

IHI JU Guidelines for in-kind contribution to additional activities (IKAA)

Disclaimer

This document is intended for guidance purposes only and will be periodically updated as further information is received. Applicants with specific queries or doubts as to interpretation should contact the IHI Programme Office. Applicants should always ensure that they are consulting the most recent version of this guidance document released by the IHI JU Office and available on [IHI website](#).

Chronology and list of reviews

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Table of Contents

1	Abbreviations	4
2	Main definitions	4
3	Introduction	5
4	IKAA Definition.....	5
4.1	Distinction between IKOP and IKAA at project level.....	6
4.2	Eligibility timeframe.....	7
5	Practical examples of IKAA.....	7
5.1	Examples of potential Programme-specific additional activities	8
5.2	Examples of potential Project-specific additional activities.....	8
5.3	Examples of what cannot constitute additional activities	10
6	IKAA Planning.....	11
6.1	Programme-specific IKAA Planning.....	11
6.2	Project-specific IKAA Planning	13
6.3	IKAA Plan form (IT planning tool).....	16
6.4	Deviations from the IKAA Plan	17
7	Cost Valuation method	19
8	IKAA Reporting and Certification.....	20
8.1	IKAA Reporting.....	20
8.2	IKAA Certification.....	22
8.3	IKAA Validation	23
9	Annexes	24

1 Abbreviations

This guidance document contains the following abbreviations/acronyms:

- CAAR: Consolidated Annual Activity Report of IHI JU
- COCIR: the European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries
- EFPIA: the European Federation of Pharmaceutical Industries and Associations
- EuropaBio: the European Association for Bioindustries
- FC: Financial contribution
- FTE: Full Time equivalent
- GB: Governing Board of IHI JU
- HE: Horizon Europe (programme)
- IHI JU: Innovative Health Initiative Joint Undertaking
- IKAA: in-kind contributions to additional activities
- IKOP: in-kind contributions to operational activities
- LEAR: Legal Entity Appointed Representative
- MedTech Europe: the European Trade Association for the medical technology industry
- MGA: Model Grant Agreement
- PIC: Participant Identification Code
- SIP: the Science and Innovation Panel of IHI JU
- SRG: the States' Representatives Group of IHI JU
- SRIA: Strategic Research and Innovation Agenda of IHI JU
- Vaccines Europe: the specialised vaccines group within the EFPIA
- WP: Work Programme of IHI JU

2 Main definitions

The following definitions are relevant to this guidance document:

- In-kind contributions to additional activities (IKAA): contributions by the constituent or affiliated entities of the private members consisting of costs incurred by them for implementing additional activities.
- In-kind contributions to operational activities (IKOP): contributions by the constituent or affiliated entities of the private members and by contributing partners, consisting of the eligible costs incurred by them for implementing the action, less the contribution of the IHI JU to those costs.
- Private member: a legal entity that is a member of the IHI JU other than the Union. The private members of IHI JU are the industry trade associations COCIR, EFPIA incl. Vaccines Europe, EuropaBio, and MedTech Europe.
- Constituent entity of a private member: a legal entity that is a member of the industry trade association COCIR, EFPIA incl. Vaccines Europe, EuropaBio, or MedTech Europe.
- Affiliated entity of a private member: a legal entity that has a legal or capital link with a member of COCIR, EFPIA incl. Vaccines Europe, EuropaBio, or MedTech Europe, which is neither limited to the action nor established for the sole purpose of the action implementation.

- Contributing partner: any country, international organisation, or legal entity other than a member of the IHI JU, or a constituent entity of a member or an affiliated entity of either, that supports the IHI JU's objectives in its specific area of research and whose application to become a contributing partner has been approved by the Governing Board.
- Council Regulation (EU) 2021/2085 or 'Single Basic Act' (SBA): The act establishing the Joint Undertakings (including IHI JU) under the Horizon Europe programme.
- Coordinator: A beneficiary of the consortium responsible for managing the project, submitting reports and deliverables, and acting as intermediary for all contacts with IHI JU.
- Funding & Tenders Portal: The entry point (the Single Electronic Data Interchange Area) for participants in funding programmes and tenders managed by the European Commission and other EU bodies.

3 Introduction

IHI JU is a public-private partnership between the EU (represented by the European Commission) and life science industries represented by COCIR, EFPIA (also representing Vaccines Europe), EuropaBio and MedTech Europe (hereafter the IHI private members).

According to the Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe (hereafter the Regulation)¹, the IHI JU private members shall make or arrange for their constituent and affiliated entities to make a total contribution of at least EUR 1 billion, consisting of:

- in-kind contributions to operational activities ('IKOP');
- in-kind contributions to additional activities ('IKAA');
- and financial contributions ('FC')².

Only IHI JU private members, their constituent and affiliated entities, are entitled to contribute IKAA. Contributing partners can only contribute IKOP and FC.

This document provides guidance regarding the main principles on what can constitute IKAA from IHI JU private members, their constituent and affiliated entities. In particular, it describes the applicable legal framework and the parties involved in the different stages of planning, evaluation, reporting and certification of IKAA, defining their role and laying down the relevant practical aspects to follow along these processes.

4 IKAA Definition

The in-kind contributions to additional activities ('IKAA') are costs incurred by IHI JU private members (i.e. COCIR, EFPIA, EuropaBio and MedTech Europe associations), their constituent and affiliated entities, in implementing additional activities.

¹ 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

² Financial contributions (FC) are financial transfers (cash contributions) made by IHI JU private members, their constituents or affiliated entities either to a project beneficiary(ies) from the same consortium or to the IHI Office to support eligible costs for the implementation of an IHI JU funded project.

‘Additional activities’ mean activities that fulfil all the following conditions:

- contribute to the general and specific objectives of the IHI JU, as they are defined in Article 115 of the Regulation³ and be directly linked to the IHI JU activities;
- be set out in the annual additional activities plan (the IKAA Plan) annexed to the IHI JU work programme (or alternatively, in a plan for additional activities annexed to relevant projects/proposals);
- not be funded by the IHI JU or any other Union funding programme;
- be carried out in the Union or in countries associated with Horizon Europe (irrespective of the country of establishment of the entity incurring the related costs);
- be either *Programme specific* or *Project specific*:
 1. *Programme-specific* additional activities contribute to the uptake of results from IMI JU, IMI2 JU, IHI JU projects or have a significant added value for the Union.
 2. *Project-specific* additional activities contribute towards the achievement of objectives⁴ of the IHI JU funded projects, or the dissemination, sustainability or exploitation of IHI JU project results.

Whenever identifying potential additional activities, IHI JU private members, their constituent and affiliated entities shall ensure that all above criteria are fulfilled to ensure the proposed activities qualify as IKAA. Additionally, a clear distinction should be made between the two possible types of additional activities, i.e. either *Programme-specific* IKAA or *Project-specific* IKAA, as it leads to different scopes and processes, in particular in term of planning.

The total IKAA⁵ shall not exceed 40% of the total in-kind contribution (IKAA + IKOP) provided by IHI JU private members, counted at IHI JU programme level. FC provided by IHI JU private members are not included in the calculation of this 40% threshold.

Additionally, the total contribution from IHI JU private members and/or contributing partners to an IHI JU (full) proposal (IKOP + *Project-specific* IKAA + FC) shall amount to at least 45% of the proposal's total eligible costs and costs for its additional activities. This threshold of 45% contribution is an eligibility condition for all IHI JU proposals. For proposals that successfully pass the evaluation stage, this threshold of 45% contribution must be maintained at the Grant Agreement signature and during the whole project implementation to remain eligible.

$$(IKOP + FC \text{ paid} + IKAA) \geq 45\% \text{ of action's (eligible costs} + IKAA)$$

4.1 Distinction between IKOP and IKAA at project level

Since private members of the IHI JU, their constituent and affiliated entities can contribute both IKAA and IKOP to IHI JU projects, a clear distinction should be made between those two types of *Project-specific* in-kind contributions.

- IKOP refers to eligible costs (as per HE's eligibility criteria in Article 6 of the HE MGA) to implement project tasks as described in the Description of the Action of a concerned project (Annex 1 of the Grant Agreement).
- IKAA refers to costs for additional activities (as per cumulative conditions mentioned above) that are not project tasks (i.e. not IKOP).

³ IHI JU's general and specific objectives are also listed on IHI website: <https://www.ihj.europa.eu/about-ihj/mission-and-objectives>

⁴ IHI JU funded projects/proposal objectives are listed in the Annex 1 part B of the concerned IHI Grant Agreements/proposal

⁵ The overall limitation of 40 % of IKAA at IHI JU programme level includes both programme-specific IKAA and project-specific IKAA.

The above distinction should be made on the basis of the specific proposal/project objectives and it is up to the consortium to identify activities that are IKOP and IKAA for their respective IHI JU proposal/project.

Additionally, to prevent double counting, costs for activities identified as IKAA in one IHI project cannot be identified as IKAA in another IHI project or as Programme-specific IKAA. Also, activities identified as IKOP in one project cannot be considered IKAA in another project.

The Annex 4 of this guidance document illustrates the main differences between *Project-specific* IKAA and IKOP.

4.2 Eligibility timeframe

IKAA benefits from a wider timeframe than IKOP.

For *Programme-specific* IKAA, costs shall be incurred during the implementation of the IHI JU Programme (i.e. from its establishment date on 19 November 2021⁶ and until the end of the JU Programme).

For *Project-specific* IKAA, costs for additional activities may be incurred between the date of submission of the proposal – or from the submission deadline of the second stage in a two-stage call process - and up to two years after the end date of the project⁷.

Nevertheless, those *Project-specific* additional activities which are contributing towards the achievement of objectives of IHI JU funded projects must be provided within a timeframe allowing that these objectives are reached before project closure. After project closure, only costs for additional activities targeting the dissemination, sustainability or exploitation of IHI JU project results may be accepted as *Project-specific* IKAA.

As a reminder for IKOP, eligible costs shall be incurred only during project implementation (i.e., between the start date and the end date of the concerned project).

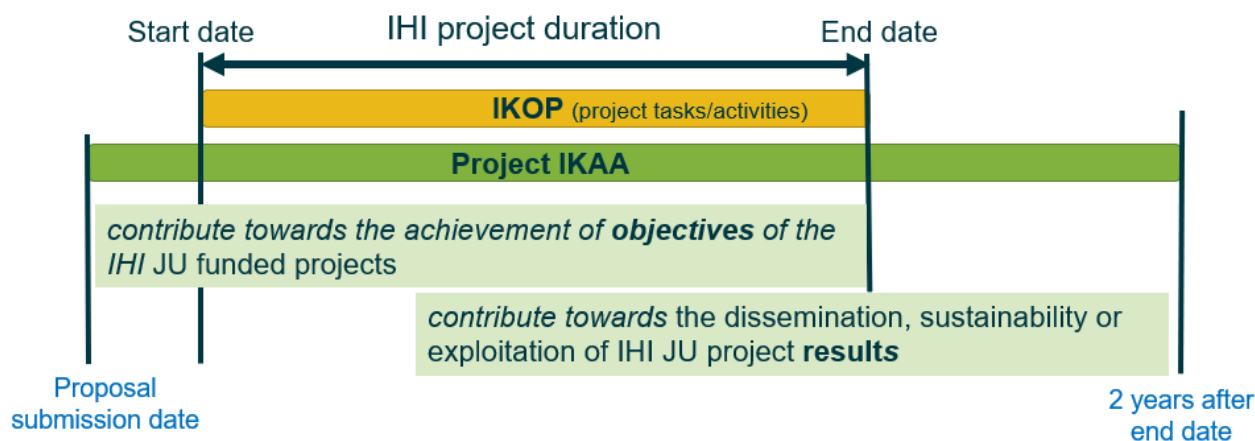


Illustration on the differences in term of eligibility timeframe between IKOP and *Project-specific* IKAA.

5 Practical examples of IKAA

⁶ The Council Regulation (EU) 2021/2085 establishing the Joint Undertakings under Horizon Europe is dated 19 November 2021

⁷ Article 120 of the of the Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe.

IKAA is an additional mechanism to acknowledge the full spectrum of in-kind contributions from the private members when they contribute to the IHI JU objectives and are directly linked to its activities. As such, additional activities shall bring value to the IHI JU Programme and/or IHI proposal/project by further achieving the desired impact.

This section provides some concrete examples of potential *Programme-specific* and *Project-specific* additional activities (non-exhaustive list).

IKAA could be any costs (FTEs, subcontracting, consultant/expert fees, travel costs...) necessary to carry out the below potential additional activities.

This section also provides examples of what cannot constitute additional activities.

5.1 Examples of potential Programme-specific additional activities

- *Example 1:* Activities for analysis/legacy management of IMI2 and/or IHI results (across several projects or in a horizontal area) to contribute to the uptake of those results.
- *Example 2:* Activities to foster and ensure synergies of IHI activities generated under SRIA specific objective X to those of other European/global initiatives to demonstrate a significant added value for the Union.
- *Example 3:* Activities to progress regulatory acceptance of results of finished IMI2 projects and potentially contribute to new or improved guidelines or qualified methodologies.
- *Example 4:* Organisation of external conferences/workshops, writing of publications to disseminate and promote uptake of outputs from finished IMI2 projects.
- *Example 5:* Creation of Spin-off entities based on outputs of an IMI1/IMI2 project.
- *Example 6:* Activities for ensuring uptake of the project outputs in clinical practice.

5.2 Examples of potential Project-specific additional activities

- *Example 1:*
 - IHI JU Project objectives: develop tools, methodologies, best practices and create a database for the use of real-world evidence in health care decision-making and establish a sustainable network to maintain the results of the project and further build on them.
 - IKOP: during the project lifetime, Companies A, B, C, D, E and F incur eligible costs to implement project tasks such as develop the tools, collect data, agree on the practices and establish a non-for-profit entity.
 - IKAA could be costs related to the below additional activities (AA):

AA contributing towards the achievement of objectives of the IHI JU funded project, before project start and/or during project implementation:

Before project start:

- Company A contributes to internal preparatory activities for the development of a digital tool that will be used in the consortium activities.
- Company E contributes to conduct an expert workshop to discuss the design of the clinical study planned in the project to ensure an efficient finalisation of the protocol and timely start of the study during the project.
- Company C contributes to initiate interactions with regulators using services offered by regulatory agencies, with the view to have a fully-fledged regulatory strategy and interaction plan at the start of the project.

During project implementation (only if the AA is not project task/not IKOP):

- Company B generates data from an internally run study using real world evidence to be used as an independent dataset to compare with data and preliminary conclusions of the project in order to identify as early as possible pitfalls in the approach developed/ best practices proposed by the project and help its finetuning. The project activities do not depend necessarily on this specific dataset, but their availability will increase the intrinsic robustness of the project results in a timely manner.

AA contributing towards the sustainability, dissemination, or exploitation of the IHI JU project results, during project implementation and/or after project end:

During project implementation (only if the AA is not project task/not IKOP):

- Company C contributes to the maintenance of the developed tools/platforms (e.g. service contract with an external company to continue updates and maintenance in the first/early period of the non-for-profit entity).
- Company D contributes to regulatory activities using services offered by regulatory agencies (advice, qualification advice procedure).
- Company E and E contribute to (internal) independent R&I studies using the tools/methodologies developed during the project to show the value of these notably to other potential industry partners and attract them to become member of the entity.
- Company F contributes to landscape plan/marketplace analysis to inform the scale-up/sustainability plan of project results.

After project end:

- Company C, D and E jointly contribute to maintain/keep updated the website with news on activities taken place after the project has ended.
- Company A and F jointly contribute to organise a symposium to disseminate the results of the IHI JU project after the project end.
- Company B contributes to open access fees for articles related to the IHI JU funded project after the project end.
- Company F contributes to activities for implementing the outputs of the IHI project into internal processes to ensure their sustainability and deployment.

• *Example 2:*

- IHI JU Project objectives: to integrate diagnostic and predictive approaches to support multi-modality cancer care (also based on advanced analytics and artificial intelligence).
- IKOP: during the project lifetime, Companies A, B, C, D and E incur eligible costs to implement project tasks such as further adapt already existing devices/software (...) to develop the integrated solutions/approaches collaboratively in the consortium and include feedback of end users.
- IKAA could be costs related to the below additional activities (AA):

AA contributing towards the achievement of objectives of the IHI JU funded project, before project start and/or during project implementation:

Before project start:

- Company A contributes to the development of an image-guided radiation therapy device that will be used for the consortium activities,
- Company E contributes to the adaptation of an already commercialised sensor that is made available to the consortium to ensure efficient/timely kick-off and in time running of the project.

During project implementation (only if the AA is not project task/not IKOP):

- Company B contributes to developing a methodology for an integrated approach to diagnosing or treating breast cancer, which may be extended to other cancers (which are those in the scope of the project, while breast cancer is not) and is provided to the consortium as a sounding board/extra element for helping the development of the one created by the consortium.
- Company C and D contribute to generating data from proprietary clinical trials using various (different/complementary/additional to those of the project) cancer treatments modalities which are used as independent datasets to further verify the usability of the integrated approach developed by the project and help its finetuning (the project activities do not depend necessarily on these specific datasets provided as AA). Note that these additional activities could have started before the start of the project, from the date of submission of the proposal.

AA contributing towards the sustainability, dissemination, or exploitation of the IHI JU project results, during project implementation and/or after project end:

During project implementation (only if the AA is not project task/not IKOP):

- Company A and E perform further analysis/enhancement of data/results generated by the project going beyond the expected outputs (e.g., considering variables that were not included in the workplan, sample analysis, etc.) and enhancing the timely uptake of such project results by end users.

After project end:

- Company A contributes costs to run a series of public webinars using knowledge and material from the project.
- Company B contributes costs to develop a training and information platform for patients and their doctors on the added value of using the integrated approach developed by the project for healthcare outcomes in cancer patients.
- Company C contributes costs for the development of a decision-making software tool that enables easier communication in the cancer care continuum and across the stakeholders, which represents a deployment/exploitation of project outputs.

5.3 Examples of what cannot constitute additional activities

Here is a non-exhaustive list of examples of what cannot constitute IKAA.

- *Preparation activities for the Consortium agreement* do not qualify as *Project-specific IKAA* as it does not specifically contribute to IHI project objective(s) but is a legal prerequisite for signing the grant agreement;
- *Activities for IHI call topic generation*;
- *Internal activities that are standard (administrative) activities necessary to prepare a project and which do not per se contribute towards the achievement of specific objectives of the IHI project (e.g. meeting to discuss structure of a work package or the workplan, resourcing of project activities..)*;
- *Dissemination activities prior to the start of the project (e.g., presentations, lectures) and during the project (as it should be IKOP)*;
- *Internal dissemination/training activities that are presented as dissemination of the IHI project results as raising internal awareness and internal trainings within the company do not fit with the definition of dissemination activities (i.e public disclosure of the results by appropriate means with the view to increase the impact of IHI project results)*;
- *Activities essential to reach project objectives (must be IKOP)*;
- *Activities carried out outside the EU or HE associated countries⁸*;

⁸ List of countries associated to Horizon Europe: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/list-3rd-countryparticipation_horizon-euratom_en.pdf

- Activities that are generic activities run by a company as part of daily business and which do not have a clear link to the project objectives;
- Activities already reimbursed by IHI or any other source of EU funding;
- Activities already considered IKOP/IKAA in another IHI proposal/project (no double counting allowed);
- Activities taking place before the (full) proposal submission;
- Costs that are not directly linked to an additional activity foreseen in the IKAA Plan (e.g., membership fee to MedTech Europe/EFPIA/COCIR/EuropaBio, cost of IKAA certification...);
- Activities for which the private member does not effectively incur costs during the eligibility timeframe (see Section 4.2 above), e.g.;
 - bringing pre-existing data to a project represents a value but if no costs are incurred by the entity relating to these data during the eligibility timeframe, it cannot be valorised as Project-specific IKAA.
 - software developed by the private member before the proposal submission and for which the entity does not incur costs anymore cannot be valorised as Project-specific IKAA. Valorising the use of this software by the consortium with licence fees is not acceptable as licence fees are not actual costs for the entity and are not recorded in the accounting system of the entity.

6 IKAA Planning

IKAA Planning process differs depending on whether additional activities are *Programme-specific* or *Projects-specific*.

Each private member can plan additional activities for it(s) affiliated entity(ies), if any, by including in its planned activities the ones of it(s) affiliated entity(ies).

6.1 Programme-specific IKAA Planning

The *Programme-specific* IKAA shall be set out in an annual additional activities plan (the IKAA Plan) annexed to the IHI JU work programme (WP). The IKAA Plan for year N shall include additional activities that are planned to start in year N.

The IKAA Plan for year N should be adopted by the IHI JU Governing Board (GB) by the end of year N-1⁹.

The IHI JU GB shall approve the IKAA Plan based on a proposal from the private members and after having consulted the Science and Innovation Panel (SIP) and the States Representatives Group (SRG) (Article 17.2.I and article 124.4.c of the Regulation).

Of note, the total IKAA (including both *Programme-specific* IKAA and *Project-specific* IKAA) shall not exceed 40% of the total in-kind contribution (IKAA + IKOP) provided by IHI JU private members, counted at IHI JU programme level.

The planning process for *Programme-specific* IKAA shall follow the below steps:

1. During the second half of year N-1, industry associations offices (i.e., Offices of EFPIA, EuropaBio, COCIR and MedTech) shall contact their respective members and consolidate their additional activities planned to start in year N into the proposal of the IKAA Plan for year N.

When identifying potential additional activities, IHI JU private members shall verify that all criteria are fulfilled (see Section 3 for IKAA Definition) to ensure the proposed activities qualify as *Programme-specific* IKAA.

⁹ Except for the IKAA Plan for year 2022

The proposal of IKAA Plan for year N shall follow the template adopted by the IHI JU for *Programme-specific* IKAA (Annex 1 of this guidance document) and shall include both publishable information and confidential information.

More specifically, the content of the IKAA Plan proposal shall contain for each additional activity:

- Publishable information (to be published in the IHI JU WP, the CAAR and on IHI website):
 - the category and the type;
 - a title (maximum 100 characters);
 - a brief description (maximum 400 characters);
 - the estimated total duration;
 - the estimated value.
- Confidential information (only disclosed to IHI JU GB and IHI JU Office):
 - the company legal name, PIC and industry affiliation; a complete description (maximum 1500 characters);
 - the link to IHI JU's objectives;
 - the contribution of the additional activity to the IMI1/IMI2/IHI project(s) or its estimated added-value for the Union (which may be shared by the IHI JU GB with the SRG and the SIP if it is necessary to provide their opinion on the concerned additional activity).

Additional activities that are planned to run several years need to be included in the IKAA Plan only once. E.g.: Additional activities planned to run from year N until year N+2 need to be included in the IKAA Plan of year N only, not in the IKAA Plan of year N+1 and year N+2.

Only additional activities not yet included in a prior version of the IKAA Plan already approved by the IHI JU GB need to be included in the IKAA Plan proposal.

For each additional activity, the closest estimated value in euro shall be specified as well as an indication of the duration in months.

All columns of the Annex on IKAA should be filled-in. There should be no empty fields.

The information included in the proposal of the IKAA Plan, in particular the additional activities title, short and complete descriptions as well as the link to the project(s) or estimated added-value for the Union should be **clear** (e.g. should not contain acronyms) and **sufficiently elaborated** to enable the assessment of the additional activities, their contributions to the IHI JU's objectives as well as their contributions to the uptake of results from IHI JU/IMI2 JU/IMI1 JU project(s) or their significant added value for the Union.

2. Industry associations offices shall send the proposal of IKAA Plan for year N to the IHI JU Office at latest 45 days before the launch for consultation of the IHI JU WP for year N. The consultation is usually launched in October of year N-1.

3. The IHI JU Office shall review the proposal of the IKAA Plan and, if necessary, shall request clarifications and/or corrections to IHI JU private members. The review and potential corrections of the IKAA Plan proposal shall be done within one month.

4. Once the proposal of the IKAA Plan is finalised (i.e. agreed between IHI JU private members and the IHI JU Office following step 3), each entity that has planned new additional activities for year N will receive a notification from the Portal with the request to encode its planned additional activity(ies) for year N in the IKAA Plan form via the Funding and Tenders Portal. This step is mandatory. See detailed information on the IKAA Plan form in Section 6.3 below.

The private member shall encode in the IKAA Plan form the exact same information as in the IKAA Plan proposal agreed between IHI JU private members and the IHI JU Office. In case of discrepancies, the IHI JU Office will have to reopen the tool for correction.

5. The publishable information encoded in the IKAA Plan form for year N shall be inserted by the IHI JU Office into the IKAA Plan annexed to the IHI JU WP of year N, following the template adopted by the EC (Annex 2 of this guidance document). The IHI JU WP of year N shall then be launched for consultation.
6. During the consultation, the IKAA Plan annexed to the IHI JU WP shall be reviewed by the IHI JU GB, the SIP and the SRG, who may, if necessary, request further clarifications to IHI JU private members on their planned additional activities. Potential clarifications shall be provided within a set deadline and corrections done in the IKAA Plan form, as necessary.
7. The IHI JU GB shall approve the IKAA Plan for year N when adopting the IHI JU WP for year N, at the end of year N-1. Subsequently, the concerned private members shall receive a notification from the Portal concerning the approval of their planned additional activities into the IKAA Plan for year N.
8. The approved IKAA Plan for year N will be published accordingly on IHI website as part of the IHI JU WP for year N. Additionally, the overall IKAA Plan will be updated accordingly and published on IHI website. The overall IKAA Plan consists of the cumulative overview of all additional activities planned by IHI JU private members (both *Programme-specific* and *Project-specific*) and approved by the IHI JU GB.

The latest version of the approved IKAA Plan can always be found on IHI website via this [link](#).

Additional activities planned to start during year N that have not been included in the IKAA Plan of year N at the end of year N-1 as explained above can still be included in the IKAA Plan of year N during that same year when the IHI JU WP is amended. In such a case, industry associations shall send the proposal of the IKAA Plan for year N to the IHI JU Office at latest 45 days before the launch for consultation of the last WP amendment foreseen in year N. Then the same process as explained above should be followed.

Additional activities planned to start during year N that have not been included in the IKAA Plan of year N, either at the end of year N-1 or during year N when the IHI JU WP is amended, cannot be added to the IKAA Plan for year N anymore and as a result, the concerned private member will not be able to report any costs for year N related to these additional activities.

Additional activities must indeed be included in the IKAA Plan, approved by the GB (following consultation of advisory bodies) and encoded in the IKAA Plan form via the Funding and Tenders Portal, before the related costs can be reported as IKAA (see Section 8.1 on IKAA reporting).

6.2 Project-specific IKAA Planning

IKAA can be a key element in an IHI JU proposal/project as it can contribute to its eligibility.

As explained above, the total contribution from IHI JU private members and/or contributing partners to an IHI JU proposal/project (i.e., the sum of IKOP, *Project-specific* IKAA and FC paid) should amount to at least 45% of the proposal/project's total eligible costs and costs for its additional activities. This threshold of 45% contribution is an eligibility condition for all IHI JU proposals/projects and can be reached with or without IKAA. *Programme-specific* IKAA is not considered for the calculation of the 45% contribution threshold. For proposals that successfully pass the evaluation stage, this threshold of 45% contribution must be maintained at the Grant Agreement signature and during the whole project implementation to remain eligible.

Considering the total IKAA cannot exceed 40 % of the total in-kind contributions (IKAA + IKOP) provided by IHI private members at overall IHI JU programme level, it is recommended that IHI JU private members also limit their IKAA to an IHI proposal/project to the same threshold (i.e. maximum 40 % of the sum of IKOP and IKAA they provide to the IHI proposal/project). If IHI private members want to contribute more IKAA than 40 %, they should inform their relevant industry office accordingly so that the overall IKAA at IHI JU Programme level can be monitored.

The planning process for *Project-specific* IKAA shall follow the below steps:

Proposal stage

1. *Project-specific* additional activities must be specified in a plan annexed to the relevant proposals using the template adopted by the IHI JU (Annex 3 of this guidance document, also available in IHI proposal documents on [IHI website](#)). The IKAA plan annexed to the concerned proposal (also referred to as 'Annex on IKAA') is compulsory in case the proposal plans some IKAA. The proposal could fail to reach the 45% eligibility threshold if the Annex on IKAA is not uploaded as part of the proposal documents by the deadline.

The Annex on IKAA shall include confidential information and publishable information.

More specifically, the content of the IKAA Plan included in the concerned proposal shall contain for each additional activity:

- Publishable information (to be published in the IHI JU WP, the CAAR and on IHI website):
 - the category and the type;
 - a title (maximum 100 characters);
 - a brief description (maximum 400 characters);
 - the estimated total duration;
 - the estimated value.
- Confidential/non-publishable information (only disclosed to evaluators, the IHI GB, the IHI Office and the concerned applicant consortium):
 - the company legal name and PIC;
 - a complete description (maximum 1500 characters);
 - the estimated period when the additional activity is foreseen to take place;
 - the link to the IHI project, i.e., the contribution of the additional activity to the achievement of objectives of the IHI project, or to the dissemination, sustainability or exploitation of the IHI project results (which may be shared by the IHI GB with the SRG and the SIP if it is necessary to provide their opinion on the concerned additional activity).

For each additional activity, the closest estimated value in euro shall be specified as well as an indication of the duration in months and an estimated timeline of when the additional activity may take place, between the (full) proposal submission date and up to two years after the end date of the project.

All columns of the Annex on IKAA should be filled-in. There should be no empty fields.

The information included in the Annex on IKAA of a proposal, in particular the additional activities title, short and complete descriptions as well as the link to the IHI project, should be **clear** (e.g. should not contain acronyms), specific and **sufficiently elaborated** to enable the assessment of the relevance of the additional activities for the achievement of objectives and impacts of the concerned IHI JU project, or for the dissemination, sustainability or exploitation of the IHI JU project results. In the field on link to the project, it should be explicit how the additional activity further contributes to the project (e.g. linked to a project objective, area of work and/or expected impact).

When additional activities are planned to be carried out **during project implementation**, it shall be specified in the Annex on IKAA in the complete description that there is **no overlap with the IKOP** of the concerned IHI proposal. E.g., during project implementation, dissemination activities are expected to be IKOP as each IHI JU project should have a deliverable on dissemination activities and it is therefore a project task. But in case there are activities to disseminate project results taking place after the project end, it could be considered IKAA.

2. The IKAA plan annexed to the relevant proposal shall be submitted as part of the proposal submission by the call deadline.

3. The IKAA plan annexed to the relevant proposal will be reviewed by the independent experts panel at the time of proposal evaluation.

If following the expert assessment some additional activities are considered ineligible, the 45% contribution eligibility threshold will need to be reassessed by the IHI JU Office, which may impact the proposal's eligibility. If following the expert assessment some additional activities are considered reasonable but not sufficiently described, the selected proposal may be required to adapt the IKAA Plan in alignment with the independent experts assessment.

4. IKAA related to IHI JU proposals is formally approved by the IHI JU GB during the award decision (i.e. when the IHI JU GB formally approves the list of selected proposals of an IHI call).

Grant Agreement Preparation stage

5. After proposals are selected and applicants informed, the Grant Preparation Phase ('GAP') will start and these additional activities will have to be reflected in a plan included in table 3.1m of the Description of the Action (DoA/Annex 1 part B of the Grant Agreement) of concerned projects, using the same template as for the proposal (Annex 3 of this guidance document). The amount of IKAA will also need to be reflected in the project estimated budget (in 'JU contribution' tab). During this phase, comments from independent experts and/or IHI scientific officer, if any, need to be addressed and the IKAA plan adapted/corrected accordingly.

In case major IKAA modifications/additions occur during the Grant Preparation phase, i.e. between the proposal selection and the grant signature, this should be duly justified and the IHI JU Executive Director may exceptionally, if needed, consult informally GB members on the acceptance of such changes, before signing the concerned grant agreement.

Grant implementation stage

6. After the grant signature, each entity that has planned additional activities for a concerned project will receive a notification from the Portal to encode its planned additional activity(ies) in the IKAA Plan form via the Funding and Tenders Portal. This step is **mandatory**.

If the IHI full proposal was submitted in year N, the IKAA Plan form will be open for year N.

The entity will need to encode its planned additional activities for the IHI project(s) whose full proposal was submitted in year N, irrespectively of when these activities are planned to take place. E.g.: if an additional activity is planned to start in 2027 while the IHI proposal was submitted in 2024, the concerned activity should be specified in the IKAA Plan form 2024.

The private member shall encode in the IKAA Plan form the same information as in table 3.1m of the Description of the Action (DoA/Annex 1 part B of the Grant Agreement) of the concerned project. In case of discrepancies, the IHI JU Office will have to reopen the tool for correction. Some additional information is also requested in the IKAA Plan form (while it is not in the Annex on IKAA), e.g., the link to IHI JU general and specific objectives (which will be communicated by IHI Office after grant signature) or the year(s) when the additional activity is planned to take place. See detailed information on the IKAA Plan form in Section 6.3 below.

7. The IHI Office will consolidate the additional activities from the signed grant agreements in the IKAA Plan in the next (amended) IHI JU WP in order to inform advisory bodies (i.e. the SRG and the SIP).

Concretely, the publishable information encoded in the IKAA Plan form shall be inserted by the IHI JU Office into the IKAA Plan annexed to the next (amended) IHI JU WP, following the template adopted by the EC (Annex 2 of this guidance document). The (amended) IHI JU WP shall then be launched for consultation.

Advisory bodies may express their opinion on the additional activities from signed grants; however, their opinion is not binding so it should not impact the formal approval of the concerned additional activities that have been previously assessed by independent experts and approved by the IHI JU GB.

8. Following the IHI JU GB adoption of the (amended) IHI JU WP, the concerned private members shall receive a notification from the Portal concerning the formal approval of their planned additional activities into the IKAA Plan. The IKAA Plan will be updated accordingly and published on IHI website. The IKAA Plan

consists of an overview of all planned additional activities by IHI JU private members that have been approved by the IHI JU GB. It includes both *Programme-specific* IKAA and *Project-specific* IKAA.

The latest version of the approved IKAA Plan can always be found on IHI website via this [link](#).

6.3 IKAA Plan form (IT planning tool)

Private members that have planned additional activities shall encode them in the IKAA Plan form via the Funding and Tenders Portal. This step is mandatory as it will enable entities to report costs for these activities at a later stage (see Section 8.1 on IKAA reporting).

Each entity will receive a notification from the Portal when it will be necessary to encode its additional activities in the IKAA Plan form. Such notification will be activated in due time by the IHI JU Office (see step 4 in Section 6.1 on Programme-specific IKAA Planning and step 6 in Section 6.2 on Project-specific IKAA Planning) and sent to the LEAR, the account administrator if any, as well as the IKAA reporter if this role has been assigned.

Entities need to have a PIC and a LEAR to access the Portal and the IKAA Plan form.

Only the persons with the role of LEAR, account administrator or IKAA reporter can view, edit and submit the IKAA Plan form.

The [LEAR](#) is validated by the EC during the validation process of an organisation and can then assign/revoke 'account administrator' and 'IKAA reporter' roles (these are 'organisation roles'). The account administrator can also assign/revoke the 'IKAA reporter' role.

Here are instructions on [how to assign/revoke organisation roles](#).

Here are [instructions on how to access, fill in and submit the IKAA Plan form](#).

There is one IKAA Plan form per year and per entity.

In the IKAA Plan form of year N the entity shall encode:

- its planned Project-specific IKAA in IHI project(s) whose full proposal was submitted in year N, if any.
- its planned Programme-specific IKAA starting in year N, if any.

For instance, if an entity has planned IKAA in two IHI projects for which the full proposal was submitted in 2024 and has also planned new Programme-specific IKAA starting in 2024, the entity needs to encode all these different additional activities in the IKAA Plan form 2024. In case the IKAA Plan form 2024 is already completed and approved by IHI in the tool while some additional activities have not yet been encoded, IHI office can re-open the form 2024 (by way of an amendment of the existing form) to enable the entity to encode the missing additional activities.

The information encoded in the IKAA Plan form should be the same as in the IKAA Plan approved by the IHI JU GB (for Programme-specific IKAA) or in the signed IHI grant (for project-specific IKAA). All fields should be completed (i.e. no empty fields allowed).

Some additional information is also requested in the IKAA Plan form, while it is not in the Annex on IKAA:

- the link to IHI JU general and specific objectives for project-specific IKAA: this information will be communicated by the IHI Office after grant signature;
- the year(s) when the additional activity is planned to take place: in the IKAA Plan form of year N, only year N and years beyond can be selected (not year N-1).

The IHI JU **strongly recommends** selecting **more years** than the one(s) normally planned for the activity because the tool will enable the entity to report costs **only for the years selected** in the IKAA Plan. In other words, if one year is not selected in the IKAA Plan form, it will not be possible to report costs for that concerned year in the IKAA Report form later on.

E.g.: if an activity is planned to take place in 2023 and 2024, it is highly recommended to select in the IKAA Plan the years 2023, 2024, 2025 and 2026. This way, the entity will be able to report costs for those years, even in case the activity is delayed compared to the initial plan.

For each additional activity encoded in the IKAA Plan form, a unique reference will be created automatically in the tool. This reference is in the form of a code (e.g.: IHI.2023.PJ.12345.1) and is composed of the following elements: [the JU acronym; the year of the Plan in which the activity is inserted; the type of IKAA ('PJ' for *Project-specific* IKAA and 'PG' for *Programme-specific* IKAA); the PIC of the entity and the number of the activity]. This unique reference enables the quick identification of an additional activity planned in the IKAA Plan form and most importantly, enables the reporting of its costs in the IKAA Report form at a later stage (see Section 8.1 on IKAA Reporting).

Once the IKAA Plan form is submitted, the IHI JU Office will review its content. In case of errors, discrepancies or fields left empty, the IHI JU Office will need to reopen the tool and ask the entity to correct and resubmit.

Note that once the planned additional activities are inserted in the IKAA Plan form and approved by the IHI JU GB, it is not possible to delete them or modify the activities descriptions in the tool anymore.

The only operations that can be performed/amended in the IKAA Plan form after it has been approved are:

- add new additional activities to take place during the ongoing or future year(s);
- modify the estimated value of additional activities (e.g., set the value to zero for one activity in case no costs have been reported and the concerned activity is cancelled);
- add years of implementation for when additional activities are planned to take place (to enable the reporting of costs for those years).

6.4 Deviations from the IKAA Plan

Additional activities may differ in implementation from initial plans.

Major deviations shall require the modification of the IKAA Plan via an amendment or shall be duly justified at reporting stage, depending on the cases.

Major deviations from the IKAA Plan are defined as:

- a new activity not yet foreseen in the Plan; or
- a significant modification of the nature or purpose of the activity foreseen in the Plan; or
- an increase of the estimated costs of more than 25% for the activity foreseen, representing an increase of at least EUR 50,000; or
- a decrease of the estimated costs of more than 25% for the activity foreseen, representing a decrease of at least EUR 50,000.

New activities not yet foreseen in the Plan or significant modification(s) of the nature or purpose of the activity (leading de facto to a new activity)

Any new activity not yet foreseen in the IKAA Plan or any activity significantly modified (leading de facto to a new activity) need to be added to the IKAA Plan.

If an additional activity is not inserted in the IKAA Plan, approved by the GB and encoded in the IKAA Plan form via the Funding and Tenders Portal, the related costs cannot be reported and accepted as IKAA.

Adding new *Programme-specific* additional activities

Industry associations offices shall consolidate the necessary additions for year N in the same template as for the IKAA Planning (Annex 1 of this guidance document) and shall send it to IHI JU Office at least 45 days before the launch for consultation of the last WP amendment foreseen in year N. The same steps as for the planning of *Programme-specific* IKAA shall then be followed (see Section 6.1 above).

If an activity starts in year N and has not been reflected in the WP during that year, it will not be possible to add that new activity to the IKAA Plan for year N anymore and as a result, the concerned private member will not be able to report any costs for year N related to that additional activity. It is therefore **important to plan additional activities well in advance** to introduce them either in the initial version of the WP or at the latest in the first amendment of the WP of the relevant year.

Adding new *Project-specific* additional activities during project implementation

The private member(s) in the relevant IHI project shall specify the new activity(ies) in the same template as for the IKAA Planning (Annex 3 of this guidance document) and shall send it to the IHI JU Office, which shall review it.

Following the review by the IHI JU Office, the relevant private member(s) will be requested to encode the new additional activity(ies) for the concerned IHI project in the IKAA Plan form via the Funding and Tenders Portal. See detailed information on the IKAA Plan form in Section 6.3 above.

The IHI GB shall approve the new additional activities following consultation of advisory bodies via an amendment of the IHI JU WP or alternatively by way of a separate GB Decision, if needed.

Request for additions in the IKAA Plan shall be consolidated as much as possible to limit the amount of separate GB Decisions related to IKAA to two per year.

New *Project-specific* IKAA must also be reflected in the grant agreement (in 'JU contributions' tab and in table 3.1m of the Description of the Action/Annex 1) by way of an amendment. It is recommended to do it after the GB approval.

All *Project-specific* additional activities need to be identified before project end (also when they are planned to be carried out after project end). Additional activities identified after project end shall be considered *Programme-specific*, if criteria are fulfilled.

Significant budget deviations of IKAA

Budget increase

When a significant increase of the total estimated value of an additional activity is identified compared to initially planned (i.e. more than 25%, representing at least EUR 50,000), such budget increase shall be duly justified and explained in the IKAA reporting, which is subject to IHI JU Office review and GB approval. Deviations not sufficiently justified shall lead to cost rejection (i.e., costs not accepted as IKAA).

IKAA increases should be monitored closely considering that no more than 40% of total in-kind contributions of the IHI JU private members (i.e. IKAA + IKOP counted at overall IHI JU programme level) can be accepted as IKAA.

If the increase is due to a significant modification of the nature or purpose of the activity foreseen in the Plan (leading de facto to a new activity), the private member shall add the new activity in the IKAA Plan, following steps explained above.

If the IKAA increase/addition in an IHI project is necessary to maintain the 45% contribution, it should be reflected in an amendment of the grant agreement. More specifically, the IHI project's estimated budget (the 'JU contribution' tab) should be updated, and the IKAA increase/addition should be explained under the initial IKAA Plan specified in table 3.1m of the DoA. Note that the initial IKAA Plan specified in table 3.1m of the DoA should not be deleted.

Budget decrease

When a significant decrease of the total estimated value of an additional activity is identified compared to initially planned (i.e. more than 25%, representing at least EUR 50,000), such budget decrease shall be duly justified and explained in the IKAA reporting.

When such budget decrease is due to the cancellation of an additional activity initially foreseen in the IKAA Plan, it is recommended to inform the IHI JU Office from the moment this deviation from the Plan is identified. The concerned private member will then be requested to set the estimated value of the additional activity to zero in the concerned IKAA Plan form via the Funding and Tenders Portal. Such change can only be done if no costs have been reported for the concerned activity.

In case of significant budget decrease of IKAA, private members should inform the relevant project's coordinator so appropriate measures can be taken to mitigate the impact and ensure the 45% contribution threshold is maintained. Grants for which the 45% contributions is not maintained during project implementation shall be considered as not eligible anymore and shall be terminated by IHI JU if not mitigation measures are found.

Mitigation measures to maintain the 45% contribution in an IHI project could be:

- add new additional activity(ies) (IKAA),
- increase financial contributions (FC),
- increase IKOP (either by increasing the total eligible costs of private member(s) and/or contributing partner(s) in the consortium or by decreasing their requested EU contribution, if any),
- a combination of the above elements.

Major budget decrease of IKAA in an IHI project leading to mitigation measures to maintain the 45% contribution should be reflected in an amendment of the grant agreement. More specifically, the IHI project's estimated budget (the 'JU contribution' tab) should be updated, and major budget deviations explained under the initial IKAA Plan specified in table 3.1m of the DoA. Note that the initial IKAA Plan specified in table 3.1m of the DoA should not be deleted.

7 IKAA Cost Valuation method

As per Article 11.2 of the Regulation, for the purpose of valuing in-kind contributions to additional activities, the costs shall be determined in compliance with:

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

In principle the costs incurred in additional activities shall not be subject to the Horizon Europe cost eligibility rules and costs calculation methods (unlike IKOP) unless the private member so requires on the basis of

specific justification to IHI Office. This can be envisaged to simplify the participation of legal entities in IHI JU actions, where a legal entity may be participating in a large number of actions funded under Horizon Europe (HE) and thus will be very familiar with the rules for reporting costs under the provisions of the Horizon Europe model grant agreement (HE MGA)¹⁰.

In such a case, a consistent approach should be ensured across projects and for all types of costs incurred for additional activities, i.e. methodologies should not be mixed across cost categories (e.g. personnel costs based on the entity's usual practice while flat rate indirect cost applied as per HE's eligibility rule).

IKAA can consist of any types of costs as far as it is directly linked and necessary for the implementation of an approved additional activity (e.g. personnel costs, subcontracting costs, financial contributions, other direct costs, etc...).

Costs incurred for additional activities shall be actually incurred by the concerned entity during the timeframe allowed for IKAA (see Section 3.2), recorded in the accounting system of the entity and shall be identifiable and verifiable (i.e. documented, evidenced) as it will be audited by an independent external auditor appointed by the entity concerned.

In duly specified cases, the IHI JU GB may authorise, for valuing the contributions, 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.

When necessary, the IHI JU private members may identify those potential activities which could fall under these specific cases and submit a proposal to the IHI JU GB. For each potential activity, the use of a simplified valuing method should be duly justified (i.e. the three above criteria should be fulfilled) and a clear cost calculation methodology should be established. Ideally, that calculation methodology should not be company specific but general enough so that different companies could apply it, if needed.

Entities following such simplified methodologies should be able to demonstrate, during the IKAA certification by an external independent auditor, that:

- the approved methodologies have been followed to exclude any profit margins;
- their usual cost accounting practices have been followed.

8 IKAA Reporting and Certification

8.1 IKAA Reporting

As per Article 11.2 of the Council Regulation, the IHI JU private members shall report by 31 May of year N+1 to the IHI JU Governing Board on the value of IKAA made in each of the previous financial years (i.e. from 1 January until 31 December of year N and potential adjustments¹¹ to prior years).

¹⁰ 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

¹¹ The IKAA tool currently does not support the submission of cost adjustments to prior years. In case of question in relation to cost adjustments to prior year(s), please contact IHI office at finance@ihi.europa.eu.

Each private member shall report for it(s) affiliated entity(ies), if any, by including in its reported costs the ones of it(s) affiliated entity(ies).

Only costs necessary for the implementation of an approved additional activity can be reported. Costs that are not directly incurred in implementing the additional activity should not be reported (e.g., membership fee to MedTech Europe/EFPIA/COCIR/Europa Bio).

The costs incurred in additional activities (both for *Project-specific* IKAA and *Programme-specific* IKAA) shall be reported by the concerned entities in the IKAA Report form via the Funding and Tenders Portal.

At the beginning of the year, each concerned entity will receive a notification from the Portal with the request to fill in and submit the IKAA Report form by the end of May. It is the same reporting tool and the same reporting deadline for both *Project-specific* IKAA and *Programme-specific* IKAA. Only the persons with the role of LEAR, account administrator or IKAA reporter can view, edit and submit the IKAA Report form.

Here are [instructions on how to access, fill in and submit the IKAA Report form](#).

Costs for additional activities incurred in year N can be reported (in year N+1) **only if**

- the additional activity is foreseen in the IKAA Plan and approved by the IHI JU GB;
- the additional activity has been encoded by the private member in the IKAA Plan form **and** year N has been selected as implementation year for the additional activity (see Section 6.3).

If the planned additional activity is inserted in the IKAA Plan form but the year N has not been selected as year of implementation, **no costs for the related activity can be reported** in the IKAA Report form for year N. If necessary, it is possible to amend the IKAA Plan form to add implementation years and enable the reporting of costs for those years.

The private member can find the additional activities for which it can report costs in the IKAA Report form by selecting their unique reference (e.g.: 'IHI.2023.PJ.12345.1').

This reference is automatic at planning stage (see Section 6.3) and is composed of the following elements: [the JU acronym; the year of the Plan in which the activity is inserted; the type of IKAA ('PJ' for *Project-specific* IKAA and 'PG' for *Programme-specific* IKAA); the PIC of the entity and the number of the activity]. This unique reference enables the reporting of the costs for a concerned additional activity in the IKAA Report form.

Each entity can only access and select the references of its own additional activities as the reference is linked to its PIC.

When selecting the unique reference of an additional activity, all information already encoded in the IKAA Plan form for the concerned planned activity will be automatically pre-filled in the IKAA Report form.

The content of the IKAA Report form is only visible by the concerned entity and the IHI Office.

The information the private member shall report in the IKAA Report form for each additional activity shall consist of:

- the actual amount in EUR incurred by the entity during year N as recognised in its accounts (and of its affiliate(s), if any);
 - the amount in EUR certified during year N (i.e.; certified by an external and independent auditor), if supported by an audit certificate;
 - the amount in EUR not yet certified (calculated automatically by the tool as the difference between the two above-mentioned elements);
 - a brief explanation on the carried-out additional activities during year N (optional);
 - a detailed, complete and clear explanation/justification in case of major budget deviations from the planning (see Section 6.4 above), e.g.:
- **increase of IKAA** (i.e.; the reported cost exceeds by more than 25% the estimated value, which represents a deviation of at least EUR 50,000).

Deviations that are not sufficiently justified may lead to cost rejection (i.e., costs not accepted as IKAA).

- **decrease of IKAA** (i.e.; the reported cost is at least 25% lower than initially estimated, which represents a deviation of at least EUR 50,000).
For cases of decrease of *Project-specific* IKAA, the provided deviation explanation should also include a statement confirming that the 45% contribution threshold for the concerned IHI project is maintained. In case the IKAA decrease led to mitigation measures reflected in a project amendment in order to maintain the 45% contribution threshold, the reference to the relevant amendment should also be specified. In case the IKAA decrease resulted from the cancellation of an activity initially foreseen, the cancelled activity should be specified.
- the success story description and the audience/target group, if any (optional).

After the private member has submitted the IKAA Report form, the IHI JU will receive a notification from the Portal that the form is ready to be assessed.

The IHI JU Office shall review the content of the IKAA Report form and, if necessary, shall reopen the IKAA Report form to request clarifications and/or corrections to the concerned IHI JU private members (e.g., the IKAA Report form will be reopened if certified costs are reported and no audit certificate is uploaded).

Only reported costs that are certified can be accepted by the IHI JU.

8.2 IKAA Certification

IHI JU private members that during year N have delivered IKAA shall have these costs certified by an independent external auditor appointed by the entity concerned (who can be the entity's usual external auditor) to have it counted towards the matching target established in article 119 of the Regulation.

Costs for additional activities that are reported but not certified by an independent external auditor cannot be accepted by the IHI JU.

Private members that have reported IKAA for their affiliated entity(ies) shall have these costs certified too, in their audit certificate (i.e., one single audit certificate is sufficient for the different entities).

The audit certificate should be uploaded in the IKAA Report form via the Funding and Tenders Portal and submitted by 31 May N+1.

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

The certificate provided by each IHI JU private member shall follow the [IHI template for the Terms of Reference and the model annexes for the IKAA Certification](#). IKAA certificates that do not comply with the IHI template cannot be accepted.

The IKAA certificate shall certify that:

- the costs reported have been incurred and recorded in the accounts according to the entity's usual cost accounting practices, the applicable accounting standards of the country where the entity is established, the applicable International Accounting Standards and the International Financial Reporting Standards;
- these practices are formalised, documented and consistently applied by the entity concerned;
- the costs have been incurred during the period declared by the entity concerned;
- the costs are identifiable, verifiable and are backed up by 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);

Private member can upload their IKAA certificate in the Funding and Tenders Portal by selecting the button "Proceed with additional information" before submitting the IKAA report form. Note that only certified costs (i.e., costs that have been audited and certified by an auditor) can be accepted by the IHI JU and count for the matching target established in article 119 of the Regulation.

Once submitted, the IHI JU Office shall review the content of the IKAA Report form, including the IKAA certification and, if necessary, shall reopen the IKAA Report form to request clarifications and/or corrections to the concerned IHI JU private members.

In case the auditor has reported exception in the audit certificate (i.e., some standard procedures could not be performed or resulted in findings), the IHI JU Office will assess and implement them. In some cases, it may require reopening the IKAA Report form to request clarifications and/or corrections to the concerned IHI JU private members.

The costs incurred in additional activities shall not be audited by the IHI JU or any Union body. However, the valuation method may be verified by the IHI JU should there be any uncertainty arising from the certification. This verification could consist of requesting clarification on some costs or on the methodology followed, if necessary.

8.3 IKAA Validation

Each year, after verification by the IHI Office of the submitted information in the IKAA Report form, the IHI JU Governing Board shall validate the total IKAA reported and certified for the previous year (and potential adjustments to prior years) and shall take note of the explanations provided in cases of major deviations. The IHI JU GB may request further clarifications and the IKAA Report form may need to be reopened for corrections, as necessary.

Following the IHI JU GB approval of the reported and certified IKAA, which is expected to take place at year end, the concerned private members shall receive a notification from the Portal concerning the formal approval of the certified costs of their carried-out additional activities.

Furthermore, the Consolidated Annual Activity Report ('CAAR') covering year N shall include information on the additional activities reported by the private members and validated by the IHI GB during year N (i.e., the amount of IKAA reported and certified), the amount of IKAA reported and not yet certified, as well as a breakdown by country where concerned entities providing IKAA are established. The IKAA section in the CAAR shall follow the template adopted by the EC (Annex 5 of this guidance document) and is published each year on [IHI website](#) following approval by the IHI JU Governing Board.

9 Annexes

- **Annex 1:** Template for the Industry Proposal of *Programme-specific* IKAA Plan for year N
- **Annex 2:** Template for the IKAA Plan for year N annexed to the IHI JU WP
- **Annex 3:** Template for *Project-specific* IKAA Plan in IHI proposal/project
- **Annex 4:** Table illustrating the main differences between IKAA and IKOP
- **Annex 5:** Template for the IKAA Report for year N in the IHI JU Corporate Annual Activity Report (CAAR)

Annex 1

Template for the Industry Proposal of **Programme-specific** IKAA Plan for year N (Proposal to send to IHI JU Office and to be approved by the IHI JU GB):

[https://www.ihj.europa.eu/sites/default/files/Template_for_the_annual_additional_activities_\(IKAA\)_plan_at_Programme_level_xlsm](https://www.ihj.europa.eu/sites/default/files/Template_for_the_annual_additional_activities_(IKAA)_plan_at_Programme_level_xlsm)

Additional activities plan template Programme-level additional activities Innovative Health Initiative Joint Undertaking (IHI JU)														
<p>The aim of this additional activities plan is to list annually the new additional activities at programme level starting in year N for the IHI JU Governing Board (GB).</p> <p>The potential programme-specific additional activities should fulfil all of the following conditions:</p> <ul style="list-style-type: none"> - contribute to IHI JU's general and specific objectives (as defined in Articles 115 of the Regulation); - be carried out in the European Union or countries associated to Horizon Europe; - not be funded by IHI JU or any other Union funding programme; - contribute to the uptake of results from IHI JU/IMI2 JU/IMI1 JU projects or have a significant added value for the Union. <p>HI private member(s) planning IKAA confirm by filling in this Annex that the additional activities specified in this Annex fulfil the above mentioned criteria.</p> <p>All fields in this Annex are mandatory.</p> <p>Instructions to fill in this template can be found here: https://www.ihj.europa.eu/sites/default/files/instructions_annual_additional_activities_(IKAA)_plan_Programme_level.pdf</p>														
IHI Work Programme:	(Insert [year])													
Company name ¹	Participant identification code (PIC)	Industry affiliation	Country of establishment	Category of the additional activity ²	Type of the additional activity ³		Title of the additional activity ⁴	Brief description of the additional activity ⁵	Complete description of the additional activity ⁶	Estimated total duration of the additional activity	Link to IHI JU's general objectives ⁷	Link to IHI JU's specific objectives ⁸	Link to project(s) or estimated added-value for the Union ⁹	Estimated TOTAL value
(Insert [Legal name])	(Insert [PIC])	(Select from the list. No multiple selection. For companies with multiple affiliations, please specify the affiliation that is the most relevant for the envisaged additional	(specify the country where the entity - or the main entity - is established)	(Select one category from the list)	(Select one type from the list)	(If 'Other', please specify)	([Free Text] to provide a short title) Max 100 characters	([Free Text] to provide a brief description) Max 400 characters	([Free Text] to provide a complete description) Max 1500 characters	(Insert the estimated duration in months)	(Select from the list one general objective)	(Select from the list one specific objective)	([Free text] to explain how the additional activity contributes to the uptake of results from IHI/IMI2/IMI1 project OR to explain its potential added value for the Union)	(Insert [amount] in EUR for the envisaged additional activity)
Total envisaged in-kind contributions to additional activities at Programme level:														0

Annex 2

Template for the IKAA Plan for year N annexed to the IHI JU Work Programme (Publishable document)

Annex 2 is filled in based on the publishable information encoded in the IKAA Plan form in the Funding and Tenders Portal by IHI JU private members.

Title	Description	Category	Scope/Type	AA linked to projects	AA Project acronym	AA linked to programme	Estimated AA total duration (in months)	Estimated AA total value	Estimated annual value for the year 2025 (<i>the year concerned</i>)	Years of implementation
							<i>Optional</i>		<i>Optional</i>	

Annex 3

Template for the Industry Proposal of **Project-specific** IKAA Plan in IHI Proposal:

Download the latest version from IHI website – Call documents page <https://www.ihi.europa.eu/apply-funding/call-documents>

If you are unsure which version to use, please contact IHI Programme Office.

[illegible]

Annex 4

Table illustrating the main differences between IKAA and IKOP

	IKAA		IKOP
	PROJECT SPECIFIC IKAA	PROGRAMME-SPECIFIC IKAA	
SCOPE	Costs in implementing additional activities that are not project tasks		Eligible costs in implementing project tasks (as specified in Annex 1-DoA of the Grant Agreement)
TIMEFRAME	Costs incurred from (full) proposal submission date and up to 2 years after project end date.	Costs incurred during IHI JU Programme implementation. Costs shall be incurred during the implementation of the IHI JU Programme.	Costs incurred during project implementation (from project start date to project end date)
CONTRIBUTORS	Only private members		Both private members and contributing partners
EU/ NON-EU	Only EU: additional activities must be carried out in the Union or in associated countries to HE		EU and non-EU: project activities can be carried out in the Union, in associated countries to HE or in third countries
AFFILIATES	One Reporting and one Certification for both the main Beneficiary and its affiliate(s) (together)		Separate Reporting and separate Certification for the main Beneficiary and for its affiliate(s)
COST VALUATION	Private members should follow their usual cost accounting practices to value IKAA (IKAA is not subject to HE MGA rules). However private members can choose to apply HE MGA eligibility rules and costs calculation methods for IKAA if specifically justified and applied consistently across projects (if applicable) and cost types.		IKOP is subject to HE MGA eligibility rules and costs calculation methods (e.g.; specific formula for personnel cost, 25% indirect cost flat rate)
REPORTING DEADLINE	Reporting due annually by 31 May of year N+1		Reporting due 60 days after the end of each project reporting period

REPORTING SCOPE	Costs for additional activities incurred during the last calendar year (1 January - 31 December of year N) + adjustment(s) to previous year(s), if any.	Eligible costs incurred between the start date and the end date of each (interim or final) project period + adjustment(s) to previous period(s), if any.
REPORTING TOOL	Activities and costs <u>not</u> reported in the project Periodic Report but in a separate IKAA reporting module accessible via the Funding and Tenders Portal	Activities and costs reported in the project Periodic Report, via the Funding and Tenders Portal
AUDIT CERTIFICATION	All IKAA should be certified to count for the matching. No minimum threshold. Certification due each year by 31 May for costs reported in the current reporting.	<p>Certificate on the statements of contributions (CCS) required at the end of the project if zero IHI funding requested and $(IKOP+FC) \geq \text{EUR } 430\,000$ (per beneficiary or affiliated entity). If threshold reached at project end, all costs must be certified.</p> <p>Certificate on the financial statements (CFS) required at the end of the project if requested IHI funding $\geq \text{EUR } 430\,000$. If threshold reached at project end, all eligible costs must be certified.</p>

Annex 5

Template for the IKAA Report for year N in the IHI JU Corporate Annual Activity Report (CAAR).

IKAA REPORT FOR YEAR N												
DESCRIPTION								Annual reporting		Cumulative reporting		
Title	Description	Category	Scope/Type	AA linked to project	Project acronym	AA linked to programme	Estimated AA total value	Incurred value for the year	Certified value for the year	Cumulative AA value incurred (A)	Cumulative AA value certified (B)	Cumulative AA value not yet certified (A-B)
										<i>data from previous reports + year N</i>	<i>data from previous reports + year N</i>	<i>Cumulative AA value incurred – cumulative AA value certified</i>

TOTAL IKAA [YEAR N]: BREAKDOWN PER COUNTRY	
Country (code)	value (€)

TOTAL IKAA 2021- [YEAR N] (Evolution- Value in €)		
Planned IKAA	Reported IKAA with pending certification	Certified IKAA