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# Global Health EDCTP3

## Info day Spain

**24 February 2025**

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# Global Health EDCTP3 Overview

Silvia Garcia

Scientific Project Officer, Global Health EDCTP3

# Global Health EDCTP3

Established in 2021, Global Health EDCTP3 is a **partnership** between the **European Union,** represented by the **European Commission**, and the **EDCTP Association**, representing the governments of 15 European and 30 sub-Saharan African countries.

Global Health EDCTP3 contributes to:

- The Sustainable Development Goals
- The EU Global Health Strategy
- The AU-EU Innovation Agenda

**Global Health EDCTP3** builds on the experience gained during the **EDCTP1** and **EDCTP2** programmes.

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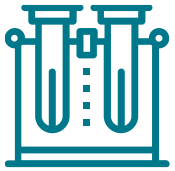
# Strategic approach



**Advance** biomedical interventions towards improved overall health

**Research** capacity development

**Enhance** coordination and alignment of countries around a common SRIA

**Strengthen** capacity for outbreaks/ epidemic/ pandemic preparedness

**Networking**, building partnerships and strategic alliances

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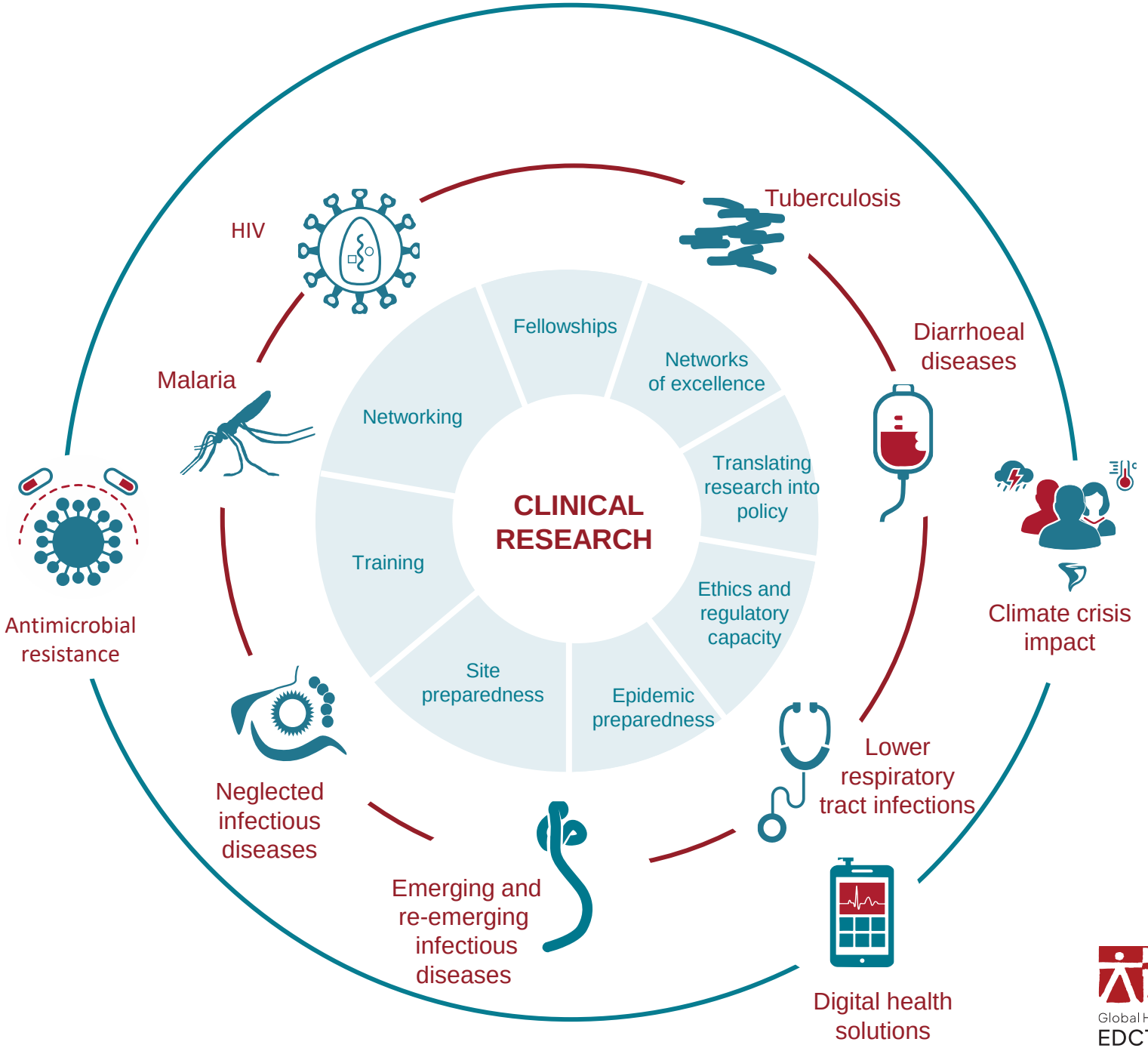
# Scope

We focus on the **major infectious disease threats** facing sub-Saharan Africa.

We tackle all stages of clinical evaluation but particularly **later-stage studies** with a special focus on vulnerable population groups.

We strengthen and build **research capacities** in sub-Saharan Africa.

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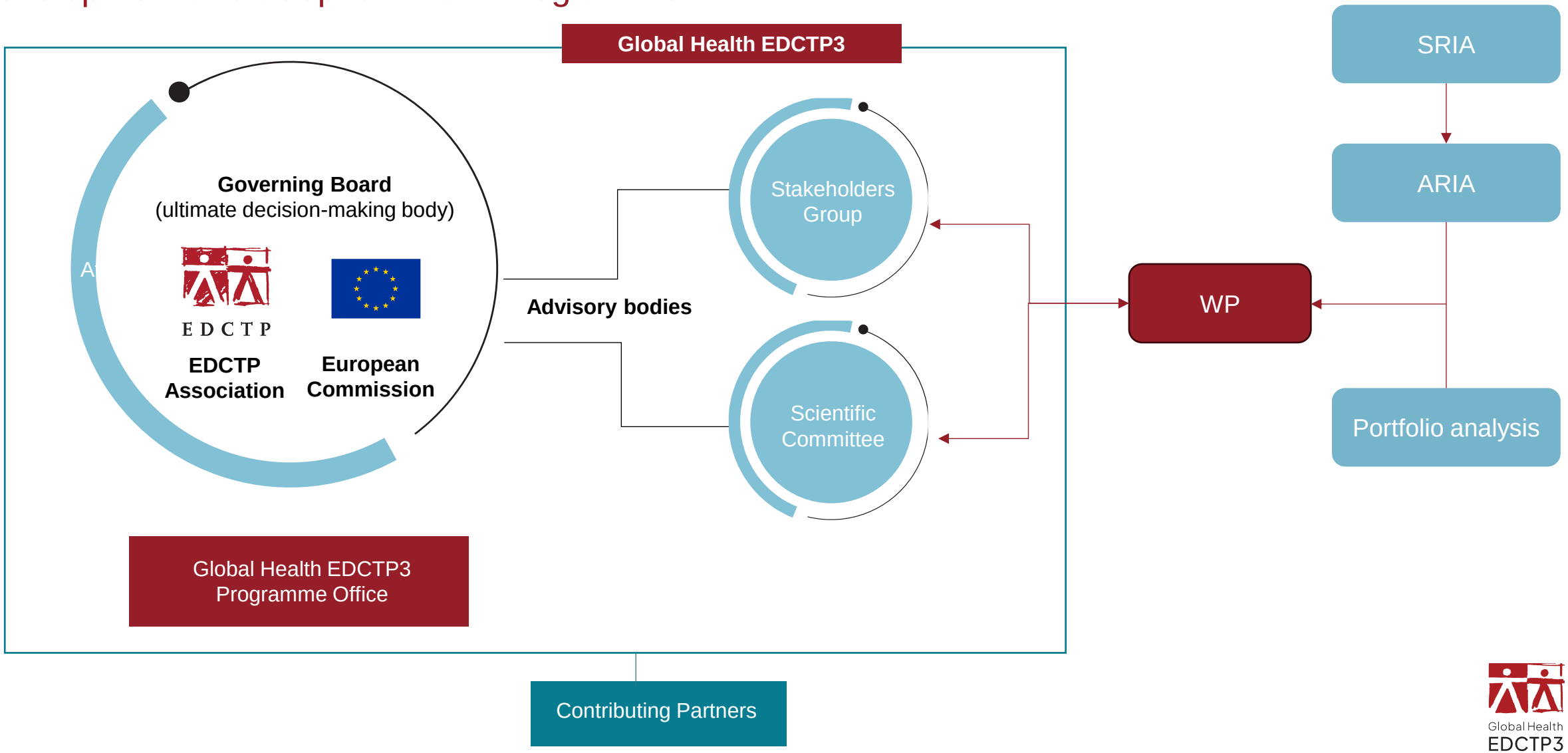
# Global Health EDCTP3 Operations

# Governance structure

## Development and adoption Work Programme




ARIA: Annual Research and Innovation Agenda; SRIA: Strategic Research and Innovation Agenda; WP: Work Programme

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# 2025 Work Programme

Adopted by the Governing Board of Global Health EDCTP3 Joint Undertaking on 13 December 2024

Includes 4 two-stage open and competitive calls covering 7 topics

Includes a “mobilisation of research funds in case of public health emergencies”

Total indicative budget for Calls for proposals and other actions not subject to Calls for proposals: € 214M*

* Additional budget of Contributing Partner under discussion

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# 2025 Work Programme – 4 open competitive Calls

| Calls | Topic Code | Call Topic Title | Budget (€) | Total budget(€) |
|---|---|---|---|---|
| 01 | HORIZON-JU-GH-EDCTP3-2025-01 -TB-01-two-stage | Global collaboration action for the development of **vaccines** for reducing the disease burden of **Tuberculosis** in sub-Saharan Africa | 45,9M | 122,7M |
| | HORIZON-JU-GH-EDCTP3-2025-01-MALARIA-02-two-stage | Global collaboration action for research on existing **Malaria therapeutics** and clinical development of new antimalarial candidates | 30,9M | |
| | HORIZON-JU-GH-EDCTP3-2025-01 -NTD-03-two-stage | Accelerating the **development of prophylactic vaccines** against **Neglected Tropical Diseases (NTDs)** in sub-Saharan Africa | 45,9M | |
| 02 | HORIZON-JU-GH-EDCTP3-2025-02-FELLOWSHIP-01-two-stage | Global Health EDCTP3 JU and contributing partners funded **Strategic Training Hubs for Fellowships in Public Health** covering Biostatistics, Epidemiology and Modelling | 6,7M* | 6,7M* |
| 03 | HORIZON-JU-GH-EDCTP3-2025-03-NETWORKS-01-two-stage | Global collaborative action for strengthening the **Regional Networks of Excellence and Epidemic Preparedness Consortia** | 40M* | 40M* |
| 04 | HORIZON-JU-GH-EDCTP3-2025-04 -CH-01-two-stage | Tackling **Diarrheal Diseases** in the context of Climate and Health | 30,6M | 44,6M |
| | HORIZON-JU-GH-EDCTP3-2025-04-ACCESS-02-two-stage | **Transformative Innovations** in global health | 14M | |

+ Mobilisation of research funds in case of **Public Health Emergencies** € 1M

* Additional budget of Contributing Partner under discussion

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# Work Programme 2025 – Calls for proposals and topics

# HORIZON-JU-GH-EDCTP3-2025-01-TB-01-two-stage

## Global collaboration action for the development of vaccines for reducing the disease burden of tuberculosis in sub-Saharan Africa

Research and Innovation Action (RIA)

Indicative call topic budget: EUR 45,9 M

Expected project size: maximum of EUR 15.3M

**Contributing Partner involvement strongly encouraged at proposal level .** In-kind and/or financial contribution

### Scope

- Development of vaccine candidates under research on licensed TB vaccines, especially targeting the population in low-middle countries, particularly in SSA
- Early and/or late-stage clinical studies to evaluate the safety, immunogenicity, efficacy and/or clinical utility on vaccine candidates under development and licensed vaccines in sub-Saharan Africa
- Proposals are to generate clinical data on TB prophylactic vaccines in adults and adolescents, and including where appropriate, pregnant and lactating women, new-borns, children, other vulnerable and neglected populations, and people with co-infections and co-morbidities at risk in SSA when relevant. A comparative arm with BCG and an assessment of overall health outcomes may be included when appropriate.
- **Out of scope:** Implementation research

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# HORIZON-JU-GH-EDCTP3-2025-01-MALARIA-02-two-stage

## Global collaboration for research on existing malaria therapeutics and clinical development of new antimalarial candidates

Research and Innovation Action (RIA)
Indicative call topic budget: EUR 30,9 M
Expected project size: maximum of EUR 10,3 M

**Contributing Partner involvement strongly encouraged at proposal level.** In-kind and/or financial contribution

### Scope

- Clinical trials (from Phase 2a onwards) evaluating safety, efficacy and effectiveness for novel therapeutic candidates or combinations of existing and new antimalarials
- Generate clinical data targeting children, pregnant women, and immune-compromised individuals or adolescents living in high transmission regions as relevant
- Interventions may target both P. Falciparum and/ or P. Vivax.
- Promising transmission blocking agents may be included as part of combination therapies
- Evidence on resistance to current treatments including combined therapies as secondary outcome
- Proposals are encouraged to embed if possible:
  - Long term effectiveness studies through aligned primary endpoints where possible;
  - Generation of pharmacovigilance data on currently registered therapeutics or candidates in late-stage efficacy trials.
- **Out of scope:** The development of prophylactic vaccines and monoclonal antibodies

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# HORIZON-JU-GH-EDCTP3-2025-01-NTD-03-two-stage

## Accelerating the development of prophylactic vaccines against neglected tropical diseases (NTDs) in sub-Saharan Africa

Research and Innovation Action (RIA)

Indicative call topic budget: EUR 45,9 M

Expected project size: maximum of EUR 15,3 M

**Scope**

- Clinical studies to evaluate the safety, immunogenicity, efficacy in Africa in NTDs
- General population and/or, when relevant, vulnerable and neglected populations morbidities at risk in SSA including pregnant/lactating women, new-borns, children, adolescents, co-infections/morbidities.
- Development of integrated preventive measures across NTDs and combined approaches targeting the host/reservoir (One Health Research) is strongly encouraged
- **Out of scope:** Implementation research and any research on Chagas, chromoblastomycosis and other deep mycoses, scabies and other ectoparasites, and snakebite envenoming.

To ensure diversification of the portfolio across different diseases, the funding decision will consider ranking of the proposals taking into account diversity of the respective diseases for proposals above the funding threshold.

**NTDs in scope:**

Buruli ulcer, dengue and chikungunya, dracunculiasis (guinea-worm disease), echinococcosis, foodborne trematodiases, human African trypanosomiasis (sleeping sickness), leishmaniases, leprosy (Hansen disease), lymphatic filariasis, mycetoma, onchocerciasis (river blindness), rabies, schistosomiasis, soil-transmitted helminthiases, taeniasis/cysticercosis, trachoma, and yaws.

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# HORIZON-JU-GH-EDCTP3-2025-02-FELLOWSHIP-01-two-stage

## Global Health EDCTP3 JU, and contributing partners funded Strategic Training Hubs for Fellowships in Public Health covering Biostatistics, Epidemiology and Modelling

Coordination and Support Action (CSA)

Indicative call topic budget: EUR 6,7 M

Expected project size: maximum of EUR 1,34 M

- **Contributing Partner involvement strongly encouraged** at proposal level. In-kind and/or financial contribution
- **Pilot Lump sum**
- **EDCTP Association as Project coordinator from the second stage application**

### Scope

- A high-quality training programme: 1) Master's training in Epidemiology and/or Biostatistics, or broader Master's in public health majoring in epidemiology or biostatistics, or 2) Specific training courses/seminars/workshops infectious disease mathematical modelling
- An open, fair and transparent procedure for selecting the fellows coming from different geographical regions of SSA, based on quality and with appropriate gender balance
- Robust mentorship and supervision mechanisms to support fellows through to timely successful course completion
- The applicant must be an organisation with an established legal entity in SSA
- Proposals must be submitted by a consortium of institutions which must provide above mentioned trainings for up to 50 early- to mid-career researchers per consortium;
- Proposals should provide details on the methodology for linking clinical research aspects with the translation into healthcare practice and policy
- The fellow must:
  - Be resident of or be willing to relocate to a sub-Saharan African country, member of the EDCTP Association;
  - Not have been funded under a similar previous EDCTP or Global Health EDCTP3 fellowship scheme before.

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# HORIZON-JU-GH-EDCTP3-2025-03-NETWORKS-01-two-stage

## Global collaborative action for strengthening Regional Networks of Excellence and Epidemic Preparedness Consortia

Coordination and Support Action (CSA)

Indicative call topic budget: EUR 40 M

Expected project size: maximum of EUR 10 M

- **Contributing Partner involvement strongly encouraged** at proposal level. In-kind and/or financial contribution
- **Pilot Lump sum**
- **EDCTP Association as Project coordinator from the first stage proposal**

### Scope

- Strengthening clinical research capacity to conduct multi-country clinical trials to ICH-GCP standards and compliance with WHO Guidance for Best Practices for Clinical Trials
- Enhancing collaboration and optimising the use of resources and infrastructures within the network
- Offering training and mentorship to senior scientists to promote professional development and scientific leadership in clinical trials
- Strengthening South-South, North-North and North-South collaborations between researchers and institutions
- Encouraging and promoting networking and dialogue between researchers, communities and policy makers to maximise the impact of clinical research in Africa.
- Promote resource sharing and harmonisation
- Establishing or strengthen partnerships with National Public Health Institutes
- Strengthening/expanding multidisciplinary epidemiology networks, generating accelerated evidence for optimal management of patients and for guiding public health response to any severe infectious outbreak caused by pathogens within the scope of Global Health EDCTP3

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# HORIZON-JU-GH-EDCTP3-2025-04-CH-01-two-stage

## Tackling diarrhoeal diseases in the context of climate and health

Research and Innovation Action (RIA)

Indicative call topic budget: EUR 30,6 M

Expected project size: maximum of EUR 5,1 M

### Scope

- Late-stage clinical studies evaluating safety, efficacy, accelerating the development of novel or existing treatment against DD, or late-stage development of novel or existing diagnostics against DD
- Where appropriate, implementation research combining interventions with current standard of care (including vaccines) as well as complementary research components that help to improve the understanding on how diarrhoeal diseases are currently influenced by climate and weather and may be further exacerbated by climate change.
- Multidisciplinary approaches integrating adjacent sectors are strongly encouraged (i.e. nutrition, IPC/WASH). Proposals are to generate clinical data serving newborns, children, people with co-infections and co-morbidities and other vulnerable and neglected populations at risk in SSA when relevant.
- Applicants are expected to provide methodologies for translating research findings into public health/climate practice and policy guidelines.

**Pathogens in scope**:

Rotavirus, shigella, cholera, enterotoxigenic E. coli, cryptosporidium, and norovirus

Including solutions having the potential to reduce AMR in context of above pathogens.

*N.B. Other pathogens are out of scope*

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# HORIZON-JU-GH-EDCTP3-2025-04-ACCESS-02-two-stage

## Transformative innovations in global health

Research and Innovation Action (RIA)

Indicative call topic budget: EUR 14 M

Expected project size: maximum of EUR 1.4-2.33 M

### Scope

- Innovations in R&D or products implementation, focusing on new or improvement of existing medicinal products and delivery systems; including but not limited to use of new technologies
- New interventions or improvements of an existing intervention for age-specific formulations or underserved populations; including but not limited to paediatric or geriatric formulations generating data for patients with co-morbidities;
- Development of tools to improve affordability or accessibility of preventative/treatment/diagnostic solutions; including but not limited to thermostable or humid resistant formulations, lower cost of goods, dose sparing approaches
- Development of delivery systems to improve efficacy or uptake of the preventative/treatment/diagnostic solution; including but not limited to assessing different route of administration ensuring easier access, new or improved devices or equipment ensuring higher efficacy or uptake, etc.
- Leverage existing data to repurpose and expand the use of the preventative/treatment/diagnostic intervention. including but not limited to using well-established safety and pharmacological data from its use in one disease area into the infectious disease field in the scope of the Global Health EDCTP3
- Scope includes infectious diseases in scope of the Global Health EDCTP3 including HIV/AIDS. The proposals are to be beyond Proof of Concept.

**Out of scope:** infectious diseases not in scope of the Global Health EDCTP3, as well as potential solutions treating chronic diseases (potentially caused by infections) and non-communicable diseases

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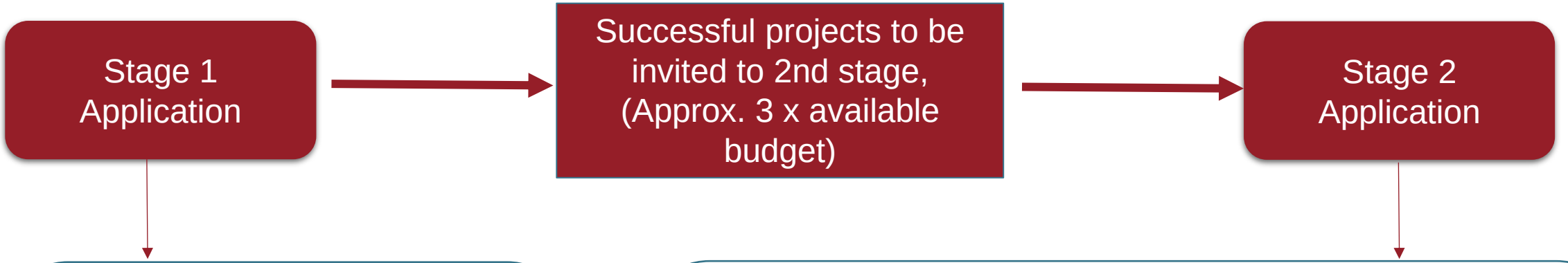
# The two-stage application process




- Shorter (outline) proposal
- Two criteria to be evaluate: Excellence and Impact

Note: For HORIZON-JU-GH-EDCTP3-2025-03-NETWORKS-01-two-stage: EDCTP Association is the coordinator at first stage

- Only by Invitation to successful stage 1 applicants
- Full proposal
- Changes in consortium allowed, including Coordinator*
- Independent evaluation from stage 1
- All three criteria -Excellence, Impact and quality /Efficiency of Implementation- to be evaluated

*Note: For HORIZON-JU-GH-EDCTP3-2025-02-FELLOWSHIP-01-two-stage and For HORIZON-JU-GH-EDCTP3-2025-03-NETWORKS-01-two-stage: EDCTP Association is the coordinator

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# Timeline


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# Other actions non-subject to calls for proposals

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## Mobilisation of research funds in case of public health emergencies

Grants not subject to calls for proposals

Research and Innovation Action (RIA) or Coordination and Support Action (CSA)

Indicative budget : EUR 1 M

**Expected Outcomes:**

- Contribute to one or several expected impacts of this work programme
- Allow the European Union and sub-Saharan African member countries of the EDCTP Association to respond to Public Health Emergencies
- Work in this area should allow a faster research response to outbreaks of epidemic or pandemic infectious diseases.

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# Legal and financial aspects


Vincent Declerfayt
Head of Finance and Administration, Global Health EDCTP3

Laurent Schell
Legal Officer, Global Health EDCTP3

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# Rules for participation

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# Eligibility to receive funding

## EU COUNTRIES

- Member States (**MS**)
- Overseas Countries and Territories (**OCT**) linked to MS



## NON-EU COUNTRIES

- Countries associated to Horizon Europe (**AC**)
- Countries which are members of **the EDCTP Association**
- Other countries when announced in the call or exceptionally if their participation is **essential**

## SPECIFIC CASES

For example:

- EU bodies
- International organisations (**IO**)

- International European research organisations are eligible for funding

- Other IO can be eligible for funding only exceptionally

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# Consortium

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**To be eligible, consortia must include:**

- At least three legal entities independent from each other and established in different countries, where legal entities are eligible to receive funding;

- At least one independent legal entity established in a Member State, or in an associated country that is a member of the EDCTP Association; and

- At least one independent legal entity established in a sub-Saharan African (SSA) country that is a member of the EDCTP Association.

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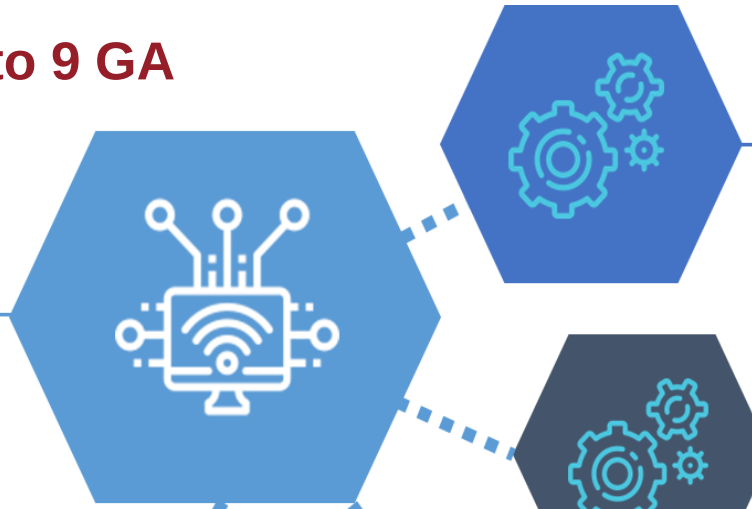
# Types of participants

**Grant Agreement articles 7 to 9 GA**



## Beneficiary

- Must be eligible for funding
- Signs the grant agreement

## Affiliated entity

- With a legal or capital link with the beneficiary
- Does work and may declare costs

## Associated partner

- Is not eligible for funding
- Performs tasks but may not claim costs

## Third party providing contributions

- Does not perform tasks, only provides a contribution to a
- beneficiary
  The beneficiary may declare the costs under its own budget

## Subcontractor

- Does work and invoices the beneficiary
- The beneficiary may declare the invoice

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# Useful documents

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# Links and resources

- AGA – Annotated Grant Agreement (https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/aga_en.pdf)
- Horizon Europe On-line Manual (https://webgate.ec.europa.eu/funding-tenders-opportunities/display/OM/Online+Manual)
- Research Enquiry Service (http://ec.europa.eu/research/enquiries)
- Templates (https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/how-to-participate/reference-documents;programCode=HORIZON)
- HE Reference and Guidance Documents (https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/how-to-participate/reference-documents?programmePeriod=2021-2027&frameworkProgramme=43108390)

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# Contributing Partners

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# Contributing Partners

## Who can be a contributing partner?

- Any country, international organisation or legal entity other than the Global Health EDCTP3 JU members that:
  - ✓ supports the objectives of the Global Health EDCTP3 JU in its specific area of research;
  - ✓ accepts the legal framework of the Global Health EDCTP3 JU by submitting an application (letter of endorsement), that details the scope of their engagement in terms of contribution (in-kind and/or financial), activities and duration;
  - ✓ is assessed and approved by the JU's Governing Board to be a Contributing Partner.

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# Contributing partners

## How to apply to become contributing partner?

- Submit an endorsement letter to the Global Health EDCTP3 JU formally addressed to its Governing Board
- The Global Health EDCTP3 Governing Board shall assess the letter and shall approve or reject the application by way of a decision.
- Informal discussion with the PRO beforehand.

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# Contributing Partners

## Why become a contributing partner?

- To be an active player in the acceleration of the development, evaluation, and implementation of interventions to prevent, identify, and treat infectious diseases and emerging/re-emerging infections.

- To trigger the possibility for Global Health EDCTP3 JU to receive and use additional EU funds.

- To have the possibility to be involved in the design of topic texts to which they participate.

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# Contributing partners

## Forms of contributions

- Financial Contributions (FC)
  - ➢ Cash

- In-kind Contributions to Operational Activities (IKOP)
  - ➢ Eligible costs incurred by the Contributing Partner in implementing the project activities without JU funding.

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# Financial aspects

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# Financial administration

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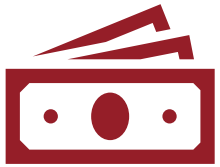

## Costs

Types of costs

Forms of costs

General eligibility conditions

Main categories

## Financial reporting

Timing

Submission

Financial statement

Currency used in reporting

Certificate on Financial Statements (CFS)

## Ex-post audit

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# Cost categories

1. A. **Personnel costs**
   A.1 Employees (or equivalent)
   A.2 Natural persons under direct contract
   A.3 Seconded persons
   A.4 SME owners and natural person beneficiaries
   A.5 Volunteers (not applicable)
   A.6 Others (includes Personnel unit costs)
2. B. **Subcontracting costs**
3. C. **Purchase costs**
   C.1 Travel and subsistence
   C.2 Equipment
   C.3 Other goods, works and services
4. D. **Other cost categories**
   D.1 Financial support to third parties
   D.2 Internally invoiced goods and services
   Others
5. E. **Indirect costs**

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# Certificate on financial statements (CFS)

- CFS to be submitted with the final report

- Threshold: EUR 430,000
  - Increased from EUR 325,000 in H2020
  - Calculated on all costs
  - Tip: familiarise yourself with the CFS template early

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# Ex-post audits

- Article 25.2 Grant Agreement (Art. 25 Checks, Reviews, Audits and Investigations-Extension of findings)
- Cost eligibility on the costs declared
- Audited by European Commission or external audit firm

Timeframe:

- Anytime after you receive first interim payment
- up to the number of years indicated in the data sheet after payment of the balance (incl. extension of findings from other grants)

Tips:

- Be diligent and keep evidence from the FIRST DAY OF THE PROJECT
- Costs declared MUST be actual and real
- Keep time records
- Best value for money and no conflict of interest

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# Lump-sums

# Why do we use lump-sum funding?

## Significant simplification potential

- Despite all simplification, funding based on reimbursement of actual costs remains complex and error-prone. Little scope for further simplification
- Lump-sums remove the obligation to report actual costs and resources
- Easier to use for beneficiaries with limited experience

## Focus on content

- Less focus on financial management and more focus on the scientific-technical content of projects

**Opportunity for the Global Health EDCTP3 to integrate the overall European Commission Research Family strategy, and pilot model for simplification in a pilot to learn from its programme specificities**

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# Basic principles

**Lump-sum evaluation and grant agreement follow the standard approach (similar as for actual costs grants) with the same:**

- Evaluation criteria
- Pre-financing and payment scheme
- Reporting periods and technical reporting, though focusing on completion of work packages

**One lump sum share is fixed in the grant agreement for each work package:**

- **Work package completed** → **PAYMENT**

- Payments do not depend on a successful outcome, but on the completion of activities

- Work packages can be modified through amendments (e.g. to take into account new scientific developments)

- No intention and nor basis for judging the performance of lump-sum grants more strictly than the performance of other grants

# Budget allocation

## Budget allocation (annex 2 to the grant agreement)

| | WP1 | WP2 | WP3 | WP4 | WP5 | WP6 | WP7 | WP8 | Total |
|---|---|---|---|---|---|---|---|---|---|
| **Beneficiary A** | 250.000 | | | 50.000 | 300.000 | 250.000 | | 300.000 | 1.150.000 |
| **Beneficiary B** | | 250.000 | 350.000 | 50.000 | | | 100.000 | 150.000 | 900.000 |
| **Beneficiary C** | 100.000 | 100.000 | | 50.000 | | 280.000 | | | 530.000 |
| **Beneficiary D** | | 120.000 | | 50.000 | | | 100.000 | 150.000 | 420.000 |
| **Total** | 350.000 | 470.000 | 350.000 | 200.000 | 300.000 | 530.000 | 200.000 | 600.000 | **3.000.000** |

Shares of the lump sum per beneficiary

Shares of the lump sum per WP

Lump sum
=
Maximum grant amount

You can **use the budget as you see fit** as long as the project is implemented as agreed. The actual distribution of the lump sum is invisible to us.

Budget transfers between work packages and/or partners require an amendment if the consortium wants to reflect them in the grant agreement.

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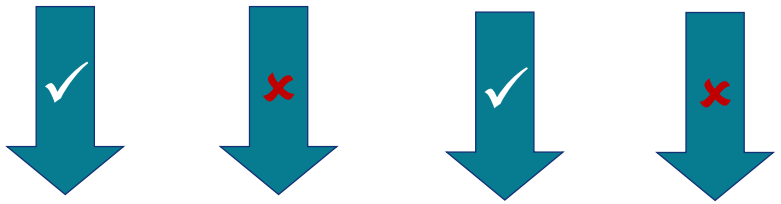
# Reporting and payment

- The financial report is much **simplified** and to a large extent automated.
- The financial statement for all beneficiaries is **automatically generated** (based on the accepted work packages and the corresponding lump sum shares).

| | WP1 | WP2 | WP3 | WP4 | WP5 |
|---|---|---|---|---|---|
| **Beneficiary A** | 250.000 | | | 50.000 | 300.000 |
| **Beneficiary B** | | 250.000 | 350.000 | 50.000 | |
| **Beneficiary C** | 100.000 | 100.000 | | 50.000 | |
| **Beneficiary D** | | 120.000 | | 50.000 | |
| **Total** | 350.000 | 470.000 | 350.000 | 200.000 | 300.000 |




Payment = 350 000 + 0 + 350 000 + 0 = 700 000 €

Interim payments pay the lump sum shares for completed work packages.

Final payments can also pay partially completed work packages.

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# Ex-post controls

## Consortium **needs to keep** (e.g.)

- Technical documents
- Publications, prototypes, deliverables
- Documentation required by good research practices such as lab books
- …any document proving that the work was done as detailed in Annex 1

**Same as for all Horizon Europe grants**

## Consortium **doesn't need to keep***

- Time-sheets
- Pay-slips or contracts
- Depreciation policy
- Invoices
- …any documents proving the actual costs incurred

*Participants still need to comply with financial record keeping **obligations outside the grant agreement**, if any (e.g., under national law or internal procedures)

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# Thank you
# for your attention!

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