

CERTIFICATE ON THE REPORT ON IN-KIND CONTRIBUTIONS TO ADDITIONAL ACTIVITIES (IKAA) of IHI Joint Undertaking private members

(To be filled out by an independent external auditor (in line with the options applicable), printed on their own letterhead and signed (on paper or with an eIDAS Regulation compliant qualified electronic signature¹) The Terms of reference (ToR) need to be signed by both the entity and the auditor. The Agreed-upon procedures (AUP) checklist(s) and the report need to be signed by the auditor. The scanned PDF should be submitted by (the constituent entity of) the IHI JU private member through the Funding and Tenders Portal.)

TERMS OF REFERENCE

1. Background and subject matter

In accordance with Article 11.2 of the Council Regulation (EU) 2021/2085² ('the Regulation') establishing the Innovative Health Initiative Joint Undertaking ('IHI JU') the private members of IHI JU³ ('the private members') shall report by 31 May each year the value of their in-kind contributions to additional activities ('IKAA') made in the previous financial year(s) to the Governing Board of IHI JU.

These reported IKAA shall consist of costs for project-specific additional activities and/or programme-specific additional activities.

In accordance with Article 120.2 of the Regulation, costs associated to project-specific additional activities must be incurred between the date of submission of the IHI proposal and up to two years after the end date of the IHI project.

For Programme-specific IKAA, costs shall be incurred during the implementation of the IHI JU Programme.

In accordance with Article 11.2 of the Regulation, for the purpose of valuing these IKAA (both project-specific and programme-specific), the costs shall be determined in accordance with

- the usual cost accounting practices of the entities concerned,
- the applicable accounting standards of the country where the entity is established,
- the applicable International Accounting Standards and International Financial Reporting Standards.

Additionally, the private members may choose to value their additional activities in accordance with the Horizon Europe model grant agreement (HE MGA)⁴ if duly justified and applied consistently for all types of costs incurred for additional activities.

In duly specified cases, the IHI JU Governing Board may also authorise the use of simplified methods such as lump sums or unit costs for valuing the additional activities, if it is necessary to achieve simplification, cost effectiveness, and appropriate level of protection of confidential commercial data.

In accordance with Article 11.2 of the Regulation, the private members shall have these costs certified by an independent audit body appointed by the entity concerned.

¹ IHI JU accepts only qualified electronic signatures which are in line with the European Union's eIDAS Regulation. Please see a list of qualified trust service providers in accordance with the eIDAS Regulation per EU member state on the eIDAS website: <https://eidas.ec.europa.eu/efda/tl-browser/#/screen/home>

² Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2021.427.01.0017.01.ENG

³ The Private members of IHI JU are the industry trade associations COCIR, EFPIA (including Vaccines Europe), EuropaBio and MedTech Europe, as well as the constituent entities of those trade associations and their affiliated entities, if any.

⁴ The Horizon Europe model grant agreement is available on the Funding and Tenders Portal: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/agr-contr/general-mga_horizon-euratom_en.pdf

A certificate on the report of in-kind contributions to additional activities ('the IKAA certificate') must be provided by the private members in order for the IHI JU to account these reported costs as IKAA.

The present Terms of Reference ('ToR') set out the procedures to be performed, define the scope and applicable standards of the IKAA certificate and who may deliver it.

The private members that report IKAA for their affiliated entity(ies) shall have these costs certified in their IKAA certificate (i.e. one certificate for the different entities).

Costs for additional activities that are not certified cannot count towards the matching target established in Article 119 of the Regulation.

In accordance with Article 11.2 of the Regulation, the costs shall not be audited by the IHI JU or any European Union body. However, the valuation method may be verified by IHI JU should there be any uncertainty arising from the certification provided by the independent audit body. For this purpose, the auditor may be asked by the IHI JU to provide access to the auditors' working papers relevant for the verification of the valuation method applied by the entity.

Complementary information on IKAA is provided in the IKAA guidelines available on IHI website⁵.

2. Scope and applicable standards

The IKAA certificate is a report on (factual) findings based on agreed-upon procedures (AUP).

The engagement is to perform specific **agreed-upon procedures** to assist the IHI JU to verify and conclude on whether the totality of the value of the costs reported in the annual IKAA report of the private member (for both the entity and its affiliated entity(ies), if any) is in line with the eligibility criteria set out in Article 11.2 of the Regulation (and with the eligibility conditions set out in Article 6 of the Horizon Europe model grant agreement if the entity has chosen to value its additional activities as per the HE MGA).

It is not an assurance engagement; the auditor does not provide an audit opinion, nor expresses assurance.

The following standards apply:

- the International Standard on Related Services ('ISRS') 4400 (revised) *Agreed-upon Procedures Engagements* as issued by the International Auditing and Assurance Standards Board (IAASB);
- the *International Code of Ethics for Professional Accountants (including International Independent Standards)* issued by the International Ethics Standards Board for Accountants (IESBA), including the independence requirements;
- the International Standard on Quality Management 1 *Quality Management for Firms that Perform Audits and Reviews of financial statements, and Other Assurance and Related Services Engagements* (or equivalent).

Supreme audit institutions applying INTOSAI-standards may carry out the procedures according to the corresponding *International Standards of Supreme Audit Institutions (ISSAIs)* and *Code of Ethics* issued by INTOSAI instead of the International Standard on Related Services (ISRS) 4400 (revised) and the Code of Ethics for Professional Accountants issued by the IAASB and the IESBA.

The IKAA certificate must be issued according to the highest professional standards.

The auditor must comply with the present Terms of Reference, including the agreed-upon procedures checklist(s) and report template – without modifying them.

The work must be planned in a way that effective verification can be performed.

⁵ IKAA guidelines of the IHI JU are available on IHI website:

https://www.ihj.europa.eu/sites/default/files/IHI_Guidelines_in_kind_contribution_additional_activities.pdf

The auditor must use the evidence obtained from the procedures performed as the basis for the certificate. Matters which are important for the findings and evidence that the work was carried out in accordance with the Terms of Reference must be documented. The findings must be described in sufficient detail and include the affected amounts, to allow the entity concerned and the IHI JU to ensure appropriate follow-up.

3. Practitioners who may deliver the IKAA certificate

The entity is free to choose a **qualified external auditor** (referred to as ‘the practitioner’), including its usual external auditor, provided that:

- the auditor is **independent** from the participant and
- the provisions of **Directive 2006/43/EC**⁶ (or similar standards) are complied with.

Although ISRS 4400 (revised) states that independence is not a requirement for engagements to carry out agreed-upon procedures, it is one of the qualities to ensure an unbiased approach and therefore required for the reporting auditors. Compliance with the IESBA Code’s independence requirements is therefore mandatory.

The **IKAA certificate costs** themselves **cannot** be charged to an IHI JU project nor reported as in kind. Nevertheless, the choice of practitioner should still comply with the minimum criteria on best value for money and no conflict of interest. If the entity uses its usual audit firm, it is presumed that they already have an agreement that complies with these provisions.

4. Procedures to be followed and expected results

The **procedures** to be carried out by the practitioner to verify if the costs reported in the annual IKAA report are in line with the eligibility criteria set out in Article 11.2 of the Regulation are listed in the agreed-upon procedures checklist as set out in Annex 1a to this Terms of Reference.

Additionally, if the entity has chosen to value its additional activities in accordance with the HE MGA, the practitioner needs to carry out the lists of procedures as set out in Annex 1b.

Such procedures may include or necessitate inquiry and analysis, (re)computation, comparison, other accuracy checks, observation, inspection of records and documents and by interviewing the entity (and the persons working for them).

4.1 Basic systems checks

The practitioner must obtain a basic understanding of the entity’s accounting system and usual practices.

The practitioner must verify, for the specific sample transactions selected, that the accounting system (analytical or other suitable internal system) makes it possible to identify that each of the associated transaction costs are linked to the reported additional activity.

4.2 Objective of the agreed upon procedures

In conducting their work, the practitioners should bear in mind that the purpose of the engagement is to assist the IHI JU to verify and conclude on whether the totality of the value of the costs reported in the annual IKAA report of the private member (for both the entity and its affiliated entity(ies), if any) is in line with the eligibility criteria set out in Article 11.2 of the Regulation (and with the eligibility conditions set out in Article 6 of the Horizon Europe model grant agreement if the entity has chosen to value its additional activities as per the HE MGA).

In that respect, for each of the specific transactions sample tested, the associated cost must:

⁶ 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 or similar national regulations (OJ L 157, 9.6.2006, p. 87).

- be directly linked to the implementation of the additional activity originally approved by the Governing Board of the IHI JU and encoded in the IKAA Plan form of the concerned entity;
- have been actually incurred during the reporting period;
- not be covered by another EU grant or other EU funding;
- be identifiable, verifiable and, in particular, recorded in the entity's accounting records and determined according to the applicable accounting standards of the country where the entity is established and its usual cost accounting practices;
- comply with the requirements of applicable national laws on taxes, labour and social security.

4.3 Expected results and IKAA findings

The result column in the agreed-upon procedures checklist(s) has three different options of findings:

- YES — means that the standard finding is confirmed and that no exception needs to be reported
- NO — means that the standard finding cannot be confirmed and that an exception needs to be reported in the report (either because the practitioner carried out the procedures but cannot confirm the standard finding or because the practitioner was not able to carry out a specific procedure, e.g. because it was impossible to reconcile key information or data were unavailable)
- N.A. — means that the standard finding is 'not applicable' and that the procedure did not have to be carried out. The reasons for the non-application must be obvious, e.g. no cost was declared.

All instances where the result of an agreed-upon procedure is not satisfied in full, should be clearly reported as a finding/exception in the report and quantified, if possible.

Other instances where the practitioner has doubts or an inability to determine with reasonable assurance that specific transaction sampled satisfied in all material respects a given agreed upon procedures test should also be reported.

In addition, the practitioner is requested to mention any general comments and other observations that may be relevant for the reported IKAA assessment (or its follow-up) by the IHI JU and/or the entity concerned.

5. Other specific terms

(The entity and the practitioner can use this section to agree other specific terms, such as the certification fees, liability, applicable law, etc. These specific terms must not contradict the terms specified above.)

SIGNATURES

For the practitioner
[forename/surname/function]
[address]
[signature]
[date] [stamp]

For the entity
[forename/surname/function]
[address]
[signature]
[date] [stamp]

AGREED-UPON PROCEDURES REPORT

ON THE CERTIFICATE ON THE REPORT OF IN-KIND CONTRIBUTIONS TO ADDITIONAL ACTIVITIES (IKAA)

To
[Organisation full name
address]

The purpose of this IKAA Certificate is to provide the Innovative Health Initiative Joint Undertaking (IHI JU) with findings in accordance with the agreed-upon procedures (AUP) set out in the Terms of Reference (ToR), in order to be able to verify and conclude on whether the totality of the value of the costs reported in the IKAA Report of the IHI JU private member is in line with the eligibility criteria set out in Article 11.2 of the Regulation (and with the eligibility criteria set out in Article 6 of the Horizon Europe model grant agreement if the entity has chosen to value its IKAA as per the HE MGA). This report is solely intended for this purpose.

The agreed-upon procedures have been set and determined as appropriate by the IHI JU.

The agreed-upon procedures engagement involves performing the agreed-upon procedures set out in the Terms of Reference, as agreed with the entity. We do not assess the appropriateness, nor do we provide an audit opinion or assurance. Had we performed additional procedures, other matters might have come to our attention that would have been reported.

We, **[full name of the audit firm]**, established in **[full address/city/country]**, represented for signature of this certificate by **[name and function of an authorised representative]**,

hereby report that

- 1 — We are qualified/authorised to deliver this certificate and are not subject to any conflict of interest.
- 2 — We have performed the agreed-upon procedures engagement in accordance with the Terms of Reference (including the agreed-upon procedures checklist(s), which forms an integral part of the Terms of Reference), and in particular the following standards:
 - the International Standard on Related Services (ISRS) 4400 (revised) *Agreed-upon Procedures Engagements* as issued by the International Auditing and Assurance Standards Board (IAASB);
 - the *International Code of Ethics for Professional Accountants (including International Independent Standards)* issued by the International Ethics Standards Board for Accountants (IESBA), including the independence requirements;
 - the International Standard on Quality Management 1 *Quality Management for Firms that Perform Audits and Reviews of financial statements, and Other Assurance and Related Services Engagements* (equivalent).
- 3 — We have performed the agreed-upon procedures on costs reported for additional activities in the IKAA Report(s) of **[organisation legal name (short name)]**, PIC **[number]**, covering the following **reporting period(s): [insert reporting year(s)]**.

The relevant costs subject to this report amount to: **EUR [insert amount]**

- 4 — The report sets out information provided to us by the management of the entity in response to specific questions or as obtained and extracted from the entity's information and accounting systems.

5 — We report below the details of the exceptions which result from the procedures that we performed.

The standard findings could be confirmed, with the following **exceptions**:

N.[insert number of not confirmed standard finding] – [insert corresponding amount(s) or insert ‘not quantifiable’]: [provide factual explanation of ‘NO’-result finding e.g. calculation error, lack of supporting document, non-compliance with national law, etc.]

Repeat as needed

The following agreed-upon procedures (and standard findings) were **not applicable**:

N.[insert number of not applicable AUP/standard finding]: [provide factual explanation of ‘N.A’-result finding e.g. no costs declared.]

Repeat as needed

Further remarks:

[insert any additional information]

Annexes: Terms of Reference and Agreed-upon procedures checklist(s) (signed and completed)

SIGNATURE

For the practitioner

[forename/surname/function]

[address]

[signature]

[date] [stamp]

ANNEX 1a - AGREED-UPON PROCEDURES CHECKLIST

to be performed by the practitioner to verify if the costs reported in the IKAA Report are in line with the eligibility criteria set out in Article 11.2 of the Regulation.

This checklist contains procedures to be performed by the practitioner in all cases, also if the entity has chosen to value its additional activities in accordance with the HE MGA.

For each of the procedures carried out, the practitioner should first acquire from the entity, via documentation and enquiries, an understanding of the usual practice and standards of the entity as regards their cost accounting. The procedures should then be carried out with reference to these standards.

For the below procedures, a random sample of relevant cost items should be drawn per declared additional activity. The sample should be of full coverage if less than 10 items, otherwise the sample should cover minimum 10 items, or 10% of the items, whichever is the greater.

#	Procedures	Standard Findings and basis for exception reporting	Result (YES/NO/N.A)
1	Confirm that all sampled costs relating to the declared additional activities have been actually incurred by the entity and recorded in its accounts in accordance with - the entity's usual cost accounting practices, which are formalised, documented and consistently applied by the entity, - the applicable accounting standards of the country where the entity is established, - the applicable International Accounting Standards (such as International Financial Reporting Standards), if applicable.	All sampled costs have been actually incurred by the entity and recorded in its accounts in accordance with: - the entity's usual cost accounting practices (i.e. used consistently by the entity for all similar activities, not just for IKAA reporting ⁷), - the applicable accounting standards of the country where the entity is established, - the applicable International Accounting Standards and International Financial Reporting Standards. If the method is not considered to be in line with the entity's usual (cost) accounting practices, it should be reported as an exception. Reconciling differences, if any, need to be explained ⁸ . Unexplained differences are not considered to be eligible and should be reported as an exception.	(YES/NO/N.A)
2	Confirm that all sampled costs have been incurred during the period declared by the entity.	All sampled costs have been incurred during the period declared by the entity. Costs incurred outside the reporting period are to be reported as an exception.	(YES/NO/N.A)
3	Confirm that all sampled costs relating to project-specific additional activities were incurred during the eligibility timeframe set in Article 120.2 of the Regulation (i.e., between the submission date of the IHI full proposal and up to maximum two	All sampled costs for project-specific additional activities have been actually incurred between the submission date of the IHI full proposal(s) and up to maximum two years after the IHI project(s) end date. Costs incurred outside the eligibility timeframe are not considered to be eligible and should be reported as an exception.	(YES/NO/N.A)

⁷ Except for modifications required to comply with rules under the Horizon Europe Model Grant Agreement, if applicable. In such a case, procedures listed in Annex 1b must also be carried-out by the practitioner.

⁸ There might be cases where statutory and cost accounting methods are not identical; or the expenditures in the statutory accounts only partially fulfil (e.g. percentage of the use basis) the definition of the Additional Activity according to the Regulation. In such cases, explanations are required, and their reasonability needs to be evaluated by the practitioner.

	years after the IHI project end date).		
4	Confirm for all sampled items that the activities were carried-out in the European Union or in countries associated to the Horizon Europe programme. ⁹	For all sampled costs the activities have been carried-out in the EU or in Horizon Europe associated countries. Costs for activities carried-out outside the EU or Horizon Europe associated countries are not considered to be eligible and should be reported as an exception.	(YES/NO/N.A)
5	Confirm for all sampled items that the costs reported are directly linked to the implementation of the additional activities.	All sampled costs are directly linked to the implementation of the Additional Activities. In case there is no direct link between actual reported figure(s) and the activity(ies) listed in the IKAA Report, it should be reported as an exception.	(YES/NO/N.A)
6	Confirm for all sampled items that the costs reported are for activities not funded by any EU funding programme. In case the cost accounting system of the entity does not enable the auditor to complete this procedure, the entity should provide the auditor with the list of other EU funded project(s) in which it participates (if any) and a formal signed attestation from the management confirming that the reported IKAA is not funded by any EU funding programme.	All sampled costs are for activities not funded by any EU funding programme. If necessary, the auditor should confirm having received the list of EU funded project(s) in which the entity participates (if any) and a formal signed attestation from the management confirming that the reported IKAA is not funded by any EU funding programme. Costs financed via the JU or other EU programme are not considered to be eligible under IKAA and should be reported as an exception.	(YES/NO/N.A)
7	Confirm that all sampled items are identifiable, verifiable and backed up by original supporting documents (originals or alternatively scanned version of the original documents/certified copy of original documents if in line with the entity's usual practice).	All sampled costs are identifiable, verifiable and backed up by relevant supporting documents. Costs lacking supporting evidence should be reported as an exception.	(YES/NO/N.A)
8	Confirm for all sampled items that in case of simplified method used to value IKAA such as lump-sums or unit costs, such methodology has been preapproved by the IHI JU Governing Board and applied by the entity excluding any profit margins and following its usual cost accounting practices.	All sampled costs for which the entity has used a simplified methodology (such as lump-sums or unit costs) have been calculated as per the methodology approved by the IHI JU Governing Board. Additionally, the entity could demonstrate that the followed methodology excludes any profit margins and is in line with the entity's usual cost accounting practices.	(YES/NO/N.A)

⁹ List of countries associated to Horizon Europe: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/list-3rd-country-participation_horizon-euratom_en.pdf

ANNEX 1b - AGREED-UPON PROCEDURES CHECKLIST

to be performed by the practitioner to verify if the costs reported in the IKAA Report are in line with the general and specific eligibility conditions set out in Article 6 of the HE MGA.

This checklist is **only applicable if the entity has chosen to value its additional activities in accordance with the HE MGA.**

This checklist contains procedures to be performed by the practitioner **in addition** to the procedures listed in the Annex 1a.

These additional procedures to be performed by the practitioner are listed in the model for certificate on the statements of contributions (CCS). This document is currently being finalized (link not yet available).

Annex 2: IKAA Report

(The IKAA Report subject to this assignment shall be attached here.

The IKAA Report for the relevant year shall be extracted from the reporting module by the Entity and shall be signed by the authorised representative person of the Entity.

In case of adjustment(s) to prior year(s), the relevant IKAA Report(s) shall also need to be attached here).