

Global Health EDCTP3 Joint Undertaking Info Day:

Presentation of 2023 Work Programme and funding opportunities

12 April 2023

Agenda

Time	Topic	Presenter/Slido Question
13:00 – 13:05 (CET)	Welcome & introduction	Thomas Nyirenda, Strategic Partnerships and Capacity Development Manager, EDCTP Association
13:05 – 13:10 (CET)	Poll (via Slido)	Jean Marie Vianney Habarugira, Senior Scientific Officer, Global Health EDCTP3
13:10 – 13:20 (CET)	Presentation on the Global Health EDCTP3 & requirements for eligibility	Elmar Nimmesgern, Interim Executive Director, Global Health EDCTP3
13:20 – 13:30 (CET)	Joining the EDCTP Association	Lara Pandya, Senior Strategic Partnerships Officer, EDCTP Association
13:30 – 13:50 (CET)	Global Health EDCTP3 2023 Work Programme: Single-stage calls	Jean Marie Vianney Habarugira, Senior Scientific Officer, Global Health EDCTP3
13:50 – 14:00 (CET)	Global Health EDCTP3 2023 Work Programme: Two-stage calls	Lydia Boudarène, Senior Scientific Officer, Global Health EDCTP3
14:00 – 14:55 (CET)	Q&A session (via Slido)	All (Moderation by Jean Marie Vianney Habarugira)
14:55 – 15:00 (CET)	Closing remarks	Thomas Nyirenda, Strategic Partnerships and Capacity Development Manager, EDCTP Association

Questions to the audience: Poll via **slido**

What field of research are you working in?

What do you expect from today's event?

Go to: <https://www.slido.com/>

Join as a participant by inserting this code: #EDCTP3InfoDay

→ Please submit your answers through the **Polls tab**

Global Health EDCTP3:
Short introduction and requirements for
eligibility & consortium composition

Elmar Nimmesgern, Interim Executive Director, Global Health EDCTP3

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

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**



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.

Eligibility requirements

Consortium composition: Cumulative conditions

- At least **three legal entities** established in **different countries**, where legal entities are eligible to receive funding, including:
 - At least **one** independent legal entity established in a **Member State or an associated country**
 - At least **one** independent legal entity established in a **sub-Saharan African country** that is a member of the EDCTP Association
- These rules apply to both Research and Innovation Actions (RIA) and Coordination and Support Actions (CSA)

Eligibility requirements

- Funding available to:
 - Legal entities established in Member States or associated countries
 - Legal entities based in all African countries member of the EDCTP Association

Scientific project leadership

- To ensure that all partners in the funded consortia, including sub-Saharan African entities, have equal opportunities to lead the scientific work of the project, the Governing Board of the Global Health EDCTP3 is discussing a new approach that would establish a “**Scientific Project Leader**” within each consortium
- If the coordinator is not established in a country in sub-Saharan Africa (SSA), the designation of a scientific project leader established in a SSA country member of the EDCTP Association will be mandatory. A work package on ‘scientific project leadership’ must be included

Scientific project leadership (2)

Tasks of the Scientific Project Leader could include:

- Acting as the key contact point for the GH EDCTP3 JU alongside the coordinator on scientific governance & leadership actions including external communication
- Monitoring that the scientific tasks are implemented properly
- Collaborating with the coordinator on the project monitoring and the adoption of appropriate internal measures to ensure that beneficiaries are fulfilling their obligations

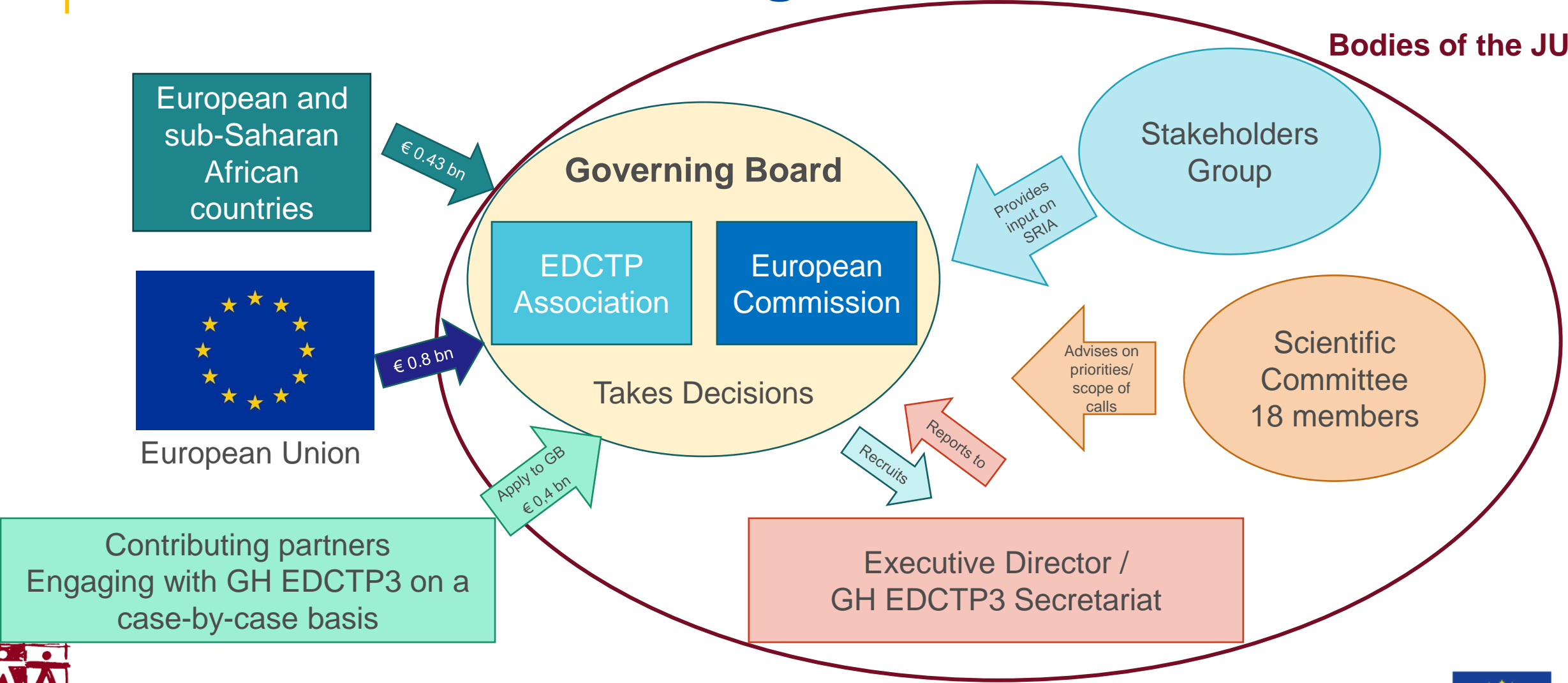
Affordable access

- The Council Regulation requires that products and services developed on the basis of results of clinical studies undertaken as part of a project are affordable, available and accessible to the public at fair and reasonable conditions
- Implemented in the work programme under certain topics with requirements for specific deliverables and additional exploitation obligations

Joining the EDCTP Association

Lara Pandya, Senior Strategic Partnerships Officer, EDCTP Association

Global Health EDCTP3 governance structure



Role of the EDCTP Association

The EDCTP Association is one of the two founding members of the Global Health EDCTP3 Joint Undertaking (JU), representing its European and sub-Saharan African Member States in the Governing Board.

The EDCTP Association has two offices:

Europe Office, The Hague, the Netherlands

- Oversees EDCTP Association governance matters in relation to the GH EDCTP JU through the EDCTP Association Board and EDCTP3 Joint Undertaking Committee
- Oversees relationship management with European and African Member States
- Contributes to GH EDCTP3 communication and outreach activities

Africa Office, Cape Town, South Africa

- Provides technical support for the design and implementation of the GH EDCTP3 capacity development activities
- Oversees relationship management with African Member States and regional stakeholders
- Contributes to GH EDCTP3 communication and outreach activities

Membership categories

As per the amended EDCTP Articles of Association, there are three membership categories according to programme participation.

Category 1
Members
participating in
EDCTP2 only

Category 2
Members
participating in GH-
EDCTP3-JU only

Category 3
Members
participating in both
EDCTP2 and GH
EDCTP3

Members of the EDCTP Association

15 European Countries

Austria, Belgium, Denmark, Finland*, France, Ireland*, Italy*, Germany, Luxembourg*, Netherlands, Norway, Portugal, Spain, Sweden and United Kingdom

24 African Countries

Burkina Faso, Cameroon, Cote d'Ivoire, Democratic Republic of Congo, Republic of Congo, Ethiopia, Gabon, Ghana, Guinea Conakry, Kenya*, Liberia, Malawi, Mali, Mozambique, Niger, Nigeria, Rwanda, Senegal, South Africa, Tanzania, The Gambia, Uganda, Zambia and Zimbabwe.

Expressions of interest received from Angola, Madagascar and Sierra Leone.

**Not (yet) committed to participation in GH EDCTP3*

Membership obligations

- **Formal letters of commitment**
- **Annual cash contributions** by category 2 and 3 members to cover the costs for the management of the Association's internal business related to participation in the GH EDCTP3 JU
 - Calculated as fixed contributions (40%) to be paid equally by all members and (60%) which will be calculated according to the member state's GDP. African members shall cover 10% and European members shall cover 90% of the cash contributions for the administrative costs.
 - Additionally, voluntary cash contributions may be made via the EDCTP Association towards the operational activities of the GH EDCTP3 JU
- **Annual in-kind contributions** by category 2 and 3 members
 - In-kind contributions to additional activities (**IKAAs**)

IKAAs explained

- IKAAs are activities funded and managed by one or more GH EDCTP3 JU participating states (PSs) – independently or jointly - that fall within the scope of the GH EDCTP3 JU
- They are the main mechanism for the EDCTP Association members to make in-kind contributions to the GH EDCTP3 JU
- IKAAs must be developed and implemented in an aligned, integrated and coherent manner by the GH EDCTP3 JU PSs and follow the GH EDCTP3 [Strategic Research and Innovation Agenda \(SRIA\)](#).
- They must be identified upfront and included in the GH EDCTP3 annual work programmes
- They contribute towards achieving the GH EDCTP3 JU objectives, including to facilitate better alignment of countries around a common SRIA, and a shared Africa-Europe research agenda
- They play an important role in informing both future national research funding priorities as well as the GH EDCTP3 JU's strategic research funding priorities.

Notes

Countries may join the EDCTP Association at any time. However, for legal entities to be eligible for funding under the open calls for proposals their respective country must be a member of the EDCTP Association by the time of grant signature (typically 6-8 months post-call closure).

→ Even if not eligible for funding, participation in a project is open to any legal entity established in any country, except for Russia and Belorussia.

→ Third countries can become associated to Horizon Europe during the Global Health EDCTP3 programme

For the purposes of the eligibility conditions, applicants established in Horizon 2020 Associated Countries or in other third countries negotiating association to Horizon Europe will be treated as entities established in an Associated Country, if the Horizon Europe association agreement with the third country concerned applies at the time of signature of the grant agreement.

Global Health EDCTP3 Work Programme 2023 & Single-stage topics

*Jean Marie Vianney Habarugira, Senior Scientific Officer, Global Health
EDCTP3*

Work Programme 2023

- The 2023 Work Programme was adopted on 3 April 2023
- The Work Programme includes the funding opportunities and can be found on the interim Global Health EDCTP3 website
- The 2023 calls for proposals will be published on the European Commission's Funding and Tenders Portal

Calls for proposals 2023

Draft topics	Budget (Eur)	Single or Two-stage
Global Health EDCTP3 Training Networks - Clinical Research Fellowships (RIA)	15 300 000	Single stage
Funding to successfully finalise EDCTP2-funded clinical trials that were negatively impacted by the COVID-19 pandemic (RIA)	14 000 000	Single stage
Implementation research/real life assessment of existing interventions in women and children's health (RIA)	14 000 000	Single stage
Research to rapidly evaluate interventions on Ebola outbreaks in sub-Saharan Africa (RIA)	11 000 000	Single stage
Strengthening ethics and regulatory capacity (CSA)	8 000 000	Single stage
Improving modes of delivery, deployment, and uptake of vaccines through phase IV/implementation research (RIA)	30 000 000	Two-stage
Advancing point-of-care diagnostics to the market (RIA)	26 000 000	Two-stage

Calls for proposals – One-Stage topics

Publication Date:

14 April 2023

Opening date:

10 May 2023

Deadline date:

29 June 2023 at
17.00.00 (Brussels
local time)

- 1) HORIZON-JU-GH-EDCTP3-2023-01-0: Global Health EDCTP3 Training Networks - Clinical Research Fellowships
- 2) HORIZON-JU-GH-EDCTP3-2023-01-02: Funding to successfully finalise EDCTP2-funded clinical trials that were negatively impacted by the COVID-19 pandemic
- 3) HORIZON-JU-GH-EDCTP3-2023- 01-03: Implementation research/real life assessment of existing interventions in women and children's health
- 4) HORIZON-JU-GH-EDCTP3-2023- 01-04: Research to rapidly evaluate interventions on Ebola outbreaks in sub-Saharan Africa
- 5) HORIZON-JU-GH-EDCTP3-2023-01-05: Strengthening ethics and regulatory capacity

HORIZON-JU-GH-EDCTP3-2023-01-01: Global Health EDCTP3 Training Networks - Clinical Research Fellowships [1]

Research and Innovation Action (RIA)

Indicative call budget EUR 15.30 M

Expected project size EUR 5 M

Scope

- The Global Health EDCTP3 Training Networks will **implement training programmes** through consortia of clinical research institutions, academia, industry, businesses (including SMEs) and other actors from different countries across SSA and Europe.
- Proposals should include training programmes for researchers, scientists, clinicians and/or other public health professionals in the area of infectious disease research, with practical field research experience. The individuals being trained will carry out ambitious and relevant clinical research projects on infectious diseases affecting SSA.
- Training Networks proposals should be submitted by a consortium of institutions which must provide training through research programmes to **early- to mid-career** researchers based in SSA.
- Maximum duration of a training programme should be **54 months**

HORIZON-JU-GH-EDCTP3-2023-01-01: Global Health EDCTP3 Training Networks - Clinical Research Fellowships [2]

The training programme should include 2 levels of fellows:

Early-Stage Career Fellowships

- Duration of a single fellowship: between a min. of 6 and a max. of 36 months with the possibility of secondments up to a third of the single fellowship duration.
- Expected min. fellowships per proposal: 4
- Expected max. fellowships per proposal: 10

Mid-Career Fellowships

- Duration of a single fellowship: between a minimum of 6 and a maximum of 24 months and can have secondments up to a third of the fellowship duration.
- Expected min. fellowships per proposal: 2
- Expected max. fellowships per proposal: 5.

HORIZON-JU-GH-EDCTP3-2023-01-02: Funding to successfully finalise EDCTP2-funded clinical trials that were negatively impacted by the COVID-19 pandemic [1]

Research and Innovation Action (RIA)

Indicative call budget EUR 14 M

Expected project size EUR 0.25-2.5 M

Expected Outcome:

Project results are expected to contribute to the following outcomes:

- Clinical trials of medical technologies that were funded by EDCTP2 and whose activities were disrupted during the COVID-19 pandemic, can be concluded;

N.B. Only proposals addressing the **23 clinical trials**, listed by their **registration number** in a clinical trial registry in the topic description (see Call topic text), can be selected for funding.

HORIZON-JU-GH-EDCTP3-2023-01-02: Funding to successfully finalise EDCTP2-funded clinical trials that were negatively impacted by the COVID-19 pandemic [2]

The proposals should:

- Demonstrate the work performed so far, such as number of recruited trial participants, follow-up status as well as analyses to be performed;
- Explain the **impact of COVID-19-related delays** and disruption in relation to the trial timing (start, recruitment, follow-up period);
- Clearly explain the **additional work to be carried out**, with a comprehensive plan and budget to conclude the planned studies in a tight timeframe;
- Proposals should present a **sound assessment of the feasibility of the planned clinical investigations**. Realistic plans for recruiting and following up trial subjects must be presented and corroborated by **demonstrated success** from previous studies and/or the current study.

HORIZON-JU-GH-EDCTP3-2023- 01-03: Implementation research/real life assessment of existing interventions in women and children's health [1]

Research and Innovation Action (RIA)

Indicative call budget EUR 26 M

Expected project size EUR 4 M

Scope

Proposals should address the following activities:

- Carry out **registration (phase III) and/or post-registration studies** of health technologies that tackle infectious diseases affecting women and children to demonstrate clinical effectiveness;
- **Demonstrate the cost-effectiveness** of the health technologies being investigated in the relevant populations and communities;
- **Identify the barriers to the uptake** of the health technologies under investigation and address them in the proposed studies;
- Develop methods that can ensure **translating clinical research results into healthcare policy** and practice in a SSA setting;
- Early involvement and regular **interaction with policy- and decision-makers**, including end-users, to ensure adoption of the health technology by health systems in SSA.

HORIZON-JU-GH-EDCTP3-2023- 01-03: Implementation research/real life assessment of existing interventions in women and children's health [2]

Expected outcomes:

- Better **understanding of the role of diseases**(*) as well as the **barriers for the uptake** of health interventions against these diseases in sub-Saharan Africa (SSA).
- **Evaluation of the real-life impact** of existing interventions in women and children's health.
- **Uptake of research findings** on medical interventions of proven efficacy into clinical practice and routine care so that women and children in SSA can have access to safe health technologies for the management of PRDs.
- **Widespread adoption of research findings** into national, regional and/or international policy guidelines.

(*)Specific conditions to consider

This call is restricted to the following diseases:

HIV, malaria, tuberculosis, diarrhoeal diseases, bacterial infections (especially those where antimicrobial resistance is an issue), sepsis and lower respiratory tract infections.

HORIZON-JU-GH-EDCTP3-2023- 01-04: Research to rapidly evaluate interventions on Ebola outbreaks in sub-Saharan Africa [1]

Research and Innovation Action (RIA)

Indicative call budget EUR 11 M

Expected project size EUR 3 M

Scope

- Proposals submitted under this call topic are expected **to advance knowledge on Ebola** virus disease with the aim of contributing to an efficient patient management and public health response, as well as better epidemic preparedness in Africa.
- Special focus should be on improving our **understanding of the Ebola Sudan virus disease**, in view of the recent outbreak in East Africa and the lack of available interventions for this viral strain.

Proposals should include one or more of the following areas:

- 1) Clinical development of therapeutics
- 2) Clinical development of point-of-care (POC) diagnostics
- 3) Social sciences research

HORIZON-JU-GH-EDCTP3-2023- 01-04: Research to rapidly evaluate interventions on Ebola outbreaks in sub-Saharan Africa [2]

Expected Outcomes

- An increased portfolio of **therapeutics and diagnostic tools** are available to researchers to move along the clinical development phases to combat Ebola disease;
- An **improved surveillance system** to rapidly detect novel Ebola virus outbreaks in Africa;
- A **better understanding of the social dynamics** within communities affected by Ebola virus outbreaks and a better awareness from these communities when it comes to the implementation of public health measures such as social restrictions and/or medical interventions.

HORIZON-JU-GH-EDCTP3-2023-01-05: Strengthening ethics and regulatory capacity [1]

Coordination and Support Actions(CSA)

Indicative call budget EUR 8 M

Expected project size EUR 1 M

Scope

- To establish and/or develop own robust **capacities for ethics review and national medicines regulatory systems**. This also includes support towards national and international collaboration in compliance with established international standards.
- This scheme targets proposals with **active involvement of National Ethics Committees (NEC) and/or National Regulatory Agencies (NRA) from SSA countries**, and in particular countries with the highest infectious disease burden.

HORIZON-JU-GH-EDCTP3-2023-01-05: Strengthening ethics and regulatory capacity [2]

Proposals should:

- Clearly indicate the mismatch between the country disease burden, research activity and level of ethical review and regulatory oversight that **justify the need for support** in these areas;
- Include **linkages of the proposal to relevant on-going initiatives** and regional bodies is encouraged and should be demonstrated;
- Include plans to **foster bi-lateral links** between the European Medicines Agency (EMA) and the national ethics and regulatory authorities in the SSA countries of the participants are encouraged;
- Each proposal should have at least two new **technical staff members recruited** to the NEC/NRA team to be trained and integrated in the new functions proposed in the action.

Calls for proposals – One Stage topics

Publication Date: 14 April 2023

Opening date: 10 May 2023

Deadline date: 29 June 2023 at 17.00.00 (Brussels local time)

Global Health EDCTP3 Work Programme 2023 & Two-stage topics

Lydia Boudarène, Senior Scientific Officer, Global Health EDCTP3

Two-stage calls: principles

1st stage

- Submission of an outline application
- Evaluation only on 'Excellence' and 'Impact' criteria
- Successful applicants invited to submit a full application

2nd stage

- Submission of a full proposal
- Full evaluation by an evaluation committee of independent external experts
- Ranking of proposals according to quality score



Calls for proposals – Two-Stage topics

Publication Date:

14 April 2023

Opening date:

27 June 2023

Deadline 1st stage:

28 September 2023 at
17.00 (UTC+2)

Deadline 2nd stage:

28 March 2024 at 17.00
(UTC+1)

- 1) HORIZON-JU-GH-EDCTP3-2023- 02-01: Improving modes of delivery, deployment, and uptake of vaccines through phase IV/implementation research
- 2) HORIZON-JU-GH-EDCTP3-2023- 02-02: Advancing point-of-care diagnostics to the market
 - Research and innovation actions (RIA)
 - Total of EUR 56 million

HORIZON-JU-GH-EDCTP3-2023- 02-01: Improving modes of delivery, deployment, and uptake of vaccines through phase IV/implementation research

- Research and Innovation Action (RIA)
- Indicative call budget EUR 30 M
- Expected project size EUR 5 M

Expected Outcomes include

- Better **access** to novel **logistical and clinical solutions** for vaccine delivery
- Better understanding of **vaccine hesitancy drivers**
- Better access, coverage and **trust in vaccines**
- Better **tools and data** on immunisation level

Health Professionals and Policy makers have access to research results, to be translated and adopted into national and international policy guidelines



HORIZON-JU-GH-EDCTP3-2023- 02-01: Improving modes of delivery, deployment, and uptake of vaccines through phase IV/implementation research

Scope

- Carry out **phase IV/implementation research studies** on the deployment and uptake of registered vaccines
- Develop and test **novel logistical** solutions for vaccination
- As relevant, develop and test **novel clinical solutions** for vaccine **delivery**, incl. new delivery modes
- Better understanding of **factors** driving **structural inequalities** in vaccine deliveries
- Identification of **factors** driving vaccine **hesitancy** in SSA and develop targeted solutions.

Specific conditions to consider

- Involvement of vulnerable groups, including poorer, underserved and hard to reach groups and consideration of the full range of relevant determining characteristics
- Invitation to propose methodologies to translate research into public health practice and policy guidelines and multidisciplinary research is expected

HORIZON-JU-GH-EDCTP3-2023- 02-02: Advancing point-of-care diagnostics to the market

- **Research and Innovation Action (RIA)**
- **Indicative call budget EUR 26 M**
- **Expected project size EUR 5 M**

Expected Outcomes

- Better access to novel and improved point-of-care diagnostic devices
- Availability of a diverse and robust pipeline of in-vitro diagnostics, for better access in outbreak context and reaching most vulnerable populations
- Better access to health data and evidence to better develop and implement informed health policies and improve surveillance



HORIZON-JU-GH-EDCTP3-2023- 02-02: Advancing point-of-care diagnostics to the marker

Proposals should address all of the following areas:

- Clinical performance studies in **several sites**, with POC diagnostics that are of high technology readiness level to **achieve regulatory approval and market launch** (post market studies excluded)
- Provide **evidence-based practice for the POC diagnostic tests**, esp. to decide on treatment options. Consideration of field deployment and its usability at **PHC or CHW** level is encouraged

HORIZON-JU-GH-EDCTP3-2023- 02-02: Advancing point-of-care diagnostics to the marker

Proposals should address all of the following areas:

- Inclusion of clear **regulatory path to market** to ensure compliance with relevant legal requirement; **early engagement with regulatory authorities** expected
- Provision of a **product development plan** from prototype to industrial design to implementation and sustainability; **data reporting and results sharing** methods to be included
- Involvement of **industry**, notably **SMEs** is expected. African SMEs involvement highly encouraged
- Where available and relevant, **WHO target product profiles for diagnostics** need to be addressed

Calls for proposals – Two-Stage topics

Publication Date: 14 April 2023

Opening date: 27 June 2023

Deadline 1st stage: 28 September 2023 at 17.00 (UTC+2)

Deadline 2nd stage: 28 March 2024 at 17.00 (UTC+1)

Q&A session via **slido**

Go to: <https://www.slido.com/>

Join as a participant by inserting this code: #EDCTP3InfoDay

→ Please submit your questions through the **Q&A tab**

Upcoming events

- **EDCTP Forum:** From 7-10 November 2023, the Eleventh EDCTP Forum will take place in Paris hosted by France (ANRS | MIE)
 - We invite **submission of abstracts** for oral presentations or e-poster presentations of original contributions on global health research.
 - **Four prizes will be awarded** to recognise outstanding individuals and research teams who have made significant achievements in their field
 - Deadlines for submission are 3 May and 31 May respectively
- **Eleventh EDCTP Forum [website](#)**

Important links and information

- [Funding and Tenders Portal](#) link where Global Health EDCTP3 calls for proposals will be published
- Global Health EDCTP3 (interim) [website](#)
- For questions, please email: EC-GLOBAL-HEALTH-EDCTP3@ec.europa.eu
- Follow us on social media for the latest updates!
 - Twitter handle: @EDCTP3
 - <https://twitter.com/EDCTP3>

**THANK YOU FOR YOUR
PARTICIPATION**