





GUIDE FOR CONTRIBUTING PARTNERS

GLOBAL HEALTH EDCTP3







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1. Glossary

Financial contributions: cash contribution to the eligible costs of entities implementing indirect actions (Global Health EDCTP3 Joint Undertaking projects).

In-kind contributions to operational activities (IKOP): eligible costs incurred in implementing indirect actions (Global Health EDCTP3 Joint Undertaking projects) less the contribution of Global Health EDCTP3 Joint Undertaking to those costs.

Letter of endorsement: application of a prospective Contributing Partner that specifies the scope of the partnership in terms of subject matter, activities and their duration and details the applicant's contribution to Global Health EDCTP3 Joint Undertaking. It is to be submitted to Global Health EDCTP3 Joint Undertaking's Governing Board.

2. Introduction

Global Health EDCTP3 Joint Undertaking (hereinafter referred as "Global Health EDCTP3") aims to reduce the individual, social, and economic burden of poverty-related infectious diseases, including neglected, emerging, and re-emerging infectious diseases, in sub-Saharan Africa.

Global Health EDCTP3's mission is to **support global collaborative research, capacity strengthening, and international initiatives** to accelerate the development, evaluation, implementation, and uptake of interventions to prevent, identify, and treat infectious diseases and emerging/re-emerging infections in sub-Saharan Africa with the overarching goal to reduce overall mortality and morbidity, and increase global health security.

Specifically, Global Health EDCTP3's general objectives are to:

- 1. Reduce the individual, social, and economic burdens of infectious diseases in sub-Saharan Africa through the development and uptake of new and improved interventions.
- 2. Increase health security in sub-Saharan Africa and globally by reducing the risk of outbreaks and pandemics, addressing antimicrobial resistance and the health effects of climate change, and enhancing national and regional capacity to address these crises.

The founding regulation of Global Health EDCTP3 encourages it to co-invest with third parties in areas of shared interest, without requiring contributors to become members of the Joint Undertaking¹.

3. How are funding priorities determined?

Funding priorities are based on six criteria, following the Global Health EDCTP3 Strategic

¹ See articles 2, 9, 11 and 102 of 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 - <u>https://eur-lex.europa.eu/legal-</u>content/EN/TXT/PDF/?uri=CELEX:32021R2085&gid=1710247204690.





Research & Innovation Agenda (SRIA)²:

- 1. **Product development landscape:** Clinical development stage of medical interventions and innovations relevant to Global Health EDCTP3, across all phases of clinical trials, particularly phases II, III and IV, and assessment of whether the candidate addresses a gap in the current product pipeline.
- 2. **Priority infections:** Based on disease burden, patterns, co-morbidities, co-infections, and potential for public health crises.
- 3. **Global and regional priorities:** Evidence informing research & development agendas, capacity development needs, and policy and knowledge gaps to support evidence-based policy and practice.
- 4. **Emerging opportunities of translational bottlenecks:** Effectiveness studies, pharmacovigilance, product-focused implementation research, and activities supporting the authorisation, manufacturing, and adoption of new and improved interventions.
- 5. **Strategic partnerships:** Public and private collaborations to align and integrate research and funding, deliver coordinated responses to policy and public health challenges, and leverage existing investments and initiatives.
- 6. **Balanced portfolio of grants:** Allocation of resources across disease areas, interventions, and study designs to maximise impact and address diverse health needs and research gaps effectively.

4. Who can be a Contributing Partner?

Global Health EDCTP3 Contributing Partners can be a country, an international organisation or any public or private legal entity, other than the Global Health EDCTP3 members or their constituent or affiliated entities. Examples of contributing partners may include: philanthropic organisations and charities that run their own research programmes; public entities like research funding agencies or universities of countries that are not members of the EDCTP Association; non-profit entities such as research and technology organisations (RTOs); governments of countries that are not members of the EDCTP Association; as well as biotech and pharmaceutical companies working in sectors related to Global Health EDCTP3.

Contributing Partners engage in specific Global Health EDCTP3 activities and do not form part of its formal governance structure.

Contributing Partners must:

- Support the objectives of Global Health EDCTP3.
- Accept the legal framework of Global Health EDCTP3.
- Submit the application (letter of endorsement) to the Global Health EDCTP3 Governing Board that details the scope of their engagement in terms of contribution (in-kind and/or financial), activities and duration.

² <u>https://www.global-health-edctp3.europa.eu/document/download/1e6b608e-3940-4821-b90e-e216da31b123</u> en?filename=Strategic%20Research%20and%20Innovation%20Agenda.pdf





• Be formally approved as a Contributing Partner by the Global Health EDCTP3 Governing Board.

Contributing Partners can invest in Global Health EDCTP3 calls and projects in the form of **financial contributions** (FC) (i.e. cash) and **in-kind contributions to operational activities (IKOP)**³ (i.e. work as beneficiaries of a project consortium in a grant agreement with Global Health EDCTP3 but not request (full) funding/reimbursement of the costs they incur). Consequently, the contributions can be made directly by providers which, depending on their type of contribution, are referred to in this document as FC providers or IKOP providers.

5. Why become a Contributing Partner?

Global Health EDCTP3 is one of the world's largest global health partnerships supporting clinical research on infectious diseases. Over the past 20+ years, EDCTP has helped develop groundbreaking technologies—from the first malaria vaccines to innovative treatments for HIV, malaria, and neglected infectious diseases. Today, our pipeline includes promising products such as new TB vaccines, advanced digital health solutions, and novel tools to tackle the health impacts of climate change. Partnering with us accelerates the development of life-saving technologies that improve health and economic opportunities for millions—especially the world's most vulnerable people.

Contributing Partners also benefit directly from their support, by:

Leveraging co-funding

Contributions from Contributing Partners allow Global Health EDCTP3 to leverage up to €400 million matched EU funds, effectively increasing its overall budget. This enables Global Health EDCTP3 to fund more and larger projects, increasing the value, scale, and impact of partners' contributions.

Global Health EDCTP3 also enhances the coherence, complementarity and alignment of investments around a common Strategic Research and Innovation Agenda, improving their cost-effectiveness.

Improving ESG performance

Investing with Global Health EDCTP3 can enhance a company's Environmental, Social, and Governance (ESG) performance. Participation in global health research initiatives—such as prioritising diseases with high disease burden in Low- and Middle-Income Countries (LMICs), promoting access plans during clinical development, and encouraging diversity in clinical trials—demonstrate ethical leadership, responsible innovation, and a commitment to inclusive healthcare. These efforts are supported by Global Health EDCTP3 and recognised by ESG ratings agencies, investors, and accountability organisations like the <u>Access to Medicines</u> <u>Foundation</u>. They also strengthen corporate reputation, build trust with stakeholders and governments, and boost staff morale by aligning company objectives with global societal goals.

Shaping research priorities

Contributing Partners inform the strategic direction and research funding priorities of Global

³ The term "in-kind contributions" is defined in Article 2.8 SBA as follows: 'in-kind contributions to operational activities' means contributions by private members, their constituent entities, the affiliated entities of either, by international organisations and by Contributing Partners, consisting of the eligible costs incurred by them in implementing indirect actions less the contribution of that joint undertaking, the participating states of that joint undertaking and any other Union contribution to those costs.





Health EDCTP3, including the design of its work programmes, and in the case of FC providers, **take part in the design of call topic texts they fund.** Partners also benefit from Global Health EDCTP3's expertise to strengthen their research proposals and projects, improving their impact and alignment with global health priorities.

Global Health EDCTP3 follows Horizon Europe evaluation rules and can therefore only appoint evaluators included in the EU expert database. **Contributing Partners may suggest expert evaluators if they are registered via this** <u>link</u>. Contributing Partners who are FC providers and are not part of any applying consortium may be granted observer status in the evaluation process of the calls they have funded and be involved in the assessment of reports and deliverables of the projects they co-fund.

Networking and mutual learning

Global Health EDCTP3 fosters international cooperation among private and public organisations across Europe, Africa, and beyond. It connects actors, facilitates the exchange of information and best practices, stimulates the translation of knowledge from research to policy, and creates an enabling environment for effective collaboration. Our <u>networking platform</u> also helps partners explore joint initiatives, attract or find research partners and investors, and seize collaboration opportunities.

Increasing visibility

Global Health EDCTP3 projects regularly appear in high-impact peer-reviewed journals and international conferences. Additionally, our biennial EDCTP Forum brings together researchers, decision-makers, innovators, civil society, and other stakeholders to discuss progress and promote the uptake of EDCTP projects. All this contributes to enhancing the reputation and visibility of project participants and contributing partners on a global scale.

6. How to apply to become a Contributing Partner?

Prospective Contributing Partners must submit a <u>letter of endorsement</u> to the Global Health EDCTP3's Governing Board.

The letter should in principle be submitted **before the adoption of the work programme** covering the relevant call(s) **or before the second stage application deadline** (see section 6 for more details, including on exceptions). In this letter, the candidate must confirm their commitment to comply with Global Health EDCTP3's legal framework and provide the following information:

- The research area to which the Contributing Partner seeks to contribute to.
- The type of contribution (FC and/or IKOP) and respective estimated amounts in EUR.
- The relevance and added value of the proposed contribution for Global Health EDCTP3 objectives.
- The projected duration of the contribution to the JU, if relevant.

Where relevant, specifics of the proposed contribution to the call and topic may be added: disease areas, project activities, work packages and deliverables to be supported, description of in-kind and/or financial total equivalent amount, and specific reporting arrangements. The Global Health EDCTP3 Governing Board will then assess the letter and approve or reject the





application by way of a decision. This result will be promptly communicated to the applicant. It is strongly recommended to consult the Global Health EDCTP3 Programme Office before formally sending letters of endorsement to ensure that they include all necessary information (partnerships@global-health-edctp3.europa.eu).

In the case of FC without involvement of the Contributing Partner in the projects funded as beneficiary, a <u>funding agreement</u> between the Contributing Partner and Global Health EDCTP3 will have to be concluded.

7. What are the different options for providing contributions?

The different options for contributing are as follows:

1. Financial contributions (FC)/cash

1 a) FC provided directly to Global Health EDCTP3

Global Health EDCTP3 and a Contributing Partner sign a funding agreement based on which the Contributing Partner transfers a FC (cash, in EUR) to Global Health EDCTP3. This funding supports one or more beneficiaries through grant agreements signed with Global Health EDCTP3 under a specific work programme topic. Beneficiaries may be selected following Global Health EDCTP3 evaluation or, in justified cases, may be pre-identified in the call topic text and brought together with other beneficiaries selected following Global Health EDCTP3 evaluation.

The funding agreement will specify the payment schedule, ensuring that contributions are made in advance of Global Health EDCTP3's obligations to pay the consortia members based on the grant agreement (pre-financing, interim and final payments).

Where beneficiaries are pre-identified in the call topic text, it must be indicated whether they are partially funded, or non-funded mandatory beneficiaries of project(s) to be supported under a call. **Pre-identified beneficiaries of the FC are part of a consortium with other participants**. This can be done through a single or two-stage selection process in the frame of a call for proposals.

As regards the process, this option is identical to option 2a described below, in the case of identified beneficiary. The difference is that it is not the Contributing Partner that is identified as participant, but a legal entity funded by the Contributing Partner through the JU.

1 b) FC provided direct to beneficiaries of a Global Health EDCTP3 project

Under a funding agreement between the Contributing Partner and Global Health EDCTP3, the Contributing Partner transfers a FC (cash, in EUR) to beneficiaries that are party to a grant agreement signed with Global Health EDCTP3 under a specific work programme topic. Beneficiaries may be selected following Global Health EDCTP3 evaluation or, in justified cases, may be pre-identified in the topic text and brought together with other beneficiaries selected following Global Health EDCTP3 evaluation.





The funding agreement must include the payment schedule to the beneficiaries, which has to be analogous to the one of the <u>Horizon Europe Model Grant Agreement</u> (pre-financing, interim and final payments) and follow the same it timeline that Global Health EDCTP3 would be bound to if it was to make the payments.

In the case of beneficiaries pre-identified in the call topic text, it should be indicated whether they are partially funded or not funded at all by Global Health EDCTP3. In this case, they are part of a consortium with other participants. This can be done through a single or two-stage selection process in the frame of a call for proposals.

Other than the financial flow (FC paid direct to beneficiaries without prior transfer to Global Health EDCTP3), this option is identical to option 1a.

As regards the process, this option is identical to option 2a described below, in the case of an identified beneficiary. The difference is that it is not the Contributing Partner that is identified as participant, but a legal entity funded by the Contributing Partner.

1 c). Financial contribution provided by an IKOP provider to a member of its consortium

This contribution refers to the situation where an IKOP provider (following options 2 a) or 2 b) mentioned below) provides a FC to another beneficiary in the same project. Eligible costs of the latter are consequently not funded by the Global Health EDCTP3. These funds may be transferred directly from the provider to the beneficiary but must be explicitly mentioned in the grant agreement to be counted as a FC to Global Health EDCTP3.

2. In-kind contributions to operational costs (IKOP)

Contributing Partners providing IKOP are to participate in projects as beneficiaries, or in certain circumstances as affiliated entity to a beneficiary.

2. a) IKOP provided by an organisation identified upfront in the call topic text

IKOP providers are identified upfront in the topic text as partially funded or as non-funded mandatory beneficiaries of project(s) to be supported under a call. They are part of a consortium with other participants. This can be done through a single or two-stage selection process in the frame of a call for proposals.

For single stage calls

It needs to be ensured that all participants preparing applications can link up with the prescribed beneficiary/ies and that there is true integration between IKOP providers and other participants. The <u>Global Health EDCTP3 networking platform</u> may be used to facilitate this process. In all cases, the call(s) for proposals will clearly detail the obligation to partner with (an) IKOP provider(s).

For two-stage calls

In case of a two-stage call process, the steps will be as follows:





- At stage 1 the Global Health EDCTP3-funded beneficiaries are selected through a call for proposals.
- After the stage 1 evaluation, the IKOP provider(s) is/are offered to partner with the top-ranked consortium selected. The <u>Global Health EDCTP3 networking platform</u> may be used to facilitate this process.
- The top-ranked consortium from the call and the IKOP provider(s) jointly prepare a full application for the second stage of the call.
- Should the preparation of a joint application for the second stage not work out, the IKOP provider(s) can be offered to partner with the second-ranked consortium from stage 1.
- Assuming the joint full application submitted at stage 2 is successfully evaluated, the IKOP provider(s) become(s) (a) non-funded beneficiar(y/ies) or partially funded beneficiar(y/ies) in a Global Health EDCTP3 project together with the beneficiaries selected through the stage 1 evaluation.

Independently from the type of call procedure, the IKOP provider(s) must report their eligible costs like any funded beneficiary, even when they receive zero reimbursement. The un-funded ("non-reimbursed") costs become the IKOP.

2. b) IKOP provided by an organisation not identified in the topic text

The IKOP providers participate in projects/grant agreements without being identified as mandatory participants in the topic text.

A Contributing Partner can apply to all calls for proposals launched by the Global Health EDCTP3. Based on successful evaluation, they can thus be part of a consortium signing a grant agreement with the Global Health EDCTP3. The unfunded part of the eligible costs count as IKOP.

While this option allows for contributions that were not necessarily foreseen before call publication, the Global Health EDCTP3 Governing Board should, in principle, approve the application of prospective Contributing Partners after it becomes clear that this type of participation is materialising – preferably before signature of the grant agreement.

For all modalities outlined under options 1 and 2 above, letters of endorsement must be submitted to and approved by the Global Health EDCTP3 Governing Board to be considered as Contributing Partner financial contributions pursuant to Article 102 of the founding regulation, regardless of their value.

8. How to establish the value of FC and IKOP?

Regarding FC, the accounted amount should correspond to the financial transfer (cash contributions) to Global Health EDCTP3 or direct to the beneficiary funded by the FC provider and to reimburse eligible costs under a project accepted by Global Health EDCTP3 (see option 1 above). Even in cases of the FC being transferred direct from the Contributing Partner to the beneficiaries, the latter must report their costs to Global Health EDCTP3 as if they were funded, in line with the provisions of the grant agreement.

IKOP consists of the unfunded eligible costs incurred in implementing the project activities. In both cases, these costs should fulfil the eligibility conditions set out in Article 6 of the Horizon





Europe Model Grant Agreement or hereinafter "MGA" (please find the text at <u>general-mga_horizon-euratom_en.pdf (europa.eu)</u> or the annotated version of the MGA, see the link <u>https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-</u>2027/common/guidance/aga_en.pdf), will be reported and may be audited in accordance with the mechanism applicable to the grant agreement.

9. What are the contractual obligations of Contributing Partners?

When participating in a project, costs being funded by or incurred by Contributing Partners (FC and/or IKOP) in Global Health EDCTP3 projects need to be reported the same way as any other beneficiar(y/ies) signing the grant agreement, in accordance with their obligation to submit the reports as per Article 21 of the MGA.

The costs reported must be within the scope of the grant agreement, i.e. – eligible costs in implementing project tasks, as specified in Annex 1 – the Description of Action of the grant agreement. The beneficiary's costs are reported as part of the project reporting as outlined in the grant agreement and through the Funding & Tenders portal.

Certificate on the Financial Statements (CFS)

As provided in Article 24 of the MGA, a beneficiary requesting from Global Health EDCTP3 funding of EUR 430,000 or more, regardless it being coupled with the provision of FC or IKOP, is required to submit a CFS with the final report. In this context, FCs directly transferred to Global Health EDCTP3 are regarded as JU funds. The beneficiaries receiving these funds are, therefore, not exempt from the CFS requirement.

<u>Statement of Contributions (SC) and Certificate on the Statement of Contributions (CCS)</u> At the end of the action, the provider(s) that have not received Global Health EDCTP3 funding under the grant agreement, must ensure that the financial and in-kind contributions of EUR 430,000 or more are supported by statements of contributions (CS) and certificates on the statements of contributions (CCS) in accordance with Annex 5 of the grant agreement.





| Before topic | Action | Responsible Actor/s |
|--------------|---|--|
| publication | | |
| 1 | An aspirant Contributing Partner informs Global Health EDCTP3 about its intention to become a partner | Aspirant Contributing Partner |
| 2 | Discussions on the terms and conditions regarding the contribution, submission of a draft concept note and the draft endorsement letter (indicatively by the end of Q1 of year N for a topic included in the work programme of year N+1). | Aspirant Contributing Partner and Global Health EDCTP3 |
| 3 | Submission of a final concept note (indicatively by the end of Q2 of year N for a topic included in the work programme of year N+1). | Aspirant Contributing Partner |
| 4 | Agreement on the draft topic text and submission of the endorsement letter to the Governing Board (indicatively by the beginning of Q4 of year N for a topic included in the work programme of year N+1). | Aspirant Contributing Partner and Global Health EDCTP3 |
| 5 | Global Health EDCTP3 Governing Board accepts (or rejects) the letter by issuing a decision. | Global Health EDCTP3 Governing Board |
| 6 | The decision is relayed to the (Aspirant) Contributing Partner. | Global Health EDCTP3 |
| 7 | Call topic is published with the inclusion of the contribution of the Contributing Partner, as detailed in the letter of endorsement. Call topic is amended to reflect the above, if originally published before approval of the endorsement letter. | Global Health EDCTP3 |
| 8 | Preparation of the contractual arrangements: For IKOP, the Contributing Partner is a member of the consortium as beneficiary. For FCs (option 1a in section 6) when the Contributing Partner is not a beneficiary: a funding agreement should be signed between Global Health EDCTP3 and the Contributing Partner | Global Health EDCTP3 and the Contributing Partner |
| | In case of FC transferred to Global Health EDCTP3, a request for payment will be sent to the Contributing Partner (following the agreed terms and conditions) Receipt of payment from the Contributing Partner (if | Global Health EDCTP3 Contributing Partner and |
| 9 | applicable) Project implementation and periodic report submission | Global Health EDCTP3 Consortium (including the Contributing Partner where relevant) |







| 10 | Final report submission by the project consortium, | Contributing Partner |
|----|---|----------------------|
| | including submission of the financial contribution report | |
| | by the Contributing Partner (where applicable) and | |
| | closing of the project | |

Diagram: FC and IKOP

