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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 programme[2] apply *mutatis mutandis* to the GH EDCTP3 work programme.

Admissibility conditions	The conditions are described in General Annex A.

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

[2] 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

Eligibility conditions	The conditions are described in General Annex B except for the specific conditions for GH EDCTP3 funding as regards Entities eligible for funding and Consortium composition 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 States[3]
- Eligible non-EU countries:
    - Countries associated to Horizon Europe[4]

[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 Horizon Europe Programme Guide for a complete list of OCTs.

[4] See list of associated countries and https://ec.europa.eu/info/research-and-innovation/strategy/strategy-2020-2024/europe-world/international-cooperation_en

- Countries that are members of the EDCTP Association[5]

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.

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

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

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

General Annex G to the Horizon Europe work programmes

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 EDCTP website

licence regarding results should apply to participants. Therefore, the provisions set out in General Annex G to the Horizon Europe work programmes on the right to object apply generally. It should be noted that in accordance with the Council Regulation 2021/2085 establishing the Joint Undertakings under Horizon Europe[6] 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-EDCTP3-2022-01	Type of Action	Indicative GH EDCTP3 Budget (EUR million)	Expected GH EDCTP3 contribution per project (EUR million)	Number of projects expected to be funded
Opening: 6 May 2022 Deadline: 30 August 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	
Expected EU contribution per project	GH EDCTP3 estimates that an EU contribution of around EUR 4.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
Indicative budget	The total indicative budget for the topic is EUR 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 Europe[7], 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 559/2014, (EU) No 560/2014, (EU) No 561/2014 and (EU) No 642/2014; OJ L 427, 30.11.2021, p. 17

Legal and financial set-up of the Grant Agreements - Additional exploitation obligations	Also in line with Article 114 of the 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.

Expected outcome: This topic aims at supporting activities that contribute to one or several of the expected impacts for this call. To that end, proposals 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 technologies[8] 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.

Scope: 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.

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

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 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 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 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.

[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 559/2014, (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.

Expected outcome: This topic aims at supporting activities that are contributing to one or several of the expected impacts for this call. To that end, proposals 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.

Scope: 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 protocol[10]. The adaptive design of the trial provides the flexibility

[10]https://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.

Collaboration between the Global Health EDCTP3 JU and the contributing partner Bill & Melinda Gates Foundation

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/

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-CALL1-01-03 and topic GH-EDCTP3-2022-CALL1-02-02.**

Specific conditions	
Expected EU contribution per project	GH EDCTP3 estimates that an EU contribution of around EUR 5.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
Indicative budget	The total indicative budget for the topic is EUR 22.00 million
Type of Action	Research and Innovation Actions
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 this topic and grants awarded under the 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.

Expected outcome: 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.

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.

Scope: 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 programme[13] 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] ec_rtd_edctp3-sria-2022.pdf (europa.eu)

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 Platform[14], the Public Health Alliance for Genomic Epidemiology (PHA4GE)[15], the Global Alliance for Genomics & Health (GA4GH)[16] and/or the European Union-funded BY-COVID project[17];
- 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-01-41[18] 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 Excellence[19], 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 CSA2020E[21] , EDCTP's Networks of Excellence, ECDC4Africa CDC initiative[22] and EDCTP's Knowledge Hub[23], 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

Expected outcome: This topic aims at supporting activities that are contributing to one or several of the expected impacts for this call. To that end, proposals 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.

Scope: 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 Excellence[24] 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 Excellence[25] 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] http://www.edctp.org/our-work/edctp-regional-networks-of-excellence/

- 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 ALERRT[26] and PANDORA[27], 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

Expected outcome: This topic aims at supporting activities that are contributing to one or several of the expected impacts for this call. To that end, proposals 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] https://www.alerrt.global/
[27] https://www.pandora-id.net/

- 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.

Scope: 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 Excellence[29], The health systems dimension of the Global Gateway investment package[30], various Team Europe initiatives such as the Team Europe initiative (TEI) on Manufacturing and Access to Vaccines, Medicines and Health Technologies (MAV+) in Africa[31].

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

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

[30] Global Gateway investment package https://ec.europa.eu/info/strategy/priorities-2019-2024/stronger-europe-world/global-gateway/eu-africa-global-gateway-investment-package_en

[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.

Expected impact: 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.

Expected outcome: 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.

Scope: 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.

Legal entity: 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

Type of Action: 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/re-emerging 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

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.

Expected outcome: 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.

Scope: 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 Excellence[33], European COVID-19 Data Platform[34] and BY-COVID project[35];
- 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 Hub[36] and/or awarded projects under the EDCTP2's CSA2020E[37];
- 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.

Legal entities: 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

Type of Action: 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] Capacity development for disease outbreak and epidemic response in sub-Saharan Africa, in collaboration with Africa CDC - 2020 - EDCTP