

Global Health EDCTP3 Joint Undertaking Info day 2022: Work Programme & Calls

02 JUNE 2022



**Global Health
EDCTP3**

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EDCTP



Agenda

Time	Topic	Presenter/Slido Question
15:30 – 15:35	Welcome and introduction	<i>Julia Molto Lopez, Policy Officer, European Commission</i>
15:35 – 15:40	Slido poll #EDCTP3InfoDay	<ul style="list-style-type: none"> ➤ In which country are you or is your organisation based? ➤ What is your main field of expertise (in one word)?
15:40 – 15:50	General presentation of the GH EDCTP3 & the WP 2022	<i>Elmar Nimmesgern, Interim Executive Director, Global Health EDCTP3</i>
15:50 – 16:15	Short presentations on each of the topics	<i>Inmaculada Peñas Jimenez, Policy Officer, European Commission; Stefanie Sowinski, Policy Officer, European Commission; Michelle Morrison, Senior Program Officer, Bill & Melinda Gates Foundation; Elmar Nimmesgern</i>
16:15 – 17:00	Q&A session on WP2022 & topics	<i>All speakers & Stéphanie Le Berre, Legal Officer, European Commission</i>
17:00 – 17:05	Slido poll #EDCTP3InfoDay	<ul style="list-style-type: none"> ➤ Which of the call topics for 2022 are you most interested in? ➤ Which other areas do you think should be funded under the GH EDCTP3 in the future?
17:05 – 17:10	Closing remarks	<i>Julia Molto Lopez</i>

Global Health EDCTP3

European Developing Countries Clinical Trials Partnership (EDCTP)

- Created in the frame of the EU comprehensive strategy with Africa and the UN SDGs
- Building on success of EDCTP and EDCTP2



Established through an EU Council Regulation: 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe [...]

General Objectives: The Global Health EDCTP3 Joint Undertaking aims to:

- (1) Reduce the socioeconomic **burden of infectious diseases** in sub-Saharan Africa by promoting the development and uptake of new or improved health technologies, and
- (2) Increase **health security** in sub-Saharan Africa and globally, by strengthening the research- and innovation-based capacities for preparedness and response to control infectious diseases

Global Health EDCTP3 Specific Objectives

Five specific objectives:

- (1) Advance the development and use of new or improved health technologies for tackling infectious diseases by supporting the conduct of the clinical trials in sub-Saharan Africa
- (2) Strengthen research and innovation capacity and the national health research systems in sub-Saharan Africa
- (3) Facilitate better alignment of countries around a common SRIA
- (4) Strengthen capacity for epidemic preparedness in sub-Saharan Africa
- (5) Promote networking and partnerships building North–South and South–South relationships with multiple private and public-sector organisations

Partners and contributions

Founding members

- European Commission - representing the European Union
- EDCTP Association - representing European and sub-Saharan African States

Contributing partners – ad hoc in specific calls

- Philanthropies
- Industry (e.g. pharma industry)
- Other third countries

Contributions

- EUR 0.8 billion from the European Union
- EUR 0.43 billion from the EDCTP Association
- EUR 0.4 billion from Philanthropies and Industry

→ **TOTAL budget of EUR 1.6 billion**



Comparison EDCTP2/EDCTP3 - SRIA

Science/mission

- Largely a continuation of EDCTP2, with adaptations such as formally including emerging epidemics and AMR
- Strategic Research and Innovation Agenda (SRIA) developed in deliberate process over two years



Organisational setup

- New legal basis: Article 187 of the Treaty on the Functioning of the European Union
- European Commission is a formal partner
- Set-up of a 'Joint Undertaking'

Global Health EDCTP3 R&I priorities

Target diseases as specified in the Strategic Research & Innovation Agenda:

HIV, TB, malaria, neglected infectious diseases (NIDs), diarrhoeal diseases, lower respiratory tract infections, and emerging/re-emerging infections affecting sub-Saharan Africa.

→ This also includes **antimicrobial resistance, climate crisis-provoked changes in infectious disease incidence, and co-infections and co-morbidities.**

NIDs include: Buruli ulcer, dengue and chikungunya, dracunculiasis (guinea-worm disease), echinococcosis, foodborne trematodiasis, human African trypanosomiasis (sleeping sickness), leishmaniases, leprosy (Hansen disease), lymphatic filariasis, mycetoma, onchocerciasis (river blindness), rabies, schistosomiasis, soil-transmitted helminthiasis, taeniasis/cysticercosis, trachoma, and yaws. Global Health EDCTP3's remit will not cover chromoblastomycosis and other deep mycoses, scabies and other ectoparasites, and snakebite envenoming.

Calls for proposals for 2022

- Call deadline 30 August; signing of the grant agreements late in 2022 or early 2023
- Eligibility for funding as defined in the Council Regulation (EU) 2021/2085 establishing the Joint Undertakings: **EU Member States, countries associated to Horizon Europe, countries members of the EDCTP Association**
- Constituent states of the EDCTP Association that are not Member States or associated countries are: Burkina Faso, Cameroon, Congo (Rep.), Côte d'Ivoire, Ethiopia, Gabon, The Gambia, Ghana, Kenya, Mali, Mozambique, Niger, Nigeria, Senegal, South Africa, Tanzania, Uganda, United Kingdom, Zambia
- At least **one legal entity from Europe** and **one from sub-Saharan Africa** with minimum of three entities eligible to receive funding for projects to be eligible
- Other conditions aligned with Horizon Europe calls in Cluster 1 (Health) – e.g. scoring, 'right to object to transfer'
- Affordable access for “[...] products and services that they develop based or partially based on the results of clinical studies undertaken as part of an indirect action are affordable, available and accessible to the public at fair and reasonable conditions.” **specific conditions for two of the topics**

Questions to the audience: Poll

In which country are you or is your organisation based?

What is your main field of expertise (in one word)?

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

- Research and Innovation Action (RIA)
- Indicative call budget EUR 38 M
- Expected project size EUR 4 M

Expected Outcomes include

- **Uptake of research results into clinical practice** in sub-Saharan Africa so that infectious diseases can be prevented or patients can have access to safe health technologies of proven efficacy
- Widespread **adoption of research results into national and international policy guidelines**

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

Scope

- Registration and post-registration studies (such as **pragmatic effectiveness studies**) of health technologies to demonstrate the **clinical effectiveness in relevant populations**
- Identification of barriers to the uptake of new health technologies and how to address them
- Develop evaluation tools for translating research results into healthcare policy & practice
- It is expected to have early involvement and regular interaction with **policy and decision makers** as well as **end-users** to have the health technology adopted by health systems

Specific conditions to consider:

- Special conditions regarding affordable access of results
- Clinical trial template to be used

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

- **Coordination and Support Action (CSA)**
- **Indicative call budget EUR 5 M**
- **Expected project size EUR 0.6 M**

Expected Outcomes include

- Enhanced **regulatory capacity** in sub-Saharan Africa countries that supports conduct of **clinical trials**
- Improved **efficiency** regarding process of **market authorisation of health technologies**
- Improved **collaboration** between **National Regulatory Agencies** and **Ethics Committees**

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

Scope

- **Training of researchers, clinicians and National Regulatory Agencies personnel** for an efficient and robust regulatory control system for conducting clinical trials and for responsive clinical trial pharmacovigilance
- **Mapping of the clinical research oversight and pharmacovigilance systems** across the involved sub-Saharan Africa countries
- Include **active participation of National Regulatory Agencies**
- **Linkage to existing regulatory initiatives** (AVAREF, PACTR, AMRH, AMA, RCOREs) and coherence with other EU and MS initiatives

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

- Research and Innovation Action (RIA)
- Indicative call budget EUR 30.85 M
- Expected project size EUR 6 to 8 M

Expected Outcomes include

- 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**
- 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
- 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**

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

Scope

- Implementation of **adaptive platform trials** in sub-Saharan Africa that are evaluating **treatment options for infectious diseases** and are able to respond 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 disease**
 - Special attention should be paid to infections that lack treatment options or where treatments are inadequate, including those hard to treat due to antimicrobial resistance.
- Training on **clinical trial implementation and laboratory analysis**, harmonized **data collection** and **management systems** to run the adaptive platform trials

Specific conditions to consider:

- Special conditions regarding affordable access of results
- Clinical trial template to be used

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

- Coordination and Support Action (CSA)
- Indicative call budget EUR 1 M
- Expected project size EUR 1 M

Expected Outcomes include

- A well-documented **overview of operational and effective regional clinical trial and laboratory networks** in different clinical settings in sub-Saharan Africa
- An **efficient coordination and collaboration mechanism** between identified **clinical trial and laboratory networks** in sub-Saharan Africa is established
- The foundation for a **coordinated, permanent, pan-sub-Saharan African clinical trial infrastructure** to optimise a coordinated response to infectious diseases threats is laid

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

Scope

- Conducting a **mapping exercise** of the current landscape of **clinical trial and laboratory networks** in sub-Saharan Africa
- Establish a larger **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 with EDCTP's Networks of Excellence**
- Planning for **common preparedness research approaches and tools within network(s) such as clinical trial protocols and data management frameworks**
- Developing a **business plan for operationalising the pan-sub-Saharan clinical trial infrastructure** that continuously evaluates health interventions for infectious diseases in sub-Saharan Africa

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 – Partnership with the Bill & Melinda Gates Foundation

- Research and Innovation Action (RIA)
- Indicative call budget EUR 22 M
- Expected project size EUR 5 M

Expected Outcomes include

- Public health authorities **have access to genomic epidemiology data** and evidence to better develop and **implement informed public health policies** in sub-Saharan Africa
- **Genomic epidemiology data are leveraged** to help inform the design and **development of health technologies** that are affordable, accessible and impactful 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

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 – Partnership with the Bill & Melinda Gates Foundation

Scope

- Implement **translational research** demonstrating **application of genomic epidemiology** to answer specific public health questions pertaining to infectious diseases, e.g. investigation of the burden, transmission, or evolution of a pathogen; characterization of a pathogen to inform product development/public health intervention design etc.
- Integrate epidemiologic, clinical, and genomic data through **data integration platforms**
- Establish a **community of practice on genomic epidemiology**

Importantly: Genomic sequencing capabilities built by **Africa Pathogen Genomics Initiative (PGI)** expected to be leveraged; Collaboration with **the Global Health Network (tGHN)** is expected for an enabling environment for **improved data science capabilities**

For this please read *Other Action #2* (Topic GH-EDCTP3-2022-CALL1-02-02) !

Questions to the audience: Q&A session

Questions & Answers with the audience on Work Programme
2022 & the call topics

SLIDO CODE:
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If your question is not answered live during this Q&A session
please submit it to the European Commission's [Research
Enquiry Service](#)

Questions to the audience: Poll

Which of the call topics for 2022 are you most interested in?

Which other areas do you think should be funded under the GH EDCTP3 in the future?

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Important links

- [Funding and Tenders Portal](#) link to the Global Health EDCTP3 topics
- Global Health EDCTP3 (interim) [website](#)
- [Work programme text](#) published on the Global Health EDCTP3 website
- [Research Enquiry Service | European Commission \(europa.eu\)](#)
- [Open consultation](#) for the AU-EU Innovation Agenda