



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, up-to-date version of this and other documents relating to the IHI Programme released by the Programme Office.

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1 Abbreviations

This guidance document contains the following abbreviations/acronyms:

- AAR: the consolidated Annual Activity Report
- 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
- MedTech Europe: the European trade association for the medical technology industry
- MGA: Model Grant Agreement
- SIP: the Science and Innovation Panel of IHI JU
- SRG: the States Representatives Group of IHI JU
- SRIA: Strategic Research and Innovation Agenda
- Vaccines Europe: the specialised vaccines group within the EFPIA
- WP: Work Programme

2 Introduction

According to the Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe (hereafter the Regulation)¹, COCIR, EFPIA (also representing Vaccines Europe), EuropaBio and MedTech Europe associations (hereafter 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 report IKAA. Contributing partners can only contribute and report IKOP and FC.

The in-kind contributions to additional activities ('IKAA') shall not exceed 40% of total in-kind contributions (IKAA + IKOP) of the IHI JU private members (counted at IHI JU programme level). Financial contributions (FC) provided by private members are not included in the calculation of this 40%.

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 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 project implementation.

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

3 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.

'Additional activities' mean activities that fulfil the following cumulative conditions:

1. contribute to the objectives and tasks of the IHI JU, as they are defined in Articles 115 and 116 of the Regulation³;
2. 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 included in relevant project proposals);
3. not be funded by the IHI JU or any other Union funding programme;
4. 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);
5. be either *Programme specific* or *Project specific*:
 - a. *Programme-specific* additional activities contribute to the uptake of results from IHI JU, IMI2 JU, IMI JU projects or have a significant added value for the Union.
 - b. *Project-specific additional activities contribute towards the achievement of objectives of the IHI JU funded projects, or the dissemination, sustainability or exploitation of IHI JU project results.*

A clear distinction should be made between the two 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 and reporting.

3.1 Distinction between IKOP and IKAA

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).

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

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

Additionally, 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 8 of this guidance document illustrates the main differences between *Project-specific* IKAA and IKOP.

3.2 IKAA Eligibility timeframe

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 2021⁴ and until the end of the JU Programme) and must be incurred during the year foreseen for the related additional activity as specified in the annual IKAA Plan annexed to the IHI JU WP of the concerned year. In case activities do not take place during the year foreseen (e.g. activity postponed, advanced or cancelled), see Section 4.3 for deviations from the IKAA Plan.

For *Project-specific* IKAA, when properly justified, costs for additional activities may be incurred between the date of submission of the proposal - or the full proposal in a two-stage call process - and up to two years after the end date of the project⁵. 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.

4 Practical examples of IKAA

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

4.1 Examples of 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.

Costs related to the above additional activities IKAA could be any cost (FTEs, subcontracting, consultant/expert fees, use fee of internal/external intelligence databases/tools, travel costs...) for e.g. establishing and running a taskforce/expert group, delivering a dossier, creating and maintaining a database, having a symposium.

4.2 Examples of Project-specific additional activities

- *Example 1:*
 - IHI JU Project objectives: develop tools, methodologies, best practices 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.

⁴ The Council Regulation (EU) 2021/2085 establishing the Joint Undertakings under Horizon Europe is dated 19 November 2021

⁵ Article 120 of the of the Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe.

- **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, 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 the project starts, **Company A** contributes costs for internal preparatory activities for development of a digital tool that will be used in the consortium activities, and **Company E** contributes costs of a legal expert/running a workshop to solve before project start any legal and IP issues that could hinder data sharing, to ensure efficient/timely kick-off and in time running of the project.
- During the project implementation, **Company B** provides costs for generating data and conclusions 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). These activities could have started before the start of the project, from the date of submission of the (full) proposal.

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

- **Company C** contributes costs to ensure 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 A** and **E** jointly contribute costs to organize a symposium to disseminate the results of the IHI JU project
 - **Company B** contributes costs for open access fees for articles related to the IHI JU funded project
 - **Company C, D** and **E** jointly contribute costs to maintain/keep updated the website with news on activities taken place after the project has ended
 - **Company D** contributes costs for regulatory activities using regulatory services offered by regulatory agencies (advice, qualification advice procedure).
 - **Company E** and **F** contribute costs of (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.
- *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 the project starts, Company A contributes costs of internal development of an image-guided radiation therapy device that will be then used for the consortium activities, while Company E contributes costs for adaptation of an already commercialized sensor that is made available to the consortium to ensure efficient/timely kick-off and in time running of the project.
- During the project implementation, Company B contributes costs of 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 costs of 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). These additional activities could have started before the start of the project.

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

- Company A and E contribute costs for performing 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, using knowledge and material from the project, Company A contributes costs to run a series of webinars and 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.
- After the project end, 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 IKAA Planning

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

5.1 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), where the estimated value of those contributions for year N is provided.

The IKAA Plan for year N should be adopted by the IHI JU Governing Board (GB) by the end of year N-1⁶.

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 17.2.1 and article 124.4.c of the Regulation).

⁶ Except for the IKAA Plan for year 2022

Private members shall send the proposal of the IKAA Plan for year N at latest 45 working days before the date of the last IHI JU GB meeting scheduled in the year N-1.

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 (to be published in the IHI JU WP and the AAR) and confidential information (only disclosed to IHI GB and IHI Office). More specifically, the content of the IKAA Plan proposal shall be made public, except the following information that shall be disclosed only to the IHI GB and IHI Office:

- the company legal name;
- the industry affiliation of the company;
- the confidential version of the additional activity description, if applicable;
- the estimated added-value or impact for the Union, if applicable (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(ies)).

The publishable information provided by private members in the proposal of IKAA Plan for year N shall be inserted by the IHI JU Office into the IKAA Plan annexed to the IHI JU WP, which shall follow the template adopted by the EC (Annex 2 of this guidance document).

The information included in the IKAA Plan should allow 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.

For each additional activity, an estimated annual value in euro for year N should be specified. As a result, additional activities that are planned to run several years shall be included in the IKAA Plan of several consecutive IHI JU WPs.

5.2 Project-specific IKAA Planning

IKAA cannot exceed 40 % of the total in-kind contributions (IKAA + IKOP) provided by IHI private members at overall IHI JU programme level⁷. It is therefore recommended to limit the IKAA of a project to the same threshold (i.e. the IKAA of a project should not exceed 40 % of the sum of IKOP and IKAA provided by IHI private members to the project). If IHI private members want to contribute more IKAA than 40 %, they should inform their relevant industry office accordingly so that it can be closely monitored.

Project-specific IKAA shall be specified in a plan annexed to the relevant project proposals - or full proposal in a two-stage call process - (Article 120.2 of the Regulation) using the template adopted by the IHI JU (Annex 3 of this guidance document). Consequently, such a plan will be reviewed by the independent experts panel at the time of proposal evaluation.

The information included in the IKAA Plan of a project proposal should allow the assessment of the relevance of the additional activities for the achievement of objectives of the concerned IHI JU funded project, or the dissemination, sustainability or exploitation of the IHI JU project results.

The IKAA Plan included in the concerned project proposal shall include confidential information (only disclosed to evaluators, the IHI GB and IHI Office) and publishable information (to be published in the IHI JU WP and the AAR). More specifically, the content of the IKAA Plan included in the concerned project proposal shall be made public, except the following information that shall be disclosed only to evaluators, the IHI GB and IHI Office:

- the company legal name;
- the industry affiliation of the company;
- the confidential version of the additional activity description, if applicable;
- the estimated period for the additional activity to take place (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(ies)).

⁷ The overall limitation of 40 % of IKAA at IHI JU programme level includes both programme-specific IKAA and project-specific IKAA.

Due to the nature and the complexity of IKAA related to projects (multi annual grants), an estimation of the total value in euro per additional activity shall be given in the IKAA Plan (instead of an estimated annual value for year N). The IKAA Plan shall also specify an estimated timeline of when the additional activities may take place, between the (full) proposal submission date and up to two years after the end date of the project.

The plans for additional activities related to IHI JU projects are formally approved by the IHI JU GB during the award decision.

The approved IKAA is a key element in the project selection decision as a project shall be eligible for IHI JU funding only if the total industry contribution to the project - consisting of IKAA, IKOP and/or FC provided by both IHI JU private members and, for the latter two, contributing partners - represents at least 45% of project total eligible costs and costs for project-specific additional activities. IHI JU proposals for which the total industry contribution (IKOP + IKAA + FC) does not reach the 45% threshold cannot be selected.

When proposals are selected, these additional activities will have to be reflected in a plan included in the Description of the Action (DoA/Annex 1 part b of the Grant Agreement) of concerned projects, using the template adopted by the IHI JU (Annex 4 of this guidance document).

Once per year, the IHI Office will consolidate the approved IKAA from the grant agreements signed during that year in a separate GB Decision (or alternatively via an amendment of the IHI JU WP) in order to inform and consult advisory bodies (i.e. the SRG and the SIP). Advisory bodies may express their opinion on the approved additional activities; 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.

This separate GB Decision (or amendment of the IHI JU WP) is also the opportunity for private members to include necessary IKAA changes (i.e. major IKAA modifications/additions) that were not initially foreseen in the IKAA Plan of proposals/projects previously selected.

In case major IKAA modifications/additions occur during the Grant Preparation phase, i.e. between the proposal selection and the grant signature, 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.

The reference number of the last approved GB Decision on IKAA shall be specified in the IKAA Plan annexed to the IHI JU WP in order to provide an overview of all additional activities in IHI JU projects and guarantee IKAA transparency.

5.3 Deviations from the IKAA Plan

Additional activities may differ in implementation from initial plans.

If deemed necessary, i.e. when major deviations are identified, the IKAA Plan – both at Programme and Project level – shall require amendment.

Major deviations 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, becoming de facto a new activity; or
- an increase of the total estimated costs of more than 25% for the activity planned, representing a deviation of at least EUR 50,000 (absolute amount to be agreed); or
- the cancellation of an activity foreseen in the Plan, leading to a significant budget decrease of at least EUR 50,000.

For *Programme-specific* additional activities, private members can request the modification of the IKAA Plan for year N using the Template for modifications request (Annex 5 of this guidance document). The modification of the IKAA Plan for year N requires an amendment of the IHI WP during that year in the two

first cases of major deviations. In the two last cases, the IKAA Plan can be amended following a separate GB decision, following consultation of advisory bodies.

For *Project-specific* additional activities, private members can request the modification of the IKAA Plan in the selected projects by using the Template for modifications request (Annex 6 of this guidance document). The IKAA Plan shall be amended following a separate GB decision, following consultation of advisory bodies.

Modifications requests of the IKAA Plan should be consolidated as much as possible to limit the amount of separate GB Decisions related to IKAA to two per year.

Project-specific IKAA must also be modified by way of an amendment of the grant agreement. It is recommended to do it after the GB Decision has been approved, in particular in case the approval of the requested IKAA modifications potentially impacts the 45% threshold of total industry contribution for the concerned project.

5.3.1 New activities not yet foreseen in the Plan or significant modification(s) of the nature or purpose of the activity

Additional activities (both at Programme or Project level) shall be included in the IKAA Plan and approved by the GB, following consultation of advisory bodies before the related costs can be accepted as IKAA by the IHI JU.

For *Programme-specific* additional activities, the IKAA Plan in the IHI JU WP of year N shall be amended in the course of that year in order to include any new activity not yet foreseen in the IKAA Plan or any activity significantly modified (leading de facto to a new activity). Since the IKAA Plan is annual and requires IHI WP Amendment, industry members should pay particular attention in identifying such major modifications from the Plan during that year. Industry members shall consolidate the necessary modifications in the Template for modifications request (Annex 5 of this guidance document) and shall send it to IHI GB at least 30 days before the last WP amendment foreseen in year N.

In case an activity foreseen in the IKAA Plan for year N is postponed to year N+1 or advanced to N-1 and it has not been possible to reflect it in the IKAA plan annexed to the WP for the relevant year, this can be reflected a-posteriori in the IKAA Plan of the relevant year via a GB Decision in year N or in year N+1 (provided that the activity was indeed included in the IKAA plan for year N), following consultation of advisory bodies. However, if an activity not yet foreseen in the IKAA Plan for year N is totally new (i.e. also not foreseen in the IKAA Plan of the previous/next year) and has not been reflected in the WP during that year, this shall require an ex-post modification of the concerned WP in a following year (or alternative solution – pending EC decision).

For *Project-specific* additional activities, the IKAA Plan shall be amended to include any new activity not yet foreseen in the IKAA Plan or any activity significantly modified before the related costs can be accepted by IHI JU. The IHI GB shall approve it on the basis of a proposal from the private members including consolidated IKAA modifications requests (Annex 6 of this guidance document) by way of a separate GB Decision, following consultation of advisory bodies (or alternatively via an amendment of the IHI JU WP).

5.3.2 Significant budget deviations

For *Programme-specific* additional activities planned in year N, when the actual annual value exceeds by more than 25% the estimated annual value, this deviation shall not require a modification of the IKAA Plan during that year but shall require an explanation in the IKAA reporting due in May the following year.

When an activity (both at Programme or Project level) is planned to run over several years and a significant increase of the total estimated value is identified compared to initially planned (i.e. more than 25%, representing at least EUR 50,000), it is recommended to reflect such budget increase in a modification

request of the IKAA Plan before the activity is finished and the related costs are reported. This modification request can be approved by way of a separate GB Decision, following consultation of advisory bodies. Alternatively, such budget increase can be explained in the IKAA reporting, which is subject to GB approval.

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.

When an activity (both at Programme and Project level) foreseen in the IKAA Plan is cancelled, leading to an important budget decrease (of at least EUR 50,000), it is recommended to reflect such change in a modification request of the IKAA Plan as well, from the moment this deviation from the Plan is identified. This modification request can be approved by way of a separate GB Decision, following consultation of advisory bodies.

In case of such decrease of IKAA, private members should take appropriate measures in order to mitigate the impact and ensure the 45% threshold is maintained.

When there are no major deviations from the IKAA Plan, there is no need for an amendment of the IKAA Plan. Minor deviations can be explained at the time of Reporting.

6 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 unless the private member so requires on the basis of specific justification. 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 HE grant agreement.

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 necessary for the implementation of an approved additional activity (e.g. personnel costs, subcontracting costs, financial contributions, other direct costs, etc...).

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. 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.

7 Reporting and Certification **(under discussion at EC level)**

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 adjustments to prior years).

The costs incurred in additional activities (both for Project-specific IKAA and Programme-specific IKAA) shall most probably be reported by the concerned entities via the Funding and Tenders Portal linked to each entities' PIC (information to be confirmed and tool to be developed by the EC).

Only reported costs for additional activities that are foreseen in the IKAA Plan can be accepted by the IHI JU. If a reported additional activity is not foreseen in the IKAA Plan, the related costs shall not be accepted as IKAA until the concerned AA is added to the IKAA Plan and approved by the IHI JU GB, following consultation of advisory bodies.

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

The information reported in the IKAA reporting may contain **(under discussion at EC level)**:

- a description of each additional activity carried out;
- the link to IHI JU's objective(s), in line with the IKAA Plan;
- the link to IHI JU funded project(s), in line with the IKAA Plan, if applicable;
- the amount planned in EUR, as stated in the IKAA Plan;
- the actual amount in EUR of the additional activities carried out during year N as recognized in the accounts of each private member constituent (and of its affiliate(s), if any)
- an explanation/justification in case the reported cost exceeds by more than 25% the annual estimated value of the foreseen additional activity in the Programme-specific IKAA Plan, if applicable.

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.

Private member constituents 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 submitted by 31 May N+1.

The certificate provided by each IHI JU private member constituent shall follow the Terms of Reference and the model for the Certification of IKAA which is currently being developed by the EC.

It shall certify a priori (pending EC confirmation), to a minimum extent, that:

- the costs reported have been incurred and recorded in the accounts according to the 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);

The costs incurred in additional activities shall not be audited by the IHI JU or any Union body. 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.

The IHI JU Governing Board shall take note of the total IKAA reported for year N by **xxx**.

Furthermore, the Consolidated Annual Activity Report ('AAR') covering year N should include information on the additional activities undertaken by the private members during year N, the amount of IKAA reported and certified, as well as a breakdown by country where concerned entities providing IKAA are established (EC to provide final AAR Template).

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8 Annexes

- **Annex 1:** Template for the Industry Proposal of Programme-specific IKAA Plan for year N
- **Annex 2:** Template for the Programme-specific IKAA Plan for year N annexed to the IHI JU WP
- **Annex 3:** Template for the Industry Proposal of Project-specific IKAA Plan in (full) IHI Project Proposal
- **Annex 4:** Template for the Project-specific IKAA Plan in the Description of the Action (DoA/Annex 1 part b of the Grant Agreement)
- **Annex 5:** Template for modification requests of Programme-specific AA
- **Annex 6:** Template for modification requests of Project-specific AA
- **Annex 7:** Template for the IKAA reporting (to embed in relevant IT tool – to be developed)
- **Annex 8:** Table illustrating the main differences between IKAA and IKOP in IHI projects

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Annex 1

Template for the Industry Proposal of Programme-specific IKAA Plan for year N (Proposal to send to IHI JU Governing Board):
[https://www.ih.europa.eu/sites/default/files/Template for the annual additional activities \(IKAA\) plan at Programme level.xlsx](https://www.ih.europa.eu/sites/default/files/Template%20for%20the%20annual%20additional%20activities%20(IKAA)%20plan%20at%20Programme%20level.xlsx)

Additional activities plan template Programme-level additional activities Innovative Health Initiative Joint Undertaking (IHI JU)												
<i>The aim of this additional activities plan is to list annually the additional activities at programme level for the IHI JU Governing Board (GB).</i>												
<i>The potential programme-specific additional activities should fulfil all of the following conditions:</i>												
<ul style="list-style-type: none"> - contribute to IHI JU's objectives and tasks (as defined in Articles 116 and 116 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/JUIMI2 projects <i>or</i> have a significant added value for the Union. 												
Instructions to fill in this template can be found here: https://www.ih.europa.eu/sites/default/files/instructions_annual_additional_activities_IKAA_plan_Programme_level.pdf												
Year:											[]	
Total annual envisaged in-kind contributions in additional activities by the private members:											EUR [] million	
Company name *	Participant identification code (PIC)	Industry affiliation	Category of additional activities *	Type of additional activities *	Publishable description of the additional activities *	Confidential description of the additional activities (if applicable) *	Estimated total duration of the additional activities	Link to IHI JU's objectives / tasks *	Link to Partnership's project(s) (if applicable)	Estimated Union added-value or impact (if applicable) *	Estimated annual value	Estimated TOTAL value*
(Insert [Legal name])	(Insert [PIC])	<i>(select from the list - no change selection. For companies with multiple affiliations - please specify the affiliation that is the most relevant for the AA)</i>	(Select one AA category from the list.)	(Select one type from the tab 'List of AA categories and types'.)	(Free Text) to provide more information on the envisaged AA.)	(Free Text) to provide more information on the envisaged AA if it needs to be kept confidential.)	(Insert the estimated duration in months for each AA.)	(Select from the list. Multiple selection possible)	(Insert [Project name(s)] if the AA contributes to the uptake of results from IHI JU/IMI2/JUIMI2 project(s).)	(Free text) to elaborate on the AA's potential added value for the Union in case it does not contribute to the uptake of results from IHI JU/IMI2/JUIMI2 project(s).	(Insert [amount] in EUR for each AA.)	(Insert [amount] in EUR for each AA.)
Total envisaged in-kind contributions to additional activities at Programme level:											Total (sum of annual value)	Total (sum of total value)

Annex 2

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

Annex 2 is filled in based on the information provided in the above Annex 1.

ADDITIONAL ACTIVITIES PLAN TEMPLATE				
VERSION TO BE INCLUDED AS AN ANNEX TO THE WORK PROGRAMME				
OVERVIEW ESTIMATED IKAA FOR [YEAR N] ¹				
Category of the Additional Activities (AA) ²	Description of the AAs ³	contribution to JU objectives or KPIs of the JU ⁴	Link to specific JU project/ call/topic ⁵	Estimated value AA for [Year N] (in M€) ⁶
[Support to additional R&I] ⁷				
[Scale up of technologies]				
[Demonstrators]				
[Creating new business opportunities]				
[Training & skills development]				
[Contribution to the development of new standards, regulations and policies]				
[Supporting ecosystem development]				
[Communication, dissemination, awareness raising, citizen engagement]				
[Others]				
TOTAL ESTIMATED IKAA				

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Annex 3

Template for the Industry Proposal of Project-specific ICAA Plan in (full) IHI Project Proposal:

[https://www.ihl.europa.eu/sites/default/files/IHI Annex declaration in kind contribution additional activities.xlsx](https://www.ihl.europa.eu/sites/default/files/IHI_Annex_declaration_in_kind_contribution_additional_activities.xlsx)

Additional activities plan template Project-level additional activities								
Innovative Health Initiative Joint Undertaking (IHI JU)								
<i>The aim of this additional activities plan is to list the additional activities for the concerned project</i>								
<p><i>The potential project-specific additional activities should fulfil all of the following conditions:</i></p> <ul style="list-style-type: none"> - contribute to IHI JUs objectives and tasks (as defined in Article 115 and 116 of the Regulation); - be carried out in the European Union or countries associated to Horizon Europe (irrespective of the country of establishment of the entity incurring the related costs); - not be funded by the IHI JU or any other EU funding programme; - contribute towards the achievement of objectives of the IHI project, or the dissemination, sustainability or exploitation of the IHI project results; - be carried out between the (full) proposal submission date and up to 2 years after the IHI project end date. 								
<p>Instructions to fill-in this template can be found here: https://www.ihl.europa.eu/sites/default/files/IHI Annex declaration in kind contribution additional activities instructions.pdf</p>								
IHI Project:	(Insert [project number] — [acronym])							
Participant number in	Company name ¹	Category of additional activities ²	Type of additional activities ³	Publishable description of the additional activities ⁴	Confidential description of the additional activities (if applicable) ⁵	Estimated period for the additional activities ⁶	Link to IHI project	Estimated TOTAL value ⁷
(Insert the [participant number] of the the company in the IHI Project)	(Insert [legal name])	(Select one AA category from the list)	(Select one type from the tab "List of AA categories and types")	((Free Text) to provide more information on the envisaged AA)	((Free Text) to provide more information on the envisaged AA if it needs to be kept confidential)	(Select from the list [the indicative timeline] for the envisaged AA)	((Free text] to explain how the AA contributes towards the achievement of objectives of the IHI project, or the dissemination, sustainability or exploitation of the IHI project results)	(Insert [amount] in EUR for each AA for each specific project)
Total envisaged in-kind contributions to additional activities for the (full) proposal:								TOTAL (Sum)

Annex 4

Template for the Project-specific IKAA Plan in the Description of the Action (DoA - Annex 1 part b of the Grant Agreement) – not available yet

Annex 4 is to be filled in based on the information provided in the above Annex 3

Annex 5

Template for modification requests of Programme-specific AA – not available yet

Annex 6

Template for modification requests of Project-specific AA – not available yet

Annex 7

Template for the IKAA reporting (to embed in relevant IT tool – to be developed by EC – not available yet)

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Annex 8

Table illustrating the main differences between IKAAs and IKOPs

	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 must be incurred during the year foreseen in the annual IKAAs Plan annexed to the IHI JU WP of the concerned year.	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 carried out in the Union or in associated countries to HE		EU and non-EU: project activities carried out in the Union, associated countries to HE or in third countries
AFFILIATES	One Reporting and one Certification for both the main Beneficiaries and its affiliate(s) (together)		Separate Reporting and separate Certification for main Beneficiaries and for its affiliate(s)
REPORTING DEADLINE	Reporting due by 31 May of year N+1		Reporting due 60 days after the end of each reporting period
REPORTING SCOPE	Costs incurred during the last calendar year (1 January - 31 December of year N)		Costs incurred between the start date and the end date of each interim and final period
REPORTING CONTENT & TOOL	Activities and costs <u>not</u> reported in the project Periodic Report but in a separate tool		Activities and costs reported in the project Periodic Report. Via the Funding and tenders Portal
AUDIT CERTIFICATION	All IKAAs should be certified to count for the matching. No minimum threshold.		Certificate on the statements of contributions (CCS) required at the end of the project if zero IHI funding

		<p>requested and IKOP+FC ≥ EUR 430 000 (per beneficiary or affiliated entity)</p> <p>Certificate on the financial statements (CFS) required at the end of the project if requested IHI funding ≥ EUR 430 000 (irrespective of the amount of IKOP and FC provided to the project)</p>
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