

## IHI JU calls for proposals Frequently Asked Questions (FAQs)

### **History of Changes**

Version	Date	Comments
1	28/06/2022	First version
2	29/07/2022	Question 13 has been updated
3	15/12/2022	Minor adaptations, additional questions added
4	20/07/2023	Added Questions 12, 22, 23 and 24
5	26/10/2023	Revised Questions 1 and 5, added Questions 25 and 2
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6	19/12/2023	Revised Question 5, added Question 9
7	12/01/2024	Revised Question 5
8	13/12/2024	Revised Questions 7, 8, 11, 12, 22 and 25 Added Question 26
9	06/03/2025	Revised Questions 5 and 6
10	17/06/2025	Revised Questions 5 and 6

The Call text provides the overall principles, expectations and requirements to be followed by applicants in the preparation of their proposals and by the panel of experts in the evaluation of the submitted proposals. This Q&A document aims to explain some aspects in more detail, but is by no means intended to be exhaustive, nor should it differ from anything stated in the Call text.

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#### 1. Where can I find more information about IHI calls?

All information is available on the IHI <u>Call Documents page</u> and, in particular, in the <u>Guide for Applicants</u>.

For links to the recordings of webinars where we explain rules and procedures applicable to each Call, please visit: <u>https://www.ihi.europa.eu/news-events/events</u>

Which are the specific actors in IHI JU?

**Private member** are European life science industry associations that are members of IHI JU (i.e. COCIR, EFPIA (including its subgroup Vaccines Europe), EuropaBio and MedTech Europe), as well as any legal entity that is a constituent and/or affiliated entity of one of those industry associations; in accordance with the rules of that association.

**Constituent entities** means the entities that constitute a private member of a joint undertaking, where the private member is an association according to that member's statutes. (e.g.: Janssen is a constituent entity of EFPIA)

**Affiliated entities** means the entities that have a capital or legal link with a beneficiary (which is in this case is a private member or a private member constituent entity) as defined in Article 8 of the Horizon Europe Model Grant Agreement.

**Contributing Partner** means any country, international organisation, or legal entity (other than a member of the IHI JU, or a constituent entity of a IHI JU 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. Contributing partners participate in a consortium and provide in-kind and/or financial contributions but do not provide in-kind contributions to additional activities (IKAA).

### 2. How many entities do I need to form a consortium? Do industry partners count towards that threshold?

In accordance with the Horizon Europe Work Programme 2023-2024 13. General Annexes (link <u>here</u>), in order for a consortium to be eligible it has to include, as beneficiaries:

- at least one independent legal entity established in an EU member state, and
- at least two other independent legal entities each established either in a different EU member state or in a Horizon Europe associated country.

In principle, in the context of a single-stage call, constituent and affiliated entities of the IHI JU private members can participate as beneficiaries and are thus counted for the minimum eligibility requirements for the consortium composition.

#### 3. Who is eligible to participate in IHI JU calls?

Any legal entity from EU Members States, HE associated countries, and third countries can participate in IHI JU calls. A notable exception is entities based in Russia, Belarus, or occupied parts of Ukraine, which are barred from participating in IHI calls.

Note however that being eligible to participate in IHI JU calls does not mean that you are eligible to receive funding from IHI JU (see below).

#### 4. Who is eligible to receive funding in IHI JU calls?

Generally, public bodies, non-profit organisations, and those small and medium enterprises ('SMEs/midsized for-profit legal entities') \* that are based in an EU Member State, HE associated countries, or low to middle income non-associated third country\*\*, are eligible to receive funding from IHI JU.

#### Single-Stage

For single-stage calls, any legal entity regardless of its profit/non-profit status or annual turnover, which is established in an EU Member State, HE associated country, or low to middle income non-associated third country, may receive funding from IHI JU.

#### Two-Stage

For two-stage calls, those legal entities described in a) above can receive funding. Large for-profit legal entities (who are larger than SMEs/mid-sized for-profit legal entities\*) cannot receive funding.

- To be considered eligible for funding, such for-profit legal entities must have an annual turnover of less than EUR 500 million\* and must not be directly or indirectly financially and/or legally linked to for profit legal entities with an annual turnover of more than EUR 500 million (downstream or upstream).
- For a list of the identified Low and Middle Income Countries, please consult the List of Participating Countries in Horizon Europe: <u>https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-</u> 2027/common/guidance/list-3rd-country-participation\_horizon-euratom\_en.pdf.
- Pre-identified private members and contributing partners are also not eligible for funding in two-stage calls.
- Lastly, legal entities from non-associated third countries may, under exceptional circumstances, also be considered for IHI JU funding. More specifically, the essentiality will be determined by the panel of experts' evaluators and endorsed by the IHI Governing Board.

\* for the definition of SME, please refer to Commission definition of micro, small and medium-sized enterprises <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32003H0361</u>

## 5. Can legal entities from the United Kingdom (the UK), Canada, Hungary, Japan, Republic of Korea and Switzerland participate in IHI JU actions and can they receive funding?

Entities based in the UK, Canada, Hungary, Japan, Republic of Korea and Switzerland can participate in IHI JU actions. For information on their eligibility for funding please see below.

For the latest list of the Horizon Europe associated countries please visit: <u>https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/list-3rd-country-participation\_horizon-euratom\_en.pdf</u>

#### 5.1 The United Kingdom (the UK) and Canada

With respect to entities based in the UK and Canada, the following approach must be followed:

#### 1. IHI JU Calls 1 – 5:

For calls IHI JU 1-5 the UK and Canadian entities are:

- Eligible to participate in IHI JU actions; but
- Not eligible to receive funding.

#### **Participation**

As a result, in projects under Calls 1-5 the UK and Canadian entities cannot sign the IHI JU Grant Agreement.

Therefore, the UK and Canadian entities <u>cannot</u> participate in projects under IHI JU Calls 1-5 as:

- Beneficiaries; or
- Affiliated Entities.

Because the UK and Canadian entities cannot take the role of Beneficiaries, they **cannot act as coordinators** in actions under IHI JU Calls 1-5.

The UK and Canadian entities may however participate as Associated Partners.

#### Funding

The UK and Canadian entities will not, generally, receive funding from IHI JU under Calls 1-5.

(For entities that are constituent or affiliated entities of either private members or contributing partners of IHI JU, please see the relevant section below).

In case of <u>UK entities</u> under Calls 1-5 they may however be eligible to receive funding from the UK Research and Innovation (**'UKRI**') through the UKRI guarantee fund (see below).

#### UK entities participating in IHI actions under Calls 1-5 and receiving funding from UKRI

The securing of funding from UKRI under Calls 1-5 is the responsibility of the UK entity. IHI JU takes no role in such arrangements. The UKRI, on its website (see link below) has laid out some guidelines for applicants.

The UK entities are urged to review the materials available and contact the UKRI directly for up-to-date information.

For the sake of clarity, you can find herewith the instructions that UKRI is providing to UK applicants, and which are for the moment compatible with IHI policy:

- UK entities should join the applicant consortia, and be described in the proposal, as beneficiaries requesting funding;
- By the GAP stage (in case the proposal is selected for funding and the consortium is thus invited to GAP), if there is no EU-UK association agreement in place, UK entities will be switched from beneficiaries to associated partners.

#### Reminder

It is the responsibility of UK entities to confirm their eligibility and subsequent remuneration from the UKRI guarantee fund under Calls 1-5.

Useful link: UKRI: https://www.ukri.org/apply-for-funding/horizon-europe/apply-for-funding/#contents-list

### UK and Canadian entities participating in IHI actions that are constituent or affiliated entities of either private members or contributing partners of IHI JU and are contributing in-kind or FCs under Calls 1-5.

Legal entities based in the UK and Canada that are providing in-kind or financial contributions to IHI actions as constituent or affiliated entities of either IHI JU private members or contributing partners that are:

• Not eligible for funding in two-stage calls for proposals or;

• Established in the UK (or in a country not generally eligible for funding in accordance with Part B of the General Annexes to the Horizon Europe Work Programme 2023 – 2024).

May exceptionally take the role of beneficiaries (and therefore sign the grant agreement).

The above is contingent upon the following conditions being met (these conditions are cumulative):

- The entity participates without requesting any funding;
- Their participation is considered essential by the granting authority.

The essentiality of the applicant's participation will be ascertained by the IHI JU programme office.

#### 2. IHI JU Calls 6 - 10

For the purposes of Calls 6-10, the United Kingdom and Canada are considered associated countries to Horizon Europe<sup>1</sup>. Therefore, the UK and Canadian entities are treated as any other entity originating from an EU or Horizon Europe associated country.

The UK and Canadian entities <u>are eligible to participate</u>, to receive funding; and to take the role in projects under IHI JU Call 6-10 of:

- Beneficiaries; or
- Affiliated Entities; or
- Associated Partners.

The UK and Canadian entities may also become a coordinator of projects under IHI JU Call 6-10.

In case of contributing partners originating from the United Kingdom and Canada, their contributions will be considered as EU.

#### 3. IHI JU Call 11

Call 11 has some specificities regarding the eligibility of the UK and Canadian applicants to receive funding from IHI JU, depending on the topic.

Topic to which participating legal entities established in the UK and Canada are eligible to receive funding:

• **Call 11 Topic 01**: Towards precision medicine: platform for transdiagnostic stratification of brain dysfunction

The UK and Canadian entities <u>are eligible to participate</u>, to receive funding; and to take the role in projects under IHI JU Call 11 Topic 01 of:

- Beneficiaries; or
- Affiliated Entities; or
- Associated Partners.

They may also become a coordinator of projects under IHI JU Call 11 Topic 01.

<sup>&</sup>lt;sup>1</sup> See List of Participating Countries in Horizon Europe <a href="https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/list-3rd-country-participation\_horizon-euratom\_en.pdf">https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/list-3rd-country-participation\_horizon-euratom\_en.pdf</a>

In case of contributing partners originating from the UK and Canada, their contributions under IHI JU Call 11 Topic 01 will be considered as EU.

Topics to which participating legal entities established in the UK and Canada are not eligible to receive funding:

- Call 11 Topic 02: Understanding how infections foster and induce non-communicable diseases
- Call 11 Topic 03: AI-Powered Signal Detection in Pharmacovigilance
- Call 11 Topic 04: Leveraging Europe's Expertise to accelerate Cell Therapy for Type 1 Diabetes
- Call 11 Topic 05: Establishing Ortho and Cardiology Ambulatory Surgical Centres in Europe

For Call 11 topics 02-05 the UK and Canadian entities are:

- Eligible to participate in IHI JU actions; but
- Not eligible to receive funding.

In projects under Call 11 topics 02-05 the UK and Canadian entities cannot sign the IHI JU Grant Agreement.

However, the UK and Canadian entities may participate as Associated Partners in projects under IHI JU Call 11 Topic 02-05.

Because UK and Canadian entities cannot take the role of Beneficiaries, they **cannot act as coordinators** in actions under IHI JU Calls 11 topics 02-05.

#### Reminder

Under Call 11 topics 02-05 UK entities may be eligible to receive funding from the UK Research and Innovation (**'UKRI'**) through the UKRI guarantee fund.

It is the responsibility of UK entities to confirm their eligibility and subsequent remuneration from the UKRI guarantee fund under Call 11 topics 02-05.

#### 5.2 Hungary

Following the <u>Council Implementing Decision (EU) 2022/2506</u>, as of 16 December 2022, no legal commitments can be entered into with Hungarian public interest trusts established under the Hungarian Act IX of 2021 or any entity they maintain.

Affected entities may continue to apply to calls for proposals. However, as long as the Council of the European Union measures are not lifted, such entities are not eligible to participate in any funded role (beneficiaries, affiliated entities, subcontractors, recipients of financial support to third parties, etc). In case of multibeneficiary grant calls, applicants will be invited to remove or replace that entity and/or to change its status into an associated partner. Tasks and budget may be redistributed accordingly.

Please also see specific information on what are *the entities 'maintained' by public interest trusts* concerned by the Council Implementing Decision 2022/2506 here: <u>https://ec.europa.eu/info/funding-</u> tenders/opportunities/portal/screen/support/faq/22172?keywords=Hungary&isExactMatch=true&status=0&type =0,1&order=DESC&pageNumber=1&pageSize=50&sortBy=publicationDate

#### 5.3 Japan

Currently, Japan is a third country to Horizon Europe and legal entities from Japan are able to participate in IHI JU Calls but are not eligible to receive funding from IHI JU.

#### 5.4 Republic of Korea

#### IHI Call 1-8

In IHI Calls 1-8 the Republic of Korea is considered a third country to Horizon Europe and legal entities from the Republic of Korea can participate in IHI JU's Calls. Legal entities from the Republic of Korea are not eligible to receive funding in IHI Calls 1-8.

#### IHI Call 9-10

Following the successful conclusion of negotiations the Republic of Korea is expected to become an associated country to Horizon Europe with retroactive effect as of 1 January 2025. In the interim the European Commission transitional arrangement will apply.

Under these transitional arrangements, legal entities from the Republic of Korea can both participate and receive funding from IHI JU for award procedures implementing European Union budget for the year 2025 and onwards. This means that legal entities from the Republic of Korea are eligible to both participate and receive funding in IHI JU's Calls 9-10.

In practice, at the proposal submission, legal entities from the Republic of Korea may take the role of beneficiary and request funding as part of an applicant consortium. If by the time of a grant agreement signature, the Association Agreement between the EU and the Republic of Korea is not signed, the legal entities from the Republic of Korea would not be able to take the role of beneficiary in the grant agreement and receive funding from IHI JU. The legal entities from the Republic of Korea would retain the possibility to be part of the consortium and take the role in the grant agreement of an associated partner case A and thereby participate at their own cost.

#### IHI Call 11

Legal entities from the Republic of Korea can participate in actions under IHI Call 11 but are <u>not eligible</u> to receive funding in IHI Call 11. They also <u>cannot</u> act as coordinators in actions under IHI JU Calls 11.

#### 5.5 Switzerland

#### IHI Call 1-8

In IHI Calls 1-8 Switzerland is considered a third country to Horizon Europe and legal entities from Switzerland can participate in IHI JU's Calls 1-8. Legal entities from Switzerland are not eligible to receive funding in IHI Calls 1-8, they also cannot act as coordinators in actions under IHI JU Calls 1-8.

#### IHI Calls 9-10

Switzerland has concluded negotiations to join Horizon Europe: <u>https://research-and-</u> <u>innovation.ec.europa.eu/news/all-research-and-innovation-news/eu-and-switzerland-successfully-conclude-</u> <u>negotiations-horizon-europe-and-euratom-2024-12-20\_en</u>

Switzerland will become an associated country to Horizon Europe with retroactive effect as of 1 January 2025, once the association agreement is signed. Until the signature of the association agreement, transitional arrangements are granted to Swiss applicants. For IHI JU's Calls the transitional arrangements will be applicable for IHI JU's Calls in Call 9-10.

Note that the association agreement is not signed yet and Switzerland is considered a third country till the association agreement is signed and entry into force is finalised. Swiss applicants that decide to participate for

IHI JU Calls 9-10 must be aware that the grant award decision may be conditional on the association agreement's signature finalisation.

In practice, at the proposal submission, legal entities from Switzerland may take the role of beneficiary and request funding as part of an applicant consortium. If by the time of a grant agreement signature, the Association Agreement between the EU and Switzerland is not signed, the legal entities from Switzerland would not be able to take the role of beneficiary in the grant agreement and receive funding from IHI JU. The legal entities from Switzerland would retain the possibility to be part of the consortium and take the role in the grant agreement of an associated partner case A and thereby participate at their own cost.

#### IHI Call 11

Legal entities from Switzerland can participate in actions under IHI Call 11 but are <u>not eligible</u> to receive funding in IHI Call 11. They also <u>cannot</u> act as coordinators in actions under IHI JU Calls 11.

Swiss applicants are welcome to contact the Swiss government directly to inquire about potential funding opportunities. Please note that securing such funding is entirely the responsibility of the Swiss applicant, and IHI JU does not facilitate these discussions or provide guidance on Swiss funding rules.

## 6. In case of a Swiss-based participant, in respect to IHI JU's Calls 1-8 and Call 11, would their budget (which would be Swiss funded, in the case of a successful application) be included in the calculation for the 45% contribution threshold?

Whether it receives funding from the Swiss government or not, in respect to IHI JU's Calls 1-8 and Call 11:

- If a Swiss entity is an IHI JU private member or a contributing partner, its eligible costs can contribute to reaching the 45% contribution threshold. The calculation of its IKOP would not be impacted by the funding received from the Swiss government. Its IKOP would also be considered non-EU IKOP.
- If a Swiss entity is not an IHI JU private member, nor a contributing partner, its costs then could not contribute to reaching the 45% contribution threshold.

For information applicable to Swiss applicants in IHI JU Calls 9-10, please see the answer to the Question 5 above.

#### 7. Can non-profit/public entities contribute in-kind in IHI JU actions?

No, unless they become contributing partners to a particular topic in IHI JU, upon acceptance by the IHI JU Governing Board (see specific questions below).

Consortia applying to single-stage IHI calls must bring 45% of the total project costs as in-kind contributions. These contributions can only come from:

- a. one of the IHI private members, which are the European life science industry, represented by the industry associations COCIR, EFPIA (including Vaccines Europe), EuropaBio and MedTech Europe. Please visit: https://www.ihi.europa.eu/about-ihi/who-we-are/partners;
- b. member of these industry trade association (listed in point a above); or
- c. an affiliated entity of one of the above categories;
- d. or/and contributing partners, (if any). On who are contributing partners, please consult the dedicated website and the IHI JU Guide for contributing partners: <u>https://www.ihi.europa.eu/shape-our-future-research/become-contributing-partner</u>

Please note that contributing partners may not contribute in-kind to additional activities ('IKAA').

#### 8. Can non-profit/public entities contribute to the 45% in-kind threshold for IHI JU actions?

No, unless they become contributing partners. The 45% threshold is satisfied by in-kind contributions and financial contributions from the private members, their constituent entities and affiliated entities of either, and/or by contributing partners (if any). For more information please read the Guide for contributing partners: <a href="https://www.ihi.europa.eu/shape-our-future-research/become-contributing-partner">https://www.ihi.europa.eu/shape-our-future-research/become-contributing-partner</a>.

## 9. Can SMEs contribute in-kind in IHI JU proposal and contribute to the 45% eligibility threshold?

SMEs are expected to request their costs to be reimbursed in an IHI project (if they fulfill the eligibility criteria to receive EU funding).

In case SMEs are private members (i.e. members of the following trade associations: EFPIA, COCIR, EuropaBio or MedTech) or affiliates to such private members (i.e. if they have a legal/financial link with those entities), they can (also) contribute in-kind and/or cash to an IHI proposal which counts as part of the 45% industry contribution (necessary threshold to be reached for a proposal to be eligible). In such a case, their IKOP is calculated as being their total eligible costs, minus their requested EU funding.

But if SMEs are neither private members nor contributing partners they cannot contribute in-kind and/or cash and therefore cannot contribute to the 45% threshold.

#### 10. Is the 45% contribution at project level?

Yes, 45% of each action's eligible costs and the costs of its related additional activities must come via contributions from the private members, constituent entities or affiliated entities of either, and/or by contributing partners.

#### (IKOP + FC + IKAA) ≥ 45% of action's (eligible costs + IKAA)

This 45% contribution threshold can be reached with one or several types of contribution (IKOP, IKAA, FC).

This threshold is an eligibility criterion. If it is not reached collectively by IHI private members and/or contributing partners, the concerned (full) proposal will be considered ineligible and will not be evaluated. The annex to the budget of IHI proposals – or full proposals in two-stage calls - calculates automatically if the concerned (full) proposal reaches the 45%.

While the minimum threshold for proposals to be considered eligible is set at 45% contribution, consortia are strongly encouraged to aim at having 50% of the action's eligible costs and costs for action related additional activities provided by the industry consortium participants.

This prudent approach is to ensure the 45% threshold is maintained during the project implementation (eligibility criterion), despite any possible changes in the consortium composition and/or in the total contributions from IHI private members and/or contributing partners.

#### 11. How does my organisation become a contributing partner?

Legal entities wishing to become contributing partners must submit a written application letter setting out the details of their organisation, their support to the objectives of IHI JU in the specific call topic, and the nature of their proposed contribution, in accordance with the compulsory template. The applications are reviewed by the IHI JU Governing Board and, if it is accepted, the applicant is confirmed as a contributing partner to IHI JU for the specific topic.

In single-stage calls in order for the in-kind contributions from a contributing partner to be counted towards the 45% threshold, a signed application letter must be submitted as a part of the proposal that is submitted by the applicant consortia and uploaded in the appropriate section of the submission environment of the Funding and Tender portal.

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 <u>one pdf document</u> containing all the contributing partners' application letters.

For further detailed instruction on the submission of the application letter and the compulsory templates please visit the dedicated contributing partners webpage and read the Guide for contributing partners: https://www.ihi.europa.eu/shape-our-future-research/become-contributing-partner.

#### 12. Which organisations cannot become IHI JU contributing partners?

IHI JU private members, their constituent or affiliated entities cannot be contributing partners. Therefore, 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. The <u>websites of our private members</u> include the lists of their corporate members, national or regional associations and other entities which are the constituent and affiliated entities of the private members.

For information on IHI JU contributing partners please read the Guide for contributing partners: <u>https://www.ihi.europa.eu/shape-our-future-research/become-contributing-partner</u>.

#### 13. When will I know whether my proposal has been successful?

All applicant consortia will be notified between 3 and a maximum of 5 months from the proposal submission deadline.

# 14. We note that the 3A provisions ('Affordable, Available, Accessible') will apply to some call topics. Which calls do they apply to and how should these be addressed by the applicant consortia in the proposals?

According to the Council Regulation establishing IHI JU: 'Participants to indirect actions funded by the Innovative Health Initiative Joint Undertaking must ensure that the products and services that they develop based or partly based on the results of clinical studies undertaken as part of an indirect actions are affordable, available and accessible to the public at fair and reasonable conditions.'

These 'Affordable, Available, and Accessible' provisions only apply to certain IHI JU call topics. In each call topic the text a) specifies whether or not these provisions apply to the specific topic, and b) details any specific conditions that are imposed by this designation.

At the proposal stage, and as part of the Plan for the Dissemination, Exploitation, and Communication Activities ('PDECA') which forms part of the proposal, the applicant consortium must identify potential and expected project results that may be subject to the 3A conditions and broadly outline their strategy to achieve the above objectives. For the 3A specific projects, the 3A content in the PDECA will be checked during the evaluation stage.

For more information on the 3A provisions please see the <u>Guide for Applicants</u> and the relevant IHI JU Work Programme.

## 15. Can for-profit entities, that are not part of the pre-identified industry consortium, participate in the two-stage calls as part of the applicant consortium? Can they receive funding?

For two-stage calls, for-profit entities that are not part of the pre-identified industry consortium may participate as part of the applicant consortium.

These for-profit entities can receive funding if (these conditions are cumulative):

- i. They are established in a Member State, an associated country, or a low to middle income third country;
- ii. They qualify as SMEs or as mid-sized companies. See relevant <u>checklist</u> for assessing IHI JU eligibility for funding of companies having an annual turnover of less than EUR 500 million

If these for-profit entities are large companies with an annual turnover of EUR 500 million or more, or companies directly or indirectly legally and/or financially linked to for-profit legal entities with an annual turnover of EUR 500 million or more, they are not eligible to receive funding in two-stage calls.

### 16. For single-stage call topics, how many projects can be funded and is there a minimum IHI JU contribution threshold?

For single-stage calls, this depends upon the total budget that is available to the topic, and the amounts requested by the highest ranked successful applicant consortia. There are no pre-defined minimum IHI Ju financial contribution thresholds. The respective topic mentions an estimated IHI JU financial contribution that would allow a proposal to address the defined outcomes appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

### 17. In IHI calls, is there a requirement to have an academic coordinator and one industry leader?

There is no such requirement. However, it is important that the consortium considers on how to best reflect the public-private partnership nature of IHI JU in the allocation of the consortium roles, for example via dual leadership of the work packages, including the appointment of a scientific leader. – please refer to the Guide for Applicants section 8 points to remember consortium roles.

#### 18. Where can I find the links to the webinars on IHI JU's calls for proposals?

The links to the webinars of IHI JU's calls for proposals can be found on IHI website at the corresponding events' section.

#### 19. What is the rate of indirect costs and how does it apply?

The indirect cost flat rate of 25% is automatically calculated for all beneficiaries that will be signing the grant agreement and for all affiliated entities, so also for IHI JU private members and contributing partners.

The indirect cost flat rate is calculated by the tool as 25% of the eligible direct costs (excluding volunteers costs, subcontracting costs, and cost for internally invoices goods and services, if any).

### 20. How do I know if my organisation is an IHI JU private member who may contribute towards the 45% threshold?

IHI JU has 4 private members – COCIR, EFPIA (which includes Vaccines Europe), EuropaBio, Medtech – these are the trade associations.

If your organisation is a member of one of these associations (listed above) or has a legal/financial link with them, you may be considered a 'constituent entity' of that Private Member or an 'affiliated entity' of the Private Member– providing that this is confirmed by that respective private member.

For such confirmation, please contact the IHI JU private member in question.

IHI JU office does not provide lists of membership of the IHI JU private members.

#### 21. How to calculate personnel costs under Horizon Europe's rules?

Personnel costs can include:

- Actual or unit costs for employees or equivalent,
- Actual costs for natural persons who have a direct contract other than an employment contract,
- Actual costs for seconded personnel,
- Unit costs for the work of SME owners without a salary.

The most common case is the cost of e Entities can use average personnel costs (if in line with their usual cost accounting practices) or actual personnel costs (as per HE calculation). In both cases, personnel costs must exclude any indirect costs as indirect costs are automatically calculated by the tool (25% flat rate).

E.g.: entities using a fully loaded FTE rate (which usually includes indirect costs) for calculating average personnel costs following their usual cost accounting practice must recalculate their rate to exclude any indirect cost. Their personnel costs will then automatically be multiplied by 1.25 as part of the 25% indirect cost calculation.

Examples of calculation methods for personnel costs are included in the <u>EU Grants - annotated model grant</u> agreement

## 22. Is there a deadline to apply to become an IHI JU contributing partner in single-stage calls?

The answer will depend on whether the contributing partner wishes to have their contribution counted towards the 45% threshold. In **single-stage calls** in order for the in-kind contributions from a contributing partner to be counted towards the additional eligibility criterion of 45% (see 2.3.4.3 IHI JU <u>Guide for Applicants</u>), a duly executed and signed contributing partner application letter must be submitted as a part of the proposal that is submitted by the applicant consortia and uploaded in the appropriate section of the submission environment of the Funding and Tender portal.

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 or is not submitted as a part of the proposal in the submission environment of the Funding and Tender portal, at the evaluation stage, its contribution will not be counted towards satisfying the 45% in-kind eligibility criterion for the proposal in question.

For further detailed instruction on the submission of the application letter and the compulsory templates please visit the dedicated contributing partners webpage and read the Guide for contributing partners: <u>https://www.ihi.europa.eu/shape-our-future-research/become-contributing-partner</u>.

## 23. If a proposal has 40% of non-EU in-kind contributions, is it still eligible in a call that sets a lower threshold for non-EU in-kind contributions? And if the proposal is selected for funding, what are the consequences at grant preparation phase?

In a Call for proposals for which IHI JU has set a specific non-EU IKOP threshold, like IHI JU Call 5 where the non-EU IKOP maximum percentage is set at 30% to individual projects, a proposal featuring 40% of non-EU IKOP will still be considered eligible and can be evaluated (as long as all other admissibility and eligibility criteria are met). However, when such a proposal is selected for funding and invited to the grant preparation phase, the consortium will be asked to remove the exceeding 10% and this reduction must not compromise the fulfilment of the 45 % contribution eligibility criterion. If this would happen, the proposal would be considered ineligible, with the immediate consequence of stopping the grant preparation phase.

#### 24. Can data and software be considered in-kind contribution (IKOP or IKAA)?

In order to be eligible, costs must fulfil the costs eligibility conditions specified in Articles 6.1 and 6.2 of the annotated HE grant agreement. This applies to costs to be reimbursed as well as to costs valorised as in-kind contribution to operational activities (IKOP).

These general eligibility conditions clearly specify, among others, that costs should be actual, recorded in the accounting system of the concerned entity, identifiable and verifiable and incurred during project implementation (i.e.; between the start date and the end date of the project).

While data may have a lot of value, it is only the actual cost of data that can be reported as IKOP, such as costs of extracting, transferring, harmonizing, reworking these data. Additionally, related data costs must be incurred during the project lifetime. As a result, costs related to existing data, hence linked to events prior to the start of the project, are not eligible.

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 as IKOP. Valorising the use of this software by the consortium with licence fees is not acceptable as licence fees include a profit margin, are not actual costs for the entity and are not recorded in the accounting system of the entity.

Note that for in-kind contributions to additional activities linked to an IHI project (project-specific IKAA), the simple principles apply, however, the timeframe of cost eligibility starts from full proposal submission date and ends up to 2 years after project end date. Additionally, Article 6 of the HE MGA do not apply, however, costs should be calculated as per the usual cost accounting practices of the private member, should be recorded in the accounting system of the entity and must be auditable (i.e. documented, supported with evidence). For more information about IKAA, please see the relevant guidelines <u>here</u>.

#### 25. Should I become a beneficiary or a contributing partner? What is the difference?

A **contributing partner** is an entity that wishes to contribute to the IHI JU strategic goals and to a particular project.

A **beneficiary** is a type of participant to a project, along with affiliated entity, associated partner and various third parties. A contributing partner may take up in a project the role of a beneficiary or an affiliated entity or an associated partner. The same applies to IHI JU private members. Beneficiaries may either contribute in-kind and/or cash (if the entity is a private member or a contributing partner); either request funding (if the entity is eligible for receiving funding) or do both (those entities that are private members or contributing partners are called 'hybrid' participants).

The primary role of **a contributing partner** is to invest its own resources (which can be researchers' time, laboratories, data) or cash in a specific IHI JU project or projects. A contributing partner, when taking a role of a beneficiary also signs the grant agreement. Contributing partners in single-stage calls also may request funding

if eligible to receive funding. In two-stage call contributing partners are not eligible to receive funding as members of the pre-identified consortium listed in the call topic text.

Please note that applying to become a contributing partner requires following the process described in the <u>Guide</u> <u>for contributing partners</u> which includes an application letter and approval from the IHI Governing Board. Furthermore, in such application process an applicant contributing partner needs to demonstrate the relevance and potential added value of the proposed contribution (scientific relevance, activities in the context of a public private partnership, duration and nature of contributions) of the applicant contributing partner for the achievement of the IHI JU project.

Therefore, please note the difference between having contributors included in a consortium (to satisfy the 45% requirement) and contributing partners which are a specific type of contributors which may be included in a consortium but only if deemed that they would strategically contribute to the achievement of the proposal objectives but also to the overall objectives of IHI JU. Furthermore, we would like to underline that it is expected that all IHI projects are public-private partnerships including industry contributors.

For more information please read the Guide for contributing partners: <u>https://www.ihi.europa.eu/shape-our-future-research/become-contributing-partner</u>.

#### 26. Are there any criteria for assessment of the contributing partners applications?

The IHI JU Governing Board assesses and accepts or rejects applications of prospective contributing partners. For the description of the process and applicable criteria please see chapter 4 of the Guide for contributing partners: <a href="https://www.ihi.europa.eu/shape-our-future-research/become-contributing-partner">https://www.ihi.europa.eu/shape-our-future-research/become-contributing-partner</a>.