

Information Guide

for IHI JU Contributing Partners

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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 | 14 December 2022 | First version | |
| | | | |

Main definitions

Affiliated entities: 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. Affiliated entities implement parts of the action and are allowed to charge costs directly to the grant.

Associated countries: third countries associated to Horizon Europe. See list of countries:

https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/list-3rd-country-participation_horizon-euratom_en.pdf and the relevant updates here:

https://ec.europa.eu/info/news/updates-association-third-countries-horizon-europe_en

Applicant: legal entity applying for a call for proposals.

Associated Members: in accordance with Article 7 SBA the IHI JU may launch open and transparent calls for expression of interest with a view to selecting associated members with the potential to contribute to the achievement of the objectives of IHI JU. The call for expression of interest shall set out the key capacities needed in order to achieve the objectives of IHI JU and may request applicants to provide an indication of their potential contributions. The IHI JU Governing Board shall assess and approve or reject applications for membership as an associated member.

Beneficiaries: a legal person, other than the IHI JU, which is a signatory of the grant agreement (either directly or through an accession form).

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: entities that constitute a member other than the Union, where that member is an association according to that member's statutes. In the context of the IHI JU, constituent entities are the members of the associations COCIR, EFPIA, EuropaBio, MedTech Europe, and Vaccines Europe.

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) 2021/2085 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 IHI JU members other than the Union, their constituent or affiliated entities and by contributing partners, consisting of the eligible costs incurred by them for implementing the action, less the contribution of the IHI JU to those costs.

In-kind contributions to additional activities or IKAA: contributions incurred by the IHI JU members other than the Union, their constituent or affiliated entities, consisting of costs for implementing additional activities.

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.

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

Members:

1. the European Union (EU), represented by the European Commission; and
2. members other than the Union.

Members other than the Union:

1. the European life science industry, represented by COCIR, EFPIA (including its subgroup Vaccines Europe), EuropaBio and MedTech Europe; and
2. associated members if selected in accordance with Article 7 of SBA.

Member State: a state that is party to treaties of the European Union and thereby subject to the privileges and obligations of European Union membership.

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

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.

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

Single-stage submission scheme: a scheme in which there is a single proposal submission and evaluation phase and there is no pre-defined industry consortium. The applicant consortium composition may include any legal entities, including members other than the Union, and/or contributing partners 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. See <https://www.ihj.europa.eu/about-ihj/research-and-innovation-agenda>

Third Country: any country outside the EU which is not associated to Horizon Europe.

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 submission scheme: a scheme in which applicants must submit a short proposal (SP) for the stage 1 evaluation. SPs must involve all applicant organisations requesting JU funding. 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: a document adopted 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.

Introduction

Innovative Health Initiative Joint Undertaking (IHI JU) is a public-private partnership (PPP¹) 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 programme² which runs until 2027.

IHI JU was formally established on 30 November 2021 by the Single Basic Act - Council Regulation (EU) 2021/2085³ 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 the European Union, represented by the European Commission, and the European life science industry, represented by the industry associations COCIR⁴, EFPIA (including Vaccines Europe)⁵, EuropaBio⁶ and MedTech Europe⁷.

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 to the achievement of its objectives without becoming IHI JU's members⁸.

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 members other than the Union.

¹ 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.

² 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>

³ 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>

⁴ COCIR is the European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries. See <https://www.cocir.org/>

⁵ EFPIA is the European Federation of Pharmaceutical Industries and Associations. See <https://www.efpia.eu/>

⁶ 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/>

⁷ MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. See <https://www.medtecheurope.org/>

⁸ 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.

This Guide aims to streamline and facilitate the discussions on becoming a contributing partner with interested entities.

This Guide provides comprehensive and practical information on:

- the rules for participation in IHI JU: members vs contributing partners, funding model, basic information on IHI JU evaluation and selection process;
- legal framework applicable to contributing partners: entities authorised to apply, rules on contributions, engagement, and contractual obligations;
- how to join an IHI JU call as a contributing partner in single-stage and two-stage calls: legal framework, application process including template application letters, procedure for submission of application letters, assessment of the applications by the IHI JU programme Office and IHI JU Governing Board.

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 calls⁹.

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](#).

⁹ Please visit: https://www.ihj.europa.eu/sites/default/files/IHI_Guide_for_Applicants.pdf

1 Participating in IHI JU actions

1.1 Participation in IHI JU projects

Any legal entity carrying out activities relevant to the IHI JU and project's objectives may participate in IHI JU projects.

A distinction must be made between legal entities eligible to participate, and legal entities eligible to receive funding from IHI JU.

Any legal entity, regardless of its place of establishment, including legal entities from non-associated third countries or international organisations, **is eligible to participate** (whether it is eligible for funding or not)¹⁰.

In order for a proposal to be considered eligible, the applicant consortium should include:

- at least one independent legal entity established in a Member State; and
- at least two other independent legal entities, each established in different Member States or associated countries.

For the up-to-date information on the [current list of associated countries and low and middle income countries](#) see the list of participating countries in Horizon Europe.

1.2 The IHI JU funding model

The total budget for IHI JU for the period 2021-2027 is up to €2.4 billion.

- up to €1 billion will come from Horizon Europe, the EU's framework programme for research and innovation;
- up to €200 million will come from Horizon Europe, provided that that amount is matched by the additional contributions from contributing partners, or from their constituent or affiliated entities if they decide to contribute to IHI JU;
- up to €1 billion will come from the IHI JU members other than the Union. Large companies that are part of the IHI JU members other than the Union contribute to the programme, primarily through in-kind contributions (e.g. their researchers' time, laboratories, data, compounds). They can also make cash contributions;
- up to €200 million will come from contributing partners, or from their constituent or affiliated entities if they decide to contribute to IHI JU¹¹.

¹⁰ Please note that no legal entity established in Russia, Belarus or non-government controlled territories of Ukraine is eligible to participate in any capacity in any Horizon Europe grant or calls with deadline after 10 May 2022.

¹¹ Please note that under Article 11.5 SBA - the contributions from contributing partners shall consist of financial contributions and in-kind contributions to operational activities. Contributing partners do not contribute in-kind contributions to additional activities.

At least 45% of each project's budget must come from members other than the Union and/or contributing partners. As a best practice the consortia should aim for at least 50% of the action's eligible costs and costs for the action's additional activities¹².

Any organisation established in the EU, or a country associated to Horizon Europe¹³ is eligible to receive IHI JU funding. In practice, IHI JU funding primarily supports the participation in its projects of organisations like universities, research organisations, patient organisations, small and medium-sized enterprises (SMEs), and mid-sized companies. Depending on the type of call for proposals, larger companies may also be eligible to receive IHI JU funding. Details of who may receive funding are available in section *Rules for funding per type of call* in the IHI guide for applicants¹⁴.

¹² Please consult page 21 IHI JU Guide for Applicants, https://www.ih.europa.eu/sites/default/files/IHI_JU_Guide_for_Applicants.pdf

¹³ For the list of countries associated to Horizon Europe please see: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/list-3rd-country-participation_horizon-euratom_en.pdf

¹⁴ Further, for Work Programmes and more information on IHI JU funding, please consult: <https://www.ih.europa.eu/about-ih/plans-reports-and-finances>

1.3 Members versus contributing partners

| Members | | Contributing partners |
|--|--|--|
| Who are they? | (1) the European Union (2) members other than the Union | 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 in general | Particular IHI call and topic they wish to support |
| How do they join IHI JU? | Established in the SBA | Approved by the IHI Governing Board based on their application letter |
| How do they contribute to IHI JU? | Members other than the Union contribute: IKOP, IKAA, FC | Contributing partners contribute: IKOP, FC (but no IKAA) |
| Relevant sections of the SBA | Article 11; 117 | Article 2; 9; 11; 28 ¹⁵ |

1.4 Contributions from members other than the Union

For details on membership in COCIR, EFPIA (including Vaccines Europe), EuropaBio and MedTech Europe, those organisations may be contacted directly.

The members other than the Union, or their constituent or affiliated entities, contribute to IHI JU projects mainly through in-kind contributions (which may under certain circumstances be matched by the IHI JU funds).

The Contribution of the members other than the Union to IHI JU may take the following form¹⁶:

At level of a project (action):

1. In-kind contributions to operational activities (IKOP) - eligible costs incurred in implementing the action.
2. In-kind contributions to additional activities (IKAA):
 - Costs for implementing additional activities (not project tasks and therefore not IKOP);
 - project-specific (i.e. dissemination, sustainability or exploitation of IHI JU project results beyond project duration).

¹⁵ For overview of the legal basis please see **Annex 3** to this guide.

¹⁶ Please note that under Article 11.5 Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe - the contributions from contributing partners shall consist of financial contributions and in-kind contributions to operational activities. Contributing partners do not contribute in-kind contributions to additional activities.

3. Financial Contribution (FC) - (cash contributions) by members other than the Union, their constituent or affiliated entities to:
- project beneficiary(ies) supporting the eligible costs incurred in implementing the IHI JU projects, or;
 - the IHI JU directly (to increase a given project funding).

At programme level:

- programme-specific IKAA (i.e. to foster uptake of results from IHI JU projects).

1.5 Summary of the IHI JU evaluation and selection process¹⁷

Every year IHI JU launches a number of calls for proposals. Proposals are then selected through these open and competitive calls for research proposals, based on independent peer review.

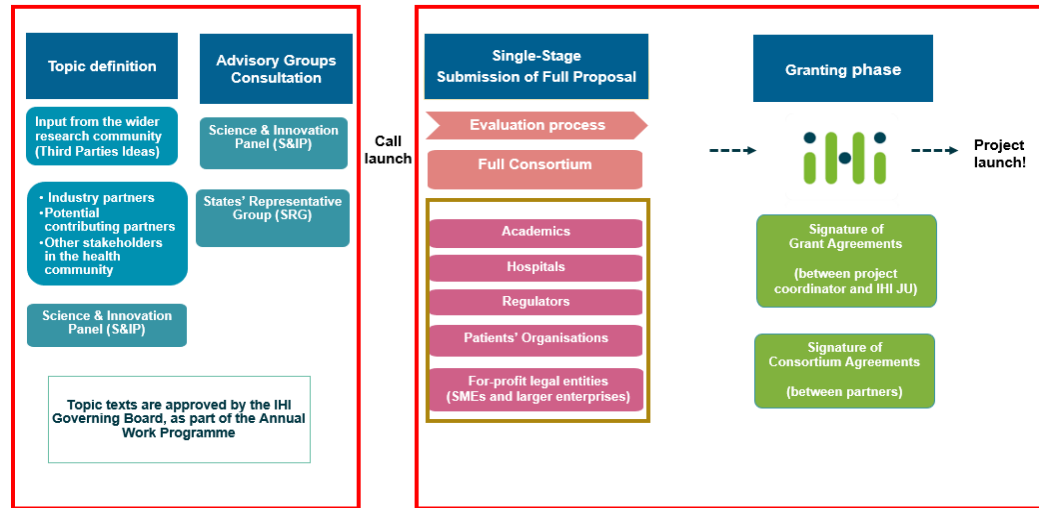
IHI JU uses two types of call structure: single-stage and two-stage calls.

For **single-stage calls**, applicant consortia may consist of different stakeholders such as academia, SMEs, large companies, regulators, etc. The proposals submitted by applicant consortia will be assessed on the basis of their quality and ability to fulfil the objectives of the specific call / topic, taking into consideration any specific requirement described in the call topic text, including the public-private partnership requirement. Therefore, applicants might need to involve participants from different health sectors to meet the specific objectives.

A single-stage submission implies a single submission and evaluation process, without a pre-defined industry consortium. Applicants must therefore submit a full proposal which includes one or several members other than the Union, their constituent or affiliated entities and/or contributing partners. To meet the eligibility criteria, applicants must ensure already at proposal stage that the collective contribution to be provided by the members other than the Union, their constituent or affiliated entities and/or contributing partners amounts at least to 45 % of the proposal's eligible costs and the costs of any related additional activities. After the evaluation, proposals above threshold may be invited for grant preparation according to the ranked list and within the available budget.

¹⁷ For more information on the IHI JU evaluation and selection process please consult IHI JU Guide for Applicants https://www.ihj.europa.eu/sites/default/files/IHI_JU_Guide_for_Applicants.pdf

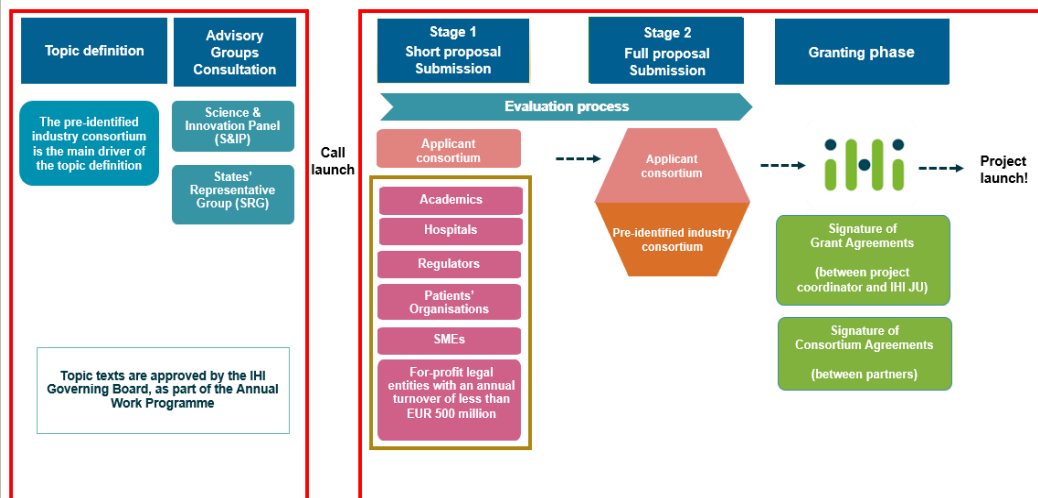
Single-stage procedure



Under a **two-stage call**, applicants must submit a short proposal for the stage 1 evaluation. All applicants requesting IHI JU funding must be part of the short proposal. At the end of the stage 1 evaluation, under each topic, only the applicant consortium of the first ranked short proposal is invited to prepare and submit a full proposal for the stage 2 evaluation together with the 'pre-identified industry consortium' (the main driver of the topic definition) for the relevant topic (see IHI JU two-stage procedure below) which includes one or several members other than the Union, their constituent or affiliated entities and/or contributing partners. To fulfil the eligibility criteria, applicants must also ensure at the full proposal stage that the collective contribution to be provided by the members other than the Union, their constituent or affiliated entities and/or contributing partners amounts at least to 45 % of the proposal's eligible costs and the costs of any related additional activities.

The full proposal must be consistent with the short proposal, taking into account the stage 1 evaluation outcome, and may not differ substantially apart from adaptation of the workplan to integrate the 'pre-defined industry consortium' contributions.

Two-stage procedure



2 Introducing contributing partners

2.1 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. In total, the EU can match up to EUR 200 million from contributing partners. 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 in a project, you will be able to influence it from the earliest stages;
- 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;
- benefits of scale: IHI JU expects to launch 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.

2.2 Who can apply?

Any country, international organisation or legal entity other than a member of IHI JU, or a constituent entity of a member or an affiliated entity of either may apply to become a contributing partner provided that:

- they support the 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 this application letter to the IHI JU Programme Office;
- the application is assessed by the IHI JU Governing Board.

Therefore, both public and private organisations of various nature 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, the contributing partner's involvement must support the objectives of IHI JU in its specific area of research. On a more specific level a contributing partner must also consider the obligations resulting from the participation in the consortium implementing an IHI JU project.

Any candidate contributing partner must submit an application letter to the IHI JU 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;

- 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; and
- in case of two-stage calls acceptance of the confidentiality obligation.

A template application letter in single-stage calls may be found in the [Annex 1](#) and for two-stage calls in [Annex 2](#) to this guide.

2.3 Contributions from contributing partners¹⁸

Contributing partners (and their affiliated entities if any) contribute to topics/ projects mainly through financial and in-kind contributions and, generally do not receive any funding from IHI JU¹⁹. The contributions from contributing partners must correspond to the amounts they have committed in the application letter when becoming a contributing partner.

The contribution 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 activities²⁰. The costs should be also compatible with the eligibility criteria set of in Article 6 of the Horizon Europe Model Grant Agreement²¹.

Costs for project activities incurred in the Union or in one of the countries associated to Horizon Europe shall be considered 'EU IKOP' while costs for project activities incurred outside the Union or outside countries associated to Horizon Europe shall be considered 'Non-EU IKOP'. Non-EU contributions cannot exceed 20% of the overall IKOP at programme level²².

In-kind contributions can take the form of different eligible cost types:

¹⁸ Article 11 of Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe.

¹⁹ 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.

²⁰ In single-stage calls, CPs may in addition to contributing, also request funding. Their net contribution will be counted as their final contribution.

²¹ 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)

²² For further information on the definition of 'non-EU' please see the [Guide for Applicants](#).

- personnel - the time of staff employed 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;
- other direct costs - consumables, equipment depreciation, samples, compounds;
- subcontracting - 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).

2. Financial Contribution (FC):

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

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

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

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

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

2.4 Scope of the engagement and contractual obligations of a contributing partner

The contributing partner's engagement with IHI JU has to 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 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 sign the grant agreement for each project they contribute to.

Contributing partners (and where relevant their constituent or affiliated entities) shall:

- sign the IHI JU grant agreement²³. 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 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 members other than the Union that is available on the websites of COCIR and EFPIA²⁴.

2.5 Reporting contributions from contributing partners

Costs incurred by contributing partners in IHI JU projects need to be reported the same way as any other beneficiary signing the grant agreement.

In-kind contributions to operational activities (IKOP) and/or financial contributions coming from contributing partners, and where relevant their affiliated entities, are reported within the scope of the grant agreement, i.e. for activities and costs which constitute IKOP - eligible costs in implementing project tasks, as specified in Annex 1- DoA of the grant agreement.

The same applies to financial contributions - cash transfers to project beneficiary(ies) supporting the eligible costs incurred in implementing the IHI JU projects.

- Eligible period: eligible IKOP incurred during project implementation and financial contribution paid, (from project start date to project end date);
- Reporting deadline for the reporting: the reporting is due 60 days after the end of each reporting period, for the costs incurred between the start date and the end date of each reporting period;
- Means of reporting: in the project Periodic Report, via the Funding and tenders Portal, which is the same tool for all beneficiaries;
- Certification: when reported in kind and financial contribution (IKOP + FC) are \geq EUR 430 000, a Certificate on the statements of contributions (CCS) is required at the end of the project. The certification must be done by an independent external auditor appointed by the respective organisation and submitted to the IHI JU 60 days after the end date of the project.

²³ 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

²⁴ The links to the template prepared by the IHI JU members other than the Union are available on IHI JU website <https://www.ihj.europa.eu/apply-funding/call-documents>

3 Applying to become a contributing partner in single-stage calls

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

Applicant contributing partners are advised to follow in detail the template of the application letter included in [Annex 1](#) to this guide when drafting their contributing partner application. A draft letter of application should be submitted via email to [the IHI JU Programme Office](#), preferably in MS Word format.

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 may be 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 letter to ensure that the draft application details all the necessary elements included in the application template, in particular:

- 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;
- activities; and
- duration.

The IHI JU Programme Office will ask the applicant contributing partner to revise the 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.

3.2 Assessment of the application by the IHI JU Governing Board

If the proposal of the applicant contributing partner's consortium is selected for funding, the application to become a contributing partner will be transmitted to the IHI JU Governing Board who will, upon consideration, accept or reject the application²⁵.

The IHI JU Governing Board will assess the application taking into account the relevance towards the objectives of IHI JU but also for the topic concerned.

The IHI JU Governing Board will also assess the committed contribution in the light of both IHI JU's aims and the objectives of the project that the applicant is intending to contribute to.

The IHI JU Governing Board will then issue a written decision. This result will be promptly communicated to the applicant.

²⁵ Article 17.2 (c) Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe

3.3 Timeline for applications and calculation of in-kind contributions towards a proposal's eligibility²⁶

In order for a proposal to be eligible, applicant consortia should 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 members other than the Union, their constituent or affiliated entities, and/or from contributing partners.

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

1. an application letter has been submitted via [email](#) and received by IHI JU Programme Office within the proposals' submission deadline;
2. the application letter bears a Blue-ink signature of a legal representative of the applying legal entity;
3. the application letter states clearly enough what the amount and the scope of the contribution to the topic and IHI JU is; and
4. the contribution envisaged in the application letter is not in any way provisional or conditional in nature;

– in such case IHI JU Programme Office considers it is a 'final application' submitted within the deadline.

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 however, such contribution can be counted towards the 45% check during grant agreement preparation.

²⁶ For more details on eligibility of proposals please consult IHI JU Guide for Applicants https://www.ihj.europa.eu/sites/default/files/IHI_JU_Guide_for_Applicants.pdf

4 Applying to become a contributing partner in two-stage calls

4.1 Timeline for applications

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

The pre-identified industry consortium described in the call text will contribute to the cross-sectoral IHI JU project. This pre-identified industry consortium is composed of the pharmaceutical and medical technology industry partners.

The call text may also specify contributing partner(s) that will participate in the IHI JU project.

If so, 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 call text therefore may include:

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

Important Note: If the contributing partner intends to have their contribution matched by the IHI JU, the IHI JU should receive their application letter prior to the publication of the two-stage call text. Therefore, contributing partner needs to submit their application letter prior to the finalisation of the call text to be included in such call text. 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 published, it may send its application letter to IHI JU. 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.

4.2 Preliminary assesment of the application by the IHI JU Programme Office

Applicant contributing partners are advised to follow in detail the template of the application letter included in [Annex 2](#) to this guide 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.

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 may be 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 letter to ensure that the draft application details all the necessary elements included in the application template, in particular:

- 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;
- activities; and
- 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.

The IHI JU Programme Office will ask the applicant to revise the letter in case it significantly deviates 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 Governing Board.

4.3 Assessment of the application by the IHI JU Governing Board

The applications of contributing partners constituting members of the pre-identified industry consortium will be transmitted to the Governing Board. The IHI JU Governing Board shall assess and accept or reject the applications²⁷.

The IHI JU Governing Board shall assess the application taking into account the relevance towards the objectives of IHI JU but also for the topic concerned.

The IHI JU Governing Board will also assess the committed contribution in the light of both IHI JU's aims and the objectives of the project that the applicant is intending to contribute to.

The IHI JU Governing Board will then issue a written decision. This result will be promptly communicated to the applicant.

²⁷ Article 17.2 (c) Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe

Annex 1

Template application letter for a new contributing partner to IHI JU regarding single-stage calls

Chair of the IHI JU Governing Board
c/o IHI JU Executive Director
Innovative Health Initiative Joint Undertaking
56 – 60 Avenue de la Toison d'Or
Brussels – 1060
Belgium

[Date]

Re: [IHI JU Call No / Topic No, Topic's title]

Dear sir/madam,

On behalf of [Organisation Name] of [Registered Address] and in accordance with Council Regulation (EU) No 2085/2021 of 19th 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 and specifically Articles 9, 17, 116, and 118 therein;

we wish to apply to become a contributing partner to the IHI JU Joint Undertaking.

[Introduction to applicant contributing partner]

[Aims/Ethos of the applicant contributing partner]

[In general terms how the applicant contributing partner is to contribute to IHI JU/What relevance and potential added value does the proposed contribution present for the achievement of the objectives of the IHI JU projected duration of contribution to the IHI JU]

[Details of IHI JU topic]

[Manner of applicant contributing partner's interaction with the IHI JU topic]

[Manner and specifics of proposed contribution to topic – for example: project areas, work packages, deliverables, and description of in-kind and/or in cash total equivalent amount (please specify value in EURO)]

We estimate the value of this contribution to be EUR [Amount] over the lifetime of the project.

Further, according to our best projections, EUR [Amount] of the above overall contribution will be considered as non-EU²⁸.

[Additional Details as relevant]

We confirm the following:

1. That we will observe in their entirety the legal rules of 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.
2. We are confident of our ability to meet the above commitments over the lifetime of the project and further confirm our understanding that the IHI JU will allocate resources to the above topic based on these commitments.

Yours faithfully,

Signed

[To be signed by representative of the contributing partner who is properly authorised to commit said contributing partner to legally binding contracts and accompanying financial obligations].

Dated

²⁸ For definition of non-EU contribution, please consult the IHI JU Guide for Applicants https://www.ihj.europa.eu/sites/default/files/IHI_JU_Guide_for_Applicants.pdf

Annex 2

Template application letter for a new contributing partner to IHI JU regarding two-stage calls

Chair of the IHI JU Governing Board
c/o IHI JU Executive Director
Innovative Health Initiative Joint Undertaking
56 – 60 Avenue de la Toison d'Or
Brussels – 1060
Belgium

[Date]

Re: [IHI JU Call No / Topic No, Topic's title]

Dear sir/madam,

On behalf of [Organisation Name] of [Registered Address] and in accordance with Council Regulation (EU) No 2085/2021 of 19th 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 and specifically Articles 9, 17, 116, and 118 therein;

we wish to apply to become a contributing partner to the IHI JU Joint Undertaking.

[Introduction to applicant contributing partner]

[Aims/Ethos of the applicant contributing partner]

[In general terms how the applicant contributing partner is to contribute to IHI JU/What relevance and potential added value does the proposed contribution present for the achievement of the objectives of the IHI JU projected duration of contribution to the IHI JU]

[Details of IHI JU topic]

[Manner of applicant contributing partner's interaction with new topic]

[Manner and specifics of proposed contribution to topic – for example: project areas, work packages, deliverables, and description of in-kind and/or in cash total equivalent amount (please specify value in EURO)]

We estimate the value of this contribution to be EUR [Amount] over the lifetime of the project.

Further, according to our best projections, EUR [Amount] of the above overall contribution will be considered as non-EUⁱ.

[Additional Details as relevant]

We confirm the following:

1. That we will observe in their entirety the legal rules of 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.
2. That we will keep all information arising from our position as contributing partner to the IHI JU confidential. This confidential obligation to apply in particular, but not be confined to, the areas of IHI JU call topic preparation and publication, proposal submission and evaluation, and consortium formation. We further understand that this obligation strictly prohibits the release of confidential information to any legal entities save where specifically authorised by IHI JU.
3. We are confident of our ability to meet the above commitments over the lifetime of the project and further confirm our understanding that the IHI JU will allocate resources to the above topic based on these commitments.

Yours faithfully,

Signed

[To be signed by representative of the contributing partner who is properly authorised to commit said contributing partner to legally binding contracts and accompanying financial obligations].

¹ For definition of non-EU contribution, please consult the IHI JU Guide for Applicants https://www.ih.europa.eu/sites/default/files/IHI_JU_Guide_for_Applicants.pdf

Annex 3

Contributing partner to IHI JU – legal basis

Council Regulation (EU) 2021/2085 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 members other than the Union and 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.

[...]
