

Information Guide for IHI JU Contributing Partners

Document version: 2.1

Last update: 16 December 2024

TABLE OF CONTENTS

Dis	claim	er	3
His	story o	of changes	4
Ма	in def	initions	5
Int	roduc	tion	8
1.	Intro	oducing contributing partners	10
	1.1	Why become a contributing partner?	10
	1.2	Who can and cannot apply?	10
	1.3	Private members versus contributing partners	11
	1.4	Contributions from contributing partners	13
2.	App	lying to become a contributing partner in single-stage calls	16
	2.1	How to prepare your application and avoid common mistakes	16
	2.2	How to submit your application	18
		2.2.1 Signing of the application letter	18
		2.2.2 Sending of the application letter	18
	2.3 prop	Calculation of in-kind contributions towards a proposal's eligibility – contributing partners applying as posal in single-stage calls	•
3.	App	lying to become a contributing partner in two-stage calls	21
	3.1	Timeline for applications	21
	3.2	Preliminary assessment of the application by the IHI JU Programme Office	21
4.	Asse	essment of contributing partner applications by the IHI JU Governing Board	23
	4.1	Process and timeline	23
	4.2	Criteria for assessing contributing partners' applications	23
5.	Cont	tributing partner's role in the grant agreement	25
	5.1	Participation of contributing partners in IHI JU projects as beneficiaries	25
	5.2	Participation of contributing partners in IHI JU projects as affiliated entities	26
	5.3	Participation of contributing partners in IHI JU projects as associated partners case B	26
	5.4	Reporting contributions from contributing partners	28
An	nex 1	Legal basis	30
۸n	nov 2	Poforoneo documente	22

Disclaimer

This guide is designed to assist legal entities interested in becoming an **IHI JU contributing partner** in preparing and submitting their applications. It is based on the rules and conditions set out in the legal framework of IHI JU, the IHI JU Work Programme and the Horizon Europe Model Grant Agreement, which are accessible through the Funding & Tenders Portal and the IHI JU website.

This guide does not supersede those documents, which are legally binding.

This guide may be subject to modifications during the implementation of the IHI JU programme.

History of changes

Version	Date	Change	Section
1.1 – 1.3	14 December 2022 – 13 June 2024	Summary of changes: - Reorganisation of the sections and language clarifications; - Updates on Associated Partners; IKOP and IKAA; - Moving of the template letter to the website, reorganisation of the annexes; - Further clarification on affiliation to private members and application process.	
2.1	16 December 2024	Summary of changes: Reorganisation of sections; Clarifications in the definitions section; Clarification on who may and who may not apply; Clarifications on private members; Clarifications on associated partners; Added: instruction on preparing, signing and submission of applications in single-stage calls; Added: criteria for assessment of CP applications.	New version

Main definitions

Affiliated entities: as defined in Article 8 of the model grant agreement, these are entities with a legal or capital link with the beneficiary, which is neither limited to the action nor established for the sole purpose of the action implementation. Contributing partners may take the role of affiliated entities in a project, please see chapter 5 of this Guide for details.

Affiliated entities of private members: in the context of the IHI JU, affiliated entities of private members are legal entities affiliated directly or via a regional or national organisation to an IHI JU private member, that is COCIR, EFPIA (including Vaccines Europe), EuropaBio and MedTech Europe. Affiliated entities of private members <u>cannot apply</u> to become contributing partners but join a project directly without a need for the contributing partner application process.

Associated countries: third countries associated to Horizon Europe, listed here, the relevant updates.

Associated partners: as defined in Article 9.1 of the model grant agreement, these are entities that do not sign the grant agreement but are identified in it. They implement action tasks, and their tasks and contributions are identified in the project's description of action (DOA). Associated partners do not receive EU funding and participate at their own cost. Contributing partners may take the role of <u>associated partners case B</u> in a project, please see chapter 5 of this Guide for details.

Applicant: legal entity applying for a call for proposals.

Beneficiary: as defined in Article 7 of the model grant agreement, a legal person, other than the IHI JU, which is a signatory of the grant agreement (either directly or through an accession form). Contributing partners may take a role of a beneficiary in a project, please see chapter 5 of this Guide for details.

Call for proposals: a procedure to invite applicants to submit project proposals with the objective of receiving funds from the European Union.

Call publication: the act of publishing calls for project proposals on the Funding and Tenders Portal.

COCIR: the European Coordination Committee of the Radiological, Electromedical and healthcare IT Industry; a European trade association representing the medical imaging, radiotherapy, health ICT and electromedical industries. See https://www.cocir.org/

Consortium agreement: an internal agreement between members of a consortium establishing their rights and obligations with respect to the implementation of an action in compliance with the grant agreement. For IHI JU projects, the consortium agreement should be finalised before the grant agreement signature.

Constituent entities of private members: entities that constitute a private member, where that member is an association according to that member's statutes. In the context of the IHI JU, constituent entities of private members are the members of the associations COCIR, EFPIA, EuropaBio, MedTech Europe, and Vaccines Europe. Constituent entities of private members <u>cannot apply</u> to become contributing partners but join a project directly without a need for the application process.

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 IHI JU Governing Board.

Council Regulation (EU) 2021/2085¹ or **Single Basic Act** or **SBA**: the act establishing the Joint Undertakings (including IHI JU) under the Horizon Europe programme.

EFPIA: the European Federation of Pharmaceutical Industries and Associations. See https://www.efpia.eu/

EuropaBio: the European association representing corporate and associate members across sectors, plus national and regional biotechnology associations which, in turn, represent over 2600 biotech companies, 2300 out of them are SMEs. See https://www.europabio.org/

Eligibility criteria: criteria used to determine whether a proposal meets the requirements to become eligible for a European Union grant.

Grant agreement: a contract concluded between the IHI JU and the beneficiaries under which the parties receive rights and obligations (e.g. the right to the Union's financial contribution and the obligation to carry out the research and development work). It consists of the basic text and annexes.

Horizon Europe: the EU's key funding programme for research and innovation. See https://ec.europa.eu/info/funding-tenders/find-funding/eu-funding-programmes/horizon-europe_en

In-kind contributions to operational activities or **IKOP**: contributions by the constituent or affiliated entities of private members and/or by contributing partners (if any), consisting of the eligible costs incurred by them for implementing the action, minus the contribution of the IHI JU to those costs (if any).

In-kind contributions to additional activities or **IKAA**: contributions incurred by the constituent or affiliated entities of private members consisting of costs for implementing additional activities. Contributing partners <u>cannot</u> bring this type of contribution.

Legal entity: any natural person, or any legal person created and recognised as such under national law, European Union law or international law, which has legal personality, and which may, acting in its own name, exercise rights and be subject to obligations.

Legal representative: a natural person who has been empowered (directly or indirectly) by a legal entity to enter into legal commitments on its behalf, in accordance with binding law.

MedTech Europe: the European trade association for the medical technology industry including diagnostics, medical devices and digital health. See https://www.medtecheurope.org/

Members of IHI JU:

- 1. the European Union (EU), represented by the European Commission; and
- 2. Members other than the Union:
 - the European life science industry, represented by COCIR, EFPIA (including its subgroup Vaccines Europe), EuropaBio and MedTech Europe (also referred to as '**Private members**'); and
 - associated members if selected in accordance with Article 7 of SBA2.

Member State: a state that is a member of the European Union, please compare the current member states list.

Model grant agreement (MGA): the compulsory form of a grant agreement. It consists of a core text (determining the basics of a project) and several annexes.

¹ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32021R2085

² As of December 2024, IHI JU does not have any associated members.

Participants: entities participating in the action as beneficiaries, affiliated entities, associated partners, third parties giving in-kind contributions, subcontractors, or recipients of financial support to third parties.

Private members: COCIR, EFPIA (including its subgroup Vaccines Europe), EuropaBio and MedTech Europe. Private members and their constituent and affiliated entities <u>cannot</u> apply to become contributing partners but join a project directly without a need for the contributing partner application process.

Submission: the formal act of submitting a proposal to IHI JU.

Single-stage calls: a scheme in which there is a single proposal submission and evaluation phase and there is no pre-identified industry consortium. The applicant consortium composition may include any legal entities, including the constituent or affiliated entities of private members, and/or contributing partners (if any) and their constituent and affiliated entities who will ensure the 45% eligibility criterion is fulfilled.

Strategic Research and Innovation Agenda: a document approved by the IHI JU Governing Board which focuses on the specific objectives of IHI JU, available on IHI JU webpage.

Topic: IHI JU calls for proposals (as defined in the annual work programme) are subdivided into topics. A topic defines a specific research and innovation subject or area for which applicants are invited to submit proposals. The description of a topic comprises the specific scope and expected impact of the projects to be funded, and also the type of project, evaluation criteria and deadline for submission of proposals.

Two-stage calls: a scheme in which applicants must submit a short proposal (SP) for the stage 1 evaluation. At the end of the stage 1 evaluation, under each topic, only the applicant consortium of the first ranked SP will be invited to prepare and submit a full proposal (FP) for the stage 2 evaluation together with the pre-identified industry consortium for the topic.

Work Programme: the corporate document adopted annually by IHI JU for the implementation of the IHI JU specific programme in accordance with Articles 23 and 25 of the SBA, and detailing call topics and associated modalities. The latest version of the Work Programme is available on the IHI JU webpage.

Introduction

The Innovative Health Initiative Joint Undertaking (IHI JU) is a public-private partnership (PPP³) between the European Union and the European life science industries.

IHI JU derives its legal basis, and much of its structure and modalities from the EU's Horizon Europe Research and Innovation funding programme⁴ which runs until 2027.

IHI JU was formally established on 30 November 2021 by the Single Basic Act - Council Regulation (EU) 2021/2085⁵ of 19 November 2021 establishing the Joint Undertakings under Horizon Europe wherein the IHI JU's form, objectives, and modalities are defined.

IHI JU works by bringing together diverse stakeholders public and private (universities, companies large and small, patient organisations and other health stakeholders) in collaborative projects that address disease areas where there is a high burden on patients and/or society. IHI JU's ambition is to support the delivery of timely and well-substantiated prevention, diagnosis, and treatment. IHI JU focuses on cross-sectoral projects involving the biopharmaceutical, biotechnology, and medical technology sectors, including companies active in the digital area to respond to unmet public health needs. For more information on the general and specific objectives of IHI JU, please consult the Strategic Research and Innovation Agenda.

The members of IHI JU are: (1) the European Union, represented by the European Commission, and (2) the private members: the European life science industry, represented by the industry associations COCIR⁶, EFPIA (including Vaccines Europe)⁷, EuropaBio⁸ and MedTech Europe⁹. Therefore, it is expected that all IHI projects are public-private partnerships including industry contributors (private members).

The 'contributing partner' category was created with the goal of opening up IHI JU to a wide range of stakeholders who may want to be involved in IHI JU and contribute strategically to the achievement of the IHI objectives without becoming IHI JU's members¹⁰.

IHI JU contributing partners invest their own resources (which can be researchers' time, laboratories, data) or cash in a specific IHI JU project or projects. Their contributions work in a similar way to contributions by the constituent or affiliated entities of the private members.

This Guide provides comprehensive and practical information on:

³ According to Article 187 Treaty on the Functioning of the European Union, the Union may set up joint undertakings or any other structure necessary for the efficient execution of Union research, technological development, and demonstration programmes.

⁴ Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe, https://eur-lex.europa.eu/eli/reg/2021/695/oj

⁵ 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, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32021R2085

⁶ COCIR is the European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries. See https://www.cocir.org/

⁷ EFPIA is the European Federation of Pharmaceutical Industries and Associations. See https://www.efpia.eu/

⁸ EuropaBio is the European association representing corporate and associate members across sectors, plus national and regional biotechnology associations which, in turn, represent over 2600 biotech companies, 2300 out of them are SMEs. See https://www.europabio.org/

⁹ MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. See https://www.medtecheurope.org/

¹⁰ The IHI JU contributing partner category builds on the associated partner status created under the Innovative Medicines Initiative 2 (IMI2) programme, the forerunner to IHI JU. By the end of the IMI2 programme, there were over 30 IMI2 associated partners from around the world including philanthropic organisations, patient groups, and companies. They are contributing to IMI2 projects in diverse fields such as diabetes, infectious diseases (including tuberculosis and Ebola), digital health, autism, cancer, neurodegenerative diseases and more.

- legal framework applicable to contributing partners: entities authorised to apply, rules on contributions, engagement, contractual obligations, and the role of contributing partners in the grant agreement;
- how to join IHI as a contributing partner in single-stage and two-stage calls: legal framework, details of the application process including template application letters, the procedure for submission of application letters;
- assessment of the applications by the IHI JU Programme Office and IHI JU Governing Board, including the assessment criteria.

This Guide should be read in parallel with IHI JU Guide for Applicants which gives a comprehensive overview of the rules applicable to the IHI JU calls¹¹.

For any questions, after having consulted this Guide, and if you are interested in becoming an IHI JU contributing partner, contact the IHI JU Programme Office via the dedicated contributing partners email address: contributingpartners@ihi.europa.eu.

¹¹ Please visit: https://www.ihi.europa.eu/sites/default/files/IHI_Guide_for_Applicants.pdf

1. Introducing contributing partners

1.1 Why become a contributing partner?

There are several benefits of becoming an IHI JU contributing partner:

- Leverage funding: in many cases, contributions from contributing partners can be matched by EU contributions to the project. In total, IHI JU can match up to EUR 200 million from all contributing partners during the entire lifetime of the IHI JU programme. Becoming an IHI JU contributing partner is an excellent way to make your resources stretch further while sharing risks.
- **Influence research**: as a contributing partner, you will be able to design a topic or influence the preparation of a proposal from the earliest stages and be part of the decision-making process of a project.
- Networking: as a contributing partner, you will be part of the wider collaborative health innovation ecosystem of IHI JU. You will engage in a neutral, pre-competitive space alongside experts from industry, universities, patient groups, regulators and others, giving you unprecedented opportunities for cross-learning. The relationships forged within an IHI project turn into long-lasting collaborations that can be beneficial to all involved in the longer term. In fact, participants in IHI projects often cite the networking aspect as one of the biggest benefits of working in a public-private partnership.
- Benefits of scale: IHI JU is launching ambitious, large-scale, cross-sector projects addressing major challenges in health research. Working at scale in this way increases the likelihood of the projects having a real impact on society, the economy and science.
- Mutual learning / sharing expertise: participants in IHI projects may gain access to other resources and
 infrastructures such as large biobanks, laboratories, clinical centres and databases. More broadly, because
 the partners in projects are so diverse, there is a huge opportunity to learn from your fellow project
 participants whose expertise and ways of working may be very different to your own.
- **Visibility**: IHI projects regularly publish research in prominent journals and present their results at international conferences. This allows all participants in a project to build their reputation and visibility on an international level.

1.2 Who can and cannot apply?

Any country, international organisation or legal entity may apply to become a contributing partner provided that:

- they contribute to the strategic and specific objectives of IHI JU in its specific area of research;
- they accept the legal framework of IHI JU by submitting a letter of application, that details the scope of their engagement in terms of contribution (in-kind and/or cash), activities and duration;
- they submit an application letter to the IHI JU Programme Office in accordance with the applicable procedure (i.e. depending on the call type);
- they are not a constituent or affiliate entity of the IHI private members i.e. COCIR, EFPIA including Vaccines Europe, EuropaBio, and MedTech Europe (see below).

Therefore, both public and private organisations of various types may consider becoming an IHI JU contributing partner. Examples of contributing partners may include philanthropic organisations and charities that run their own research programmes, as well as legal entities and private companies working in sectors related to IHI JU such as ICT, MedTech, imaging, diagnostics, animal health, etc.

Importantly, as the contributing partner's involvement must strategically support IHI JU in its specific area of research, each potential applicant should duly consider the public-private component of the partnership, the strategic and specific objectives of IHI JU and the nature of its contributions to a call or project. **Participating in IHI JU activities should reflect a strategic engagement from the potential contributing partner**.

On a more specific level a contributing partner must also consider the obligations resulting from participation in a consortium implementing an IHI JU project.

Before applying to become a contributing partner to IHI JU – please check that your legal entity is not affiliated directly or via a national, regional or local organisation to an IHI JU private member, that is COCIR, EFPIA (including Vaccines Europe), EuropaBio and MedTech Europe.

IHI JU private members, their constituent and affiliated entities <u>cannot apply to become</u> IHI JU contributing partners but join a project directly without a need for the contributing partner application process.

The <u>websites of IHI JU private members</u> include the lists of their corporate members, national associations and other entities which are their constituent and affiliated entities.

Any candidate contributing partner must submit an application letter to the IHI JU Programme Office which later will be transmitted to the IHI JU Governing Board. A letter of application should confirm the organisation's willingness to observe the IHI JU legal framework and detail the scope of application in terms of:

- the IHI JU call and topic the applicant contributing partner would like to join;
- in case of single-stage calls the name of the proposal that the applicant contributing partner would like to join;
- how the applicant contributing partner wishes to contribute to IHI JU;
- what relevance and potential added value does the proposed contribution present for the achievement of the objectives of IHI JU;
- the projected duration of the contribution to IHI JU;
- the amount of the contribution (in-kind and/or cash) in EUR:
- how much of the overall contribution will be considered as non-EU (according to the best projections of the applicant);
- manner and specifics of proposed contribution to the call and topic, for example: project areas, work packages, deliverables, and description of in-kind and/or in cash total equivalent amount;
- a confirmation that the candidate contributing partner is not affiliated to an IHI JU member, that is COCIR, EFPIA (including Vaccines Europe), EuropaBio and MedTech Europe and neither is their constituent nor affiliated entity, directly or via a national or regional association; and
- in case of two-stage calls acceptance of the confidentiality obligation.

The most updated template application letters in single-stage and two-stage calls may be found on <u>IHI JU</u> contributing partners website.

1.3 Private members versus contributing partners

Table 1 below presents the main differences between the private members and contributing partners and their participation in IHI JU and IHI projects.

Table 1

	Private members	Contributing partners
Who are they?	COCIR, EFPIA (including its subgroup Vaccines Europe), EuropaBio and MedTech Europe (and their constituent and /or affiliated entities)	Any country, international organisation or legal entity other than a member or a constituent entity of a member or an affiliated entity of either, which became an IHI JU contributing partner
What do they participate in?	IHI JU strategic vision, governance as well as administrative and operational activities	IHI JU operational activities they commit to support (via the involvement in specific calls and projects in specific areas of research)
How do they join IHI JU?	Established in the SBA	Approved by the IHI JU Governing Board following assessment of their application letter
How do they contribute to IHI JU?	IKOP, IKAA, FC	IKOP and/or FC only (but not IKAA)
Eligible to Receive IHI JU Funding	Subject to eligibility of the participating legal entity and particular call conditions	Subject to eligibility of the participating legal entity and particular call conditions.
Legal basis - SBA	Articles 11; 117	Articles 2; 9; 11; 28 ¹²

¹² For overview of the legal basis please see **Annex 1** to this Guide.

1.4 Contributions from contributing partners¹³

Contributing partners (and their affiliated entities if any) contribute to IHI objectives/topics/projects through financial and/or in-kind contributions to operational activities (FC / IKOP – see below) and generally do not request/receive any funding from IHI JU¹⁴.

The contributions from contributing partners must correspond to the amounts they have committed in the application letter when becoming a contributing partner.

The contributions of a contributing partner may take the following forms:

1. In-kind contributions to operational activities (IKOP): eligible costs incurred in implementing the action.

In-kind contributions are contributions by the contributing partners and their affiliated entity(ies) if any, consisting of the costs incurred by them (and as such recorded in their accounting system) in implementing the project activities. The costs must be also compatible with the general and specific eligibility conditions set of in Article 6 of the Horizon Europe model grant agreement¹⁵. In the case of contributing partners in single-stage calls who also request funding, the requested IHI JU funding will be deducted from the value of their contribution¹⁶.

Costs for project activities incurred in the EU or in one of the countries associated to Horizon Europe will be considered 'EU IKOP' while costs for project activities incurred outside the EU or outside countries associated to Horizon Europe will be considered 'non-EU IKOP'¹⁷. Non-EU IKOP cannot exceed 20% of the overall IKOP at programme level.

IKOP can take the form of different eligible cost types, e.g.:

- personnel costs the time of staff employed/contracted by a contributing partner directly working on IHI JU
 projects. This is important because IHI JU's success is based on the way it brings together the expertise of
 people working in the relevant partner organisations with the expertise found in other organisations, like
 universities, SMEs, and patient groups;
- purchase costs consumables, equipment depreciation, travel, samples, compounds;
- subcontracting costs e.g. for clinical trials, subcontracting to clinical research organisations, subcontracting to data management companies, lab services, communication, project management support, etc.;
- indirect cost which is calculated automatically as 25% of the direct costs (excluding subcontracting costs and internally invoices goods and services).

2. Financial Contribution (FC):

Financial transfer (cash contributions) to project beneficiary(ies) supporting their eligible costs incurred in implementing the IHI JU project.

Important note: contributing partners may not contribute in-kind contributions to additional activities (IKAA).

¹³ Article 11 of Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe.

¹⁴ Contributing partners can potentially receive funding in IHI JU single-stage calls and depending on additional factors in two-stage calls. Please refer to sections 2.3 on eligibility for funding in the IHI JU Guide for Applicants.

¹⁵ Please consult Model Horizon Europe Grant Agreement (https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/agr-contr/unit-mga_he_en.pdf

¹⁶ In single-stage calls, contributing partners may in addition to contributing, also request funding, if eligible for funding. Their net contribution will be counted as their final contribution. For details on how to calculate the net contribution please see the template application letter for applications in single-stage calls: https://www.ihi.europa.eu/shape-our-future-research/become-contributing-partner.

¹⁷ For further information on the definition of 'non-EU' please see the Guide for Applicants.

Eligibility of contributions (IKOP and FC)

When establishing the value of in-kind contributions to the IHI JU projects, contributing partners must comply with:

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

If financial contributions are paid to project beneficiary(ies), there should be a bilateral agreement between the concerned parties specifying the amount and the project activities to be carried out using the financial contributions.

As mentioned above, resources contributed to a project (IKOP and FC) may be matched by IHI JU funds, making this a good way of leveraging precious resources.

Important note: It is essential that the costs incurred by contributing partners in implementing IHI JU projects <u>fulfil</u> the <u>general</u> and <u>specific</u> eligibility <u>conditions</u> as specified in the Articles 6.1 and 6.2 of the Horizon Europe model grant agreement <u>to be valorised and accepted as their in-kind contribution to operational activities (IKOP).</u>

The general eligibility conditions clearly specify, among others,

- that cost should be actual, i.e. should not include any profit margin;
- that cost should be recorded in the accounting system of the concerned contributing partner;
- that cost should be identifiable and verifiable (e.g. the auditor needs to be able to reconcile figures that are reported to IHI JU and costs that are recorded in the accounts of the contributing partner);
- that cost must be incurred during project implementation (i.e.; between the start date and the end date of the project).

In some cases, unit costs¹⁸ can be used (e.g., average personnel costs, unit personnel costs for SME owners, internally invoiced goods and services). Specific eligibility conditions per cost type are specified in Article 6.2 of the Horizon Europe model grant agreement.

The Single Basic Act does not allow IHI JU to deviate from the eligibility conditions above for IKOP.

Examples of non-eligible costs (i.e. not IKOP)19:

- Data: data that are pre-existing the start of the project and for which the entity does not incur costs anymore during the project implementation are not eligible. Only actual costs and which are incurred during the project implementation for those data (e.g., harmonisation costs, transfer costs) can be valorised as IKOP.
- **Software licence fees**: software developed by the entity before the start of the project and for which the entity does not incur costs anymore during the project implementation are not eligible. Valorising the use of

¹⁸ For more information on unit costs please see page 23, Article 6.1 of the Horizon Europe Model Grant Agreement https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/agr-contr/general-mga_horizon-euratom_en.pdf

¹⁹ In case of specific questions on the eligibility of some contributions please contact the IHI JU office directly via email.

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.					

2. Applying to become a contributing partner in single-stage calls

2.1 How to prepare your application and avoid common mistakes

Applicant contributing partners are obliged to follow in detail **the latest version of the template of the application letter** for single-stage calls posted on <u>IHI JU contributing partners web page</u> when drafting their contributing partner application. Use of the template is mandatory. A failure to provide the information requested in the template may result in the contributing partner application being rejected.

The website also contains a **checklist for preparing an application letter** in a single-stage calls; this is designed to help the applicants write their application.

When filling in this template, we strongly advise applicants to read the guidance for contributing partners on the IHI JU website and make sure that the application letter complies with the application checklist.

A draft letter of application may be submitted via email to the IHI JU Programme Office, at contributingpartners@ihi.europa.eu preferably in MS Word format, for a preliminary review. This review is not compulsory and only conducted by the IHI JU Programme Office if the letter is received well in advance of the call deadline (in case of contributing partners applying as part of a proposal).

Important note: Applicant contributing partners who wish to have their draft application letter reviewed are advised to make sure that the draft letter is submitted to the IHI JU Programme Office sufficiently ahead of the deadline for submission of proposals. Submitting the draft application last minute will prevent the IHI JU Programme Office from conducting its preliminary review and may result in an invalid application.

Upon receipt of the draft letter of application, the IHI JU Programme Office will conduct a preliminary review and provide the applicant with feedback. This review is limited only as to the completeness of the application, its format and editing.

The IHI JU Programme Office will assess the letter to ensure that the draft application details all the necessary elements included in the application template, in particular:

- using the most recent template;
- a clear description of the applying entity;
- a clear indication of the call and topic applied for;
- the scope of the application in terms of amount of contribution (in-kind or cash) in EUR and a detailed description of the contribution which allows assessing its eligibility, in particular by providing a breakdown of the costs in accordance with the template;
- activities;
- duration; and
- a confirmation that the candidate contributing partner is not affiliated to a private member, that is COCIR, EFPIA (including Vaccines Europe), EuropaBio and MedTech Europe, neither directly or via a regional or national organisation, and neither is their constituent nor affiliated entity.

The IHI JU Programme Office will ask the applicant contributing partner to revise the draft letter in case it significantly departs from the template or is missing the compulsory elements mentioned above.

The preliminary assessment by the IHI JU Programme Office does not consider the merits of the application. The final decision as to acceptance or rejection of a new contributing partner rests with the IHI JU Governing Board.

Avoid these common mistakes when preparing your application letter:

- Proposed contributions not eligible for recognition by IHI JU.

Not all contributions are eligible. Please read in detail point 1.4 of this Guide.

- Your organisation is in fact affiliated to an IHI JU private member.

Every entity considering applying to become a contributing partner must check thoroughly that they are not affiliated to a private member, that is COCIR, EFPIA (including Vaccines Europe), EuropaBio and MedTech Europe. IHI JU private members, their constituent and affiliated entities may not apply to become IHI JU contributing partners. The websites of our private members include the lists of their corporate members, national associations and other entities which are the constituent and affiliated entities of the private members. Please check these lists carefully before moving on to the next steps with your application.

→ <u>Example</u>: an Irish pharmaceutical company interested in becoming a contributing partner is a part of an Irish national association for MedTech industry companies. That Irish association is then in turn a member of MedTech Europe. This might make the Irish company an affiliated entity of MedTech Europe, a private member of IHI JU. Therefore, the Irish company may not apply to become a contributing partner but is welcome to join a project as a private member and may contribute IKOP (without the need for the contributing partner application process).

Important note: If an applicant contributing partner is unsure whether they are an affiliate or not, they should contact the private members directly.

Other common mistakes:

- Mismatch between the contributing partner's application letter and the information on the contributing partner's role as provided in the proposal;
- Information on the value of any non-EU contribution missing. If the figure is zero, please state this clearly;
- Letter template not followed and key information missing:
- Letter not signed by someone who is legally authorised to sign on behalf of the organisation (please read point 2.2.1 of this Guide);
- Letter signed by an electronic signature which is not a qualified electronic signature (please read point 2.2.1 of this Guide);
- Letter signed using a scanned (and not handwritten) signature and therefore not signed and invalid (please read point 2.2.1 of this Guide).

2.2 How to submit your application

2.2.1 Signing of the application letter

An application to become a contributing partner must be signed by a representative of the applying organisation who is properly authorised to commit that organisation to legally binding contracts and accompanying financial obligations in accordance with the applicable law. In many cases this will be a general director or a chief executive officer, but the representation might vary from one organisation to another. It is the responsibility of the applicant contributing partner to make sure that the person signing the application letter is authorised to do so.

There are two ways for the legal representative to sign the application letter:

- print the final letter, sign it manually on paper with a handwritten signature, and scan it. The applicant must keep the original as the IHI JU Programme Office might ask to send it by post at a later stage;
- alternatively, the legal representative may use a qualified electronic signature (QES). IHI JU accepts
 only qualified electronic signatures which are in line with the European Union's elDAS Regulation.
 Please see a list of qualified trust service providers in accordance with the elDAS Regulation per EU
 member state on the elDAS website.

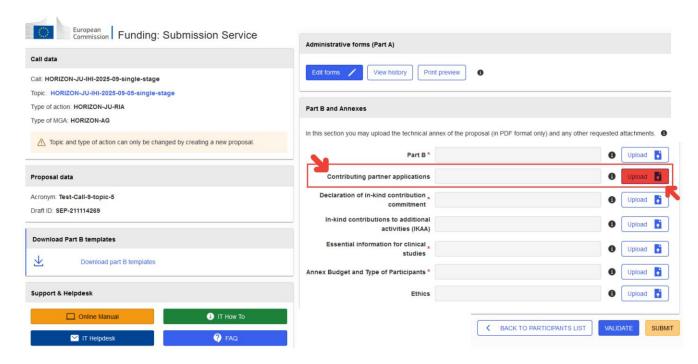
2.2.2 Sending of the application letter

Organisations applying to become contributing partners as part of a proposal being submitted in response to a single-stage call

As of IHI call 9, applications to become a contributing partner in single-stage calls become a part of the proposal that is submitted by the applicant consortia in response to an open call.

The applicant contributing partner must send the pdf of the final signed letter to the coordinator of their proposal. The coordinators are responsible for uploading the final application letters in the EU Funding and Tenders Portal along with the rest of the proposal documents, as a part of the wider proposal. If the proposal includes more than one contributing partner, the coordinator must prepare **one pdf document** containing all the contributing partners' application letters.

That pdf must be uploaded in the appropriate section of the submission environment of the Funding and Tender portal as illustrated below:



For more information on proposals submissions, please see the IHI website.

A failure to include the contributing partner application letters as a part of the proposal, will mean that the contributions of those contributing partners will not to be counted towards the 45% proposal eligibility threshold²⁰.

Organisations applying to become contributing partners at other points in the project lifecycle

If an applicant contributing partner applies to join an ongoing IHI JU project, they should <u>e-mail</u> their application letter to the **IHI JU Programme Office**, using the address given in the guide for contributing partners. The IHI JU Programme Office will instruct the applicant on the next steps.

2.3 Calculation of in-kind contributions towards a proposal's eligibility21 – contributing partners applying as part of a proposal in single-stage calls

In order for a proposal to be eligible, applicant consortia must ensure that at least 45% of the action's eligible costs and costs for additional activities related to the action are provided by contributions (IKOP, FC, IKAA) from the constituent or affiliated entities of private members and/or from contributing partners (if any).

In order for the in-kind contribution from a contributing partner to be counted towards the 45% threshold, <u>all of the following conditions need to be met</u> by the deadline for submission of proposals:

- an application letter has been submitted as a part of the proposal in accordance with the instruction in point 2.2.2 above and received by IHI JU Programme Office within the proposal submission deadline;
- the application letter bears a handwritten signature or a valid electronic signature of a legal representative of the applying legal entity in accordance with the instruction in point 2.2.1 above;

²⁰ Please see point 2.3 below.

²¹ For more details on eligibility of proposals please consult IHI JU Guide for Applicants https://www.ihi.europa.eu/sites/default/files/IHI
<u>JU Guide for Applicants.pdf</u>

- the application letter utilises the most recent template and states clearly enough what the amount and the scope of the contribution to the topic and IHI JU is;
- the contribution envisaged in the application letter is not in any way provisional or conditional in nature;
- the contribution envisaged in the application letter is eligible²² in accordance with Article 6 of the Horizon Europe Model Grant Agreement; and
- the application letter includes a confirmation that the candidate contributing partner is not affiliated to an IHI JU member, and neither is their constituent nor affiliated entity.

Important note: it is advisable that the in-kind contribution amounts in EUR (i.e. IKOP, FC, non-EU IKOP) provided by the candidate contributing partner(s) spelled out in the application letters are equivalent to the ones provided in the proposal's budget. Therefore, applicant contributing partners should always keep the proposal's coordinator informed about the financial figures and any change thereof. This will support the IHI JU office in the overall evaluation process.

It is also possible to apply to become a contributing partner after the submission of the proposal by the consortium. However, if the application to become a contributing partner is submitted after the deadline for the submission of a proposal, at the evaluation stage, its contribution will not be counted towards satisfying the 45% in-kind eligibility criterion for the proposal in question.

If the consortium proposal is selected for funding and an applicant contributing partner successfully applies after the evaluation but before grant agreement signature, their contribution can be counted towards the 45% check during grant agreement preparation.

²² For more details on eligibility of contributing partners' contributions, please consult point 1.4 of this Guide.

3. Applying to become a contributing partner in two-stage calls

3.1 Timeline for applications

The IHI JU two-stage call topics are built upon identified scientific challenges agreed by the IHI JU members.

The pre-identified industry consortium described in the topic text will participate in and contribute to the selected IHI JU project. This pre-identified industry consortium is composed of private members, their constituent and affiliated entities. The topic text may also specify contributing partner(s) that will participate in and contribute to the selected IHI JU project.

In case the contributing partner(s) are part of the pre-identified industry consortia they support a particular IHI JU topic and not a particular proposal.

The topic text therefore may include:

- the name of the contributing partner(s);
- indicative budget, including the indicative in-kind and/or financial contribution from IHI JU contributing partners.

Important Note: If the contributing partner intents to have their contribution matched by the IHI JU, the IHI JU Programme Office shall receive their final and signed application letter prior to the finalisation of the two-stage call text to be included in the relevant call. The IHI JU may decide to match such contribution.

If the contributing partner wants to join the pre-identified industry consortium after the call topic text has been adopted by the IHI JU Governing Board, it may send its application letter to IHI JU Programme Office. In such case:

- the fact of joining should be agreed with the pre-identified industry consortium; and
- IHI JU cannot at this point match the applying contributing partner's contribution anymore.

3.2 Preliminary assessment of the application by the IHI JU Programme Office

Applicant contributing partners are obliged to follow the latest version template of the application letter for two-stage calls posted on IHI JU contributing partners web page when drafting their contributing partners applications. A draft letter of application should be submitted via email to the IHI JU Programme Office, preferably in MS Word format at contributingpartners@ihi.europa.eu.

Upon receipt of the letter of application, the IHI JU Programme Office will conduct a preliminary review and provide the applicant with feedback before it is submitted to the IHI JU Governing Board. This review is limited only as to the completeness of the application, its format and editing.

The IHI JU Programme Office will assess the letter²³ to ensure that the draft application details all the necessary elements included in the application template, in particular:

²³ Following submission of the application letter the IHI JU Programme office will request the applicant contributing partner to send to the IHI JU Programme Office's official address the original signed copy of the application via post. In case of applications signed via a valid

- a clear description of the applying entity;
- a clear indication of the call and topic applied for;
- the scope of the application in terms of amount of contribution (in-kind and/or cash) in EUR; and a detailed description of the contribution which allows assessing its eligibility, in particular by providing a breakdown of the costs;
- activities;
- duration;
- an obligation of confidentiality applicable in particular to the areas of IHI JU call topic preparation and publication, proposal submission and evaluation, and consortium formation; and
- a confirmation that the candidate contributing partner is not affiliated to an IHI JU private member, that is COCIR, EFPIA (including Vaccines Europe), EuropaBio and MedTech Europe, neither directly or via a regional organisation, and neither is their constituent nor affiliated entity.

The IHI JU Programme Office will ask the applicant to revise the application letter in case it significantly derives from the template or is missing the compulsory elements mentioned above.

The preliminary assessment by the IHI JU Programme Office does not consider the merits of the application. The final decision as to acceptance or rejection of a new contributing partner rests with the IHI JU Governing Board.

4. Assessment of contributing partner applications by the IHI JU Governing Board

4.1 Process and timeline

In accordance with article 17. 2 (c) of the SBA, the IHI JU Governing Board assesses and accepts or rejects applications of prospective CPs in accordance with Article 9.

The timing of this assessment depends on the call type.

Single-stage calls

Applications to become a contributing partner as part of a proposal being submitted in response to a singlestage call are only reviewed if the proposal of the applicant contributing partner's consortium is selected for funding.

In such case the application to become a contributing partner will be transmitted to the IHI JU Governing Board who will, upon consideration, accept or reject the application. The assessment by the IHI JU Governing Board takes places during the Grant Agreement preparation phase. Before sending of the application to the IHI JU Governing Board, the IHI JU Programme Office will review the content of the application letter to ensure that the application details all the necessary elements included in the application template and is in line with the proposal selected for funding. In case of discrepancies, typing mistakes or missing elements that do not put into question the decision on the evaluation results, the IHI JU Programme Office will ask the applicant contributing partner to prepare a revised version of the application letter.

Contributing partner applications that are part of proposals not selected for funding will not be transmitted to the IHI JU Governing Board. This does not prevent any entities from applying to become a contributing partner again in the future calls, as a member of a different proposal.

In the case of organisations applying to become contributing partners at other points in the project lifecycle, wishing to join an ongoing project via an amendment to the grant agreement agreed by the consortium, their applications will be submitted to the IHI JU Governing Board once received. The amendment to the grant agreement acceding a new contributing partner cannot be finalised before the IHI JU Governing Board has taken its decision to accept or reject their application.

Two-stage calls

In two-stage calls, contributing partners should predominantly apply as members of the pre-identified industry consortia. The applications of contributing partners constituting members of the pre-identified industry consortium will be transmitted to the IHI JU Governing Board after the call topic text is adopted. The IHI JU Governing Board shall assess and accept or reject the applications before the grant agreement preparation phase is finalised²⁴.

4.2 Criteria for assessing contributing partners' applications

The IHI JU Governing Board adopted a two-criteria approach for the assessment of applications of all contributing partners wishing to strategically support the IHI JU's objectives in its specific area of research by joining specific IHI JU project(s).

²⁴ Article 17.2 (c) Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe

1. Is the applicant a potential 'partner'?

An applicant contributing partner must demonstrate its ability to contribute to the strategic and specific objectives²⁵ of IHI JU in its specific area of research.

The application will be assessed to ensure that the legal entity will not only be contributing to the immediate project or topic for which they have applied, but also to these wider strategic IHI JU objectives and activities.

Key amongst these strategic objectives is cross-sectoriality and the integrative nature of IHI JU as a public-private partnership. Therefore, the contributing partner applications will be scrutinised as to whether they contribute to the specific project's/topic's embodiment of these concepts.

In the wider context of a mature and effective public-private partnership, it is recognised that contributing partners will not, in themselves, provide the essential component of an IHI JU project, and thus the involvement of the IHI JU private members in projects is considered crucial.

2. Is the applicant actually 'contributing'?

It is axiomatic that, in order for an application to be accepted by the IHI JU Governing Board, the prospective contributing partner must 'contribute'. This contribution is however a subjective concept and must be assessed holistically. While it may be tempting to consider only the financial elements (reflected as 'incurred costs'), contributions may take several forms that can be valuable to IHI JU projects/programme.

The assessment of 'contributing' therefore, will examine:

- a) the type / the nature of the contribution and how this particular asset (resources) meets the objectives of the IHI JU topic and/or project;
- the net value (EUR) of the proposed contribution (in-kind and/or financial contributions) in terms of eligibility of the incurred costs per article 6.1 of the Horizon Europe grant agreement;
- c) in case of 'hybrid' contributing partners (contributing partners in single-stage calls eligible for funding and requesting funding), the net value (EUR) of the proposed contribution obtained by subtracting the amount of IHI JU funding requested by the applicant contributing partner in the topic/project for which they are applying to contribute to, with a special attention to cases when the amount of contribution equals the amount of requested funding:
- d) any other relevant contributions that, while not constituting incurred costs per se, nevertheless constitute a valuable resource to the potential project.

Following the assessment, the IHI JU Governing Board will issue a written decision. This result will be promptly communicated to the applicant.

- the scientific priorities expressed in the specific IHI JU work programme.

²⁵ The strategic and specific objectives of IHI JU are derived from the Single Basic Act, primarily article 115 ('Additional objectives of the Innovative Health Joint Undertaking') and article 116 ('Additional tasks of the Innovative Health Initiative Joint Undertaking'); as expressed through:

the IHI JU Strategic Research and Innovation Agenda;

5. Contributing partner's role in the grant agreement

The contributing partner's engagement with IHI JU must be compatible with IHI JU's strategic objectives and those programmatic goals determined by the IHI JU Strategic Research and Innovation Agenda. Contributing partners are not involved in the governance structure of IHI JU and do not have voting rights in the IHI JU Governing Board.

There is no limitation on the number of topics / projects that interested contributing partners may contribute to. However, participation in multiple topics / projects requires a contributing partner to prepare a separate topic / project specific application to the IHI JU Governing Board.

Contributing partners become a part of the applicant consortium and may participate in a project, as appropriate as:

- · Beneficiaries; or
- · Affiliated entities in the meaning of Article 8 of the Horizon Europe model grant agreement; or
- Associated Partners in the meaning of Article 9.1 of the Horizon Europe model grant agreement.

5.1 Participation of contributing partners in IHI JU projects as beneficiaries

It is expected that the contributing partners not established in an EU Member State, a country associated to Horizon Europe or low- and middle-income countries will take up the role of beneficiaries in the project.

Where the contributing partners participate as beneficiaries, they sign an accession form to accede to the grant agreement for each project they contribute to.

Specifically, contributing partners (and where relevant their constituent or affiliated entities) shall:

- sign the IHI JU grant agreement via the accession form²⁶. Therefore, contributing partners shall notably comply with the entirety of the legal rules of the Horizon Europe framework as they pertain to the IHI JU, and in particular the Articles of: Regulation on the Rules for Participation in Horizon Europe (EU) No 2021/695; Council Regulation (EU) No 2085/2021 establishing the Joint Undertakings under Horizon Europe; the Model Grant Agreement for Horizon Europe and the Horizon Europe Work Programme General Annexes;
- sign the consortium agreement. All project beneficiaries and potentially affiliated entities and associated partners shall sign a consortium agreement that sets out participants' rights and obligations and addresses issues like governance, liability and intellectual property rights. The agreement should be adapted to the needs of each project. Several available templates show what a consortium agreement might look like; including a template prepared by the IHI JU private members that is available on the websites of COCIR and EFPIA²⁷.

For rules on reporting contributions of contributing partners participating in a project as a beneficiary see point 5.4 of this Guide below.

²⁶ Please consult the HE Model Grant Agreement https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/agr-contr/unit-mga_he_en.pdf

²⁷ The links to the template prepared by the IHI JU private members are available on IHI JU website https://www.ihi.europa.eu/apply-funding/call-documents

5.2 Participation of contributing partners in IHI JU projects as affiliated entities

Affiliated entities are defined in Article 8 of the model grant agreement as entities with a legal or capital link with the beneficiary, which is neither limited to the action nor established for the sole purpose of the action implementation.

The legal link covers for example: permanent legal structures, and contractual cooperation not limited to the action (e.g. an existing collaboration agreement for activities in a field relevant to the action).

A capital link includes direct or indirect control of the beneficiary, being under the same direct or indirect control as the beneficiary or directly or indirectly controlling the beneficiary.

Legal supporting documentation as evidence of the existence of a capital or legal link between the project participant to whom the contributing partner is affiliated will be requested by IHI JU in all cases.

Affiliated entities28:

- don't sign the grant agreement, but are identified therein;
- implement parts of the action and are allowed to charge costs directly to the grant;
- sign the consortium agreement.

5.3 Participation of contributing partners in IHI JU projects as associated partners case B

Contributing Partners may take the role of associated partners in a project. While there are two types of associated partners – case A²⁹ and B, contributing partners however **may only use case B** for their participation in the project.

'Case B' associated partners are:

- a contributing partner to IHI JU; or
- a constituent or affiliated entity of a contributing partner to IHI JU.

Example of an associated partner case B: a non-EU based legal entity that is an affiliate of an IHI JU contributing partner.

Characteristics of associated partners case B in IHI JU:

- They participate at their own cost, but their contribution may be counted as financial contributions and/or in-kind (IKOP) towards IHI JU projects. Contributing partners or their affiliated entities <u>may never contribute</u> <u>IKAA</u>;
- They implement action tasks but without receiving EU funding;
- They should be connected to a *designated beneficiary* who will take responsibility for the associated partner's proper implementation of tasks in the project. They must have a legal/capital to that designated beneficiary in the project;
- They do not sign the grant agreement (as they are not beneficiaries);

²⁸ For more information on rights and obligations of affiliated entities please see Article 8 of the Annotated Horizon Europe model grant agreement: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/aga_en.pdf

²⁹ For more information on case A associated partners please see IHI JU Guide for Applicants: https://www.ihi.europa.eu/apply-funding/call-documents

- They are, however, identified in the grant agreement; they must be listed in Article 9.1 grant agreement, and their tasks must be mentioned in the proposal Part B and subsequent project DOA;
- The grant agreement defines their role, but since there is no direct contractual link between the associated partner and IHI JU, the associated partner's obligations will always be enforced through the responsible beneficiaries and the designated beneficiary. The associated partner's rights and obligations may be expanded upon within the specific project's consortium agreement;
- Because associated partners perform those project tasks attributed to them in the project DOA, the consortium collectively and a designated beneficiary with whom the associated partner case B is cooperating takes responsibility for the associated partner's work in the project;
- Associated partners may sign the consortium agreement wherein those rights and responsibilities that
 accrue to beneficiaries and affiliated entities under the grant agreement (e.g., access rights) may also be
 conferred on the associated partner as long as not contrary to grant agreement;

Responsibility of the consortium and the designated beneficiary for the associated partner case B:

- The consortium is responsible for the proper implementation of the tasks performed by associated partners (proper quality, timely delivery, etc.) unless it is agreed and reflected in the consortium agreement that such responsibility should instead be taken by a designated beneficiary in the consortium who is a constituent or affiliated entity of a private member, a contributing partner to IHI JU, or a constituent entity or affiliated entity thereof. The relationship, responsibilities, and issues of liability should be reflected in the consortium agreement and, where appropriate, an ancillary agreement between the parties, so long as the provisions therein are not contrary to the grant agreement. However, in case the respective beneficiary fails to implement the tasks of its associated partner and leaves the action (irrespective of the reason), the remaining beneficiaries must carry out the action as set out in the description of the action (DoA; Annex 1) including the part of the defaulting beneficiary and the third parties linked to it (e.g., affiliated entities, associated partner(s)). They will have to do this without any additional funding. The grant agreement will have to be amended to redistribute the tasks, terminate the beneficiary's participation, and/or add a new beneficiary (see Article 39 of the Horizon Europe model grant agreement).
- The beneficiaries must ensure that their contractual obligations under Articles of the Horizon Europe model grant agreement: 11 (proper implementation), 12 (conflict of interests), 13 (confidentiality and security), 14 (ethics), 17.2 (visibility), 18 (specific rules for carrying out action), 19 (information) and 20 (record keeping) also apply to the associated partners. The beneficiaries must ensure that the bodies mentioned in article 25 Horizon Europe model grant agreement (e.g., granting authority, OLAF, Court of Auditors (ECA), etc.) can exercise their rights also towards the associated partners. The above-mentioned obligations as well as any relevant obligations further mentioned in the call conditions and/or Annex 5, e.g. (additional) obligations regarding results, open access to peer-reviewed scientific publications etc., must be respected. It is advisable to embed these either in a side agreement between the beneficiaries and the associated partners or in the consortium agreement.

Table 2

Type of participant	Do they sign the grant agreement	Do they sign the consortium agreement
Contributing partner as a beneficiary (point 5.1 above)	YES (via the accession form)	YES
Contributing partner as an affliated entity (point 5.2 above)	NO	YES
Contributing partner as an associated partner case B (point 5.3 above)	NO	YES

5.4 Reporting contributions from contributing partners

The following reporting requirements apply when the **contributing partner participates in IHI JU project as a beneficiary/affiliated entity**.

Periodic reporting

Costs incurred and activities carried-out by contributing partners in IHI JU projects need to be reported in the periodic report, like for any other beneficiary/affiliated entity of the grant agreement.

Each project is divided into periods and the periodic report is due within 60 days after each project period.

The periodic report consists of two technical parts (A and B) and one financial part and needs to be prepared via the Funding and Tenders Portal by all project beneficiaries.

- Technical part A: document automatically generated in the system based on the information beneficiaries have inserted in the continuous reporting module (e.g. summary for publication, deliverables, milestones, dissemination & exploitation of results, etc.). For more information, see the Horizon Europe Part A template and the instructions on the continuous reporting.
- Technical part B: narrative description of the work carried out during the reporting period. For more information, see the IHI-specific part B template and the instructions on the periodic reporting.
- Financial part: online financial statements and explanations on the use of resource by project beneficiaries. Costs reported must fulfil the eligibility conditions specified in Article 6 of the HE model grant agreement (e.g., actual costs, incurred during the project implementation, recorded in the entity's accounts, etc). For more information, see <u>instructions on how to complete the financial part</u> of the periodic report.

Final report and certification

At project end, in addition to the periodic report, contributing partners must provide an audit certificate in some cases.

The certification must be done by an independent external auditor appointed by the contributing partner

and submitted to the IHI JU 60 days after the end date of the project. The same rule applies to all beneficiaries and affiliated entities.

- Certificate on the statements of contributions (CCS) required at the end of the project if reported in kind and financial contribution (IKOP + FC) >=EUR 430 000,
- Only if receiving IHI JU funding: **Certificate on the financial statements (CFS)** required at the end of the project if total requested IHI JU funding ≥ EUR 430 000 (irrespectively of the amount of IKOP and FC provided to the project).

Annex 1 Legal basis

Contributing partner to IHI JU - legal basis

<u>Council Regulation (EU) 2021/2085</u> establishing IHI JU defines what is meant by the term 'contributing partner' and outlines the process for becoming a contributing partner, among other things.

Article 2 Council Regulation (EU) 2021/2085 - Definitions

7. 'contributing partner' means any country, international organisation or legal entity other than a member of a joint undertaking, or a constituent entity of a member or an affiliated entity of either, that supports the objectives of a joint undertaking in its specific area of research and whose application has been approved in accordance with Article 9.

Article 9 Council Regulation (EU) 2021/2085 - Contributing partners

- 1. Any candidate contributing partner as defined in Article 2, point (7), shall submit a letter of endorsement to the governing board. The letter of endorsement shall specify the scope of the partnership in terms of subject matter, activities and their duration and detail the applicant's contribution to the joint undertaking.
- 2. The governing board shall assess the letter of endorsement and shall approve or reject the application.
- 3. Contributing partners shall not have voting rights in the governing board of a joint undertaking.

Article 11 Council Regulation (EU) 2021/2085 - Contributions from contributing partners

[...] 5. The contributions from contributing partners shall correspond to the amounts they have committed in the letter of endorsement when becoming a contributing partner and shall consist of financial contributions and in-kind contributions to operational activities. [...]

Article 28 - Council Regulation (EU) 2021/2085 - Sources of financing

1. Each joint undertaking shall be jointly funded by the Union, the members other than the Union and the contributing partners through financial contributions and in-kind contributions to operational activities.

[...]

- 3. The operational costs of a joint undertaking shall be covered by means of the:
- (a) financial contribution by the Union;
- (b) financial contributions by the private members or their constituent or affiliated entities, by contributing partners or by an international organisation that is a member of a joint undertaking;
- (c) where applicable, financial contributions by the participating states;
- (d) in-kind contributions defined in Article 2, point (8).
- 4. In accordance with Articles 10 and 11, the resources of a joint undertaking entered in its budget shall be composed of the following contributions:
- (a) members' financial contributions to the joint undertaking for the administrative costs, divided equally on an annual basis between the Union and the members other than the Union, unless specified otherwise in Part Two due to the specific membership nature of a joint undertaking;

- (b) members' or contributing partners' financial contributions to the joint undertaking for the operational costs;
- (c) any revenue generated by the joint undertaking;
- (d) any other financial contributions, resources and revenues.

[...]

5. Any unused part of the contribution for administrative costs may be made available to cover the operational costs of the joint undertaking concerned.

[...]

7. The resources of the joint undertaking and its activities shall be used for the fulfilment of its objectives and tasks.

[...]

Annex 2 Reference documents

Guide for applicants

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

IHI JU contributing partner website: https://www.ihi.europa.eu/shape-our-future-research/become-contributing-partner

List of countries associated to Horizon Europe:

 $\underline{https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/list-3rd-country-participation_horizon-euratom_en.pdf}$

Work Programmes and more information on IHI JU funding:

https://www.ihi.europa.eu/about-ihi/plans-reports-and-finances