

Guide for financial and in-kind contributions to operational activities from contributing partners to the Global Health EDCTP3 Joint Undertaking

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#### 1. Introduction

Global Health EDCTP3 Joint Undertaking (hereinafter referred as "Global Health EDCTP3 JU") aims to reduce the individual, social, and economic burden of poverty-related infectious diseases, including the neglected, emerging, and re-emerging infectious diseases, in sub-Saharan Africa. Global Health EDCTP3 JU's mission is to support global collaborative research, capacity strengthening, and international initiatives to accelerate the development, evaluation, and implementation 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.

The Global Health EDCTP3 JU's 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 or improved interventions, and (2) increase health security in sub-Saharan Africa and globally, in particular in the context of environmental change and the climate crisis, by reducing the risk of outbreaks and pandemics, and enhancing national and regional capacity to address antimicrobial resistance.

The founding regulation of Global Health EDCTP3 JU (or Single Basic Act – "SBA") offers the opportunity for organisations interested in supporting its objectives in their specific areas of research to provide contributions to it, without becoming a member of Global Health EDCTP3 JU<sup>1</sup>.

# 2. How does the Global Health EDCTP3 JU determine its funding priorities?

The research and research capacity priority setting at Global Health EDCTP3 are based on the following six criteria, which are also covered in the published <u>Strategic Research & Innovation Agenda (SRIA)</u>:

- 1. State of the global product development landscape: comprehensive analysis of the current state of clinical development of medical interventions and innovations within the Global Health EDCTP3 diseases and interventions' scope.
- 2. Priority infections: consideration of disease burdens, evolving patterns of disease, effect of interactions with co-morbidities and coinfections, extent of unmet medical needs, and their potential to lead to a public health crisis.
- Global and regional policy and knowledge gaps: Research & development and associated capacity priorities based key knowledge gaps and need for new evidence to support policy and practice.
- 4. Emerging opportunities of translational bottlenecks with a focus on segments in the translational and implementation pathway that delay the clinical development and uptake of

<sup>&</sup>lt;sup>1</sup> 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 - <a href="https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R2085&qid=1710247204690">https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R2085&qid=1710247204690</a>.

- novel and improved interventions, supporting effectiveness studies, pharmacovigilance, and product-focused implementation research.
- 5. Strategic engagements aimed to improve regional and global alignment of the Global Health EDCTP3 implementation approaches and priorities with other partners, to promote better coordinated responses in addressing evidence/policy/public health gaps and capacity development needs. This includes leveraging of investments from other EU initiatives and promising prior EDCTP investments.
- 6. Need for a balanced portfolio of grants across disease areas, interventions, and study designs, to ensure a well-adjusted allocation of resources.

## 3. Who can be a contributing partner?

Any country, international organisation or legal entity other than the Global Health EDCTP3 JU members or their constituent or affiliated entities of either, may apply to become a contributing partner provided that:

- they support the objectives of the Global Health EDCTP3 JU in its specific area of research;
- they accept 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;
- they submit this letter to the Global Health EDCTP3 JU through the Executive Director;
- the application is assessed by the JU's Governing Board and formally approved.

Therefore, both public and private organisations of various nature may consider becoming contributing partner. Examples of contributing partners may include philanthropic organisations and charities that run their own research programmes, as well as research organisations and private companies working in sectors related to Global Health EDCTP3 JU.

**Contributing partners** can bring their investment into the Global Health EDCTP3 JU in the form offinancial contributions (FC) (i.e. cash) and in-kind contributions to operational activities (IKOP)<sup>2</sup>.

Consequently, the contributions can be made directly by <u>providers</u>, which depending on their contribution are referred to in this document as **financial contributions (FC) providers or IKOP providers**.

<sup>&</sup>lt;sup>2</sup> 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.

# 4. How to apply to become contributing partner?

Any candidate contributing partner must submit an endorsement letter to the Global Health EDCTP3 JU formally addressed to its Governing Board. The letter should in principle be submitted as early as possible before the adoption of the work programme where the topic(s) to be contributed to are included (see exception in section 6, option 2 b below). In this letter, the candidate should confirm its willingness to comply with the JU's legal framework and detail the scope of application in terms of:

- the area of research the applicant contributing partner would like to contribute to (where relevant, specifying the JU's call/topic);
- how the applicant contributing partner wishes to contribute to the JU (financial and/or IKOP);
- what relevance and potential added value does the proposed contribution present for the achievement of the objectives of the JU;
- the projected duration of the contribution to the JU, if relevant;
- the amount of the contribution (financial and/or IKOP) in EUR;
- manner and specifics of proposed contribution to the call and topic for example: project areas, work packages, deliverables, and description of in-kind and/or in cash total equivalent amount; reporting arrangements and
- in case of two-stage calls, acceptance of the confidentiality obligation.

The Global Health EDCTP3 Governing Board shall assess the letter and shall approve or reject the application by way of a decision. This result will be promptly communicated to the applicant. It is recommended to consult the Global Health EDCTP3 Programme Office before formally sending letters of endorsement.

In the case of FC transferred to the JU, a funding agreement between the contributing partner and the JU will have to be concluded before the adoption of the relevant call text.

# 5. Why become a contributing partner?

Contributions from contributing partners trigger the possibility for Global Health EDCTP3 JU to receive and use additional EU funds. The involvement of contributing partners therefore has the effect of increasing the budget of Global Health EDCTP3 JU, in accordance with Article 103 of the SBA, and make possible the funding of more research projects. In addition, contributing partners are involved in the design of topic texts to which they participate. This enables them in respect of their contribution 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 in Sub-Saharan African countries to reduce overall individual, social and economic burden caused by these diseases.

Global Health EDCTP3 JU is bound to follow the rules of Horizon Europe with regard to independent evaluation of project proposals and may therefore not appoint evaluators chosen by contributing partners. However, in cases where the contributing partner provides a financial contribution and is not part of the consortia, it may be envisaged to grant an observer status in the evaluation process to a representative of the contributing partners.

## 6. What are the different options for providing IKOP/FC?

The different options for FC/IKOP are the following:

#### 1. Financial contributions (FC)

#### 1 a) Financial contribution provided directly to the JU

Under a funding agreement, a FC provider transfers of FC (in cash) to the JU for beneficiary/ies to be funded under a specific topic. Such beneficiary/ies may be selected following Global Health EDCTP3 JU evaluation or in justified cases be identified in the topic text and brought together with other beneficiaries selected following Global Health EDCTP3 JU evaluation. The funding agreement is to include the timeline for payments of the financial contribution. Payments must take place sufficiently in advance before the JU must pay the members of the funded consortia based on the grant agreement (pre-financing, interim and final payments).

The beneficiary/ies are therefore identified in the topic text as partially funded or as non-funded mandatory beneficiaries for 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-staged selection process in the frame of a call for proposals.

As regards process, this option is identical to option 2a, as per below, in 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). Financial contribution provided by an IKOP provider to a member of its consortium

An IKOP provider (following options 2 a) or 2 b) as per below) also provides FC (in cash), but to another beneficiary in the same project for the latter's eligible costs that are consequently not funded by the JU. These funds may be transferred directly from the provider to the beneficiary. In order this is counted as FC to the JU in accordance with Article 103 of the SBA, it shall be explicitly mentioned in the grant agreement.

#### 2. IKOP.

In principle contributing partners providing IKOP are to participate to projects as beneficiaries. Depending on the circumstances, a participation as main beneficiary, affiliated entity or associated partner (if the organisation is not eligible for JU funding) may be envisaged.

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

**IKOP** providers are identified in the topic text as partially funded or as non-funded mandatory beneficiaries for 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-staged 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 make sure that there is true integration between IKOP providers and the other participants and the work to be carried out is of high scientific merit. In all cases the call(s) for proposal will very clearly spell out the obligation to partner with (an) IKOP provider(s).

#### For two-stage calls

In case of a **two-stage call procedure**, the steps will be the following:

- At stage 1 the Global Health EDCTP3 JU-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 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 beneficiaries in a JU project together with the beneficiaries selected through the stage 1 evaluation.

Independently from the type of call procedure, the IKOP provider(s) has/have to report its/their eligible costs like any funded beneficiary, even when they receive 0 reimbursement. The un-funded ("non-reimbursed") costs become the IKOP.

The consortia must ensure that that there is true integration between IKOP providers and the other participants and the work to be carried out is of high scientific merit. In all cases

the call(s) for proposal will very clearly spell out the obligation to partner with (an) IKOP provider(s).

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

While this option allows for contributions that were not necessarily foreseen before call publication, it needs to be ensured that the Global Health EDCTP3 JU Governing Board timely approves the application of prospective contributing partners after it becomes clear that this type of participation in a project's grant agreements (about to be signed) is materialising.

#### 7. 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 JU or to the beneficiary funded by the FC provider (see option 1 above).

IKOP consists of the unfunded eligible costs incurred in implementing the project activities. These costs, which 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 <a href="mailto:general-mga-horizon-euratom-en.pdf">general-mga-horizon-euratom-en.pdf</a> (europa.eu) or the annotated version of the MGA, see check the link "<a href="https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/aga-en.pdf">https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/aga-en.pdf</a>) will be reported and may be audited in accordance with the mechanism applicable to the grant agreement.

They can take the form of all eligible cost categories, in accordance with Article 6 as per above, and among which:

#### **Direct Costs:**

- Personnel Costs the time of staff employed directly working on JU projects.
- Subcontracting e.g. for clinical trials, subcontracting to Clinical Research Organisations, subcontracting to data management companies, lab services, communication, project management support, etc.;
- Purchase costs travel and subsistence, equipment, other goods, works and services, e.g. consumables, equipment depreciation, samples, compounds;

• Other cost categories – e.g. financial support to 3<sup>rd</sup> parties if foreseen in the call, internally invoiced goods and services, transnational access to research infrastructure unit costs, virtual access to research infrastructure unit costs.

Indirect Costs: which is calculated automatically as 25% flat rate of the eligible direct costs, except subcontracting costs, financial support to third parties and exempted specific cost categories, if any.

## 8. What are the contractual obligations of FC/IKOP providers?

When participating in a project, costs incurred by FC/IKOP providers in Global Health EDCTP3 JU projects need to be reported the same way as any other beneficiary signing the grant agreement, even if they do not receive JU funding, in accordance with their obligation to submit the reports as per Article 21 of the MGA.

In this context, IKOP is reported within the scope of the grant agreement, i.e. for activities and costs which constitute IKOP - eligible costs in implementing project tasks, as specified in Annex 1- DoA 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 F&T portal.

At the end of the action, the provider that have not received funding under the grant, must ensure that the financial and in-kind contributions of EUR 430 000 or more (see Article 21) are supported by statements of contributions (CS) and certificates on the statements of contributions (CCS) in accordance with Annex 5 of the grant agreement.

If the provider has received cumulative at least EUR 430 000 of requested JU contribution (JU funding), it must submit a Certificate on the Financial Statements (CFS - see Art. 24.2 of the MGA) (irrespectively of the amount of IKOP and FC provided to the project).

In all cases, the project consortium proposal will have undergone an evaluation by the JU and meet the required threshold. As indicated in the section 5 of this document, there has to be true integration of the beneficiary (IKOP provider and/or beneficiaries funded by the FC provider) within the consortium and the work to be carried out must be of high merit.

# 9. Process flow regarding contributing partners

Before topic	Action	Responsible Actor/s
publication		
1	An aspirant Contributing Partner makes known to GH EDCTP3 JU 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 GH EDCTP3 JU
	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
3	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 GH EDCTP3 JU
4	JU Governing Board accepts (or reject) the letter by issuing a decision	JU Governing Board
5	The decision is relayed to the (Aspirant) Contributing Partner	GH EDCTP3 JU
6	Call topic is published with the inclusion of the contribution of the contributing partner, as this was detailed in the letter of endorsement and further arrangements. Call topic is amended to reflect the above, if originally published before approval of the endorsement letter.	GH EDCTP3 JU
7	<ul> <li>Grant Agreement Preparation Phase</li> <li>The contributing partner is a member of the consortium as beneficiary (concerns IKOP).</li> <li>The contributing partner is not a beneficiary; a funding agreement should be signed between the JU and the contributing partner (concerns FC- option 1a) )</li> </ul>	GH EDCTP3 JU and the Contributing partner
	An invoice, in case of FC transferred to the JU will be sent to the Contributing Partner (following the agreed terms and conditions)  Receipt of payment from the Contributing Partner (if	GH EDCTP3 JU  Contributing partner
8	applicable)  Project implementation and periodic report submission	and GH EDCTP3 JU  Consortium (including the contributing

		partner where relevant)
9	Final report submission by the project consortium,	
	submission of the financial contribution report by	
	the contributing partner (where applicable) and	
	closing of the project	

#### **Diagram: FC and IKOP**

Aspirant **Contributing Partner** – contacts EDCTP3 JU expressing interest in investing towards objectives in line with EDCTP3. The terms and conditions of the investment are agreed with EDCTP3 JU.



Applies and seeks approval as Contributing Partner by submitting a "Letter of endorsement".





Becomes part of a project consortium as an un-funded or partially funded (by the JU) beneficiary. The eligible costs that are not funded by the JU will be **IKOP**.

As a beneficiary, the Contributing Partner may be designated as "mandatory" or "prescribed" in the relevant topic text.

Funds a beneficiary(ies) in a project consortium by transferring cash (FC) to GH EDCTP3 or directly to the beneficiary (ies). The terms and conditions will be set out in a Funding Agreement between EDCTP3 JU and the Contributing Partner (option 1 a)).

The beneficiary(ies) may be fully or partially funded by the Contributing Partner (or by another Contributing Partner). It (they) may be designated as "mandatory" or "prescribed" beneficiaries.





Signs/accedes to the Grant Agreement.

Submit a 'Financial contribution report' indicating the actual contribution value at the end of the project.