the emergence and success of large-scale, multi-country adaptive platform trials to evaluate therapeutics for COVID-19. Adaptive platform trials have the ability to evaluate simultaneously multiple interventions in one trial answering multiple questions based on a master protocol¹⁰. The adaptive design of the trial provides the flexibility

¹⁰https://www.nature.com/articles/s41573-019-0034-3.pdf

for promising new therapies to enter clinical evaluation and for poor-performing ones to discontinue based on interim evaluations, paving a pathway for efficient clinical trial research. Adaptive platform trials help to establish an efficient research ecosystem that can build clinical trial capacity for long-term sustainability in a coordinated and collaborative manner across institutions in different countries.

The COVID-19 pandemic has shown a lack of COVID-19-related large-scale clinical trials in sub-Saharan Africa, while this region could greatly benefit from more resource-efficient clinical trials that are investigating novel treatments for existing infectious diseases and that are able to react to future threats. Implementation of adaptive platform trials in sub-Saharan Africa has the potential to improve the identification of safe and efficacious interventions and save resources that are particularly scarce in this region of the world. In addition, the conduct of adaptive platform trials with the in-built operational ability to rapidly implement clinical evaluation of treatment options for when an epidemic-prone pathogen strikes, is key to being prepared for infectious disease epidemics or pandemics.

This topic aims to support the implementation of adaptive platform trials for the evaluation of candidate treatments for infectious diseases in sub-Saharan Africa. These trials should also be able to rapidly evaluate treatments in response to an emerging infectious disease threat.

Pathogens within the scope of this call topic are those that cause lower respiratory tract infections, emerging and re-emerging infections, neglected infectious diseases, and diarrheal diseases. Special attention should be paid to infections that lack treatment options or where treatments are inadequate. This includes for example infections that are hard to treat due to antimicrobial resistance. HIV, malaria and tuberculosis are excluded from this call topic due to previous investments in these areas.

As appropriate, using rapid multiplex platforms for diagnosis of parasitic, bacterial, fungal and/or viral infections should be considered.

The proposals should address **all** of the following:

- Implementation of adaptive platform trials in sub-Saharan Africa that are routinely evaluating treatment options for infectious diseases within the scope of this topic in 'inter-epidemic' times, while also considering in their trial design the ability to be 'epidemic-fit' and ready for the timely assessment of treatments in the face of an infectious diseases outbreak with epidemic or pandemic potential;
- Training on clinical trial implementation and laboratory analysis, harmonized data collection and management systems to run the adaptive platform trials and at the same time create a coordinated network of clinical trial sites and research laboratories for longer-term usability;
- Hurdles related to ethical, administrative, regulatory and logistical aspects should be addressed in order to allow smooth implementation of adaptive platform trials and avoid such barriers when the trial needs to adapt in response to an epidemic or pandemic;
- Outreach to sub-Saharan African clinical researchers and biostatisticians to build and increase the capacity for the design and implementation of further adaptive platform trials across sub–Saharan Africa;
- Promotion of close communication between clinical experts, patient communities, regulators, health care workers and policy makers to increase understanding of and trust in adaptive platform trials as an efficient design for clinical research in sub-Saharan Africa;

- Interaction with relevant national public health institutes, Africa CDC, World Health Organisation -Regional Office for Africa and/or other regional and international relevant organisations to adequately address health research systems needs in adaptive platform trial study design;
- Sex and gender aspects should be taken into account. All data should be disaggregated by sex, age and other relevant variables, such as by measures of socioeconomic status (i.e. take into account the socioeconomic gradient).

Populations for intervention development and evaluation should also include vulnerable populations which need treatment options, including children, pregnant women, people with co-infections and co-morbidities, older people, and people living in hard-to-reach communities.

Collaboration and coordination with existing adaptive platform trials in Africa and Europe, EDCTP's Networks of Excellence and other EDCTP funded initiatives is expected, where relevant.

<u>Collaboration between the Global Health EDCTP3 JU and the contributing partner Bill & Melinda Gates</u> <u>Foundation</u>

HORIZON-JU-GH-EDCTP3-2022-CALL1-01-03: Genomic epidemiology for surveillance and control of poverty-related and emerging/re-emerging infections in sub-Saharan Africa

The collaboration between the Global Health EDCTP3 Joint Undertaking and the Bill & Melinda Gates Foundation aims to leverage the genomic sequencing capacity being built in Africa to support epidemiology and surveillance of endemic and epidemic pathogens. In order to achieve this, partnerships between epidemiology sites (such as population cohorts and clinical trial sites) and genomic sequencing labs in national public health institutes (NPHIs) are needed, sharing and leveraging resources and expertise.

The establishment of the Africa Pathogen Genomics Initiative (Africa PGI)¹¹ with Africa Centre for Disease Control and Prevention (Africa CDC), coupled with the accelerated interest in genomic surveillance due to the COVID-19 pandemic has led to increasing capacity for genomic sequencing in Africa. There is an opportunity to advance the impact of genomic surveillance in Africa by better integrating it with epidemiology expertise and study infrastructure. The integration of epidemiology and genomics, so-called 'genomic epidemiology', would enable countries in Africa to better understand the epidemiology of infectious pathogens, characterize pathogens, and support public health product and intervention design and effectiveness monitoring. While expertise and resources for both epidemiology and genomics exists in Africa, linking the Africa PGI to the Global Health EDCTP3 Joint Undertaking presents an opportunity to support better integration through partnerships between African and European organizations working on collaborative research. A key element of the partnership will be the Global Health Network (tGHN)'s support to Global South leadership and the creation of an enabling environment for improved health research and data science capabilities through tGHN's 'Ecosystem for Health Research & Data Science' initiative.¹²

¹¹ https://ipg.africacdc.org/

¹² https://tghn.org/

Annex 1 of the Global Health EDCTP3 work programme 2022: call topics

This partnership aims to:

- 1. Increase the use of genomic epidemiology by Africa CDC and NPHIs across Africa to answer public health questions of most concern nationally and regionally.
- 2. Create data platforms through which integrated epidemiologic, clinical, and genomic data can be collected and combined by African researchers and NPHIs.
- 3. Pilot selected projects of translational research for the application of genomic epidemiology for specific pathogens/disease areas in low- and middle-income countries (LMICs), translating these applications to inform public health decision-making and/or product development.
- 4. Establish a community of practice, training programmes, and fellowship opportunities in genomic epidemiology, increasing the literacy of genomics experts in the principles and methods of epidemiology and of epidemiologists in the use of genomic data.

The collaboration is being implemented through two topics.

Through the topic GH-EDCTP3-2022-CALL1-01-03 within this collaboration presented here, funding from the Global Health EDCTP3 JU is made available. This will be complemented by the grant to identified beneficiaries (topic GH-EDCTP3-2022-CALL1-02-02) which supports coordination activities for the collaboration and brings together the contribution from the Bill & Melinda Gates Foundation. **Applicants to each of the topics are strongly encouraged to read the topic description for both topics: GH-EDCTP3-2022-CALL1-02-02.**

Specific conditions	
Expected EU contribution	GH EDCTP3 estimates that an EU contribution of around EUR 5.00
per project	million would allow these outcomes to be addressed appropriately.
	Nonetheless, this does not preclude submission and selection of a
	proposal requesting different amounts.
Indicative budget	The total indicative budget for the topic is EUR 22.00 million
Type of Action	Research and Innovation Actions
Legal and financial set-up of	Grants awarded under this topic will be linked to the following actions:
the Grant Agreements –	Grants awarded under this topic and grants awarded under the
linked action	corresponding topic under this collaboration HORIZON-GH-EDCTP3-
	2022-CALL1-02-02. Signing of a collaboration agreement as linked
	actions in accordance with Article 7 of the Model Grant Agreement will
	be required.

<u>Expected outcome</u>: Whilst 2021 has seen an unprecedented expansion in global genomic sequencing capacity for SARS-CoV-2 also in Africa, many challenges remain. The translation of genomic data to inform public health decision making is needed to realize the full impact of this sequencing capacity. In order to achieve this public health impact, there needs to be improved integration of genomics capabilities with complementary disciplines, in particular epidemiology. Purposeful use of genomic sequencing beyond COVID-19 through improving the ability to link genomic sequencing data to clinical and epidemiological data has the opportunity to strengthen both epidemiological research and genomic surveillance in order to create integrated surveillance systems to monitor infectious diseases in sub-Saharan Africa.

Annex 1 of the Global Health EDCTP3 work programme 2022: call topics

This topic aims to support activities to strengthen genomic epidemiology and its application to inform public health decision making. To that end, proposals under this topic should aim to deliver results that are directed, tailored towards, and contributing to all of the following expected outcomes:

- Public health professionals and researchers in sub-Saharan Africa have a better understanding of poverty-related and emerging/re-emerging infectious diseases affecting these countries and use genomic epidemiology evidence as part of surveillance and disease control programmes;
- Public health authorities have access to genomic epidemiology data and evidence to better develop and implement informed public health policies in sub-Saharan Africa;
- More researchers and public health professionals (both genomics and epidemiology specialists) have competencies in genomic epidemiology, including how to design studies using genomic epidemiology and how to use and interpret data to answer questions of public health significance in sub-Saharan Africa;
- Researchers and public health professionals have access to improved and integrated research and surveillance infrastructure and capabilities that enables the combination of genomic and epidemiology data for the understanding of infectious disease epidemiology and the development of new, low-cost, easy-to-implement solutions for improved delivery of public health interventions for vulnerable populations in low-resource settings;
- Genomic epidemiology data are leveraged to help inform the design, development, and prioritization of public health products such as diagnostics, therapeutics, and vaccines that are affordable, accessible, and impactful for populations across sub-Saharan Africa;
- Genomic epidemiology capabilities and capacity are strengthened at National Public Health Institutions and regional public health organizations in sub-Saharan Africa;
- More researchers and public health professionals at the early stages of their research and/or public health career (e.g. Master's, PhD or post-doctoral level) are able to develop their own scientific career in sub-Saharan Africa and/or establish themselves as scientific and public health leaders in sub-Saharan Africa.

<u>Scope:</u> Proposals should address all of the following:

- Strengthen countries' capacity for early detection and/or characterization of any poverty-related infectious diseases (PRDs) disease, group of PRDs or emerging or re-emerging infectious disease affecting sub-Saharan Africa and that are within the scope of the current EDCTP3 programme¹³ In view of the amount of work already carried out, this call topic excludes proposals working on genomic epidemiology in the context of COVID-19;
- Implement at least one selected project of translational research demonstrating the application
 of genomic epidemiology to answer specific public health questions pertaining to infectious
 diseases. These projects should go beyond the generation of data. They should include translation
 to decision making through active engagement with public health officials and other stakeholders.
 Examples of potential projects demonstrating the application of genomic epidemiology to answer
 specific public health questions pertaining to infectious diseases could include investigation of the
 burden, transmission, or evolution of a pathogen, investigation of the pathogens causing a specific
 disease/clinical presentation, characterization of a pathogen to inform product development/
 public health intervention design, evaluation of the effect of public health interventions (such as

¹³ <u>ec rtd edctp3-sria-2022.pdf (europa.eu)</u>

vaccination programmes) on the epidemiology of a pathogen. Public health areas that are not mentioned as an example but apply genomic epidemiology and are of relevance for public health decision-making and/or product or intervention design will also be considered;

- Proposals are expected to partner with National Public Health Institutes (with the support of the Africa Pathogen Genomics Initiative (PGI) as described in GH-EDCTP3-2022-CALL1-02-02);
- Proposals should explicitly outline how proposed partnerships with NPHI or other government entities will support definition of questions of greatest public health importance and allow applicants to leverage and integrate the use of genomic sequencing in Africa to answer the prioritized public health questions through integration with epidemiology data and approaches;
- Integrate epidemiologic, clinical, and genomic data through data integration platforms, with the need for this integration built into the design of the research study/surveillance programmes prior to data collection. Collaboration with the Global Health Network and harmonization across awarded projects (see GH-EDCTP3-2022-CALL1-02-02) is expected for the development of these data platforms, which should also leverage experiences and tools from existing initiatives such as the European COVID-19 Data Platform¹⁴, the Public Health Alliance for Genomic Epidemiology (PHA4GE)¹⁵, the Global Alliance for Genomics & Health (GA4GH)¹⁶ and/or the European Unionfunded BY-COVID project¹⁷;
- Strengthen and harmonize data standards and tools to enable the integration of epidemiological and genomics data collection, storage, sharing, and analysis. Collaboration with the Global Health Network and PHA4GE is expected for this task (see GH-EDCTP3-2022-CALL1-02-02);
- Proposals should ensure that resulting data comply with the FAIR principles and collaboration with the future awardee of HORIZON-WIDERA-2021-ERA-01-41¹⁸ is encouraged to increase international cooperation on FAIR data;
- Establish a community of practice on genomic epidemiology including expertise in bioinformatics to increase the literacy of genomics experts in the principles and methods of epidemiology and the literacy of epidemiologists on the use of genomic data. This community of practice will be formed in collaboration with the consortium under the grant agreement GH-EDCTP3-2022-CALL1-02-02 which could include : Global Health Network and the Africa PGI, as well as linking to existing communities of practice established through PHA4GE, the EDCTP's Network of Excellence¹⁹, and the African Society for Laboratory Medicine (ASLM)²⁰;
- Support the generation of harmonized training resources, including for young African scientists with gender balance through degree training in genomic epidemiology and/or hands on training during implementation of research projects to assist them in advancing their scientific careers. Training resources should be developed in collaboration with the consortium under grant agreement GH-EDCTP3-2022-CALL1-02-02 including Africa PGI's Next-Generation Sequencing (NGS) Academy and the Global Health Network for: 1) genomic expertise in the principles, methods, and application of epidemiology methods; 2) epidemiologists in the principles,

¹⁴ The European COVID-19 Data Platform : COVID-19 Data Portal (covid19dataportal.org)

¹⁵ PHA4GE - Genomic Epidemiology

¹⁶ Data Use Ontology approved as a GA4GH technical standard

¹⁷ BY-COVID | BY-COVID

¹⁸ Funding & tenders (europa.eu)

¹⁹ Networks of Excellence - EDCTP

²⁰ Home - African Society for Laboratory Medicine (aslm.org)

methods, and applications of genomics; 3) both communities in the combined principles, methods, and applications of genomic epidemiology and its use for public health decision making and surveillance programmes. It is expected that training will be harmonized across funded projects and collaboration with existing initiatives and projects, such as the awarded projects under the EDCTP2's CSA2020E²¹, EDCTP's Networks of Excellence, ECDC4Africa CDC initiative²² and EDCTP's Knowledge Hub²³, should be sought where possible;

- Promote the integration of research with public health organizations and disease control programmes at a national and regional level. Collaboration between relevant stakeholders in National Public Health Institutes and academic/research centres is expected at a national level. On a regional level, regional consortia and organizations such as Africa CDC, should be engaged where appropriate;
- Proposals should include organizations with expertise in epidemiology and those with expertise in genomics, with a willingness to work together to establish joint projects and achieve the aims outlined above;
- Proposals should consider gender equality in the design of their projects and justify how they will be gender intentional in their proposed aims and activities.

HORIZON-JU-GH-EDCTP3-2022-CALL1-01-04: Creating a sustainable clinical trial network for infectious diseases in sub-Saharan Africa

Specific conditions	
Expected EU contribution per project	GH EDCTP3 estimates that an EU contribution of around 1.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
Indicative budget	The total indicative budget for this topic is EUR 1.00 million
Type of Action	Coordination and Support Actions

<u>Expected outcome</u>: This topic aims at supporting activities that are contributing to one or several of the expected impacts for this call. To that end, proposals under this topic should aim for delivering results that are directed towards and contributing to the following expected outcomes:

- A well-documented overview of operational and effective regional clinical trial and laboratory networks in different clinical settings in sub-Saharan Africa, and the existing coordination mechanisms within and between the networks, is developed;
- An efficient coordination and collaboration mechanism between identified clinical trial and laboratory networks in sub-Saharan Africa is established and sustained;

²¹ Capacity development for disease outbreak and epidemic response in sub-Saharan Africa, in collaboration with Africa CDC - 2020 - EDCTP

²² EU and AU sign partnership to scale up preparedness for health emergencies (europa.eu)

²³ EDCTP Knowledge Hub - EDCTP

- The foundation for a coordinated, permanent, pan sub-Saharan African clinical trial infrastructure to optimise a coordinated response to infectious diseases threats, including emerging infections, is laid, taking advantage of the existing EDCTP's Networks of Excellence;
- The role of Africa in clinical research preparedness for future epidemics and pandemics is strengthened.

<u>Scope</u>: The work carried out under this topic should lay the foundation for the establishment of a pan sub-Saharan African infrastructure of clinical trial facilities that continuously evaluate health interventions (incl. vaccines, treatments and diagnostics) for infectious diseases in a coordinated, harmonized manner to maximize trial efficiency. Such an infrastructure should leverage the work done by EDCTP Networks of Excellence²⁴ through interaction with these networks. It should also be capable of quickly and easily adapting ongoing clinical trials for vaccines, treatments or diagnostics to tackle emerging infectious disease threats, if and when the need arises.

The purpose of this topic is to support one project, which will carry out a desk review and mapping exercise of the current landscape of clinical trial and laboratory networks in sub-Saharan Africa. Such an exercise would provide the basis for the creation of the intended network. The network could be composed of regional networks in Sub-Saharan Africa, each regional network with its connected clinical trial sites and laboratories. The structure to be built needs to ensure a harmonised approach to clinical trial implementation.

Relevant regional and international organisations, such as the World Health Organization - Regional Office for Africa, the African Medicines Agency (AMA) or the Africa Centre for Disease Control and Prevention (Africa CDC), should be consulted when developing the plans for the future network.

Proposals should address the following areas:

- Conducting a mapping exercise to analyse the operational and effective clinical trial and laboratory networks in different clinical settings in sub-Saharan Africa, including their related coordination mechanisms;
- Establishing a clinical trial network, possibly composed of sub-networks in sub-Saharan Africa, under which the clinical sites and laboratories will collaborate and coordinate their activities. The network(s) should work in close collaboration EDCTP's Networks of Excellence²⁵ and take into account the work and operational network infrastructure established by the Networks of Excellence;
- Planning for common preparedness research approaches and tools within the network(s), such as clinical trial protocols including master protocols, as well as a comprehensive data management framework allowing the collection, storage, analysis and sharing of standardised data between relevant clinical sites and laboratories;
- Developing an electronic registry of trial sites and laboratories, covering relevant information on their capacity to implement clinical trials, as a tool to enable large-scale trials;

²⁴ https://www.edctp.org/our-work/edctp-regional-networks-of-excellence/

²⁵ <u>http://www.edctp.org/our-work/edctp-regional-networks-of-excellence/</u>

- Establishing a strong coordination and collaboration mechanism to support the harmonization of clinical trials across the sub-Saharan African infrastructure of clinical trial facilities;
- Coordinating and collaborating with relevant other initiatives including those funded by previous EDCTP programmes such as the epidemic preparedness and response research networks ALERRT²⁶ and PANDORA²⁷, to avoid duplication of activities and ensure complementarity;
- Developing a business plan for operationalising the pan sub-Saharan infrastructure of clinical trial facilities that continuously evaluate health interventions (incl. vaccines, treatments and diagnostics) for infectious diseases in sub-Saharan Africa and which, in case of a health threat, are able to quickly and easily adapt to tackle such threat;
- This business plan should be developed through consultation with relevant African stakeholders, such as representatives from regulatory authorities, industry, policy makers, patient organisations, etc., as well as relevant European trial coordinators and stakeholders;
- Promoting the visibility and attractiveness of the future infrastructure for investigators and sponsors of clinical trials in infectious diseases; as well as active communication with the science community, patient advocacy groups and other stakeholders.

HORIZON-JU-GH-EDCTP3-2022-CALL1-01-05: Strengthening regulatory capacity for supporting conduct of clinical trials

Specific conditions	
Expected EU contribution per project	GH EDCTP3 estimates that an EU contribution of around EUR 0.60 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
Indicative budget	The total indicative budget for the topic is EUR 5.00 million.
Type of Action	Coordination and Support Actions

<u>Expected outcome:</u> This topic aims at supporting activities that are contributing to one or several of the expected impacts for this call. To that end, proposals under this topic should aim for delivering results that are directed towards and contributing to the following expected outcomes:

- Enhanced regulatory capacity to conduct clinical trials in sub-Saharan Africa countries, complementing the work of the African Vaccine Regulatory Forum (AVAREF);
- Increased common regulatory mechanisms across sub-Saharan Africa countries, including better alignment with regional standards and overarching continental mechanisms such as the African Medicines Agency;
- Better equipped health systems to integrate new or improved health technologies;
- Improved efficiency regarding the process of market authorisation of new or improved health technologies;
- Improved efficiency of the National Regulatory Agencies (NRAs) concerning clinical trials oversight;

²⁶ <u>https://www.alerrt.global/</u>

²⁷ <u>https://www.pandora-id.net/</u>

- Lessons and principles that will help continental or regional Regulatory Agencies in sub-Saharan Africa to better define their function, frameworks and capabilities;
- Stronger African ownership and leadership of clinical research in sub-Saharan Africa countries;
- Better collaboration between NRAs and national and institutional research ethics committees, research integrity offices and data access committees;
- Accelerated maturity towards level 4 of the Regulatory Agencies in sub-Saharan Africa.

<u>Scope:</u> The purpose of this call for proposals is to fund projects designed to support regulatory capacity and develop technical expertise reinforcing regulatory systems in sub-Saharan Africa countries for supporting the conduct of clinical trials.

These objectives should contribute to strengthening frameworks and capabilities, including issuance of relevant permits, clinical trials oversight and clinical research pharmacovigilance and post-trial market authorisation by NRAs. The funded projects should train researchers, clinicians and Regulatory Agency authorities' personnel for an efficient and robust regulatory control system for approving the conduct of clinical trials and for a responsive clinical trials pharmacovigilance.

The proposals should address several of the following activities:

- Desk review and mapping of the clinical research oversight and pharmacovigilance systems across the involved sub-Saharan Africa countries through country questionnaires and (virtual) participatory workshops to identify gaps and needs;
- Develop approaches and provide training to develop personal and institutional capacities on clinical trial oversight and pharmacovigilance of the NRA staff, researchers, clinicians and other healthcare workers, including knowledge exchange through South-South and North-South partnerships;
- NRAs should recruit at least two new staff members to be trained on clinical trials regulatory framework and be integrated, with a well-defined function and objectives, in the participating Agency in a systems approach. The new staff members should stay in the Agency team for at least two years and participate in networking events, such as the Scientific Conference on Medical Products Regulation in Africa;
- Facilitate and promote harmonised regulatory pathways for clinical research and joint assessment of market authorisations in line with regional and national guidelines;
- Define strategies or practices that can inform policy revisions to improve the efficiency of the NRAs, by introducing innovative systems, practices, and/or technologies that improve the quality and timelines of these bodies as regards clinical research oversight and clinical research pharmacovigilance;
- Promote international cooperation in clinical research regulatory activities with regional and international regulatory harmonization bodies by transferring promising and successful innovative systems and/or technologies from other regions outside Africa and within Africa, fostering national and regional collaboration with regional and international regulatory harmonization bodies;
- Strengthen linkages between regulatory functions and clinical trial registries, such as the Pan African Clinical Trials Registry (PACTR: https://pactr.samrc.ac.za/), while enforcing data sharing in compliance with global requirements;
- Support already established training centres to provide both innovative clinical research training and mentorship to NRAs;

• Plans to foster links between NRAs and initiatives reinforcing collaboration between NRAs and National Ethics Committees in sub-Saharan Africa.

Proposals should clearly describe the national mismatch between disease burden, research activity and level of regulation that justify the need for support. Proposals should explain the links of the proposed activities to existing regulatory initiatives, such as the Africa Vaccines Regulators Forum (AVAREF), the Pan-African Clinical Trials Registry (PACTR), the African Medicines Regulatory Harmonisation (AMRH), the African Medicines Agency (AMA) and the Regional Centres of Regulatory Excellence in Africa (RCOREs)²⁸. Other regional bodies to be taken into account where appropriate are the African Medicines Quality Forum (AMQF), Africa Centre for Disease Control and Prevention (Africa CDC) and Regional Economic Communities.

Particular attention should also be paid to ensuring complementarity and coherence with other activities supported by the European Union and EU Member States in the countries involved in the proposal; for example: EDCTP Regional Networks of Excellence²⁹, The health systems dimension of the Global Gateway investment package³⁰, various Team Europe initiatives such as the Team Europe initiative (TEI) on Manufacturing and Access to Vaccines, Medicines and Health Technologies (MAV+) in Africa³¹.

²⁸ African Regulatory Centres of Excellence (RCOREs) were mandated by the African Medicines Regulatory Harmonization (AMRH) initiative. There are currently 11 RCOREs throughout Africa: <u>https://www.nepad.org/publication/regional-centres-regulatory-excellence-rcores</u>

²⁹ EDCTP regional networks of excellence strengthen regional networking and provide platforms for research training and multicentre studies <u>http://www.edctp.org/our-work/edctp-regional-networks-of-excellence/</u>

³⁰ Global Gateway investment package <u>https://ec.europa.eu/info/strategy/priorities-2019-2024/stronger-europe-world/global-gateway/eu-africa-global-gateway-investment-package en</u>

³¹ Team Europe initiative (TEI) on Manufacturing and Access to Vaccines, Medicines and Health Technologies (MAV+)

https://ec.europa.eu/commission/presscorner/detail/en/ip_21_2594 will directly fund, starting in 2022/2023, the European Medicines Agency (EMA), African Medicine Agency AUDA-NEPAD (AMA) and the World Health Organisation (WHO).

Other actions not subject to calls for proposals

1. Grant to identified beneficiary - Support for an Africa office

(Topic GH-EDCTP3-2022-CALL1-02-01)

GH EDCTP3 will support an Africa office to facilitate implementation of the GH EDCTP3 programme in sub-Saharan Africa.

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

<u>Expected outcome</u>: The proposal under this topic should aim at delivering results contributing to all of the following expected outcomes:

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

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

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

- Provide technical support for the design and implementation of the GH EDCTP3 activities concerning networking and training on clinical research and regulatory and ethical issues in sub-Saharan Africa;
- Organise workshops on proposal preparation and project and financial management in the main (European) languages of sub-Saharan Africa;
- Organise exchanges between the EDCTP Regional Networks of Excellence promoting synergies and collaborations;
- Organise the annual scientific meeting of EDCTP fellows in Africa;
- Promote the EDCTP alumni association and following up on career development of former fellows;

- Develop further links in Africa with industry, funders and other bodies working in the field to speed up the R&I process in sub-Saharan Africa;
- Contribute to the GH EDCTP3 communication and outreach activities on the EDCTP achievements to increase visibility in Africa;
- Contribute to the organisation of the EDCTP Forum;
- Develop Memoranda of Understanding with relevant regional players in sub-Saharan Africa (e.g. Africa CDC) to bring them into the GH EDCTP3 framework and to contribute to this effort.

<u>Legal entity</u>: The European and Developing Countries Clinical Trials Partnership Association (EDCTP Association) - Anna van Saksenlaan 51- 2593 HW The Hague - The Netherlands

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

Form of Funding: Grants not subject to calls for proposals

<u>Type of Action</u>: Grant to identified beneficiary according to Financial Regulation Article 195(e) and Article 24(3) (a) of the Horizon Europe Regulation - Coordination and Support Action.

Indicative timetable: 4th quarter 2022

Indicative budget: EUR 3 million from the 2022 budget

2. Grant to identified beneficiaries

Collaboration between Global Health EDCTP3 and the contributing Partner Bill & Melinda Gates Foundation: Genomic epidemiology for surveillance and control of poverty-related and emerging/reemerging infections in sub-Saharan Africa

(Topic GH-EDCTP3-2022-CALL1-02-02)

The collaboration between the Global Health EDCTP3 and the Bill & Melinda Gates Foundation Joint Undertaking aims to leverage the genomic sequencing capacity being built in Africa to support epidemiology and surveillance of endemic and epidemic pathogens. In order to achieve this, partnerships between epidemiology sites (such as population cohorts and clinical trial sites) and genomic sequencing labs in national public health institutes (NPHIs) are needed, sharing and leveraging resources and expertise.

The establishment of the Africa Pathogen Genomics Initiative (Africa PGI) with Africa Centre for Disease Control and Prevention (Africa CDC), coupled with the accelerated interest in genomic surveillance due to the COVID-19 pandemic has led to increasing capacity for genomic sequencing in Africa. There is an opportunity to advance the impact of genomic surveillance in Africa by better integrating it with epidemiology expertise and study infrastructure. The integration of epidemiology and genomics, so-called 'genomic epidemiology', would enable countries and regional health organizations in Africa to better understand the epidemiology of infectious pathogens, characterize pathogens, and support public health product and intervention design and effectiveness monitoring. While there exist many expertise and resources for both epidemiology and genomics in Africa, linking the Africa PGI to the Global Health EDCTP3

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Joint Undertaking presents an opportunity to support better integration through partnerships between African and European organizations working on collaborative research. A key element of the partnership will be the Global Health Network (tGHN)'s support to Global South leadership and the creation of an enabling environment for improved health research and data science capabilities through tGHN's 'Ecosystem for Health Research & Data Science' initiative.³²

This partnership aims to:

- 1. Increase the use of genomic epidemiology by Africa CDC and NPHIs across Africa to answer public health questions of most concern nationally and regionally.
- 2. Create data platforms through which integrated epidemiologic, clinical, and genomic data can be collected and combined by African researchers and NPHIs.
- 3. Pilot selected projects of translational research for the application of genomic epidemiology for specific pathogens/disease areas in low- and middle-income countries (LMICs), translating these applications to inform public health decision-making and/or product development.
- 4. Establish a community of practice, training programmes, and fellowship opportunities in genomic epidemiology, increasing the literacy of genomics experts in the principles and methods of epidemiology and of epidemiologist in the use of genomic data.

The partnership is being implemented through two topics.

The grant agreement to be concluded under this topic GH-EDCTP3-2022-CALL1-02-02 brings together the contribution from the Bill & Melinda Gates Foundation and supports coordination activities for the collaboration. Through the second topic within this partnership GH-EDCTP3-2022-CALL1-01-03, Research and Innovation Actions in the area of genomic epidemiology research are supported by the Global Health EDCTP3 JU. Applicants to each of the topics are strongly encouraged to read the topic description for both topics: GH-EDCTP3-2022-CALL1-01-03 and GH-EDCTP3-2022-CALL1-02-02.

Specific conditions	
Expected EU contribution per project	GH EDCTP3 estimates that an EU contribution of around EUR 0.05 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
Indicative budget	The total indicative budget for this topic is EUR 50,000
Type of Action	Coordination and Support Action
Eligibility and admissibility conditions	Due to the focus on leveraging the African side of the established Africa Pathogen Genomics Initiative (PGI) and the Global Health Network (tGHN) platforms and the policy objectives of the GH EDCTP3 JU programme, legal entities forming a consortium shall be eligible for participation in actions under this topic provided that the consortium includes at least two independent legal entities established in two different sub-Saharan African countries that are member of the EDCTP Association.

³² https://tghn.org/

Legal and financial set-up of the Grant Agreements - Costs for providing financial support to third parties allowed	Beneficiaries may provide financial support to third parties. The maximum amount to be granted to each third party is EUR 1,000,000 due to the need to directly support genomic sequencing at centres throughout Africa.
Legal and financial set-up of the Grant Agreements – linked action	Grants awarded under this topic will be linked to the following actions: Grants awarded under the corresponding topic under this collaboration HORIZON-GH-EDCTP3-2022-CALL1-01-03. Signing of a collaboration agreement as linked actions will be required in accordance with Article 7 of the Model Grant Agreement.

<u>Expected outcome</u>: Bringing together the Africa Pathogen Genomics Initiative (PGI) and the Global Health Network platforms enable the Global Health EDCTP3 Joint Undertaking-funded actions to access expertise and resources in genomics (from PGI) and clinical trials research and data science (from tGHN). Importantly, these platforms will also support important functions to help to coordinate and find synergies between pre-existing partners and initiatives (including those previously funded by EDCTP programmes) in their respective fields of genomics and epidemiology & data science. Such coordination would happen at the global level as well as regionally within Africa. Africa CDC are the lead partner for both Africa PGI and tGHN in Africa. Africa CDC also have existing partnerships in place with the European Union for health security and field epidemiology. The role of Africa CDC, therefore, presenting an opportunity to integrate and find synergies between multiple engagements with complementary objectives to advance genomic epidemiology and improve public health in Africa.

Expected outcomes from this topic are:

- Through the Africa PGI, providing core capabilities to Global Health EDCTP3-funded actions in genomics through its (1) secretariat function at Africa CDC and the Africa Society for Laboratory Medicine (ASLM), (2) genomic laboratory network across NPHIs, (3) the NGS training academy, (4) genomic data architecture for Africa, and (5) close partnership with African Union member states to develop national strategic plans and use-cases for genomic surveillance;
- Through the tGHN, providing important functions in supporting (1) research and data science capabilities, (2) coordination and strengthening of the data access, sharing, and use ecosystem, including support for data platform development as appropriate and (3) support for the partnership governance and administrative execution;
- Support coordination with relevant activities in genomic epidemiology and data science.

<u>Scope:</u> Through this action the Bill & Melinda Gates Foundation will be contributing significant investments in the Africa PGI to the Global Health EDCTP3 Joint Undertaking, including but not limited to its Next-Generation Sequencing (NGS) Academy and the Public Health Alliance for Genomic Epidemiology (PHA4GE), and tGHN, to provide foundational platforms to achieve the programmatic partnership aims outlined in the introduction for this programme.

The proposal should address all of the following activities:

• Encompass the secretariat to lead and manage the Africa PGI as well as providing financial means to laboratories across the continent to directly support genomic sequencing with the expectation to support African states and their national public health institutes;

- Working with Africa CDC, synergize existing initiatives and partnerships in Africa related to epidemiology, data science, and genomics, including Africa PGI, and as well as other European Union and EDCTP-funded projects and initiatives where relevant, such as the EDCTP's Networks of Excellence³³, European COVID-19 Data Platform³⁴ and BY-COVID project³⁵;
- Develop curricula for training in genomic sequencing and provide training for genomic sequencing and genomic epidemiology, in partnership with the Calestous Juma Fellows, NGS academy, tGHN and, where possible, with other relevant projects funded under EDCTP2 such as EDCTP's Networks of Excellence, EDCTP's Knowledge Hub³⁶ and/or awarded projects under the EDCTP2's CSA2020E³⁷;
- Build consensus standards; document and share best practices; improve the availability of critical bioinformatics tools and resources, and advocate for greater openness, interoperability, accessibility and reproducibility in public health microbial bioinformatics;
- Support research capacity building and communities of practice in data science, including increasing data access, sharing, and use.

<u>Legal entities:</u> University of the Western Cape, Robert Sobukwe Road, Bellville 7535, South Africa; African Society for Laboratory Medicine (ASLM), Joseph Tito Street, Nega City Mall, Suite 800 P.O. Box 5487 Kirkos Subcity, Kebele 08 Addis Ababa, Ethiopia; University of Oxford, University Offices Wellington Square, Oxford OX1 2JD, United Kingdom; University of Cape Town, Private Bag X3, Rondebosch 7701, South Africa

Form of Funding: Grants not subject to calls for proposals

<u>Type of Action</u>: Grant to identified beneficiary according to Financial Regulation Article 195(e) - and Article 24(3) (a) of the Horizon Europe Regulation - Coordination and Support Action

Indicative timetable: 3rd quarter 2022

Indicative budget: EUR 50,000 from the 2022 budget

3. External expertise

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

Form of Funding: Other budget implementation instruments

Type of Action: Expert contract action

Indicative timetable: 2022

Indicative budget: EUR 0.7002 million from the 2022 budget.

³³ Networks of Excellence - EDCTP

³⁴ The European COVID-19 Data Platform : COVID-19 Data Portal (covid19dataportal.org)

³⁵ BY-COVID | BY-COVID

³⁶ EDCTP Knowledge Hub - EDCTP

³⁷ <u>Capacity development for disease outbreak and epidemic response in sub-Saharan Africa, in collaboration with</u> <u>Africa CDC - 2020 - EDCTP</u>

ANNEX 2 GH EDCTP3 ANNUAL WORK PROGRAMME 2022 IN KIND CONTRIBUTIONS TO ADDITIONAL ACTIVITIES TO BE INITIATED IN 2022

In-kin	d contributions (IKAA) s	tarting in 2022 by	GH EDCTP3 Member S	tate and Type of A	tion	
	Research and	Coordination	Strategic partnership	Training	Other	Total
GH EDCTP3 Member State	Innovation	and support	building			
Belgium	900.000	7.347.800				8.247.800
France	20.795.000	19.885.400	1.367.000	2.100.000	1.850.000	45.997.400
Germany	125.619.580	2.900.000	3.000.000			131.519.580
Mozambique	20.811		100.000			120.811
Netherlands	30.000.000					30.000.000
Norway	5.888.522					5.888.522
Portugal	249.289					249.289
Spain		1.450.000				1.450.000
Sweden	11.600.000		3.700.000	2.700.000		18.000.000
United Kingdom	57.707.567			1.803.361		59.510.928
Total	252.780.769	31.583.200	8.167.000	6.603.361	1.850.000	300.984.330

	ANNEX 2 GH EDCTP3 ANNUAL WORK PROGRAMME 2022 IN KIND CONTRIBUTIONS TO ADDITIONAL ACTIVITIES TO BE INITIATED IN 2022														
Nr	GH EDCTP3 Member State	Title	Short description	Funding organisation	Duration (months)	sub-Saharan African countries involved	Keywords	Type of Activity	Comments	Co-funding	Contribution to GH EDCTP3 specific objectives	Contribution to Horizon Europe operational objectives	Planned task to link with other EDCTP Member State Additional Activity	Estimated budget commitment (€)	
IKAA2022- 3320	Sweden	Support to TDR	TDR, the Special Programme for Research and Training in Tropical Diseases, is a global programme of scientific collaboration that helps facilitate, support and influence efforts to combat diseases of poverty.	Swedish International Development Cooperation Agency (Sida)	12	All	Operational research; Implementation research; Capacity development; Lymphatic filariasis; Onchocerciasis (river blindness); Schistosomiasis; Buruli ulcer, Soil- transmitted helminthiases; Leprosy (Hansen disease); Trachoma; Yaws; Malaria; Tuberculosis; Dengue/Severe Dengue; Human African trypanosomiasis (sleeping sickness); Leishmaniases; Cysticercosis/Taeniasis; Drugs	Research and Innovation	The work of TDR is of relevance for all countries in sub- Saharan Africa, therefore, no countries have been specified.	n/a	Strengthen research and innovation capacity	Support the scientific evidence- based implementation of related Union policies, as well as regulatory, standardisation and sustainable investment activities at national, European and global levels	Besides Sweden, EDCTP3 member states Belgium, Germany, Norway, Spain and UK are core donors of TDR. EDCTP has programmatic collaboration with TDR. It is planned to continue regular dialogue.	4.400.000	
IKAA2022- 3321	Sweden	Support to AHPSR	The Alliance for Health Policy and Systems Research promotes the generation and use of health policy and systems research as a means to strengthen the health systems of LMICs.	Cooperation	12	All	Health systems	Strategic partnership building	The work of AHPSR is of relevance for all countries in sub- Saharan Africa, therefore, no countries have been specified.	n/a	Promote networking, building partnerships and strategic alliances	Support the scientific evidence- based implementation of related Union policies, as well as regulatory, standardisation and sustainable investment activities at national, European and global levels	EDCTP3 member states Sweden and Norway provide core support to AHPSR. It is planned to continue dialogue between donors.	2.200.000	
IKAA2022- 3322	Sweden	Support to CARTA	The Consortium for Advanced Research Training in Africa (CARTA) aims at creating and sustaining African research intensive universities that prioritize maintenance of a pipeline of high- quality multidisciplinary early career researchers in public and population health in the sub-Saharan African region.	International	24	Kenya; Malawi, Nigeria, Rwanda, South Africa, Tanzania, Uganda	Implementation research; Pharmacovigilance; Demography; Capacity development; Health systems	Training	n/a	n/a	Strengthen research and innovation capacity	Strengthen scientific excellence, including by considering, where relevant, state-of-the-art basic and frontier research findings in the implementation of their activities	EDCTP3 member states Sweden and UK support CARTA, and it is planned to continue donor dialogue. The CARTA- programme includes short fellowships involving different member states.	2.700.000	
IKAA2022- 3323	Sweden	Support to ReAct	ReAct is an international network focusing on the development of sustainable solutions to tackle antibiotic resistance. ReAct generates change through evidence-based advocacy, particularly by translating scientific evidence into policy, by sharing information generated through partnerships, pilots and programs.	Swedish International Development Cooperation Agency (Sida)	12	All	Regulatory affairs; Pharmacovigilance; Drugs; AMR; One Health	Strategic partnership building	ReAct works in the whole region of sub- Saharan Africa, therefore, no countries have been specified.	n/a	Promote networking, building partnerships and strategic alliances	Support the scientific evidence- based implementation of related Union policies, as well as regulatory, standardisation and sustainable investment activities at national, European and global levels	The African ReAct office is located Zambia. ReAct maintains regular contact and joined activities with other GH EDCTP3 partner states in the region to find synergies between GH EDCTP3 additional activities.	1.500.000	

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IKAA2022- 3324	Sweden	Support to IVI	The International Vaccine Institute (IVI) is dedicated to vaccines and vaccination for global health, and its mission is to discover, develop and deliver safe, effective and affordable vaccines for global public health. IVI focuses on vaccines against infectious diseases affecting the world's most impoverished.	Swedish International Development Cooperation Agency (Sida)	36	Burkina Faso, Madagascar, Malawi, Mozambique	Schistosomiasis; Diarrhoeal diseases; Dengue/Severe Dengue; COVID-19; Vaccines	Research and Innovation	IVI works with a total of 18 countries in sub- Saharan Africa in its different vaccine programs. The countries listed above are involved in IVI's cholera, schistosomiasis, COVID- 19 vaccine programs.	n/a	Advance development and use of new or improved technologies	Strengthen scientific excellence, including by considering, where relevant, state-of-the-art basic and frontier research findings in the implementation of their activities	Besides Sweden, EDCTP3 member states Germany and UK are funding IVI. The EC is supporting IVI through EDCTP. It is planned to continue donor dialogue.	2.800.000
IKAA2022- 3325	Sweden	Joint Programming Initiative on Antimicrobial Resistance (JPIAMR) research projects	JPIAMR is an international collaborative platform engaging 28 nations and the European Commission to curb AMR. JPIAMR coordinates national research funding for filling knowledge gaps on AMR with a One Health approach. Sida engages in JPIAMR research calls to support participation of researchers from LICs in sub-Saharan Africa.	Swedish International Development Cooperation Agency (Sida)	48	Burkina Faso, Democratic Republic of the Congo, Kenya, Madagascar, Malawi, Mali, Mozambique, Senegal, Tanzania, Gambia, Togo, Uganda, Zambia	Capacity development; Drugs; Diagnostics; AMR; One Health	Research and Innovation	n/a	The Sida- funded projects involve funding from at least 16 other European and non- European national funding	Strengthen research and innovation capacity	Strengthen scientific excellence, including by considering, where relevant, state-of-the-art basic and frontier research findings in the implementation of their activities	Several EDCTP3 member states are members of JPIAMR and the partnership is supported by the EC. It is planned to continue the dialogue between member states.	4.400.000
IKAA2022- 3326	Mozambiq ue	Biomedical Research in the Manhiça Health Research Center	General Objective: Strengthen the capacities of health research in Mozambique as a tool to provide the National Health System and international partners with scientific evidence in decision-making. Specific objective: Consolidate the Fundação Manhiça/ Manhiça Health Research Center as a Mozambican institution of reference in biomedical research.	Ministry of Health	12	Mozambique	Maternal and child health, Ethics; Operational research; Capacity development	Strategic partnership building	n/a	n/a	Promote networking, building partnerships and strategic alliances	Strengthen international cooperation in support of Union policy objectives and international commitments	Short exchange of fellows with another GH EDCTP3 Member State additional activity to find synergies between GH EDCTP3 Member States additional activities.	100.000
IKAA2022- 3327	Mozambiq ue	COVID DEMO SOC		National Research Fund	18	Mozambique	COVID-19	Research and Innovation	n/a	n/a	Strengthen capacity for epidemics preparedness	Increase public awareness and acceptance, respond to demand and encourage the diffusion and uptake of new solutions by involving, where appropriate, citizens and end- users in co-design and co- creation processes	Short exchange of fellows with another GH EDCTP3 Member State to find synergies between GH EDCTP3 Member States additional activities.	20.811
IKAA2022- 3328	Norway	Core support to Armauer Hansen Research Institute (AHRI)	Armauer Hansen Research Institute (AHRI) serves as a Centre of Excellence and receives support for its work on medical research and capacity building in Ethiopia and Africa.	Norwegian Agency for Development Cooperation - Norad	60	Ethiopia	Epidemiology; Capacity development; Health systems; HIV; Leprosy (Hansen disease); Malaria; Tuberculosis; Leishmaniases; COVID-19; Vaccines; Drugs; Diagnostics	Research and Innovation	This is core support to AHRI. This means that a portion (not calculated here) of the funding will ultimately be used to support clinical trials.	SIDA (Sweden) also supports AHRI, the amount is uncertain.	Strengthen research and innovation capacity	Strengthen scientific excellence, including by considering, where relevant, state-of-the-art basic and frontier research findings in the implementation of their activities	Norad and SIDA collaborates closely on the core support to AHRI through continuous information exchange and dialogue.	4.019.522

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IKAA2022- 3329	France	ANRS-MIE Annual Call for Proposals 2021-1	The ANRS-Emerging Infectious Diseases funds grant applications for clinical research, capacity building initiatives, doctoral and post-doctoral grants, via the launch of two annual generic calls for proposals (CFP) on HIV, STIs, viral hepatitis, TB, including research on co-infections. EIDs are covered by other CFP.	ANRS Emerging Infectious Diseases (ANRS EID)	48	Mali, Zambia	HIV; Tuberculosis	Coordination and support	n/a	n/a	Strengthen capacity for epidemics preparedness	Reinforce the link between research, innovation and, where appropriate, education, training and other policies, including complementarities with national, regional and Union research and innovation policies and activities	Workshops between recipients and feedback discussions between european funding institutions and networks (ex-GloPID-R) including GH EDCTP3 Member States representatives to find synergies between GH EDCTP3 Member States additional activities.	350.000
IKAA2022- 3330	France	ANRS-MIE Annual Call for Proposals 2021-2	The ANRS-MIE funds grant applications for clinical research, capacity building initiatives, doctoral and post-doctoral grants, via the launch of two annual generic calls for proposals (CFP) on HIV, STIs, viral hepatitis, TB, including research on co-infections.	ANRS Emerging Infectious Diseases (ANRS EID)	48	Benin, Guinea, Uganda, Senegal, Burkina Faso, Cote D'Ivoire, Togo, Mauritania, The Democratic Republic of the Congo, Zambia, Cameroon, Mali	HIV; Tuberculosis; COVID-19	Coordination and support	n/a	n/a	Strengthen capacity for epidemics preparedness	Reinforce the link between research, innovation and, where appropriate, education, training and other policies, including complementarities with national, regional and Union research and innovation policies and activities	Workshops between recipients and feedback discussions between european funding institutions and networks (ex-GloPID-R) including GH EDCTP3 Member States representatives to find synergies between GH EDCTP3 Member States additional activities.	2.800.000
IKAA2022- 3331	France	ANRS-MIE Ad Hoc Call for Proposals COVID 2021	The ANRS-MIE may also launch one or more ad hoc CFP per year to address important scientific issues and support research on any new emergence. The 2021 Ad Hoc CFP aims to fund research grants specifically on COVID in LMCs to strengthen the preparedness and response of national authorities.	ANRS Emerging Infectious Diseases (ANRS EID)	48	Burkina Faso, Cameroon. Cote d'Ivoire, Gabon, Mali, Chad, The Democratic Republic of the Congo, Senegal	COVID-19	Coordination and support	Out of 25 projects submitted, 6 were finally funded, including 3 in SSA countries	n/a	Strengthen capacity for epidemics preparedness	Reinforce the link between research, innovation and, where appropriate, education, training and other policies, including complementarities with national, regional and Union research and innovation policies and activities	Workshops between recipients and feedback discussions between european funding institutions and networks (ex-GloPID-R) including GH EDCTP3 Member States representatives to find synergies between GH EDCTP3 Member States additional activities.	1.100.000
IKAA2022- 3332	France	ANRS-MIE Annual support for Research Partner Sites 2021	funding, to establish a secretariat and a	ANRS Emerging Infectious Diseases (ANRS EID)	12	Burkina Faso, Cameroon, Cote d'Ivoire, Senegal	HIV; Tuberculosis; COVID-19	Coordination and support	n/a	n/a	Strengthen capacity for epidemics preparedness	Reinforce the link between research, innovation and, where appropriate, education, training and other policies, including complementarities with national, regional and Union research and innovation policies and activities	Workshops between recipients and feedback discussions between european funding institutions and networks (ex-GloPID-R) including GH EDCTP3 Member States representatives to find synergies between GH EDCTP3 Member States additional activities.	1.130.000

Nr	GH EDCTP3 Member State	Title	Short description	Funding organisation	Duration (months)	sub-Saharan African countries involved	Keywords	Type of Activity	Comments	Co-funding	Contribution to GH EDCTP3 specific objectives	Contribution to Horizon Europe operational objectives	Planned task to link with other EDCTP Member State Additional Activity	Estimated budget commitment (€)
IKAA2022- 3333	Norway	Support to Covid-19 Therapeutics Accelerator	The COVID-19 Therapeutics Accelerator (CTA) is a philanthropic collaboration supporting efforts to research, develop and bring effective treatments against COVID-19 to market quickly and accessibly. Through the CTA and the Wellcome Trust, The Research Council of Norway supports the RECOVERY trial that includes sites in Ghana and South Africa.	The Research Council of Norway	36	Ghana, South Africa	COVID-19; Drugs; Diagnostics	Research and Innovation	n/a	The Wellcome Trust	Advance development and use of new or improved technologies	Reinforce and spread excellence, including by fostering wider participation and boosting collaborative links throughout the Union	Monthly web-meetings between the Wellcome Trust, Foreign, Commonwealth & Development Office (UK), Swiss Agency for Development and Cooperation, the Research Council of Norway + more, that include GH EDCTP3 Member States representatives will take place to find synergies between GH EDCTP3 Member States additional activities.	200.000
IKAA2022- 3334	France	ANRS-MIE Annual Call for Proposals 2022-1	The ANRS-MIE funds grant applications for clinical research, capacity building initiatives, doctoral and post-doctoral grants, via the launch of two annual generic calls for proposals (CFP) on HIV, STIs, viral hepatitis, TB, including research on co-infections.	ANRS Emerging Infectious Diseases (ANRS EID)		Burkina Faso, Madagascar, Cameroon, Cote d'Ivoire	HIV; Tuberculosis; COVID-19; Hepatitis; Viral hemorrhagic fever (VHFs)	Coordination and support	n/a	n/a	Strengthen capacity for epidemics preparedness	Reinforce the link between research, innovation and, where appropriate, education, training and other policies, including complementarities with national, regional and Union research and innovation policies and activities	The project is linked to the EDCTP-funded trial with reference RIA2019PD-2884- PMC-II. A meeting will be organised with other EDCTP3 Member State(s) to find synergies between GH EDCTP3 additional activities.	1.000.000
IKAA2022- 3335	France	ANRS-MIE Annual Call for Proposals 2022-2	The ANRS-MIE funds grant applications for clinical research, capacity building initiatives, doctoral and post-doctoral grants, via the launch of two annual generic calls for proposals (CPP) on HIV, STIs, viral hepatitis, TB, including research on co-infections.	ANRS Emerging Infectious Diseases (ANRS EID)	48	TBD	HIV; Tuberculosis; COVID-19; Hepatitis; Viral hemorrhagic fever (VHFs)	Coordination and support	n/a	n/a	Strengthen capacity for epidemics preparedness	Reinforce the link between research, innovation and, where appropriate, education, training and other policies, including complementarities with national, regional and Union research and innovation policies and activities	Workshops between recipients and feedback discussions between european funding institutions and networks (ex-GloPID-R) including GH EDCTP3 Member States representatives to find synergies between GH EDCTP3 Member States additional activities.	3.000.000
IKAA2022- 3336	France	ANRS-MIE Ad Hoc Call for Proposals LONG COVID 2022	The 2022 Ad Hoc CFP aims to fund research grants specifically on Long COVID.	ANRS Emerging Infectious Diseases (ANRS EID)	48	TBD	COVID-19	Coordination and support	n/a	n/a	Strengthen capacity for epidemics preparedness	Reinforce the link between research, innovation and, where appropriate, education, training and other policies, including complementarities with national, regional and Union research and innovation policies and activities	Workshops between recipients and feedback discussions between european funding institutions and networks (ex-GloPID-R) including GH EDCTP3 Member States representatives to find synergies between GH EDCTP3 Member States additional activities.	1.000.000

Nr	GH EDCTP3 Member State	Title	Short description	Funding organisation	Duration (months)	sub-Saharan African countries involved	Keywords	Type of Activity	Comments	Co-funding	Contribution to GH EDCTP3 specific objectives	Contribution to Horizon Europe operational objectives	Planned task to link with other EDCTP Member State Additional Activity	Estimated budget commitment (€)
IKAA2022- 3337	France	ANRS-MIE Annual support for Research Partner Sites 2022	The ANRS-MIE ensures, through annual funding, to establish a secretariat and a common management for the research in progress, to rehabilitate and strengthen infrastructures, to support the training of young national researchers, to multiply the exchanges between North-South and South-South researchers, and to develop the interactions with the civil society	ANRS Emerging Infectious Diseases (ANRS EID)	12	Burkina Faso, Cameroon, Cote d'Ivoire, Senegal	HIV; Tuberculosis; COVID-19; Hepatitis; Viral hemorrhagic fever (VHFs)	Coordination and support	n/a	n/a	Strengthen capacity for epidemics preparedness	Reinforce the link between research, innovation and, where appropriate, education, training and other policies, including complementarities with national, regional and Union research and innovation policies and activities	Workshops between recipients and feedback discussions between european funding institutions and networks (ex-GloPID-R) including GH EDCTP3 Member States representatives to find synergies between GH EDCTP3 Member States additional activities.	1.230.000
IKAA2022- 3338	France	ANRS-MIE Ad Hoc Call for Proposals EID 2022	The 2022 Ad Hoc CFP aims to fund research on any emerging infectious disease that needs further support in LMICs, such as Ebola, Lassa fever, Marburg fever, etc, depending on the urgency and the needs expressed by local authorities.	ANRS Emerging Infectious Diseases (ANRS EID)	48	TBD	Emerging infections, incl. Ebola, Lassa Fever; COVID-19	Coordination and support	n/a	n/a	Strengthen capacity for epidemics preparedness	Reinforce the link between research, innovation and, where appropriate, education, training and other policies, including complementarities with national, regional and Union research and innovation policies and activities	Discussion with European funders to present and align our efforts and present the previous CFP results in order to better align. (ex GloPID-R) including GH EDCTP3 Member States representatives to find synergies between GH EDCTP3 Member States additional activities.	6.000.000
IKAA2022- 3339	France	ANRS-MIE Special projects funded outside CFPs	The ANRS-MIE funds grant applications for clinical research, capacity building initiatives, doctoral and post-doctoral grants, via the launch of two annual generic calls for proposals (CFP) on HIV, STIs, viral hepatitis, TB, including research on co-infections. The ANRS- MIE can also fund special projects outside annual CFPs or ad hoc CFPs	ANRS Emerging Infectious Diseases (ANRS EID)	24	TBD	Viral hemorrhagic fever (VHFs)	Coordination and support	n/a	n/a	Strengthen capacity for epidemics preparedness	Reinforce the link between research, innovation and, where appropriate, education, training and other policies, including complementarities with national, regional and Union research and innovation policies and activities	Workshops between recipients and feedback discussions between european funding institutions and networks (ex-GloPID-R), including with one or more GH EDCTP3 Member State will take place to find synergies between GH EDCTP3 Member States additional activities.	600.000
IKAA2022- 3340	France	Operational Research Call for proposal 2022	Support to operational research projects on HIV, HPV and associated cancers	L'Initiative/Exp ertise France	48	TBD	HIV; Human papillomavirus (HPV)	Research and Innovation	Final selection of projects in October 2022	n/a	Strengthen research and innovation capacity	Strengthen scientific excellence, including by considering, where relevant, state-of-the-art basic and frontier research findings in the implementation of their activities	A teleconference with one or more GH EDCTP3 Member State to find synergies between GH EDCTP3 Member States additional activities.	3.600.000

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IKAA2022- 3341	France	Strategic research funding on Artemisia	Support to a multidisciplinary project around a public health crucial issue in Sub-saharan Africa: "Increasing use of Artemisia herbal teas as antimalarials: societal reality, health risk and therapeutic potential, a multidisciplinary approach"	L'Initiative/Exp ertise France	36	Benin, Cameroon, Gabon	Malaria	Research and Innovation	n/a	AVIESAN-I3M, Coromandel Fund, Ingelheim Fund	Strengthen research and innovation capacity	Strengthen scientific excellence, including by considering, where relevant, state-of-the-art basic and frontier research findings in the implementation of their activities	A team from Germany (University of Tübingen) is involved. We will organise a meeting with GH EDCTP3 Germany representative to discusst the study and to find synergies between GH EDCTP3 Member States additional activities.	880.000
IKAA2022- 3342	Norway	Implementing Post-discharge Malaria Chemoprevent ion (PMC) to reduce child mortality	The project will study the implementation of routine malaria prevention among children in Malawi who have suffered and treated at hospital for severe anaemia to reduce child mortality and morbidity. The project will use an innovative two-stage formative research approach to prospectively study the full-scale implementation of PMC in Malawi.	The Research Council of Norway	72	Malawi	Implementation research; Health systems; Malaria; Drugs	Research and Innovation	n/a	n/a	Advance development and use of new or improved technologies	Reinforce and spread excellence, including by fostering wider participation and boosting collaborative links throughout the Union	The project is linked to the EDCTP-funded trial with reference RIA2019PD-2884- PMC-II. A meeting will be organised with other EDCTP3 Member State(s) to find synergies between GH EDCTP3 additional activities.	1.669.000
IKAA2022- 3343	France		To boost Covid-19 variant surveillance in 13 African countries by strengthening laboratory genomic sequencing capacity.	French development agency (AFD)	24	Benin, Burkina Faso, Cameroon, Cote d'Ivoire, Ghana, Guinea, Madagascar, Mali, Niger, The Democratic Republic of the Congo, Central African Republic.	COVID-19	Research and Innovation	Funding approved in 2021 and activities launched at the end of 2021 but project mainly implemented in 2022 and 2023	n/a	Strengthen research and innovation capacity	Strengthen international cooperation in support of Union policy objectives and international commitments	Discussions within the working group of the Team Europe initiative on epidemic surveillance and preparedness led by the European Commission (INTPA) and attended by several EU member states and with other GH EDCTP3 Member State(s) to find synergies between GH EDCTP3 additional activities.	10.000.000
IKAA2022- 3344	France	DNDi+	To support the development and access to adapted, affordable and safe treatments against neglected tropical diseases via support to DNDi programmes on tripanosomiasis, HIV and dengue	French development agency (AFD)	36	TBD	HIV; Dengue/Severe Dengue; HIV: Dengue/Severe Dengue; Human African trypanosomiasis (sleeping sickness)	Research and Innovation	Pluri annual support awarded in 2019. This IKAA refers to the funding awarded for specific years 2021 and 2022.	Several	Strengthen research and innovation capacity	Strengthen international cooperation in support of Union policy objectives and international commitments	Funding contributing to broaded projects/ programmes approved by DNDi board on which several representatives from EU member states sit, and co-funded by several donors(other EU member states and GH EDCTP3 Member States). Discussion will take place to find synergies with other GH EDCTP3 Member States additional activities.	3.000.000

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IKAA2022- 3345	France	Funding of a doctoral thesis	ARTS - capacity building programme in southern countries to promote the completion of doctoral theses and the scientific training of students from southern countries	Institut de Recherche pour le Développeme nt (IRD)	36	Burkina Faso, Senegal, Cote d'Ivoire, Mali, Benin, Ghana, Cameroon	HIV; Malaria; Tuberculosis; Neglected Infectious Diseases (NID)	Training	In 2021 the global health situation, and the resulting travel restrictions, have impacted these activities to varying degrees. Some activities have been rescheduled for 2022.	n/a	Strengthen research and innovation capacity	Strengthen international cooperation in support of Union policy objectives and international commitments	Short exchange of Member IRD with another GH EDCTP3 Member State to find synergies between GH EDCTP3 additional activities.	100.000
IKAA2022- 3346	France	International Research Network (IRN/GDRI- Sud)	challenges posed by falciparum malaria	Institut de Recherche pour le Développeme nt (IRD)	36	Senegal, Mali, Mauritania	Malaria; Emerging infections, incl. Ebola, Lassa Fever, NID; AMR	Coordination and support	In 2021 the global health situation, and the resulting travel restrictions, have impacted these activities to varying degrees. Some activities have been rescheduled for 2022.	n/a	Strengthen research and innovation capacity	Strengthen international cooperation in support of Union policy objectives and international commitments	Short exchange of Member IRD with another GH EDCTP3 Member State to find synergies between GH EDCTP3 additional activities.	80.000
IKAA2022- 3347	France	Young Teams Associated with IRD (JEAI)	The Young Team Associated with IRD contributes to the emergence and strengthening of research structures in partner countries by supporting the development of research teams in the South	Institut de Recherche pour le Développeme nt (IRD)	36	Burkina Faso, Benin, Cameroon, Senegal, Guinea	Malaria; Emerging infections, incl. Ebola, Lassa Fever, NID; AMR	Coordination and support	In 2021 the global health situation, and the resulting travel restrictions, have impacted these activities to varying degrees. Some activities have been rescheduled for 2022.	n/a	Strengthen research and innovation capacity	Strengthen international cooperation in support of Union policy objectives and international commitments	Short exchange of Member IRD with another GH EDCTP3 Member State to find synergies between GH EDCTP3 additional activities.	95.400
IKAA2022- 3348	France	MERIT Activities	particular malaria and helminths) aimed	Institut de Recherche pour le Développeme nt (IRD)	24	Benin, Ghana	Malaria; Lower respiratory infections; Non-communicable diseases; Climate crisis-related infect diseases	Research and Innovation	n/a	n/a	Strengthen capacity for epidemics preparedness	Strengthen international cooperation in support of Union policy objectives and international commitments	Short exchange of Member IRD with another GH EDCTP3 Member State to find synergies between GH EDCTP3 additional activities.	730.000
IKAA2022- 3349	France	TRANSVIHMI Activities	THE UMR 233 mainly studies the specificities of HIV infection in the South and its consequences for consequences for the populations. also Tuberculosis and other neglected tropical diseases such as filariasis and, more and more recently the Ebola virus infection.	Institut de Recherche pour le Développeme nt (IRD)	60	Guinea, Cameroon, The Democratic Republic of the Congo, Senegal, Mali, Cote D'Ivoire, Uganda	HIV: Emerging infections, incl. Ebola, Lassa Fever, Tuberculosis; AMR	Research and Innovation	n/a	n/a	Strengthen capacity for epidemics preparedness	Strengthen international cooperation in support of Union policy objectives and international commitments	Short exchange of Member IRD with another GH EDCTP3 Member State to find synergies between GH EDCTP3 additional activities.	770.000

Nr	GH EDCTP3 Member State	Title	Short description	Funding organisation	Duration (months)	sub-Saharan African countries involved	Keywords	Type of Activity	Comments	Co-funding	Contribution to GH EDCTP3 specific objectives	Contribution to Horizon Europe operational objectives	Planned task to link with other EDCTP Member State Additional Activity	Estimated budget commitment (€)
IKAA2022- 3350	France	MIVEGEC Activities	The mission of the unit is to understand the replication and transmission processes of infectious agents and their transmission dynamics, to study their possible vectors, and to analyse the strategies and mechanisms.	Institut de Recherche pour le Développeme nt (IRD)	60	Senegal, Burkina Faso, Cameroon, Cote d'Ivoire, Zimbabwe	HIV; Malaria; Emerging infections, incl. Ebola, Lassa Fever	Research and Innovation	n/a	n/a	Strengthen capacity for epidemics preparedness	Strengthen international cooperation in support of Union policy objectives and international commitments	Short exchange of Member IRD with another GH EDCTP3 Member State to find synergies between GH EDCTP3 additional activities.	120.000
IKAA2022- 3351	France	INTERTRYP Activities	The research focuses on the integrated study of humans and animals, with a One Health approach, of trypanosomiasis, leishmaniasis and Chagas disease in order to improve the control and elimination of these diseases.	Institut de Recherche pour le Développeme nt (IRD)	60	Guinea, Burkina Faso, Senegal, Cote d'Ivoire	Neglected Infectious Diseases (NID)	Research and Innovation	n/a	n/a	Strengthen capacity for epidemics preparedness	Strengthen international cooperation in support of Union policy objectives and international commitments	Short exchange of Member IRD with another GH EDCTP3 Member State to find synergies between GH EDCTP3 additional activities.	450.000
IKAA2022- 3352	France	VITROME Activities	The unit develops its activities on Vector-borne diseases and their arthropod vectors (such as mosquitoes, ticks, lice, fleas,), zoonoses, the IRD teams based in Dakar conduct research on malaria and emerging diseases in particular	Institut de Recherche pour le Développeme nt (IRD)	24	Senegal, Mali, Mauritania	Malaria; Emerging infections, incl. Ebola, Lassa Fever;	Research and Innovation	n/a	n/a	Strengthen capacity for epidemics preparedness	Strengthen international cooperation in support of Union policy objectives and international commitments	Short exchange of Member IRD with another GH EDCTP3 Member State to find synergies between GH EDCTP3 additional activities.	110.000
IKAA2022- 3353	France	Support to Laboratory at the University Hospital	Strenghtening of the laboratory at the University Hospital of Bobo Dioulasso in terms of diagnosis capacity, and epidemic surveilance and research with a focus on AMR	Fondation Mérieux	24	Burkina Faso	AMR	Other	Fondation Mérieux is a foundation with a public-interest status	n/a	Strengthen capacity for epidemics preparedness	Strengthen scientific excellence, including by considering, where relevant, state-of-the-art basic and frontier research findings in the implementation of their activities	A virtual presentation of the RESAMAD network with improved facilities will be organised for other GH EDCTP3 Member States to find synergies with other GH EDCTP3 additional activities	1.400.000
IKAA2022- 3354	France	RESAMAD	Network building for laboratories at public hospitals. Implementation and improvement of Quality Management Systems, implementation and improvement of Bacteriology Unit, implementation of laboratory-based epidemic surveillance	Fondation Mérieux	36	Madagascar	AMR	Other	Fondation Mérieux is a foundation with a public-interest status	n/a	Strengthen capacity for epidemics preparedness	Strengthen international cooperation in support of Union policy objectives and international commitments	A virtual presentation of the RESAMAD network with improved facilities will be organised for other GH EDCTP3 Member States to find synergies with other GH EDCTP3 additional activities	450.000
IKAA2022- 3355	France	CircUs	To characterize the circulation of antimicrobial resistance in the three One Health areas and in three habitat types (urban, peri-urban and rural)	Institut national de la santé et de la recherche médicale (INSERM)		Madagascar, Cote d'Ivoire	AMR	Research and Innovation	n/a	n/a	Promote networking, building partnerships and strategic alliances	Strengthen international cooperation in support of Union policy objectives and international commitments	Exchanges with the SHARENET project partners in Laos, Mauritius and Senegal, and with experts and representatives of the GH EDCTP3 JU to find synergies between GH EDCTP3 additional activities.	700.000

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IKAA2022- 3356	France	RAMSES	To explore the socio-economic and regulatory factors influencing the emergence and spread of antimicrobial resistance, understand the links between these factors, and identify ways of improving AMR monitoring and control actions in LMICs	Institut national de la santé et de la recherche médicale (INSERM)	18	Burkina Faso, Madagascar, Cote d'Ivoire	AMR	Research and Innovation	n/a	n/a	Promote networking, building partnerships and strategic alliances	Strengthen international cooperation in support of Union policy objectives and international commitments	Exchanges with the SHARENET project partners in Laos, Mauritius and Senegal, and with experts and representatives of the GH EDCTP3 JU to find synergies between GH EDCTP3 additional activities.	308.000
IKAA2022- 3357	France	AMR-Sud 2021	Creation of a research network with low- and middle-income countries to develop transnational collaborative research on antimicrobial resistance	Institut national de la santé et de la recherche médicale (INSERM)	12	Burkina Faso, Madagascar, Cote d'Ivoire	AMR	Strategic partnership building	n/a	n/a	Promote networking, building partnerships and strategic alliances	Strengthen international cooperation in support of Union policy objectives and international commitments	Exchanges with the SHARENET project partners in Laos, Mauritius and Senegal, and with experts and representatives of the GH EDCTP3 Ju to find synergies between GH EDCTP3 additional activities.	50.000
IKAA2022- 3358	France	AMR-Sud 2022	Creation of a research network with low- and middle-income countries to develop transnational collaborative research on antimicrobial resistance	Institut national de la santé et de la recherche médicale (INSERM)	12	Burkina Faso, Madagascar, Cote d'Ivoire	AMR	Strategic partnership building	n/a	n/a	Promote networking, building partnerships and strategic alliances	Strengthen international cooperation in support of Union policy objectives and international commitments	Exchanges with the SHARENET project partners in Laos, Mauritius and Senegal, and with experts and representatives of the GH EDCTP3 JU to find synergies between GH EDCTP3 additional activities.	317.000
IKAA2022- 3359	France	Inserm support to IDs research in Africa - 2021	Translational research activities on TB, Malaria, and other chronic and emerging infections	Institut national de la santé et de la recherche médicale (INSERM)	12	Burkina Faso, South Africa, Chad, Uganda, Zambia, Gambia	Malaria; Emerging infections, incl. Ebola, Lassa Fever; Tuberculosis; Translational research; Chronic infections	Research and Innovation	Contribution to the salaries of staff members working in studies with African countries	n/a	Advance development and use of new or improved technologies	Strengthen scientific excellence, including by considering, where relevant, state-of-the-art basic and frontier research findings in the implementation of their activities	A teleconference will be organized with one or more GH EDCTP3 Member State(s) to find synergies between GH EDCTP3 additional activities.	54.000
IKAA2022- 3360	France	Inserm support to IDs research in Africa - 2022	Translational research activities on TB, Malaria, and other chronic and emerging infections	Institut national de la santé et de la recherche médicale (INSERM)	12	Burkina Faso, South Africa, Chad, Uganda, Zambia, Gambia	Malaria; Emerging infections, incl. Ebola, Lassa Fever, Tuberculosis; Translational research; Chronic infections	Research and Innovation	Contribution to the salaries of staff members working in studies with African countries	n/a	Advance development and use of new or improved technologies	Strengthen scientific excellence, including by considering, where relevant, state-of-the-art basic and frontier research findings in the implementation of their activities	A teleconference will be organized with one or more GH EDCTP3 Member State(s) to find synergies between GH EDCTP3 additional activities.	73.000

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IKAA2022- 3361	United Kingdom	MRC Research Grants 2022	MRC funds research through a range of grants and highlight notices in response-mode via MRC Research Boards and Panels. The MRC supports research in all major disease areas across the biomedical spectrum, from fundamental lab-based science to early phase clinical trials.	Medical Research Council	60	TBD	TBD	Research and Innovation	n/a	n/a	Advance development and use of new or improved technologies	Strengthen scientific excellence, including by considering, where relevant, state-of-the-art basic and frontier research findings in the implementation of their activities	Information exchanged with other GH EDCTP3 Member States in preparation for dialogue on partnership opportunities and to find synergies between GH EDCTP3 additional activities.	3.606.723
IKAA2022- 3362	United Kingdom	MRC Fellowships 2022	MRC offers a range of fellowship schemes to meet diverse needs allowing training placements in the UK, abroad or in industry. Aimed at supporting a range of career development and capacity strengthening opportunities for scientists at all levels and across the breadth of biomedical research	Medical Research Council	60	TBD	TBD	Training	n/a	n/a	Advance development and use of new or improved technologies	Strengthen scientific excellence, including by considering, where relevant, state-of-the-art basic and frontier research findings in the implementation of their activities	Information exchanged with other GH EDCTP3 Member States in preparation for dialogue on partnership opportunities and to find synergies between GH EDCTP3 additional activities.	1.803.361
IKAA2022- 3363	United Kingdom	MRC Unit The Gambia at LSHTM	The Unit's vision is to improve health worldwide by leading health research in Africa. It aims to deliver this through investment in three major research themes: Disease Elimination and Control, Vaccines and Immunity and Nutrition Planetary Health	Medical Research Council, Foreign, Commonwealt h & Development Office	60	Gambia, Senegal	Maternal and child health; Pharmacovigilance; Capacity development; Health systems; Diarrhoeal diseases; Malaria; Co- infections; Tuberculosis; Vaccines; Drugs; Diagnostics	Research and Innovation	n/a	n/a	Advance development and use of new or improved technologies	Strengthen international cooperation in support of Union policy objectives and international commitments	Information exchanged with other GH EDCTP3 Member States in preparation for dialogue on partnership opportunities and to find synergies between GH EDCTP3 additional activities.	43.280.675
IKAA2022- 3364	United Kingdom	Global Health Trials 2022	Randomised controlled trials addressing any major health related problem affecting LMICs, particularly those that affect the most vulnerable populations. Focus on late-stage (equivalent to phase III/IV) clinical and health intervention trials that evaluate efficacy and effectiveness	Medical Research Council, Foreign, Commonwealt h & Development Office	60	TBD	TBD	Research and Innovation	n/a	n/a	Advance development and use of new or improved technologies	Strengthen scientific excellence, including by considering, where relevant, state-of-the-art basic and frontier research findings in the implementation of their activities	Information exchanged with other GH EDCTP3 Member States in preparation for dialogue on partnership opportunities and to find synergies between GH EDCTP3 additional activities.	9.617.928
IKAA2022- 3365	United Kingdom	Applied Global Health Research 2022	the health of vulnerable populations living in LMICs to develop practical solutions to health challenges. This includes implementation research	Medical Research Council, Foreign, Commonwealt h & Development Office	60	TBD	TBD	Research and Innovation	n/a	n/a	Advance development and use of new or improved technologies	Strengthen scientific excellence, including by considering, where relevant, state-of-the-art basic and frontier research findings in the implementation of their activities	Information exchanged with other GH EDCTP3 Member States in preparation for dialogue on partnership opportunities and to find synergies between GH EDCTP3 additional activities.	1.202.241

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IKAA2022- 3367	Spain	Mozambique: Health research capacity for evidence based decisions	To build research capacity and promote translation of evidence into interventions to reduce the burden of infectious diseases in sub-Saharan Africa. The specific objective of this lkka is to consolidate the Fundação Manhiça Research Center as a Mozambican institution of reference in biomedical and public health research.	Spanish Agency of Cooperation for the Development	12	Mozambique	Maternal and child health; Epidemiology; Implementation research; Demography; Capacity development; Health systems; HIV; Diarrhoeal diseases; Lower respiratory infections; Tuberculosis; COVID-19; Vaccines; Drugs; Diagnostics	Coordination and support	It is a continuous Heal research program periodically incorporate new activities while others close. Is a Spanish Research platform on PRNED leading by GHI f Barcelona in partnership with the FM	Cataluya Government	Strengthen research and innovation capacity	Reinforce the link between research, innovation and, where appropriate, education, training and other policies, including complementarities with national, regional and Union research and innovation policies and activities	It is about fully open program GHI of Barcelona/Fund Manhia are active organisations, participating in almost all EDCTP Calls always in partnership with some of the European member GH EDCTP3 Member State to find synergies between GH EDCTP3 additional activities.	1.125.000
IKAA2022- 3368	Spain	Equatorial Guinea : Support for health research capacities	Spanish National Centre of Tropical Medicine supporting scientifically to the EG National Endemic Control programs for prevention and control of HIV / AIDS, Malaria, tuberculosis and neglected tropical diseases. Evidence- based research on the prevention and control for policy making. Counterpart: Public Health and Social Being Ministry of EG	Spanish National Agency for Cooperation and Development	12	Equatorial Guinea	Maternal and child health; Epidemiology; Operational research; Implementation research; Capacity development; Health systems; HIV; Echinococcosis; Foodborne trematodiases; Lymphatic filariasi; Onchocerciasis (river blindness); Schistosomiasis; Buruli ulcer; Soil-transmitted helminthiases; Leprosy (Hansen disease); Trachoma; Malaria; Human African trypanosomiasis (sleeping sickness); Cysticercosis/Taeniasis; COVID- 19; Drugs	Coordination and support	It is a continuous HR program which periodically incorporate new activities while others close. Is one of the Spanish HR platform on PRNED in partnership with Public Health Well Being Ministry.	WHO Expanded Special Project for elimination of NTD	Strengthen research and innovation capacity	Strengthen international cooperation in support of Union policy objectives and international commitments	Both CNMT (implementing unit) and TBIV Program are having talks currently in order to add a new EG clinical trail site into the ongoing new born TBC vaccine phase II assay (MTBVAC project). Discussion with other GH EDCTP3 Member State(s) will take place to find synergies between GH EDCTP3 additional activities.	325.000
IKAA2022- 3369	Belgium		To increase the quality of, and access to health care; includes 7 African country- programms with development, education, research and synergy building activities. A flanking subprogram (i) offers scholarships to African staff and students, (ii) enables synergies with relevant African and international programs like EDCTP3, and network opportunities on transversal themes	Belgian Directorate- general for Development Cooperation and Humanitarian Aid (DGD)	60	Benin, Burkina Faso, Burundi, Cameroon, DR Congo, Ethiopia, Guinea, Kenya, Madagascar, Mozambique, Niger, Rwanda, Senegal, South Africa, Tanzania, Uganda, Zimbabwe	Maternal and child health; Capacity development; Health systems; HIV; Malaria; Emerging infections, incl. Ebola, Lassa Fever; Tuberculosis; Human African trypanosomiasis (sleeping sickness); Leishmaniases; Vaccines; Drugs; Diagnostics, Sexual and Reproductive Health; AMR; NTDs; One Health; Climate Change and Health	Coordination and support	This program also includes research & innovation, training and strategic partnership building.	n/a	Strengthen research and innovation capacity	Strengthen international cooperation in support of Union policy objectives and international commitments	Meetings with one or more other EDCTP Member States active in the African countries targeted by this BE program to find synergies with other GH EDCTP3 Member States additional activities.	6.447.800

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IKAA2022- 3370	Belgium	ITM Clinical Trial Unit	to ensure the coordination, quality assurance, efficiency, conformity, and technical support of clinical studies for new drugs, vaccines, diagnostics and/or anti-human disease in developing countries for infectious diseases and other research domains relevant for ITM, with a multidisciplinary team (10- 12 FTE) that supports, sets-up and coordinates GCP-regulatory compliant observational/interventional studies.	Flemish Ministry of Economy, Sciences and Innovation	36	Benin, Burkina Faso, Burundi, Cameroon, DR Congo, Ethiopia, Guinea, Kenya, Madagascar, Mozambique, Niger, Rwanda, Senegal, South Africa, Tanzania, Uganda, Zimbabwe	Ethics; Data management; Capacity development; HIV; Malaria; Emerging infections, incl. Ebola, Lassa Fever; Tuberculosis; Human African trypanosomiasis (sleeping sickness); Leishmaniases; COVID- 19; Vaccines; Drugs; Diagnostics; AMR; NTDs; One Health	Coordination and support	Also includes training	n/a	Advance development and use of new or improved technologies	Strengthen scientific excellence, including by considering, where relevant, state-of-the-art basic and frontier research findings in the implementation of their activities	Interaction with other GH EDCTP3 Member States through participation in the clinical research networks active in African continent to find synergies with other GH EDCTP3 Member States additional activities.	900.000
IKAA2022- 3371	Belgium	ITM Outbreak Research Team	The multidisciplinary team (7-8 FTE) conducts research and builds capacity in low-resources settings with a mission to strengthen the evidence-base for improved outbreak preparedness, response, recovery and resilience through inter-disciplinary applied research.	Flemish Ministry of Economy, Sciences and Innovation	36	Benin, Burkina Faso, Burundi, Cameroga, DR Congo, Ethiopia, Guinea, Kenya, Madagascar, Mozambique, Niger, Rwanda, Senegal, South Africa, Tanzania, Uganda, Zimbabwe	Epidemiology; Capacity development; Malaria; Emerging infections, incl. Ebola, Lassa Fever; Dengue/Severe Dengue; COVID-19; Drugs; Diagnostics; NTDs; One Health; Climate Change and Health	Research and Innovation	Also includes support and training.	n/a	Strengthen capacity for epidemics preparedness	Strengthen scientific excellence, including by considering, where relevant, state-of-the-art basic and frontier research findings in the implementation of their activities	Interaction with other GH EDCTP3 Member States through participation in the outbreak and response networks active in African continent to find synergies with other GH EDCTP3 Member States additional activities.	900.000
IKAA2022- 3372	Netherlan ds	Product Development Partnerships IV	Funding development of more effective, simple and cheaper drugs, vaccines, diagnostics and other products developed for SRHR and poverty-related conditions and diseases in the product pipeline and in the market, especially for to women and girls of reproductive age in LMIC.	Ministry of Foreign Affairs	60	TBD	Drugs; Vaccines; Diagnostics; Sexual and Reproductive Health	Research and Innovation	Ministerial approval anticipated in March 2022	n/a	Advance development and use of new or improved technologies	Reinforce and spread excellence, including by fostering wider participation and boosting collaborative links throughout the Union	NL will coordinate and align with other GH EDCTP3 PSs on support for PDPs through its participation in the PDP Funders Group teleconferences and meetings.	30.000.000
IKAA2022- 3373	Portugal	Minimizing the emergence and dissemination of HIV-1 drug resistance	Generation of more accurate information about circulating antiretroviral drug resistance in HIV-1 strains in Africa, treatment experience and levels of transmitted and acquired drug resistance, through a combination of data collection with portable high-throughput sequencing, mathematical modelling and data mining.The researchers expect to influence public health policies and treatment guidelines.	Fundação para a Ciência e a Tecnologia	36	Mozambique, Sao Tome and Principe	HIV	Research and Innovation	n/a	n/a	Advance development and use of new or improved technologies	Encourage exploitation of research and innovation results and actively disseminate and exploit results, in particular for leveraging private investments and for policy development	A teleconference or workshop is going to be organised with one or more GH EDCTP3 Member State to find synergies with other GH EDCTP3 Member State(s) additional activities.	249.289

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IKAA2022- 3374	Germany	CEPI Core funding	Stimulating and accelerating the development of vaccines against emerging infectious diseases and enable access to these vaccines for people during outbreaks	Federal Ministry of Education and Research (BMBF)	60	South Africa	Vaccines	Research and Innovation	n/a	n/a		Reinforce the link between research, innovation and, where appropriate, education, training and other policies, including complementarities with national, regional and Union research and innovation policies and activities	Other relevant partners (e.g. Sweden, France) will be contacted in Q2/Q3 for further activities to find synergies with other GH EDCTP3 Member State(s) additional activities.	14.000.000
IKAA2022- 3375	Germany	JPIAMR	JPIAMR coordinates member states' activities and national research funding on the topic of antibiotic resistance. Through joint, transnational funding initiatives, gaps between scientists and other stakeholders (e.g. industry, healthcare systems, politics) are to be closed in particular in order to generate new research results and to lead these into application.	Federal Ministry of Education and Research (BMBF)	36	South Africa	Drugs	Coordination and support	n/a	n/a	Facilitate better alignment of countries around a common Strategic Research and Innovation Agenda	Strengthen international cooperation in support of Union policy objectives and international commitments	Other relevant partners (e.g. Sweden, France) will be contacted in Q2/Q3 for further activities to find synergies with other GH EDCTP3 Member State(s) additional activities.	2.900.000
IKAA2022- 3376	Germany	PDP core funding	Product development partnerships to develop prevention methods, vaccines, and drugs or diagnostics for the cost- effective treatment of neglected and poverty-associated diseases.	Federal Ministry of Education and Research (BMBF)	60	South Africa	HIV; Malaria; Tuberculosis; Leishmaniases	Research and Innovation	n/a	n/a	Advance development and use of new or improved technologies	Accelerate industrial transformation and resilience across the value chains, including through improving skills for innovation and advancing digital technology	Other relevant partners (e.g. Sweden, France) will be contacted in Q2/Q3 for further activities to find synergies with other GH EDCTP3 Member State(s) additional activities.	15.000.000
IKAA2022- 3377	Germany	Support to WHO TDR Programme	Building research capacity and promote translation of evidence into interventions to reduce the burden of infectious diseases in sub-Saharan Africa	Federal Ministry for Economic Cooperation and Development (BMZ)	60	TBD	Malaria; Tuberculosis; Dengue/Severe Dengue	Research and Innovation	n/a	n/a		Reinforce the link between research, innovation and, where appropriate, education, training and other policies, including complementarities with national, regional and Union research and innovation policies and activities	Other relevant partners (e.g. Sweden, France) will be contacted in Q2/Q3 for further activities to find synergies with other GH EDCTP3 Member State(s) additional activities.	4.000.000
IKAA2022- 3378	Germany	German Global Health Research Alliance (GLOHRA)	The networking platform GLOHRA aims to strengthen interdisciplinary research activities and cooperation in global health, to enable the early involvement of young scientists and to promote the translation of research results into practice and politics.	Federal Ministry of Education and Research (BMBF)	60	TBD	None	Research and Innovation	n/a	n/a		Reinforce the link between research, innovation and, where appropriate, education, training and other policies, including complementarities with national, regional and Union research and innovation policies and activities	Other relevant partners (e.g. Sweden, France) will be contacted in Q2/Q3 for further activities to find synergies with other GH EDCTP3 Member States additional activities.	10.000.000

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IKAA2022- 3379	Germany	UNITE4TB	Accelerating the development of new treatment regimens for Tuberculosis	Federal Ministry of Education and Research (BMBF)	24	South Africa	Tuberculosis	Research and Innovation	n/a	n/a	Advance development and use of new or improved technologies	Reinforce and spread excellence, including by fostering wider participation and boosting collaborative links throughout the Union	Other relevant partners (e.g. Sweden, France) will be contacted in Q2/Q3 for further activities to find synergies with other GH EDCTP3 Member State(s) additional activities.	7.800.000
IKAA2022- 3380	Germany	BE READY	The Coordination & Support Action (CSA) BE READY (Building a European strategic REsearch and innovation Area in Direct synergY with EU and international initiatives for Pandemic Preparedness) will prepare a European partnership for pandemic preparedness and develop a Strategic Research and Innovation Agenda for this partnership.	Federal Government (BReg)	36	TBD	COVID-19	Strategic partnership building	n/a	n/a	Strengthen capacity for epidemics preparedness	Reinforce and spread excellence, including by fostering wider participation and boosting collaborative links throughout the Union	Other relevant partners (e.g. Sweden, France) will be contacted in Q2/Q3 for further activities to find synergies with other GH EDCTP3 Member State(s) additional activities.	3.000.000
IKAA2022- 3381	Germany	Research Networks for Health Innovations in Sub-Sahara Africa	Establishing and expanding research capacities and strengthening intra- African and inter-African-German networking	Federal Ministry of Education and Research (BMBF)	60	TBD	Lymphatic filariases; Tuberculosis; Cysticercosis/Taeniasis	Research and Innovation	n/a	n/a	Strengthen research and innovation capacity	Strengthen scientific excellence, including by considering, where relevant, state-of-the-art basic and frontier research findings in the implementation of their activities	Other relevant partners (e.g. Sweden, France) will be contacted in Q2/Q3 for further activities to find synergies with other GH EDCTP3 Member State(s) additional activities.	20.000.000
IKAA2022- 3382	Germany	Global Health Protection Programme (GHPP)	The GHPP supports the expansion of international cooperation capacities to ensure necessary epidemiological investigations, the implementation of infection control measures, adequate laboratory diagnostics, patient support and accompanying research studies.	Federal Ministry of Health (BMG)	36	TBD	Malaria; COVID-19	Research and Innovation	n/a	n/a	Strengthen research and innovation capacity	Reinforce the link between research, innovation and, where appropriate, education, training and other policies, including complementarities with national, regional and Union research and innovation policies and activities	Other relevant partners (e.g. Sweden, France) will be contacted in Q2/Q3 for further activities to find synergies with other GH EDCTP3 Member State(s) additional activities.	44.819.580
IKAA2022- 3383	Germany	DZIF Core Funding	The DZIF works on prevention, diagnostics and therapy of infectious diseases with the focus on translation to clinics and back.	Federal Ministry of Education and Research (BMBF)	60	TBD	HIV; Malaria; Emerging infections, incl. Ebola, Lassa Fever; Tuberculosis	Research and Innovation	n/a	n/a	Strengthen research and innovation capacity	Reinforce the link between research, innovation and, where appropriate, education, training and other policies, including complementarities with national, regional and Union research and innovation policies and activities	Other relevant partners (e.g. Sweden, France) will be contacted in Q2/Q3 for further activities to find synergies with other GH EDCTP3 Member State(s) additional activities.	10.000.000

Nr	GH EDCTP3 Member State	Title	Short description	Funding organisation	Duration (months)	sub-Saharan African countries involved	Keywords	Type of Activity	Comments	Co-funding	Contribution to GH EDCTP3 specific objectives	Contribution to Horizon Europe operational objectives	Planned task to link with other EDCTP Member State Additional Activity	Estimated budget commitment (€)
IKAA2022- 3384	France	REPAIR		French Ministry of Foreign Affairs		Senegal, Cote d'Ivoire, Guinea, Niger, Central African Republic, Cameroon, Madagascar	COVID-19	Training	The countries are part of the Pasteur Network	Institut Pasteur		Strengthen international cooperation in support of Union policy objectives and international commitments	Joint online meetings gathering virologists of the IKAA2022-3384, and virologists of the AFROSCREEN project (IKAA2022-3343) are periodically organised. The objective is to maximize sharing of informations, and lessons learnt at the regional African scale with other GH EDCTP3 Member States.	2.000.000
IKAA2022- 3385	France	SARA: Surveillance of AMR in Africa	Setting up a Antimicrobial resistance surveillance in clinical samples will focus on priority pathogens (Escherichia, Klebsiella, Salmonella, Shigella and Neisseria gonorrhoeae), defined sources (urinary and blood infections; diarrhea; genital infections) and community-acquired infections.	French Ministry of Foreign Affairs	36	Cameroon, Senegal, Benin, Madagascar, Central African Republic	Klebsiella; Shigella; Gonorrhoeae	Strategic partnership building	The countries are part of the Pasteur Network		J.	Strengthen international cooperation in support of Union policy objectives and international commitments	Mutualization of training sessions on AMR with other ongoing projects in the same field for the benefit of other GH EDCTP3 Member State, to promote synergies between GH EDCTP3 Member States, and avoid any overlap.	1.000.000
IKAA2022- 3386	France	Project Monitoring of SARS-Cov 2 in wastewater		Agence Française de Développeme nt (French Agency for Development)	12	12 countries	COVID-19	Coordination and support	The countries are part of the Pasteur Network	Institut Pasteur	for epidemics	Strengthen international cooperation in support of Union policy objectives and international commitments	A teleconference with representatives of other GH EDCTP3 member countries will be organised to share their experience, and lessons learnt.	1.500.000
TOTAL CU			GET ON IKAA TO BE INITIATED IN 2022	,										300.984.3

The time for an additional activity 'to be initiated' includes the time of the call publication, the grant signature or the time when the actual research work will start.