

# Terms of Reference and annexes for the Certification of the declaration of in-kind contributions to additional activities (IKAA) of IHI Joint Undertaking Private members

*Version 1.0 dated 31 January 2023*

## Table of Contents

Introduction.....	3
Terms of Reference for the certification of the declaration of in-kind contributions to additional activities (IKAA) of IHI Joint Undertaking private members in accordance with Article 11.2 of Council Regulation (EU) 2021/2085.....	4
Annex 1: Model Report – ISA 805.....	7
Annex 2: Model Report – ISAE 3000.....	10
Annex 3: Declaration of IKAA.....	13

## Introduction

As per Article 11.2 of the Council Regulation (EU) 2021/2085<sup>1</sup>, the IHI JU private members<sup>2</sup> shall report by 31 May of year N+1 to the IHI JU Governing Board the value of their in-kind contribution to additional activities ('IKAA') made in each of the previous financial years (i.e. from 1 January to 31 December of year N and potential adjustments to prior years). The IHI JU private members shall have these costs certified by an independent external auditor appointed by the entity concerned (who can be the entity's usual external auditor) in order for the IHI JU to account these reported costs as IKAA.

The costs incurred for additional activities shall be determined in compliance with the usual cost accounting practices of the IHI private members. Additionally, the IHI JU private members may choose to value their additional activities in accordance with the Horizon Europe model grant agreement (HE MGA)<sup>3</sup>. In this case, the entity concerned should apply the HE MGA cost eligibility rules and cost calculation methods (Article 6) consistently for all types of costs incurred for additional activities.

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

IHI JU private members that have reported IKAA for their affiliated entity(ies) shall have these costs certified in their audit certificate (i.e. one single audit certificate is sufficient 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.

IHI JU private members must submit to IHI JU three separate documents as part of the IKAA certification:

1. the Terms of Reference (which corresponds to the engagement letter between the IHI JU private member and the Auditor);
2. the Model Report using the Annex 1 (Model Report under ISA 805) or using the Annex 2 (Model Report under ISAE 3000). The choice between Annex 1 or Annex 2 lies with the IHI JU private member and the Auditor;
3. the signed IKAA declaration(s) (Annex 3) as extracted from the reporting module by the IHI JU private member.

This document should be read in conjunction with the IKAA guidelines available on IHI website.<sup>4</sup>

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<sup>1</sup>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](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2021.427.01.0017.01.ENG)

<sup>2</sup>The Private members of IHI JU are the industry trade associations COCIR, EFPIA (also representing Vaccines Europe), EuropaBio and MedTech Europe, as well as the constituent entities of those trade associations and their affiliated entities, if any.

<sup>3</sup>The Horizon Europe model grant agreement is available on IHI website: [https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/agr-contr/general-mga\\_horizon-euratom\\_en.pdf](https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/agr-contr/general-mga_horizon-euratom_en.pdf)

<sup>4</sup>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](https://www.ihj.europa.eu/sites/default/files/IHI_Guidelines_in_kind_contribution_additional_activities.pdf)

# **Terms of Reference for the certification of the declaration of in-kind contributions to additional activities (IKAA) of IHI Joint Undertaking private members in accordance with Article 11.2 of Council Regulation (EU) 2021/2085**

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

The following are the Terms of Reference ('ToR') on which

[name of the entity] 'the Entity', founding Member of the Innovative Health Initiative Joint Undertaking (hereinafter 'IHI JU') or constituent entity to one of the founding Members of the IHI JU (if applicable: and affiliated entities(s) [....., ....., .....])

agree(s) to engage

[name of independent audit body] 'the Auditor'

to certify the declaration of the in-kind contributions to additional activities (hereinafter 'IKAA') submitted by the Entity to IHI JU in accordance with Article 11.2 of Council Regulation (EU) 2021/2085 (hereinafter 'the Regulation') for the period [01/01/20XX to 31/12/20XX] (if applicable: and adjustment(s) to the prior year(s) [yyyy], [yyyy]...).

The IHI JU is not a party to this engagement.

## **1. Subject of the Engagement**

In accordance with Article 11.2 of the Regulation, the Entity 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 IHI JU.

In accordance with Article 11.2 of the Regulation, for the purpose of valuing these IKAA, the costs shall be determined in accordance with the usual cost accounting practices of the Entity, the applicable accounting standards of the country where the Entity is established, the applicable International Accounting Standards and International Financial Reporting Standards. Additionally, the Entity may choose to value its additional activities in accordance with the Horizon Europe model grant agreement (HE MGA)<sup>5</sup> 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 costs shall be certified by an independent audit body appointed by the Entity, and this is the subject of this engagement.

In accordance with Article 11.2 of the Regulation, the costs shall not be audited by IHI JU or any Union body. 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 IHI JU to provide access to the Auditors' working papers relevant for the verification of the valuation method applied by the Entity.

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<sup>5</sup>The Horizon Europe model grant agreement is available online:  
[https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/agr-contr/general-mga\\_horizon-euratom\\_en.pdf](https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/agr-contr/general-mga_horizon-euratom_en.pdf)

## 2. Responsibilities of the Parties to the Engagement

The Entity is responsible for reporting by 31 May each year the value of its IKAA in the reporting module accessible via the EU Funding and Tenders Portal<sup>6</sup>. The reported IKAA shall be reflected in the IKAA declaration that the Entity shall extract from the reporting module (Annex 3). The Entity shall provide the signed IKAA declaration to the Auditor and ensure that the costs so declared can be properly reconciled to the Entity's cost accounting system and underlying accounts and records.

Notwithstanding the audit to be carried out, the Entity remains at all times responsible and liable for the accuracy of the aforementioned declaration.

1. The Entity is responsible for providing all statements and supporting information which will enable the Auditor to perform its work and certify the IKAA declared. The Entity will provide the Auditor with a written representation letter supporting the declaration reported under Annex 3 as well as all supporting statements, clearly dated and stating the period covered by the statements.
2. The Entity accepts that the ability of the Auditor to perform the audit required by this engagement effectively depends upon the Entity providing full and free access to the Entity's 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 IKAA declared.

The Auditor shall be independent from the Entity.

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. Applicable standards and scope of work

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

1. with the relevant International Standard on Auditing 805 ('ISA 805') or with International Standard on Assurance Engagements 3000 ('ISAE 3000'), promulgated by the International Federation of Accountants ('IFAC');
2. with the *Code of Ethics for Professional Accountants* issued by the IFAC.

## 4. Report

The certification of the IKAA annual declaration must be established in the format of the Model Report as attached in Annex 1 (ISA 805) or in Annex 2 (ISAE 3000) to these ToR and shall be written in English.

The Auditor shall include in its Report a statement that no conflict of interest<sup>7</sup> exists with the Entity in establishing this Report.

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<sup>6</sup>The EU Funding and Tenders Portal is accessible at <https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/home>

<sup>7</sup>A conflict of interest arises when the Auditor's objectivity in establishing the audit report is compromised in fact or in appearance when the auditor, for instance:

- was involved in the preparation of the IKAA declaration;
- stands to benefit directly should the report be accepted;
- has a close relationship with any person representing the Entity;
- is a director, trustee or partner of the Entity;
- is in any other situation that compromises his or her independence or ability to establish the report impartially.

**5. Timing**

The Report shall be provided by [date].

**6. Other terms**

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

[Legal name of the Entity]  
[Name and function of the authorised representative]  
[Signature, date]

[Legal name of the Auditor]  
[Name and function of the authorised representative]  
[Signature, date]

## Annex 1: Model Report – ISA 805

### Model Report for the certification of the declaration of in-kind contributions to additional activities (IKAA) to IHI JU 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 Entity]

To: [name and address of the Entity]

Dear [name of contact person]

As agreed under the Terms of Reference dated [dd Month yyyy]

with [name of the Entity] (the Entity)

we [name of the auditor] (the Auditor)

established at [full address]

represented by [name and function of Auditor's authorised representative]

have audited:

the accompanying declaration of the in-kind contribution in implementing additional activities (hereinafter IKAA) from [name of the Entity] (if applicable: and its affiliated entity(ies) [....., ....., .....]) related to the calendar year [yyyy] (if applicable: and adjustment(s) to the prior year(s) [....])

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

#### Responsibility of the Entity

The Entity is responsible for the preparation and submission to the Innovative Health Initiative Joint Undertaking (hereinafter 'the IHI JU') of the declaration of IKAA in accordance with the Article 11.2 of the Council Regulation (EU) 2021/2085 (hereinafter 'the Regulation') and to maintain adequate accounting records and documentation to support and justify the cost and information declared.

#### Auditor's responsibility

Our responsibility is to audit and report on the value of the declared IKAA; and the additional information presented based on our audit procedures in order to meet the requirements of Article 11.2 of the Regulation and other relevant provisions.

Our audit, subject to the 'Additional conditions' mentioned in the next section of this report, comprised an assessment of whether the amounts declared as IKAA is determined, in all material aspects, in accordance with the Regulation.

#### Additional conditions

We conducted this engagement in accordance:

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

3. with the provisions of the Regulation.

The International Standards on Auditing require 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.

An audit engagement involves performing procedures to obtain audit evidence about the amounts and disclosures in the declaration of IKAA. The audit engagement also includes procedures to obtain audit evidence about the appropriateness of accounting practices used for the preparation of the declaration of IKAA as well as about the overall presentation of the declaration of IKAA. 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 IKAA in order to design audit procedures that are appropriate in the circumstances and 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 Entity in relation to the authenticity and completeness of the supporting documentation provided to us.

We believe that the audit 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 IKAA is determined in all material respects, in compliance with Article 11.2 of the Regulation, which states that the costs for additional activities shall be determined in compliance with the usual cost accounting practices of the Entity, the applicable accounting standards of the country where the Entity is established, the applicable International Accounting Standards and International Financial Reporting Standards.

(If applicable: Additionally, the Entity chose to value its additional activities in compliance with the Horizon Europe model grant agreement (HE MGA)<sup>8</sup> and consistently applied HE cost eligibility rules and cost calculation methods for all types of costs incurred for additional activities).

(If applicable: Additionally, in accordance with Article 11.2 of the Regulation, the IHI JU Governing Board has authorised the use of simplified methods for valuing the additional activities in (a) specific case(s) and the Entity has followed the approved methodology(ies) in compliance with its usual cost accounting practices.)

We would like to point out that this work is limited in its scope to auditing the IKAA declared.

## **Emphasis of matters**

*(This section should be used by the auditor to bring to the attention of IHI JU any matters to be considered as a recommendation and as such to be changed in future calculations.)*

Despite the additional explanations provided in this section to be considered as improvement recommendations, our conclusion is not qualified in respect of these matters.

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<sup>8</sup>The Horizon Europe model grant agreement is available online:  
[https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/agr-contr/general-mga\\_horizon-euratom\\_en.pdf](https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/agr-contr/general-mga_horizon-euratom_en.pdf)



[Place, Date]  
[Legal name of the Auditor]  
[Signature]  
[Name of Auditor's authorised representative]

**Annex:** Signed declaration of ICAA from *[Name of the Entity]* for the calendar year [...] (including for the adjustment(s) to the prior year(s) [...] if applicable).

## Annex 2: Model Report – ISAE 3000

### Model Report for the certification of the declaration of in-kind contributions to additional activities (IKAA) to IHI JU 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 Entity*]

To: [name and address of the Entity]

Dear [name of contact person]

As agreed under the Terms of Reference dated [dd Month yyyy]

with [name of the Entity]

we [name of the auditor] (the Auditor)

established at [full address]

represented by [name and function of Auditor's authorised representative]

have been engaged to provide a Report of reasonable assurance in respect of the accompanying declaration of the in-kind contribution in implementing additional activities (hereinafter IKAA) from [*Name of the Entity*] (if applicable: and affiliated entity(ies) [....., ....., .....]) related to the calendar year [....] (if applicable: and adjustment(s) to the prior year(s) [....])

and hereby provide our report on the declaration of IKAA using the report format agreed with you.

#### Responsibility of the Entity

The Entity is responsible for the preparation and submission to the Innovative Health Initiative Joint Undertaking (hereinafter 'the IHI JU') of the declaration of IKAA in accordance with the Article 11.2 of the Council Regulation (EU) 2021/2085 (hereinafter 'the Regulation') and to maintain adequate accounting records and documentation to support and justify the cost and information declared.

#### Reporting accountant's responsibility

Our responsibility is to express an opinion, based on the procedures performed and evidence obtained, to confirm with reasonable assurance the value of IKAA declared; and the additional information presented based on our procedures.

Our engagement, subject to the 'Additional conditions' mentioned in the next section of this report, comprised assessing whether the amounts declared as IKAA is determined, in all material aspects, in accordance with Article 11.2 of the Regulation.

#### Additional conditions

We conducted this engagement in accordance with:

1. the International Standard on Assurance Engagements 3000 ('ISAE 3000') *Assurance Engagements other than Audits or Reviews of Historical Financial Information (Revised)*, issued by the International Auditing and Assurance Standards Board;
2. the Code of Ethics for Professional Accountants issued by the IFAC;
3. the provisions of the Regulation.

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.

A reasonable assurance engagement involves performing procedures to obtain sufficient appropriate evidence to give reasonable assurance regarding the IKAA 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 Entity's preparation and presentation of the IKAA 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 Entity's internal control over the preparation and presentation of the IKAA declaration.

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 Entity 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 IKAA is determined in all material respects to be in compliance with Article 11.2 of the Regulation, which states that the costs for additional activities shall be determined in compliance with the usual cost accounting practices of the Entity, the applicable accounting standards of the country where the Entity is established, the applicable International Accounting Standards and International Financial Reporting Standards.

(If applicable: Additionally, the Entity chose to value its additional activities in compliance with the Horizon Europe model grant agreement (HE MGA)<sup>9</sup> and consistently applied HE cost eligibility rules and costs calculation methods for all types of costs incurred for additional activities.)

(If applicable: Additionally, in accordance with Article 11.2 of the Regulation, the IHI JU Governing Board has authorised the use of simplified methods for valuing the additional activities in (a) specific case(s) and the Entity has followed the approved methodology(ies) in compliance with its usual cost accounting practices.)

We would like to point out that this work is limited in its scope to provide reasonable assurance that the IKAA declared are determined in compliance with Article 11.2 of the Regulation, as described in the section 'Reporting Accountant's Responsibility' for the purpose of valuing the in-kind contribution without providing any certainty for other purposes.

## **Emphasis of matters**

*(This section should be used by the auditor to bring to the attention of IHI JU any matters to be considered as a recommendation and as such to be changed in future calculations.)*

Despite the additional explanations provided in this section to be considered as improvement recommendations, our conclusion is not qualified in respect of these matters.

[Place, Date]

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<sup>9</sup>The Horizon Europe model grant agreement is available on IHI website:  
[https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/agr-contr/general-mga\\_horizon-euratom\\_en.pdf](https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/agr-contr/general-mga_horizon-euratom_en.pdf)

[Legal name of the Auditor]  
[Signature]  
[Name of Auditor's authorised representative]

**Annex:** Signed declaration of ICAA from *[Name of the Entity]* for the calendar year [...] (including for the adjustment(s) to the prior year(s) [...] if applicable).

## **Annex 3: Declaration of IKAA**

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

*The IKAA declaration 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 declaration(s) shall also need to be attached here).*