

Instructions on filling in the annex on IKAA of a full project proposal

The purpose of this document is to provide IHI private members with detailed instructions and concrete examples on how to fill in the <u>annex on in-kind contributions to additional activities ('IKAA') of a (full) project proposal</u> in single-stage calls or in the second stage of two-stage Calls.

Instructions are provided step-by-step as follows:

- 1. get familiar with the concept of IKAA;
- 2. identify additional activities for the full IHI proposal;
- 3. insert the necessary information in the IKAA plan;
- 4. A practical example of an IKAA plan

1 Get familiar with the concept of IKAA

The very first step is to read the 'IHI JU Guidelines for in-kind contributions to additional activities (IKAA)' in order to understand the general principles of IKAA. The guidelines explain clearly what can constitute IKAA from IHI private members, and describes the different stages of planning, evaluation, reporting and certification of IKAA, as well as the role of the different parties involved in these processes. More specifically, the document covers the following points:

- IKAA definition:
 - distinction between project-specific additional activities and programme-specific additional activities;
 - distinction between IKAA and IKOP¹ (in-kind contributions to operational activities);
 - IKAA eligibility timeframe;
- practical examples of IKAA;
- planning and deviations from the IKAA plan;
- cost valuation methods for IKAA;
- IKAA reporting and certification.

2 Identify additional activities for the full IHI proposal

The purpose of the annex on IKAA is to list the potential additional activities that IHI private members could contribute in the context of the full IHI proposal.

The potential additional activities should fulfil all the following conditions:

contribute to IHI JU's objectives and tasks (as defined in Article 115 and 116 of the Regulation)?;

² IHI JU's general and specific objectives are also listed on IHI website: https://www.ihi.europa.eu/about-ihi/mission-and-objectives;













¹ In-kind contributions to operational activities ('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 (full) proposal

- 2. be carried out in the European Union (EU) or countries associated to Horizon Europe (irrespective of the country of establishment of the entity incurring the related costs):
- 3. not be funded by the IHI JU or any other EU funding programme;
- 4. be carried out between the full proposal submission date and up to 2 years after the IHI project end date;
- 5. be <u>project-specific</u>, i.e. contribute towards the achievement of the objectives of the IHI project, or the dissemination, sustainability or exploitation of the IHI project's results.

The following elements should be considered while identifying additional activities for the IHI full proposal.

- Only IHI private members (COCIR, EFPIA (including Vaccines Europe), EuropaBio and MedTech Europe associations), their constituent and affiliated entities, can contribute IKAA. IHI contributing partners cannot contribute IKAA.
- Only project-specific additional activities should be listed in the annex, not programme-specific additional activities.
- Activities identified as IKAA in one IHI project cannot be identified as IKAA in another IHI project, as programme-specific IKAA, or as IKOP.
- IKAA cannot exceed 40 % of the total in-kind contributions (IKAA + IKOP) provided by IHI private members at overall IHI JU programme level³. 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.

IKAA is a key element in the project selection decision because a project can only be eligible for IHI JU funding if the total contribution to the project from private members, their constituent entities or affiliated entities, and contributing partners (consisting of IKOP, IKAA and FC4) represents at least 45 % of the project's total eligible costs and costs for project-related additional activities.

While private members can contribute any of those contribution types, contributing partners can only contribute IKOP and FC, not IKAA.

The 45% threshold can be reached by providing one, two or three of these contribution types. It can also be reached with the contribution provided by private member(s)/contributing partner(s) only or by both.

Full IHI proposals for which the total industry/contributing partner contribution (IKOP + IKAA + FC) does not reach the 45 % threshold cannot be selected.

3 Insert the necessary information in the IKAA plan

Once the additional activities are identified, they can be inserted in the IKAA plan in the annex of the full project proposal, using the IKAA plan template.

The IKAA plan consists of an Excel table. There is one IKAA plan per full project proposal.

At the top of the table, projects should insert their project number and acronym. Below that, each additional activity should be listed on a separate row, irrespectively of the company contributing it (e.g if a company plans to provide three types of additional activities in a full project proposal, there will be three rows for that company in the IKAA plan).

In the final row, the project should give the total value of all IKAA contributions to the project.

The table below details the information to be inserted in the IKAA plan for each activity.

³ The overall limitation of 40 % of IKAA at IHI JU programme level includes both programme-specific IKAA and project-specific IKAA.

⁴ Financial contributions ('FC') are financial transfers (cash contributions) made by IHI private members, their constituent 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.

INFORMATION	INSTRUCTIONS
Participant number in Project	Insert the [participant number] the Company has in the IHI Project
Company name	 Insert the legal name of the company that will carry out the additional activity. Each company shall plan for it(s) affiliated entity(ies), if any, by including in its planned activities those of it(s) affiliated entity(ies). The legal name(s) of affiliated entity(ies) should not be inserted, only that of the main legal entity.
Category of additional activity	 Select one category for the activity from the following list: Support to additional research and innovation (R&I) This category covers research and innovation activities that are not already funded by any EU programmes. Scale-up of technologies This category covers different scale-up activities (typically at technology readiness level (TRL) 4-5). These are mostly trials/tests of proof-of-concept models, e.g. validation of the technology in a lab or relevant environment. Demonstrators This category covers demonstrations of a prototype. These demonstration activities would typically be at TRL levels 6-8. Creating new business opportunities This category includes activities which aim to turn a fully developed and functional innovation into a business opportunity. It covers activities such as investing in start-ups, spin-offs, incubators, accelerators etc. that will take forward the solutions/products developed within the IHI project(s). Training and skills development This category covers activities that aim to identify and run the skills and training programmes needed for the workforce that will produce and/or use the new product/service. Contribution to the development of new standards, regulations and policies This category includes activities that aim at the development of new standards and regulations and new public policy in the area of the new product/innovation, and that will help in introducing the innovation into the market and/or enhance its societal uptake. Supporting ecosystem development This category includes activities that aim to further develop and intergate the R&I ecosystem in the partnership's area - for example, knowledge sharing with technology clusters, innovation hubs, networking structures and other R&I bodies. Communication, dissemination, awareness-raising, citizen engagement This category includes activities in the areas of communicati

Other These nine categories are fixed and cannot be modified. If the activity does not match categories 1 to 8, select '9. Other'. Type of additional Once you have selected your category, select one type for the activity activity from the following list: Types under "Category 1. Support to additional R&I": Complementary research and innovation activities with a clear link to the IHI Strategic Research and Innovation Agenda, but not funded by IHI/another EU programme Low-TRL research activities, feeding into IHI project(s) • Support to public-private partnership cooperation • Other: Insert [a new type] Types under "Category 2. Scale-up of technologies": Pre-commercial trials and field tests • Validation of the technology in a lab or in the 'real' operational environment Scale-up and uptake of results from IHI projects into product / proof of concept • Bridging between projects with real-field implementation instruments or initiatives Other: Insert [a new type] Types under "Category 3. Demonstrators": • Carry out demonstrations of a prototype in an operational environment, with the view to local, regional and EU-wide deployment Other: Insert [a new type] Types under "Category 4. Creating new business opportunities": • Invest in start-ups, spin-offs on solutions developed within the projects Start incubators/accelerators Matchmaking between different start-ups, SMEs, participating companies, stakeholders • Investments in procurement of innovative solutions Other: Insert [a new type] Types under "Category 5. Training and skills development": Training programmes Contributing to the identification of gaps and needs in skills development and training Other: Insert [a new type] Types under "Category 6. Contribution to the development of new standards, regulations and policies": Contributions to groups that develop new standards/standardisation efforts Contributions to groups that develop input to public policy-making in the area of the new products/innovation (e.g. governmental ministries) Other: Insert [a new type] Types under "Category 7. Supporting ecosystem development":

	 Industrial partner engages with a regional technology cluster / innovation hub (supports capacitybuilding and knowledge sharing) Industry partners provide mentoring/coaching to SMEs Investments in synergies with other European partnerships and with other initiatives at international, EU, national, and regional level (including missions) Activities to develop the ecosystem at EU/national/regional or international level that will enable or accelerate the development of the solutions from the concerned project(s)/IHI Programmep Activities to support open science, open innovation and data sharing Other: Insert [a new type] Types under "Category 8. Communication, dissemination, awareness-raising, citizen engagement": Investment in societal uptake and citizen engagement Contribution (generation/collaboration) to publications Organisation of conferences and webinars on specific topics, networking events Knowledge building in the specific area and/or among stakeholder communities Activities to ensure a stronger engagement at local level with regions, cities, citizens and other local stakeholders Other: Insert [a new type] Types under "Category 9. Other": Insert [a new type] If there is no type appropriate for the concerned activity in the suggested list, a new activity type can be specified.
Publishable description of the additional activity	 Insert free text to provide more information on the additional activity. The description should be brief and to the point (long, detailed descriptions should be avoided).
Confidential description of the additional activity	 Insert free text] to provide more information on the additional activity only if the information is not yet provided in the publishable description and only if this information should be kept confidential (i.e. should not be made public).
Estimated period for the additional activity	 Select one indicative timeline for the activity from the following list: Before project start date Before and during project implementation During project implementation During and after project implementation After project end date and up to 2 years after Before project start date and up to 2 years after project end Note that activities contributing towards the achievement of the objectives of the IHI project must be provided within a timeframe that allows these objectives to be reached before project closure. After project closure, only activities targeting the dissemination, sustainability or exploitation of the IHI project results may be accepted.
Link to IHI project	 Insert free text to explain how the additional activity contributes towards the achievement of: The objectives of the IHI project; or

	 the dissemination, sustainability or exploitation of the expected project results.
Estimated TOTAL value of the additional activity	 Insert the total amount in EUR for the activity linked to the specific project. If an activity is linked to several IHI projects, only the estimated value corresponding to the part allocated to the full proposal for the project under discussion should be specified.

The IKAA plan consists of an excel table and includes both confidential information and publishable information. More specifically, the content of the IKAA plan included in the annex will be made public (i.e. published in the IHI Annual Work Programme and the Consolidated Annual Activity Report), except for the following information which will only be disclosed to the full proposal evaluators, the IHI Governing Board and the IHI Programme Office:

- the company name;
- the confidential version of the additional activity description, if applicable;
- the estimated period for the additional activity to take place (the IHI GB may share this information with the advisory bodies (i.e. the SRG and the SIP)⁵ if they need it to provide an opinion on the additional activity).

The IKAA plan will be reviewed by the panel of independent experts when the full proposal is evaluated. The information provided in the IKAA plan should be concise and allow the assessment of the additional activities, and in particular their relevance for the achievement of

- the objectives of the IHI project;
- the dissemination, sustainability or exploitation of the expected project results.

The next section provides concrete examples on how to include additional activities in the IKAA plan and the level of detail that is expected.

⁵ The States Representatives Group of IHI JU ('SRG') and the Science and Innovation Panel of IHI JU ('SIP') are the IHI JU Governing Board's advisory bodies.



4 A practical example of an IKAA plan

The purpose of this section is to illustrate with a practical example how additional activities planned for an IHI project could be reflected in the IKAA plan annexed to a full proposal. The content of this example is just illustrative and represents only one possible scenario.

In the example below we consider the IHI project objectives and IKOP for the project to be as follows:

- **Project A objectives:** to integrate diagnostic and predictive approaches to support multi-modality cancer care (also based on advanced analytics and artificial intelligence).
- **IKOP to Project A:** during the project lifetime, Companies A, B, C, D and E incur eligible costs to implement project tasks such as developing integrated solutions/approaches collaboratively in the consortium and get feedback from end users to further improve multi-modal cancer care.

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Based on the above, the IKAA for the concerned proposal could be costs related to the following additional activities (AA):

IHI project:		xxxxx - Project	A					
Partici pant numb er in projec t	Company name	Category of additional activities	Type of additional activities	Publishable description of the additional activities	Confidential Description of the additional activities (if applicable)	Estimated period for the additional activities	Link to the IHI project	Estimated TOTAL value in EUR
2	Company A	1. Support to additional R&I	Low-TRL research activities, feeding into IHI projects	Internal development activities of an image-guided radiation therapy device (which is not a project task)		Before project start date	The device will be used for the consortium activities and as a result will contribute to achieving Project A's objectives.	10 000
2	Company A	8. Communicatio n, dissemination, awareness-	Organisation of conferences and webinars on specific topics, networking events	Organise a symposium to disseminate the results of Project A. Company A and its affiliated entities X and Y will work on this symposium		5. After project end date and up to 2 years after	The symposium will disseminate Project A results among relevant stakeholders.	15 000

		raising, citizen engagement		together for an estimated total value of EUR 15 000.			
3	Company B	1. Support to additional R&I	Complementary research and innovation activities with a clear link to the IHI Strategic Research and Innovation Agenda, but not funded by IHI/another EU programme	Activities for developing a methodology for an integrated approach to diagnosing breast cancer (which is not in the scope of Project A), which may be extended to other cancers which are in the scope of Project A.	3. During project implementation	The methodology will be provided to the consortium as a sounding board/extra element for helping the development of integrated solutions to be developed by Project A.	7 000
3	Company B	5. Training and skills development	Training programmes	Develop training programmes for patients and their doctors on the added value of using the integrated approach developed by Project A for healthcare outcomes in cancer patients.	5. After project end date and up to 2 years after	These training programmes will contribute to the dissemination of Project A's results.	5 000
4	Company C	1. Support to additional R&I	Complementary research and innovation activities with a clear link to the IHI Strategic Research and Innovation Agenda, but not funded by IHI/another EU programme	Activities for generating data from proprietary clinical trials using various (different/complementary/add itional to those of the project) cancer treatments modalities which are used as independent datasets.	2. Before and during project implementation	These data will further contribute to verifying the usability of the integrated approach developed by Project A and help its finetuning (the project activities will not depend on these specific datasets).	11 000
4	Company C	2. Scale-up of technologies	Scale-up and uptake of results from IHI projects into product / proof of concept	Development of a decision- making software tool that enables easier communication in the cancer care continuum and between stakeholders.	5. After project end date and up to 2 years after	This tool will contribute to the deployment/exploita tion of Project A's outputs.	12 000

5	Company D	1. Support to additional R&I	Support to public- private partnership cooperation	Contract a legal expert to solve legal and intellectual property (IP) issues.		Before project start date	Solving potential legal and IP issues before the project starts could avoid difficulties with data sharing and ensure the efficient/timely kick-off of project A.	8 000
6	Company E	1. Support to additional R&I	Complementary research and innovation activities with a clear link to the IHI Strategic Research and Innovation Agenda, but not funded by IHI/another EU programme	Activities for adapting a sensor that has already been commercialised to make it available for the consortium.		Before project start date	Adaptation of the sensors is not a project task, but will contribute to ensuring the timely start of project A.	8 000
Total envisaged in-kind contributions to additional activities for the full proposal: 7							76 000	