Global Health
EDCTP3

GUIDANCE FOR MEMBERS OTHER THAN THE UNION AND INDEPENDENT AUDIT BODIES and COMPETENT INDEPENDENT PUBLIC OFFICERS (CIPO):

PLANNING, REPORTING AND CERTIFICATION OF IN-KIND CONTRIBUTIONS TO ADDITIONAL ACTIVITIES (IKAA)

Version 2.0 – September 2025

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IMPORTANT NOTES

The Global Health EDCTP3 Joint Undertaking (hereinafter the "JU") has been established via the 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[1] ("the Regulation"), hereinafter the "Founding Regulation"

This guidance document explains how the requirements of **Article 11.2 of the founding regulation about the independent audit certificate** needed from Global Health EDCTP3 Joint Undertaking private members and its constituents are to be applied in practice. It helps the Association and its constituents in planning, reporting, and certifying their costs for the purpose of establishing In-Kind Contributions to Additional Activities (IKAA).

Private Member is any legal entity established under public or private law that is a member of a joint undertaking other than the Union, participating states or international organisation. In the context of this guidance document, the Private Member is the EDCTP Association (herein after "the Association")

Constituent entity of EDCTP Association is a member of the Association according to its statutes.

Organisation implementing AA is the entity effectively running an additional activity and incurring the related costs. In practice, it may be a private member, a constituent entity or an entity related to the latter.

'Additional activity' (AA) means an activity, included in the annual additional activities plan annexed to the main part of the work programme, that does not receive financial support from the joint undertaking but contributes to its objectives and is directly linked to the uptake of results from projects under that joint undertaking or its preceding initiatives or that has a significant Union added value;

Additional activities plans are approved by the Governing Board (GB) (Article 17(2), point (n) of the founding regulation) and annexed to the Work Programme.

IKAA are defined as contributions by the private members, their constituent entities or their affiliated entities of either, and by international organisations, consisting of the costs incurred by them in implementing Additional Activities less any contribution to those costs from the Union and from the participating states of that joint undertaking, in accordance with Article 2(10) of the founding regulation.

IKAA are valued in accordance with the usual cost accounting practices of the entities concerned, to the applicable accounting standards of the country where the entity is established, and to the applicable International Accounting Standards and International Financial Reporting Standards (Article 11(2) of the founding regulation).

AA costs must be certified by an independent audit body appointed by the entity concerned and shall not be audited by the JU concerned or any Union body. (Article 11(2) of the founding regulation).

Independent Audit Body is an organisation formally recognised and accredited to conduct audits based on the International Standard on Auditing (ISA) and other relevant regulations. It must operate independently, providing unbiased evaluations while adhering to the Code of Ethics for Professional Accountants issued by the International Federation of Accountants (IFAC). The requirements for the Independent Audit Body are listed in section 4 of the Annex 3 (Terms of Reference for reporting of the IKAA). The member may opt to engage their usual external Auditor if they meet the afore-mentioned requirements. In case of public entities and constituent entities of EDCTP Association, the Independent Audit Body may be a competent independent public officer (CIPO) who is a member of staff (e.g. Internal Auditor), but their independence must be formally established by the relevant national authorities.

IKAA should be reported by the Association by 31 May each year at the latest to their respective Governing Board (GB) (Article 11(2) of the founding regulation).

IKAA IT tool guidance is available at the following link: IKAA Planning and Reporting Module - User Manual

1. Introduction

The JU represents a strategic partnership between the European Commission, on behalf of the European Union, and the EDCTP Association (the Association), which represents the governments of European and sub-Saharan African countries participating in this collaborative initiative. This JU plays a crucial role in facilitating collaboration and innovation by prompting entities beyond the European Union to integrate their research and innovation endeavours with those of the joint undertaking.

The Union's financial contribution to the Global Health EDCTP3, including EEA appropriations, is limited to EUR 910M[1]. By the conclusion of the ongoing programme, the IKAA level is expected to reach at least EUR 550M. If the target amount from contributing partners is not reached, the contribution from the Association, in the form of IKAA, IKOP and/or Financial Contribution may be made higher than the minimum legally required to compensate for the shortfall. This is so that the Union's maximum contribution amount may be reached [2].

Members are obligated to sign a commitment letter that defines their membership's scope in terms of content, activities, and duration, and outlines their specific contributions to the JU's collective efforts[3]. This letter also addresses potential additional activities as per Article 11(1), point (b), requiring Governing Board approval, thus ensuring members' compliance and effective contribution to the founding regulation's objectives.

The Association must adhere to Article 11(1) of the founding regulation by providing in-kind contributions to approved Operational or Additional Activities, ensuring alignment with JU objective.

The JU receives contribution from the Association, predominantly in the form of IKAA. The contributions for 'Additional Activities' are required to be certified by an independent audit body[4] to ensure accuracy and transparency in the IKAA valuation process. The legal basis for valuing these in-kind contributions is established in Article 11(2) of the founding regulation, which mandates private members to report the value of such contributions annually by 31 May.

The costs of in-kind contributions are to be determined in line with the usual accounting practices of the entities involved, ensuring compliance with relevant accounting standards. The certification of these costs by an independent audit body, appointed by the entity making the contribution, strengthens the credibility and reliability of the valuation

[1] As per SBA Article 102 and new HE Third Countries contribution approved by the Horizon Europe Steering Board
[2] Article 102 of the SBA
[3] Article 6 (3) of the SBA
[4] Defined in Page 3 of this document

process. The JU reserves the right to verify the valuation method in cases of uncertainty, safeguarding the integrity of the valuation process.

1.1 Objective

This document serves as a comprehensive guide for the Association and the organisations implementing AA, detailing the criteria for certifying the costs of Additional Activities (AA). It clarifies the relevant legal framework and outlines the responsibilities involved in planning, reporting, certifying, and valuing these contributions. Additionally, it offers guidance for independent audit body on how to issue the Certificate on AA costs in accordance with Article 11(2) of the founding regulation.

By providing a clear definition and process for valuating costs of AA, this document aims to streamline and standardize the valuation of in-kind contributions within the context of the founding regulation. Its goal is to enhance transparency, accountability, and compliance with established financial reporting standards among private members and its constituent entities.

The proper valuation of IKAA is essential for ensuring that these operations align with the strategic planning, reporting, monitoring, and evaluation requirements set forth by Horizon Europe, as specified in Articles 50 and 52 of the Horizon Europe Regulation. This includes adhering to the common policy feedback framework, thereby reinforcing the connection between in-kind contributions and the broader strategic objectives of the Horizon Europe initiative[5].

[5] Article 5.2 (d) of the SBA

2. In-Kind Contributions to Additional Activities (IKAA)

2.1 Definition

'Additional Activities' (AA) should fulfil all the following conditions:

- The AA must contribute to the general and specific objectives of the JU[6], defined in the Article 99 of the founding regulation;
- Follow the JU Strategic Research and Innovation Agenda (SRIA)[7] and defined criteria[8];
- It should provide meaningful participation and involvement of the sub-Saharan countries in the decision-making process, which is essential for tackling the burden of diseases in sub-Saharan countries;
- Should be included in the Annual Additional Activities Plan of the JU annexed to the main part of the Work Programme[9];
- Should be approved by the Governing Board.
- Not be funded by the JU or any other Union funding programme[10] (see example section 2.3);
- Be related either to Additional Activities "programmes" or "project"

When identifying possible AA, the Organisations implementing AA must verify that all criteria mentioned above are met to confirm that the suggested activities meet the requirements to be accounted as IKAA.

IKAA are defined as costs incurred by the Organisations implementing AA, in implementing 'Additional Activities' less any contribution to those costs from the Union and from the private member of that joint undertaking[11].

2.2 Differences between in-kind contributions to Additional Activities and to Operational Activities

As the private member of the JU, the Association, with its constituent entities, can provide both in-kind contributions to Additional Activities and to Operational Activities to the JU, it is important to clearly differentiate between the two types.

In-kind contributions to Operational Activities (IKOP) consists of the eligible costs incurred by them in implementing indirect actions less the contribution of that joint undertaking

[6] GH EDCTP3's objectives are also listed in https://globalhealth-edctp3.eu/about-us/who-we-are
[7] GH EDCTP3 's Strategic Research and Innovation Agenda https://globalhealth-edctp3.eu/resources/strategic-research-and-innovation-agenda
[8] It is essential that the research activities funded by Global Health EDCTP3 Joint Undertaking, or otherwise covered by its work programme, are in full compliance with the Charter of Fundamental Rights of the European Union. Recital 71 of SBA
[9] Article 2(9) of the SBA
[10] Recital 30 of the SBA
[11] Article 2(10) of the SBA. It should be read in connection with Recital 30 of the SBA.

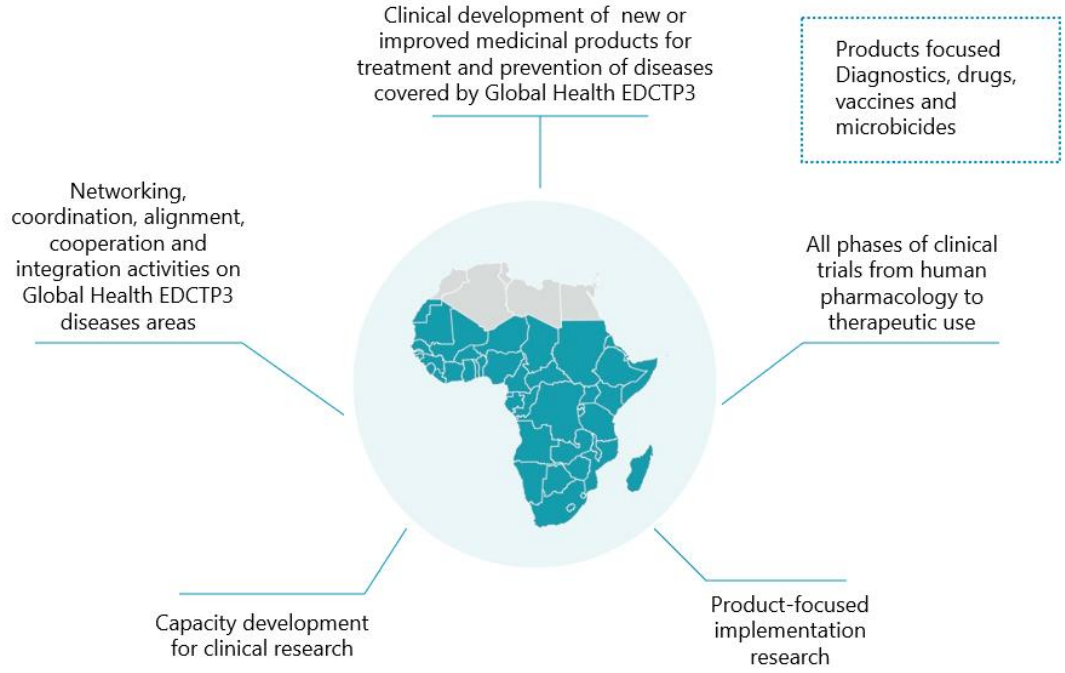
and of the participating states of that joint undertaking to those costs. Consequently, IKOP is accounted for solely on the basis of eligible costs and reported and audited in accordance with the mechanism applicable to the specific grant agreement. Such accounting on the basis of eligible costs allows for the automated calculation of in-kind contributions to operational activities via the Horizon Europe IT tools (Sygma/Compass).

In-kind contributions to Additional Activities (IKAA) consists of costs for additional activities and shall be accounted according to the usual accounting practices of the entity concerned, to the applicable accounting standards of the country where the entity is established, and to the applicable International Accounting Standards and International Financial Reporting Standards[12]. The use of the entity's internal cost accounting systems for this purpose should be considered the relevant starting point, to be complemented as necessary by the relevant aforementioned standards.

The contributions received from the Organisations implementing AA will largely be IKAA rather than IKOP[13].

2.3 Examples of 'Additional Activities'

Activities within the scope of Global Health EDCTP3 that can be considered eligible for IKAA:



[12] Recital 30 of the SBA.
[13] Recital 69 of the SBA.

Examples of eligible IKAA include:

- Equatorial Guinea: Support for health research capacities.
- Support to operational research projects on HIV, HPV and associated cancers.
- Biomedical Research in Health Research Center in Mozambique.
- Age-specific impact of seasonal malaria chemoprevention in Mali.
- Evaluate the POC syndromic diagnostics with Meningitis/Encephalitis/Respiratory testing at bedside in children under 5 years of age in Burkina Faso, Cameroon, and Cote d'Ivoire compared to Standards of Care alone to reduce mortality and morbidity. Strengthen local diagnostics and clinical capacity at hospital level.
- First multi-stage vaccine designed to target multiple stages of the P. falciparum malaria parasite's life-cycle, including the sporozoite, liver, blood and mosquito stages. The aim is to develop vaccines for African infants and children at risk of malaria disease and transmission (Burkina Faso, Sierra Leone, Tanzania).
- Pandemic Ethics will develop country-based and global agendas for a just and practicable post-trial arrangements (PTA) for low- and middle-income countries (LMICs) during epidemic/pandemic situations. The project has partners from Kenya, Tanzania, India, the Philippines, Nepal, Brazil and Norway.

2.4 Examples of what cannot be considered as 'Additional Activities'

- Activities essential to reach Global Health EDCTP3 project objectives, consisting of the eligible costs incurred in implementing indirect action (must be IKOP).
- Activities that have been already reimbursed by Global Health EDCTP3 or any other source of EU funding.
- Activities that are standard operations conducted by an entity as part of its regular business and do not have a direct connection to the JU's objectives.
- Activities already considered IKOP/IKAA in another JU proposal/project (no double counting allowed).
- Activities for which the private member does not effectively incur costs during the eligibility timeframe.

3. AA Plan (annex to the Work Programme)

The Association has the ability to plan 'Additional Activities' for its constituent entities, if any, by including the activities of them in its planned activities.

AA must be detailed in AA Plan, which is annexed to the Global Health EDTCP3 Work Programme (WP)[14]. The AA Plan for year N should outline the 'Additional Activities' scheduled to commence during that year.

3.1 Planning process for AA Year N-1

Step 1: During Q2 of year N-1, the Association reaches out to its constituents to compile the 'Additional Activities' planned to commence in year N into the proposal for the AA Plan for that year.

When identifying potential 'Additional Activities', the Association should ensure that all criteria are met (refer to Section 2 AA Definition) to confirm that the proposed activities meet the requirements for AA Programme Plan.

The proposal for the AA Plan for year N must adhere to the template approved by the JU for AA Programme (PG) and for Project Specific (PJ) (found in Annex 2 of this guidance document) and should include both information that can be made public and confidential information. All sections of the 'Annex 2' must be completed with relevant information. Under EDCTP3 Programme, it is not expected to receive Project Specific AA.

The details provided in the AA Plan proposal, such as the titles and descriptions of 'Additional Activities', as well as links to projects or estimated added value for the Union, should be clear and comprehensive. Avoid using acronyms and ensure the information is detailed enough to facilitate the assessment of the activities' contributions to Global Health EDCTP3's objectives, or their significant benefits for the Union.

'Additional Activities' planned for multiple years must be included in the AA Plan once. For example, activities scheduled from year N to year N+2 should be listed in the AA Plan for year N only, rather than in the plans for years N+1 and N+2.

Important Note: Only 'Additional Activities' that have not been previously included in an approved version of the AA Plan by the JU Governing Board need to be added to the AA Plan proposal. Each activity should include the best estimate euro value and duration in months.

Step 2: EDCTP Association must submit the draft of the proposal of the AA Plan for year N to the JU during Q3 of the year N-1, and no later than 45 days before the launch of the

[14] Article 2 (9) of the SBA

consultation for the Work Programme for year N. Typically, the consultation is initiated in November of year N-1.

Step 3: The JU may conduct an informal review before the formal submission of the AA Plan using the "Funding & Tenders Portal's AA Planning module"[15] (refer to 3.4 AA Plan form using IT planning tool).

The JU will engage in consultations with key stakeholders, primarily internal operational and legal teams, and the Scientific Committee (SC)[16], regarding the draft AA Plan and will consider any feedback received when offering input to the EDCTP Association.

This feedback will collaboratively incorporate received comments and suggestions for enhancement or better alignment with the founding regulation. Requests for adjustments, removals, and clarifications may be made.

The review and potential adjustments to the AA Plan proposal should be completed within one month.

Step 4: Once the initial AA Plan proposal is finalized (following agreement between the Association and the JU as per step 3), the Association will receive a notification from the Funding & Tenders Portal. This notification will request the encoding of planned Additional Activities for year N in the AA Plan form via IKAA Planning module, which is a mandatory step (detailed information on the AA Plan form can be found in section 3.3 below).

The Association must input the exact same information in the AA Plan form as outlined in the agreed-upon AA Plan proposal. If any discrepancies are identified, the JU will need to reopen the tool for corrections.

Step 5: During the consultation process, the AA Plan attached to the JU Work Programme will be evaluated by the Governing Board (GB). If deemed necessary, these entities may request additional clarifications from the JU regarding its planned Additional Activities. Any requested clarifications should be provided within a specified timeframe, and any necessary corrections should be made in the AA Plan form. If necessary, steps 3 and 4 will be repeated.

Step 6: Beginning of November Year N-1, the information entered in the AA Plan form for year N will be incorporated by the JU into the AA Plan attached to the Global Health EDCTP3 Work Programme. Subsequently, the Work Programme for year N will be made available for consultation.

Step 7: The JU Governing Board (GB) will endorse the AA Plan for year N upon approving the Global Health EDCTP3 Work Programme for that year, typically at the conclusion of year N-1[17]. Following this approval, the Association will receive a notification via the

[15] Article 5.2 (i) of SBA.
[16] Article 17 (2)(n) of SBA
[17] The IKAA plan should be submitted ideally by end of November N-1, according with https://webgate.ec.europa.eu/funding-tenders-opportunities/pages/viewpage.action?pageId=60850559

Funding & Tenders Portal confirming the inclusion of their planned Additional Activities in the AA Plan for the year.

Step 8: The approved AA Plan for year N will be published on the JU website as part of the Global Health EDCTP3 Work Programme for the same year. Furthermore, the comprehensive AA Plan will be updated and published on the JU website[18]. This overall AA Plan encompasses a comprehensive summary of all Additional Activities planned by Global Health EDCTP3 private members that have been approved by the Governing Board.

3.2 AA Plan amendment of the Year N

The Association is to propose an annual amendment to the initial AA Plan if significant deviations are expected in the current year's work programme plan (year N).

New 'Additional Activities' planned to start in year N that were not included in the initial AA Plan (Section 3.1) at the end of the previous year (year N-1) or significant modifications to the nature or purpose made in the activities can still be incorporated into the AA Plan for year N during the same year when the JU Work Programme is amended.

This amendment should be prepared in the beginning of Q3 of year N for integration into the Global Health EDCTP3 Work Programme (amendment) and approval by the GB in Q4 of year N. This amendment will be processed together with the Additional Activities Plan of Year N+1).

Significant deviations will either require the modification of the IKAA Plan through an amendment or must be adequately justified during the reporting stage (section 8 below), depending on the specific case.

Major deviations from the AA Plan are classified as:

- Introducing a new activity that was not previously anticipated in the AA Plan.
- Making a significant alteration to the nature or purpose of an activity outlined in the AA Plan.
- A change in the duration of the plan and validity of costs incurred.

In such instances, the Associations must submit the proposal for the amendment of AA Plan for year N to Global Health EDCTP3 at least 60 days before the scheduled launch of the final Work Programme amendment in year N. The subsequent process should follow the steps outlined above in the section 3.1 Planning process for AA.

With regards to cost deviations, the JU will consider them at programme level. A clarification for a significant change in the total amount will be looked at in relation to the

[18] Last version of the IKAA plan can be found on GH EDCTP3 website via this link: https://globalhealth-edctp3.eu/resources

total IKAA. Additional activities with certified values which are significantly lower than planned could prompt the JU to adopt an action plan to ensure that the targeted contribution from its member is achieved.

Important note: Before the related incurred costs can be reported as AA in the Annual Activity Report (section 7, Reporting), Additional Activities must be included in the AA Plan of the work programme and be approved by the Governing Board (following consultation of SC) and entered into the "IKAA Plan form" via the Funding and Tenders Portal.

If an Additional Activity is not included in the AA Plan (initial or amendment of the work programme), the incurred costs cannot be reported and recognized as IKAA.

3.3 AA Plan form using IT planning tool

The Association is required to enter Additional Activities in the IKAA Plan form via the "Funding and Tenders Portal". This step is crucial as it allows to report costs for these activities at a later stage (refer to section 7.1 on IKAA reporting).

The Association must possess a PIC (Participant Identification Code) and a LEAR (Legal Entity Appointed Representative) to access the Portal and the IKAA Plan form. The Association will receive a notification from the Portal requesting the input of its Additional Activities in the IKAA Plan form. This notification will be activated at the appropriate time by the JU Office and sent to the LEAR, the account administrator if applicable, and the IKAA reporter if assigned to that role.

The LEAR is confirmed by the European Commission validation service as part of an organization's validation process and has the authority to assign or revoke the roles of 'account administrator' and 'IKAA reporter' (referred to as 'organization roles'). Additionally, the account administrator has the capability to assign or revoke the 'IKAA reporter' role as well.

Only individuals with the roles of LEAR, account administrator, or IKAA reporter can view, edit, and submit the AA Plan form.

Accessing, Completing, and Submitting the IKAA Plan Form (Annex 2)

1. Accessing the Form:
   - Visit the designated platform in Funding and Tenders Portal.
   - Log in using your credentials. If you don't have an account, you may need to register or request access from your organization's administrator.

2. Filling in the Form:
   - Carefully read the instructions provided at the beginning of the form.
   - Fill in all required fields accurately. Make sure to provide detailed information where necessary.
   - Review your entries to ensure completeness and correctness before moving on to the next section.

3. Submitting the Form:
   - Once you have completed all sections of the form, review it one final time for any errors or omissions.
   - Click the 'Submit' button to send your completed IKAA Planning form.
   - You should receive a confirmation message or email indicating that your submission was successful.

If you encounter any issues during the process, please reach out to the JU Office for assistance.

For more information about the access, complete and submit the IKAA Plan form refer to the following link.

Each additional activity entered in the IKAA Plan form will be assigned a unique reference code automatically by the tool. This reference code, such as 20XX.PG.12345.1, comprises the year of the Plan, the AA type ('PG' for Programme-specific AA), the entity's PIC, and the activity number. This unique reference facilitates the swift identification of a planned additional activity in the IKAA Plan form and is essential for reporting its costs in the IKAA Report form at a later stage (see Section 7.1 on IKAA Reporting).

The information is entered into the IKAA Plan form should be approved by the JU Governing Board before acceptance in the tool. The AA Plan is considered accepted in the tool when the IKAA Planning workflow in the tool is concluded. Accuracy and consistency between the approved plan and the data in the IKAA Plan form are crucial to ensure proper tracking and reporting of Additional Activities and associated costs.

Upon submission of the IKAA Plan form, Global Health EDCTP3 will conduct a review of its content (section 3.1, Step 7). If errors or discrepancies are identified, the JU will reopen the tool to allow for corrections.

It is important to note that once planned Additional Activities are inputted in the IKAA Plan form and approved by the Governing Board, they cannot be modified in the tool.
During Amendment, the operations permitted in the IKAA Plan form are:

- Adding new Additional Activities.
- Amending the costs and duration of the planned Additional Activities

4. Cost Valuation Method

AA costs should be accounted for as 'in-kind contributions to Additional Activities' when:

1. They meet the AA criteria mentioned in Section 2.1 (AA Definition) and
2. It has been approved by the Global Health EDCTP3 Governing Board through the initial or amendment AA Plan process mentioned in Section 3.

"The costs shall be determined in accordance with the usual cost accounting practices of the entities concerned, to the applicable accounting standards of the country where the entity is established, and to the applicable International Accounting Standards and International Financial Reporting Standards"[19].

As a rule, the costs incurred for AAs are not subject to the Horizon Europe cost eligibility rules and cost calculation methods. These are more restrictive than the general rule provided under Art 11.2 of the founding regulation. The JU encourages the calculation method that optimally captures the real value of the activity.

In some instances, the Organisations implementing AA may consider the application of HE rules to simplify the participation of legal entities in Global Health EDCTP3 actions, for example if they are involved in a large number of actions funded under Horizon Europe and are therefore familiar and want to maintain consistency in reporting across their EC-funded activities.

IKAA can include various types of costs necessary for the implementation of approved activities, such as personnel costs, subcontracting costs, financial contributions, and other direct or indirect costs (as long as they are in accordance with the Article 11.2 of the founding regulation).

The costs incurred for 'Additional Activities' must be:

1. expensed (incurred[20]) by the entity during the specified timeframe and related to AA reported in the Work programme Plan (section 3),
2. recorded in the entity's accounting system, and
3. be identifiable and verifiable through proper documentation and evidence.

These costs will be subject to audit by an independent audit body[21] appointed by the entity. In case of public entities, an Independent Audit Body may be a competent independent public officer who is a member of staff (e.g. Internal Auditor), **but their independence must be formally established by the relevant national authorities**.

[19] Article 11.2 of the SBA
[20] Expenditure is considered incurred when it is recognized as expenditure in the financial statements of the Organisations implementing the AA for the corresponding financial year
[21] Defined in Page 3 of this document

In certain specified cases, the GB may authorize the use of simplified methods, such as lump sums or unit costs, for valuing contributions if it is necessary to achieve simplification, cost-effectiveness[22].

The Association may identify potential activities that could benefit from these specific cases and submit a proposal to the Global Health EDCTP3 GB. For each potential activity, the use of a simplified valuation method should be justified by fulfilling the three criteria mentioned above. Additionally, a clear cost calculation methodology should be established. Ideally, this calculation methodology should be general enough so that different organisations implementing AA could apply it if needed.

This process allows for flexibility in valuing contributions in a streamlined and efficient manner, while still ensuring appropriate levels of protection and cost-effectiveness in the implementation of activities within the JU framework.

[22] Recital 30 of the SBA

5. Accounting practices for Organisations implementing AA

5.1 Accounting Standards

According to Article 11.2 of the Regulation, the value of IKAA should be determined in compliance with:

- The usual cost accounting practices of the entity concerned.
- Local country accounting standards – these are defined as the set of accounting standards applicable under the legislation of the country where the member is registered.
- International Accounting Standards and International Financial Reporting Standards – these are internationally recognized standards applicable to accounting for revenue and expenditure of an entity in accordance with the relevant legislation.

The use of other accounting standards is substantially discouraged and may result in the JU raising concerns to the Governing Board on the IKAA valuation with the JU not being able to confirm the implementation of the adopted AA Plans.

5.2 Accounting System

An Accounting System serves as an internal reporting tool for an organization's management, aiding in decision-making and margin calculation. It allows the entity to estimate product costs for profitability analysis, inventory valuation, and cost control. While a cost accounting system may support the preparation of financial reports periodically, it is important to note that the system and its generated reports are not always bound by rules and standards such as the Generally Accepted Accounting Principles (GAAP). Consequently, there exists a diverse range of cost accounting systems across organizations, and sometimes even within different divisions of the same organization. Therefore, the Organisations implementing AA should ensure that the AA cost is reported in line with the accounting standards mentioned above in section 5.1.

Regardless of the accounting framework used, the financial reporting process in the accounting system generally involves the following:

1. Recording Transactions: All financial transactions are recorded using double-entry bookkeeping.
2. Posting to ledger: Transferring journal entries to the general ledger, which summarises all the accounts,
3. Adjusting Entries: At the end of the reporting period, adjusting entries are made to accounts for accrued and deferred items, ensuring that transactions are recognized in the correct period.
4. Trial Balance: A trial balance is prepared to ensure that debits equal credits, which helps in identifying errors in the accounting records.

5. Statements Preparation: Based on the adjusted report, the statements are prepared according to the relevant accounting framework.

The accounting system should contain a Charts of Accounts which includes a structured list of all accounts used by the organization, categorized into assets, liabilities, equity, revenues and expenses, this helps in organizing financial data for reporting.

6. IKAA Certification

The Organisations implementing AA who has delivered in-kind contribution to the Additional Activities during year N are required to have these costs certified by an independent audit body[23] appointed by the entity concerned[24]. This auditor can be the entity's usual external auditor. The certification by the independent audit body is necessary for these costs to count towards the matching target established in Article 103 of the Regulation.

It is important to note that value of IKAA that was planned and incurred[25] but not certified by an independent audit body cannot be reported as "certified" by the JU. Therefore, certification by the auditor is a critical step in ensuring validity and accuracy of the reported costs.

The Association must also ensure that these costs are certified in accordance with this guidance document. Failure to do so may result in not being recognized as IKAA.

A single audit certificate can cover the costs of the different Organisations implementing AA and for different years.

The costs incurred as IKAA within the Global Health EDTCP3 framework are not audited by the JU or any Union body. However, in cases where there is uncertainty arising from the certification process, the cost valuation method used for the in-kind contributions may be verified by the Global Health EDTCP3 Joint Undertaking[26].

This verification process may involve requesting clarification on specific costs or the methodology followed by the entity in valuing the in-kind contributions. If necessary, the JU may seek additional information to ensure transparency and accuracy in the reported costs for Additional Activities. This verification process is aimed at addressing any uncertainties or discrepancies that may arise during the certification of in-kind contributions.

6.1 Scope of Work of Independent Audit body

The scope of work of an independent audit body shall be providing assurance in respect of the AA as declared by the Organisations implementing AA, defined under and in compliance with articles 2(9), 2(10) and 11(2) of the founding regulation.

In doing so, the independent audit body has to provide assurance that the IKAA resulting from the relevant accounting system of the Association is determined according to the usual cost accounting practices of the entities concerned, to the applicable accounting

[23] Defined in Page 3 of this document
[24] Article 11 (2) of the SBA
[25] Expenditure is considered incurred when it is recognized as expenditure in the financial statements of the entity implementing the AA for the corresponding financial year
[26] Recital 30 of the SBA

standards of the country where each entity is established, or to the applicable International Accounting Standards and International Financial Reporting Standards.

In addition, the Independent Audit Body:

- should ensure that the calculation of IKAA is mathematically correct;
- should bring to the attention of the JU any issue, which, although not material to impact the overall report, might be deemed as useful based on their professional audit experience.

The IKAA certificate that is provided by the independent audit body appointed by the entity concerned should certify the following:

1. The costs reported for the IKAA have been incurred and recorded in the accounts in accordance with the entity's usual cost accounting practices, the applicable accounting standards of the country where the entity is established, or the applicable International Accounting Standards and International Financial Reporting Standards.
2. Figures should be verifiable in the general ledger records, and the system must facilitate reconciliation with the general ledger.
3. The cost accounting practices of the entity are formalized, documented, and consistently applied.
4. The costs have been incurred during the period declared by the entity concerned for the specific activities.
5. The use of lump sum, standard cost, and unit costs for the IKAA must be approved in advance by the Governing Board in accordance with the founding regulations, with proper justification provided.
6. The costs reported are identifiable, verifiable, and supported by relevant and adequate supporting documents. These supporting documents should either be originals or scanned versions of the original documents. Alternatively, certified copies of original documents can be provided if it aligns with the usual practice of the entity.

Ensuring that the IKAA certificate covers these key aspects is crucial for verifying the accuracy and validity of the reported IKAA in accordance with the founding regulation.

6.2 Independent Audit Body's Certificate submission

Following established practice, it was concluded that the following standards provide sound basis for the certification in accordance with the founding regulation article 11.2:

- International Standard on Auditing (ISA805 (Revised));
- International Standard on Assurance Engagements ('ISAE') 3000 (Revised), Accounts or Items of a Financial Statements as promulgated by the IFAC.

The Annex 4 and 5 include the "Model Report" which encompasses the concept here above of independent audit body's certificate.

Annex 3 contains the proposed Terms of References and Annex 4 and 5 the Model Report which shall be provided in English only. Nevertheless, in case an independent audit body would consider applying other ToRs than those included in Annex 3 of this document, with the agreement of the Association, the JU shall be consulted ex-ante for confirmation.

The independent audit body[27] shall be qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC or similar national regulations. In exceptional cases, where the aforementioned Body would not comply with the above, the Association shall assess how to deal with different approaches, and consult the JU ex-ante for confirmation.

In case of public entities, the Independent Audit Body may be a competent independent public officer who is a member of staff (e.g. Internal Auditor), but their independence must be formally established by the relevant national authorities. The declaration of independence should be provided to the JU (template available in Annex 8).

The audit certificate, following the template (annexed to this guidance document) for Terms of Reference and the model annexes for IKAA Certification, should be uploaded in the IKAA Reporting form via the Funding and Tenders Portal and submitted by the specified deadline, which is typically 31 May of the following year (year N+1). Refer to Section 7.

Important Note: It is essential that the certificate provided by the Association (including Organisations implementing AA) complies with the Global Health EDCTP3 template for certification, as certificates that do not meet these requirements cannot be accepted by the JU.

[27] Refer to section 4 of Annex 3 Terms of Reference for reporting of the IKAA

7. Reporting (IKAA Report form)

7.1 IKAA Reporting (Consolidated Annual Activity Report) – Year N+1

As per Article 11.2 of the founding regulation, the Association is required to submit the Annual IKAA Report (value of IKAA incurred in financial year N) to the JU Governing Board before 31 May of the year N+1.

This report serves as a consolidation of the IKAA delivered by the Organisations implementing AA during the specified year N. It encompasses the information outlined in the AA Plan (initial or amended work programme) as approved by the GB.

The costs associated with 'Additional Activities', must be reported by the Association in the Funding & Tenders Portal's IKAA Reporting module.

Important note: As mentioned in Section 3.2, new activities, i.e., not part of the existing plan approved by the GB, cannot be integrated into the reporting. Costs can only be reported for 'Additional Activities' that were included in the AA Plan (the initial or amended work programme) and approved by the JU Governing Board. These activities were initially entered by the Association in the IKAA Plan form and can be identified in the IKAA Report form by selecting their unique reference code (e.g., 'EDCTP3.2024.PG.12345.1') as explained in Section 3.3.

Instructions how to access, fill in and submit the IKAA report form

Step 1: At the start of the year N+1, the Association will receive a notification (when the workflow is launched) from the Portal requesting the completion and submission of the IKAA Report form by the mid of May.

Only individuals with the roles of LEAR, account administrator, or IKAA reporter have access to view, edit, and submit the IKAA Report form.

When selecting the unique reference of an 'Additional Activity', all information previously entered in the IKAA Plan form for that specific activity will be automatically populated in the IKAA Report form.

The Association is required to report specific information for each 'Additional Activity' in the IKAA Report form. This information should include:

1. The actual amount in EUR incurred by the entity during year N, as recognized in its accounts (if applicable).
2. The amount in EUR certified during year N, if supported by an audit certificate from an external and independent auditor.
3. The amount in EUR not yet certified, which is automatically calculated by the tool as the difference between the actual amount and the certified amount.
4. With regards to cost deviations, the JU will consider them at programme level. A clarification for a significant change in the total amount will be looked at in relation to the total IKAA. Additional activities with certified values which are significantly

lower than planned could prompt the JU to adopt an action plan to ensure that the targeted contribution from its member is achieved.

5. In addition to the financial information provided for each additional activity in the IKAA Report form, The Association is also required to include a success story description and the audience/target group information (if applicable) for each activity. These details help provide context and impact assessment for the reported activities.

The content of the IKAA Report form is visible only to the concerned entity and the Global Health EDCTP3.

Step 2: Once the Association submits the IKAA Report form, the JU will receive a notification from the Portal indicating that the form is ready for assessment.

The Global Health EDTCP3 then will check the content of the IKAA Report form, and the justification of deviation if applicable.

It is essential to ensure that the reported costs are accurate and supported by certification (when applicable) from independent audit body appointed by the entity concerned.

Only costs that have been certified can be accepted by the JU, as this certification provides assurance of the reliability and validity of the reported financial information and is legally required.

Step 3: The JU will organize consultation with the relevant stakeholders, about the reported IKAA Report form and certification and takes into account comments received when providing feedback to the EDCTP Association.

If the JU deems it necessary, they may reopen the IKAA Report form to request clarifications or corrections from the private members of the Global Health EDTCP3.

Step 4: After having performed its verification, the JU submits for validation the Consolidated Annual Activity Report (CAAR) package to the GB including the IKAA Report form by 31 of May of Yearn N+1[28].

8. IKAA report consulted by the Governing Board

Following the submission for adoption of the Consolidated Annual Activity Report (CAAR)[29] package by JU, the GB will be proposed to acknowledge in year N+1 the total IKAA reported and certified for the previous year (year N), including any potential adjustments[30].

[28] Article 26 (1):
[29] Information available in https://www.europarl.europa.eu
[30] Article 26 (e)

The GB will also review and take note of any explanations provided for major deviations (mentioned in section 3.2). If necessary, the GB may request further clarifications and the IKAA Report form may need to be reopened for corrections.

Once the GB approves the CAAR, typically at the end of June year N+1, EDCTP Association will receive a notification through the Funding and Tenders Portal confirming the certified costs for their 'Additional Activities'.

9. AA Timeframe

Costs for AAs must be incurred throughout the execution of the Global Health EDCTP3 Programme, starting from its inception on November 19, 2021, until the conclusion of the Global Health EDTCP3 Programme by December 31, 2031[31].

10. Conclusion

This guidance material has been established by Global Health EDCTP3's programme office after consultation with the Association.

Organisations implementing AA which are impeded or are experiencing significant difficulties in following the general established practice of IKAA certification, will be granted the opportunity to pilot the simplified certification approach and use the Model report presented in Annex 6.

This guidance will be applied with immediate effect from the date of its communication by the JU. It may be subject to revision to reflect lessons learned through its implementation, the result of internal and/or external audits on the JU and its members as well as any other element which would ensure a cost-efficient/effective approach.

[31] Article 3 of the SBA

Annex 1: Calendar

AA Plan – Work Programme (and Work Programme Amendment (during Year N))

YEAR N-1	September	Organisations implementing AA submit the plan of AA Year N to the Association The Association submit the draft plan to the JU
		JU provides feedback to the Association
	October	Association submits the IKAA Plan in the F&T Planning tool
		JU reviews the AA plan in the tool and submits the plan to the GB
	November	GB consults the AA Plan in conjunction with the SC
		JU provides feedback to the Association if applicable
	December	GB approves the WP (including the AA Plan)

IKAA Reporting – CAAR

YEAR N+1	April	1.The Association collects the IKAA cost information from the Organisations implementing AA 2. Association submits IKAA Report form to the JU using the F&T Portal 3. JU provides feedback to the Association
	May-June	1. JU submits for validation the CAAR to GB including IKAA 2. GB validates CAAR including IKAA Report form

Annex 2: IKAA Plan form

IKAA Planning

Joint Undertakings
Global Health EDCTP3 Joint Undertaking

Year of Reference
2024

Click *here* to find guidance on the IKAA IT Tool.

Additional activities name of reference

Reference of the additional activity
EDCTP3.202X.PG.XXXXXXXXX.X

Title of the additional activity

Complete description of the additional activity

Description of the additional activity

Type of IKAA

- ○ IKAA related to project
- ○ IKAA related to programme

Additional activity scope, in accordance with Article 104 of the SBA

- ○ Activities of constituent or affiliated entities of the EDCTP Association aligned with similar activities from other constituent or affiliated entities of the EDCTP Association and independently managed in accordance with national funding rules
- ○ Activities implemented by sub-Saharan African governmental research organisations
- ○ Activities which promote networking and partnerships building relationships with multiple private and public-sector organisations
- ○ Support for the development of research infrastructures such as clinical trial networks or cohorts related to the scope of the Global Health EDCTP3 Joint Undertaking, and support for strengthening health systems' preparedness for carrying out research activities within the scope of the Global Health EDCTP3 Joint Undertaking
- ○ Other

Additional activity category

Definition

General objectives for Global health EDCTP 3 JU, in accordance with Article 99(1) of the SBA

- ☐ To contribute to the reduction of the socio-economic burden of infectious diseases in sub-Saharan Africa by promoting the development and uptake of new or improved health technologies
- ☐ To contribute to the increase of health security in sub-Saharan Africa and globally by strengthening the research- and innovation-based capacities for preparedness and response to control infectious diseases

Specific objectives for Global health EDCTP 3 JU, in accordance with Article 99(2) of the SBA

- ☐ To advance the development and use of new or improved health technologies for tackling infectious diseases by supporting the conduct of the clinical trials, in sub-Saharan Africa
- ☐ To strengthen research and innovation capacity and the national health research systems in sub-Saharan Africa for tackling infectious diseases
- ☐ To facilitate better alignment of Member States, associated countries and sub-Saharan countries around a common Strategic Research and Innovation Agenda in the field of global health to increase the cost-effectiveness of European public investment
- ☐ To strengthen capacity in sub-Saharan Africa for epidemic preparedness through Effective and rapid research response to develop essential diagnostics, vaccines and therapeutics for early detection and control of emerging diseases of epidemic potential

Annex 3: Terms of Reference for reporting of the IKAA

Terms of Reference for the Independent Audit Body's Report on In-Kind Contributions to Additional Activities from Organisations implementing AA of the Global Health EDCTP3, in accordance with articles 11.1(b) and 11.2 of Council Regulation (EU) 2021/2085

How to use these terms of reference MODEL

- (also applies to Annex 4 and 5)
- insert the information requested between <…>.
- choose the optional text between […] highlighted in grey when applicable or delete.
- delete all yellow instructions and the present text box.

1. INTRODUCTION

Organisations implementing AA must adhere to Article 11(1) of the Council Regulation (EU) 2021/20851 (the founding regulation) by providing in-kind contributions to approved Operational and Additional Activities, ensuring alignment with JU objective. The Global Health EDCTP3 receives contribution from its member, the Organisations implementing AA, predominantly in the form of IKAA.

According with the Article 11(2) of the founding regulation, the contributions for 'Additional Activities' are required to be certified by an independent audit body, who may be the entity's regular external auditor, to ensure accuracy and transparency in the IKAA valuation and reporting process. The certification by the independent audit body is necessary for these costs to count towards the matching target established in Article 103 of the Regulation.

This document and its annexes outline the Terms of Reference (ToR) under which the Contractor engages 'The Independent Audit Body' to certify the in-kind contributions for Additional Activities reported by the Organisations implementing AA.

The ToR forms an essential part of the contract between the Organisation implementing the additional activity and the 'Independent Audit Body' and apply to the Additional Activities (AA) previously planned in the Work Programme (initial or amendment) by The Association. This certification ensures proper oversight and compliance.

2. OBJECTIVE AND CONTEXT

The Independent Audit Body is expected to:

Perform an assurance engagement and to issue a report based on the template in Annex 4 or Annex 5 which will support the opinion of the organisation implementing the additional activity and to provide conclusions on the valuation of the reported In-kind contributions to Additional Activities (AA).

3. STANDARDS AND ETHICS

The Independent Audit Body shall undertake this engagement in accordance with:

- Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC or similar national regulations;
- in accordance with the relevant International Standard on Auditing (ISA805 (Revised)) or with International Standard on Assurance Engagements ('ISAE') 3000 (Revised), Accounts or Items of a Financial Statements as promulgated by the IFAC;
- the IFAC Code of Ethics for Professional Accountants, developed and issued by IFAC's International Ethics Standards Board for Accountants (IESBA), which establishes fundamental ethical principles for Auditors with regard to integrity, objectivity, independence, professional competence and due care, confidentiality, professional behaviour and technical standards.

The Independent Audit Body should be independent from the organisation implementing the Additional Activity (including the Association EDCTP) and should comply with the independence requirements of the IFAC Code of Ethics for Professional Accountants.

4. REQUIREMENT FOR THE INDEPENDENT AUDIT BODY

By agreeing these ToR, the Independent Audit Body confirms meeting at least one of the following conditions:

- The Independent Audit Body is a member of a national accounting or auditing body or institution which in turn is a member of the International Federation of Accountants (IFAC).

- The Independent Audit Body is a member of a national accounting or auditing body or institution. Although this organisation is not member of the IFAC, the Independent Audit Body commits to undertake this expenditure verification in accordance with the IFAC standards and ethics set out in these ToR.

- The Independent Audit Body is registered as a statutory auditor in the public register of a public oversight body in an EU member state in accordance with the principles of public oversight set out in Directive 2006/43/EC of the European Parliament and of the Council (this applies to auditors and audit firms based in an EU member state)[32].

3

- The Independent Audit Body is registered as a statutory auditor in the public register of a public oversight body in a third country and this register is subject to principles of public oversight as set out in the legislation of the country concerned (this applies to auditors and audit firms based in a third country).

In case of public entities, the Independent Audit Body may be a competent independent public officer who is a member of staff (e.g. Internal Auditor), but their independence must be formally established by the relevant national authorities.

Examples of how the relevant national authorities formally establish this independence:

- Formal Appointment: The relevant national authorities can issue a formal appointment letter that explicitly states the officer's role, responsibilities, and independence. This letter should clarify that the officer operates independently of the entity's management.

- Internal Policies: Internal policies and guidelines that outline the independence of the auditing function. These policies can specify the auditor's authority to report directly to the governing body or audit committee, rather than to management.

- Conflict of Interest Policies: Strict conflict of interest policies that require auditors to disclose any potential conflicts and refrain from participating in areas where they might have a vested interest.

- Regular Training and Certification: Ensuring that the Internal Auditor receives regular training on ethical standards and independence requirements. This can include obtaining certifications from recognized professional bodies

- Reporting Mechanisms: Clear reporting mechanisms that allow the Internal Auditor to report findings directly to the governing body or external stakeholders without interference from management.

- Performance Evaluations: Evaluation and compensation of the Internal Auditor are not influenced by the management of the entity. This could involve having an independent review process for their performance.

[32] Directive 2006/43 of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253 EEC

- Legal Framework: Legal framework defines the independence of the Internal Auditor, including protections against dismissal or retaliation for performing their duties.

These measures can help reinforce the independence of the auditing function within public entities, ensuring that audits are conducted objectively and without undue influence.

Constituent entities of EDCTP Association may choose a CIPO to express opinion on the IKAA statements. CIPO must be independent in fact and appearance. A CIPO can be a member of staff of the organisation implementing AA, but she/he must not be involved in the authorisation, recording and preparation of the IKAA statements. A CIPO must have the delegated authority and capacity to audit the organisation implementing AA, and their independence must be formally established by the relevant national authorities.

A CIPO could be internal auditors of the organisation implementing AA or any responsible officer who has the delegated authority and capacity.

The CIPO is responsible for expressing opinion on the IKAA statements prepared by reporting entities, including compliance with Article 11.2 of the SBA. A CIPO, in issuing their opinion, shall ensure that the costs reported by the organisation implementing AA are:

- Incurred (recognised as expenditure) during the relevant reporting period;
- Incurred on AA that are indicated in one of the approved GH EDCTP3 work programme plans; and
- Are accurate and presented fairly, in all material respects.

5. SCOPE

5.1 Subject covered by these ToR

The cost incurred to implement the AA, in accordance with the provisions of Article 11.2 of the founding regulation and the aforementioned Letter of Commitment.

5.2 Conditions for validation of the IKAA Cost

The Independent Audit body must satisfy itself that relevant, reliable and sufficient evidence exists that:

a) The costs reported for the IKAA have been incurred and recorded in the accounts in accordance with the entity's usual cost accounting practices, the applicable accounting standards of the country where the entity is established, or the applicable International Accounting Standards and International Financial Reporting Standards.
b) Figures should be verifiable in the general ledger records, and the system must facilitate reconciliation with the general ledger.

c) The cost accounting practices of the entity are formalized, documented, and consistently applied.
d) The costs have been incurred during the period declared by the entity concerned for the specific activities.
e) The Additional Activity was included in the Work Programme (before the audit process) and Approved by the Governing Board (GB) of the Global Health EDCTP3.

6. CONTRACT SUMMARY

(To be prepared on Auditor's letterhead paper and addressed to the Entity)

[Name of the organisation implementing AA]

agrees to engage

[name of the independent Audit Body] 'the Auditor'

to certify the cost related to AA submitted by Organisation implementing AA in accordance with Article 11.2 of Council Regulation (EU) 2021/2085 (hereinafter 'the founding regulation').

1) Subject of the Engagement

In accordance with Article 11.2 of the founding regulation, the Private member must report by 31 May each year the value of its IKAA made in each of the previous financial years to the Governing Board of the JU.

In accordance with Article 11.2 of the founding regulation, for the purpose of valuing these IKAA, the costs shall be determined in accordance with the usual cost accounting practices of the Entity, to the applicable accounting standards of the country where the Entity is established, and to the applicable International Accounting Standards and International Financial Reporting Standards.

In accordance with Article 11.2 of the founding regulation, the costs shall be certified by an independent audit body appointed by the Organisation implementing AA and this is the subject of this engagement.

In accordance with Article 11.2 of SBA, the costs shall not be audited by the JU or any Union body. The valuation method may be verified by the JU should there be any uncertainty arising from the certification by the independent audit body.

The subject of this engagement is to certify the cost incurred to implement the IKAA, in accordance with the provisions of Article 11.2 of the founding regulation and the aforementioned Letter of Commitment.

2) Responsibilities of the Parties to the Engagement

The organisation implementing AA is responsible for preparing the IKAA declarations submitted in accordance with the model template provided in Annex 4 or 5 of guidance of the "*Global Health EDCTP3 Guidance for Private Founding Members and Independent Audit Bodies*", according to the provisions of the founding regulation. The Organisation implementing AA shall provide the IKAA declarations to the Auditor and ensure that the costs declared can be properly reconciled in its cost accounting system and underlying accounts and records.

Notwithstanding the audit to be carried out, the Organisation implementing AA remains at all times responsible and liable for the accuracy of the aforementioned declarations.

- The Organisation implementing AA is responsible for providing all statements and supporting information, which will enable the Auditor to perform its work and certify the declared IKAA. The Organisation implementing AA will provide the Auditor with a written representation letter supporting the declaration and all supporting statements, clearly dated and stating the period covered by the statements.
- The Organisation implementing AA accepts that the ability of the Auditor to perform the audit required by this engagement effectively depends upon them by providing full and free access to their staff and its accounting and other relevant records.

'The Auditor' is responsible for performing the procedures necessary to be able to certify the value of the declared IKAA.

The Auditor shall be independent from the Organisation implementing AA .

The Auditor shall be qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC or similar national regulations.

3) Engagement Type and scope

This constitutes an audit engagement to provide an audit report on the annual declarations of the IKAA sustained during the period [……] to the Organisation implementing AA , in compliance with the provisions of the founding regulation, in particular Article 11.2 thereof.

The Auditor shall include in its Report that no conflict of interest[33] exists with the audited organisation implementing AA in establishing this Report.

4) Applicable standards

The Auditor shall undertake this engagement in accordance with these ToR and:

- in accordance with the relevant International Standard on Auditing (ISA805 (Revised)) or with International Standard on Assurance Engagements ('ISAE') 3000 (Revised), Accounts or Items of a Financial Statements as promulgated by the IFAC;
- in compliance with the *Code of Ethics for Professional Accountants* issued by the IFAC.

5) Reporting

The Report on the annual declarations of the IKAA must be established in the format of the Model Report (either based on ISA805 (Revised) or on ISAE3000 (Revised)) as attached to these Terms of Reference (provided in the Annex 2 to the document "*GH EDCTP3 Guidance for Private Founding Members: Declaration and certification of IKAA & self-certification/statement of total project costs*") and shall be written in English.

6) Timing

The Report shall be provided by [insert date].

7) Other Terms

(The Organisation implementing AA and the Auditor can use this section to agree other specific terms, such as the Auditor's fees, liability, applicable law, etc. Those specific terms must not contradict the terms specified above.)

[33] A conflict of interest arises when the auditor's objectivity to establish the audit report is compromised in fact or in appearance when the auditor, for instance:
- was involved in the preparation of the Financial Statements (Forms C) and/or of the Declaration of the Total Projects' Cost and/or the IKAA declaration;
- stands to benefit directly should the report be accepted;
- has a close relationship with any person representing the beneficiary;
- is a director, trustee or partner of the beneficiary;
- is in any other situation that compromises his or her independence or ability to establish the report impartially.

Legal name of the Organisation implementing AA

Name and function of the authorized representative

Signature, date

Legal name of the Independent auditor

Name and function of the authorized representative

Signature, date

Annex 4: Model Report - ISA805 (Revised)

Model Report on the declarations of costs of additional activities of the [Organisation implementing the AA] in accordance with Article 11.2 of Council Regulation (EU) 2021/2085

for the period 01/01/20XX to 31/12/20XX […….]
established by [*Name of the Organisation implementing AA*]

To: [name and address of the Organisation implementing AA]

Dear [name of contact person]

As agreed under the terms of reference dated ( )

with (insert name of the Organisation implementing AA)

we (insert name of the independent Audit Body) (the Auditor)

established at (full address)

represented by (insert name and function of authorised representative)

have audited:

the accompanying declarations of the costs of additional activities from [*Name of the* Organisation implementing AA] related to the calendar year [....]

and hereby provide our Report on the declaration of costs of additional activities using the report format agreed with you.

Opinion

We have audited the accompanying declaration of costs of additional activities of (insert name of the Organisation implementing AA) for the period 01/01/20XX to 31/12/20XX prepared and submitted to the Global Health EDCTP3 Joint Undertaking in accordance with the Article 11.2 of the Council Regulation (EU) 2021/2085 (hereinafter 'the founding regulation').

In our opinion, the accompanying declaration presents fairly, in all material respects, the costs of additional activities of the organisation implementing AA for the period 01/01/20XX to 31/12/20XX.

Basis for Opinion

We conducted our audit in accordance with International Standards on Auditing (ISAs). Our responsibilities under those standards are further described in the *Auditor's Responsibilities for the Audit of the Declaration* section of our report. We are independent of the Organisation implementing AA, in accordance with the ethical requirements that are relevant to our audit of the declaration of the IKAA, and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Emphasis of Matter

(This section should be used by the auditor to bring to the attention of the Organisation implementing AA any matters to be considered as a recommendation and as such to be changed in future calculations.) – to delete if not applicable

Our opinion is not modified in respect of this matter.

Responsibilities of Management and Those Charged with Governance for the Declaration

Management of the Organisation implementing AA is responsible for the preparation and submission to the EDCTP Association or the Global Health EDCTP3 JU of the declaration of costs of additional activities in accordance with the Article 11.2 of the founding regulation and to maintain adequate accounting records and documentation to support and justify the cost and information declared and for such internal control as management determines is necessary to enable the preparation of a declaration that is free from material misstatement, whether due to fraud or error.

Auditor's Responsibilities for the Audit of the Declaration

Our objectives are to obtain reasonable assurance about whether the declared costs of additional activities as a whole is free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance but is not a guarantee that an audit conducted in accordance with ISAs will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of this statement on costs of additional activities.

Other Matters

We conducted this engagement:

1. in accordance with the International Standard on Auditing ('ISA') 805 Special Considerations, Audit of Single Financial Statements and Specific Elements, Accounts or Items of a Financial Statements as promulgated by the IFAC;
2. in compliance with the Code of Ethics for Professional Accountants issued by the IFAC; and
3. the provisions of the founding regulation.

An audit engagement involves performing procedures to obtain audit evidence about the amounts and disclosures in the Declaration of costs of additional activities. The audit engagement also includes procedures to obtain audit evidence about the appropriateness of accounting practices used for the preparation of the declaration of costs of additional activities as well as about the overall presentation of the declaration of costs of additional activities. The procedures selected depend on the auditor's judgement, including the assessment of the risks of material misstatement of the declaration, whether due to fraud or error.

In making those risk assessments, the auditor considers internal controls relevant to the entity's preparation and presentation of the declaration of costs of additional activities in order to design audit procedures that are appropriate in the circumstances relevant for the scope of this engagement, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control system.

Furthermore, we have evaluated the appropriateness of accounting policies used and the reasonableness of accounting estimates, if any, and related disclosures made by management.

Our work is not designed specifically to identify incidences of fraud. Accordingly, fraud may occur and not be detected. We have nevertheless obtained representations made by the member in relation to the authenticity and completeness of the supporting documentation provided to us.

(Name legal entity of Auditor)
(Auditor address)
(Date)

(Signature)
(Name Auditor)

Annex I: Signed declaration of IKAA from *[Organisation implementing AA]* for the calendar year [....] (See Annex 7)

Annex 5: Model Report – ISAE3000 (Revised)

Model Report on the declarations of costs of additional activities of the [Organisation implementing the AA] in accordance with Article 11.2 of Council Regulation (EU) 2021/2085

for the period 01/01/20XX to 31/12/20XX […….]
established by [*Name of the Organisation implementing AA*]

To: [name and address of the Organisation implementing AA]

Dear [name of contact person]

As agreed under the terms of reference dated ( )

with (insert name of the O*rganisation implementing AA*)

we (insert name of the independent Audit Body) (the Auditor)

established at (full address)

represented by (insert name and function of authorised representative)

have been engaged to provide a report of reasonable assurance in respect of the accompanying declarations of the costs incurred in implementing Additional Activities (hereinafter AA) from [*Name of the Organisation implementing AA*] related to the calendar year [....]

and hereby provide our Report on the declaration of costs of additional activities.

Independent practitioner's assurance report

Scope

We have been engaged by [name of the Organisation implementing AA] to perform a 'reasonable assurance engagement,' as defined by International Standards on Assurance Engagements, here after referred to as the engagement, to report on the accompanying Declaration of costs of additional activities of the organisation implementing AA for the period 01/01/20XX to 31/12/20XX.

Criteria applied by the Member

The Organisation implementing AAhas prepared the Declaration, in accordance with Article 11.2 of the Council Regulation (EU) 2021/2085 (hereinafter 'the founding regulation'); As a result, the subject matter information may not be suitable for another purpose.]

Responsibility of the Organisation implementing AA

The Organisation implementing AA is responsible for the preparation and submission to the EDCTP Association or the Global Health EDCTP3 JU of the declaration of costs of additional activities in accordance with the Article 11.2 of the Council Regulation (EU) 2021/2085 (hereinafter 'the founding regulation').This responsibility includes establishing and maintaining internal controls, maintaining adequate records and making estimates that are relevant to the preparation of the subject matter, such that it is free from material misstatement, whether due to fraud or error.

Auditor's Responsibility

Our responsibility is to express an opinion, on the costs of additional activities declared based on the evidence we have obtained.

We conducted our engagement in accordance with the International Standard for Assurance Engagements Other Than Audits or Reviews of Historical Financial Information ('ISAE 3000 (Revised)'), and the terms of reference for this engagement as agreed with the Member on [insert date of signed engagement letter].Those standards require that we plan and perform our engagement to obtain reasonable assurance about whether, in all material respects, the Declaration of costs of additional activities is presented in accordance with the founding regulation, and to issue a report. The nature, timing, and extent of the procedures selected depend on our judgment, including an assessment of the risk of material misstatement, whether due to fraud or error.

We believe that the evidence we have obtained is sufficient and appropriate to provide a reasonable basis for our opinion.

ISAE 3000 requires that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the financial statements are free from material misstatement.

Emphasis of Matter

(This section should be used by the auditor to bring to the attention of the Organisation implementing AA any matters to be considered as a recommendation and as such to be changed in future calculations.) – to delete if not applicable

Our opinion is not modified in respect of this matter.

Other Matters

A reasonable assurance engagement involves performing procedures to obtain sufficient appropriate evidence to give reasonable assurance over the Declaration. The procedures selected depend on our judgement, including the assessment of the risks of material misstatement of the Declaration whether due to fraud or error. In making those risk assessments we considered internal control relevant to the Organisation's preparation and presentation of the Declaration to design assurance procedures that are appropriate in the circumstances, but not for the purpose of expressing a conclusion on the effectiveness of the Organisation's internal control over the preparation and presentation of the Declaration.

Furthermore, we have evaluated the appropriateness of accounting policies used and the reasonableness of accounting estimates, if any, and related disclosures made by the management.

Our work is not designed specifically to identify incidences of fraud. Accordingly, fraud may occur and not be detected. We have nevertheless obtained representations made by the member in relation to the authenticity and completeness of the supporting documentation provided to us.

We believe that the evidence we have obtained is sufficient with respect to the objectives relevant for our engagement and appropriate to provide a basis for our report.

Opinion

In our opinion, the accompanying declaration presents fairly, in all material respects, the costs of additional activities of the Organisation implementing AAfor the period 01/01/20XX to 31/12/20XX.

(Place), (Date)

(Name legal entity of Auditor)
(Signature)
(Name Auditor)

Annex I: Signed declaration of IKAA from *[Organisation implementing AA]* for the calendar year [....] (See Annex 7)

Annex 6: Model Competent Independent Public Officer's report on the declarations of costs of In-Kind Contributions to Additional Activities (IKAA)

To: [name and address of the Organisation implementing AA]

My opinion

I have audited the accompanying declaration of costs of additional activities of [*Name of the relevant organisation responsible for submitting the IKAA certificate to the EDCTP Association*] for the period [1 January 20XX to 31 December 20XX].

In my opinion the accompanying declaration of costs for the period 01/01/20XX to 31/12/20XX.has been prepared, in all material respects, in accordance with the requirements set out in Article 11.2 of Council Regulation (EU) 2021/2085.

The costs reported:

- Have been incurred (recognised as expenditure) during this reporting period;
- Have been incurred on AA that are indicated in one of the approved GH EDCTP3 work programme plans; and
- Are accurate and presented fairly, and in all material respects

Basis for my opinion

I conducted my audit of the declaration of costs of additional activities in accordance with [Name of country] law, and in accordance with the requirements set out in Article 11.2 of Council Regulation

I am not involved in the authorisation, recording and execution of IKAA of [insert name of Organisation implementing AA].

I believe the audit evidence I have obtained is sufficient and appropriate to provide a basis for my opinion.

Responsibilities of management of the reporting entity for the IKAA Statement

The management is responsible for preparing the declaration of costs of additional activities in accordance with the Article 11.2 of the Council Regulation, and for maintaining adequate accounting records and documentation to support and justify the declared costs.

Competent Independent Public Officer's responsibilities

My objective is to plan and perform my audit in a manner that allows me to obtain sufficient and appropriate audit evidence for my opinion. I have performed my audit with a high, but not absolute, level of assurance, which means I may not detect all material misstatements due to fraud or error during my audit.

Signature of the CIPO

[Competent Independent Public Officer's name]
[Job title and name of the employer of the CIPO]
[Date]

Annex I: Signed declaration of IKAA from *[Organisation implementing AA]* for the calendar year [....] (See Annex 7)

Annex 7: Signed declaration of IKAA from the Organisation implementing AA for the calendar year

Declaration and certification of IKAA based on the information from the adopted AA Plan.

OVERVIEW ESTIMATED AMOUNT OF IKAA FOR [YEAR XXXX]				
Reference of the addditional activity (as in the adopted AA Plan)	**Title of the AA (as in the adopted AA Plan)**	**AA category (please select one from the drop-down menu)**	**Total Amount (in EUR)**	**Country of establishment of the contributor**
EDCTP3.2022.PG.929737435.XX				
EDCTP3.2023.PG.929737435.XX				
EDCTP3.2024.PG.929737435.XX				
TOTAL CERTIFIED IKAA			-	

Annex 7 Signed declaration of IKAA fo

(Place), (Date)

(Name Private Founding Member)

(Signature)

(Name authorised representative)

Annex 8: Declaration of independence template

CIPO Letter head

Declaration of independence from authorisation, recording and execution of IKAA expenditure

(To be completed and signed by the CIPO)

I, [insert full official name], the undersigned, in my capacity as [insert job title and name of employer] declare that:

1. I have not been involved in the authorisation, recording and execution of IKAA of [insert name of country] and therefore there are no conflicts of interest which would prevent me from certifying the reported expenditure for the year ended 31 December [insert the year].

2. I have the delegated authority to give such approvals

Signature: _____

[Name of the CIPO]
[Job Title of CIPO}
[Organisation]
[Date/Place]