

# 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 10 has been updated
3	15/12/2022	Minor adaptations, additional questions added
4	20/07/2023	Added Questions 20, 21, 22 and 23

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 Call Documents page and, in particular, in the Guide for Applicants.

#### 2 Which are the specific actors in IHI JU?

**Private member** means European life science industry associations: 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.

**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).

#### 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?

a. Generally, public bodies, non-profit organisations, and those small and medium enterprises ('SMEs/mid-sized 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

b. 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

- c. 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: <a href="https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/quidance/list-3rd-country-participation horizon-euratom en.pdf">https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/quidance/list-3rd-country-participation horizon-euratom en.pdf</a>.
- Pre-identified private members and contributing partners are also not eligible for funding in two-stage calls.
- d. Lastly, legal entities from non-associated third countries may, under exceptional circumstances, also be considered for IHI JU funding.

# 5 Can legal entities from the UK and Switzerland participate in IHI JU actions and can they receive funding?

Entities based in the UK and Switzerland can participate in IHI JU actions. However, the situation regarding their eligibility for funding is different.

The UK and Switzerland are not currently associated countries to Horizon Europe, nor are they low to middle income countries. The association negotiations with the UK are still ongoing. Details can be found here: <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>

Here you may also find the latest updates on Horizon Europe association negotiations: <a href="https://ec.europa.eu/info/news/updates-association-third-countries-horizon-europe en decomposition-third-countries-horizon-europe en decomposition-europe en decomposition-euro

#### UK

In light of the ongoing negotiations and to provide for the conclusion of an association agreement between the UK and the EU, UK participants are currently considered eligible for funding in IHI JU actions. This will, however, be reviewed at grant agreement signature.

Consortia therefore that contain UK participants should plan for those participants to possibly be deemed ineligible for IHI JU funding at Grant Agreement signature, depending on the outcome of the association negotiations – please refer to the Guide for Applicants Annex III.

#### **Switzerland**

Switzerland's association to Horizon Europe is not considered imminent, therefore participants from Switzerland are not eligible to receive funding from IHI JU. Swiss participants may however be able to receive funding from their national authorities.

For more information on IHI JU funding please visit the website <a href="https://www.ihi.europa.eu/apply-funding">https://www.ihi.europa.eu/apply-funding</a>

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

Yes, but the non-profit/public entities would be required to become a Contributing Partner.

By default, in-kind can be contributed only by the constituent and affiliated entities of IHI JU private members (which means constituent and affiliated entities of COCIR, EFPIA, EuropaBio, MedTech Europe, and Vaccines Europe) or/and by IHI JU contributing partners. Please note that contributing partners may not contribute in-kind to additional activities ('IKAA').

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

Non-profit/public entities have the option to become contributing partners to a particular topic in IHI JU, where, upon acceptance by the IHI JU Governing Board (see specific question below), the contributing partner could contribute financially or in-kind.

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

No, unless they are 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.

#### 8 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.

While the minimum threshold for proposals to be considered eligible is set at 45%, 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.

#### 9 How does my organisation become a contributing partner?

Legal entities wishing to become contributing partners must submit a written application letter to the IHI JU programme office, 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. This application is then 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 via <a href="mailto:em

Further information on contributing partners and templates of the application letters can be found on the IHI JU webpage, <u>Become a contributing partner</u>.

#### 10 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.

# 11 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.

# 12 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 that apply for the two-stage call? Can they receive funding?

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

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

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.

## 13 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.

# In single-stage 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.

#### 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 at the corresponding events' section.

#### 16 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, 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).

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

IHI JU has only 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.

#### 18 How to calculate Personnel costs under Horizon Europe's rules?

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).

As a result, entities using a fully loaded FTE rate (which 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.

# In case of a Swiss-based participant, 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?

If a Swiss entity is an IHI JU private member or a contributing partner, their eligible costs can contribute to reaching the 45% contribution threshold.

If a Swiss entity is not an IHI JU private member, nor a contributing partner, their costs then would not be factored into considering in-kind whether they receive funding from the Swiss government or not.

#### 20 Which organisations cannot become IHI JU Contributing partners?

Private members, their constituent or affiliated entities cannot be contributing partners. Therefore, before applying to become a contributing partner, we suggest checking with the IHI JU private members that your organisation does not qualify as a constituent or affiliated entity of a private member. More information on IHI JU contributing partners is available in this guide.

## 21 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 and received by IHI JU Programme Office in advance of the proposals' submission 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.

Further information on contributing partners and templates of the application letters can be found on the IHI JU webpage: <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>

# 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, 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 % eligibility criterion. If this would happen, the proposal would be considered ineligible, with the immediate consequence of stopping the grant preparation phase.

#### 23 Can 'data' be considered in-kind contribution (IKOP or IKAA)?

While data may have a lot of value, it is only the actual cost of data that can be reported as in-kind contribution to operational activities (IKOP). For this reason, related data costs must be incurred during the project lifetime (from project start date to project end date), such as costs of extracting and/or reworking data. For more details about cost eligibility, please see <a href="art.6">art. 6</a> of the MGA. Costs related to existing data, hence linked to events prior to the start of the project, are not eligible. Note that for in-kind contributions to additional activities linked to the action (IKAA), the timeframe of cost eligibility starts from full proposal submission date and ends up to 2 years after project end date. For more information about IKAA, please see the relevant guidelines <a href="here">here</a>. In general, costs must be recorded in the accounting system of the entity that declares it as an in-kind and must be auditable.