



- Call 9
Single Stage call

Rules and Procedures

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Online - 15 January 2025

Before we start...

- We are recording this session and it will be published on the IHI website. We will also publish the presentation slides.
- The call will be launched shortly and all links and details of how to apply will be published on the IHI website and the Funding and Tenders Portal.
- If you want to ask a question please use the Q&A function on the right corner of your screen.

Outline



Participation rules



Funding rules



Intellectual property rules



From call to grant award



Call timelines



Points to remember



- Participation rules

Single-stage procedure

Call launch

Topic texts are approved by the IHI Governing Board, as part of the Annual Work Programme

Single-Stage Submission of Full Proposal

Evaluation process

Full Consortium (Public & Private Partners & CP)

- Academics
- Hospitals
- Regulators
- Patients' Organisations
- For-profit legal entities (SMEs and larger enterprises)

Granting phase



Signature of Grant Agreements
(between project coordinator and IHI JU)

Signature of Consortium Agreements
(between partners)

Project launch! 



IHI Call 9 - Overall objective

Boosting innovation for a competitive European health ecosystem



Overall objective



To fund pre-competitive research and innovation actions that are in line with the general objectives of IHI and address at least one of IHI specific objectives as set out in the IHI [Strategic Research and Innovation Agenda \(SRIA\)](#)

IHI Call 9 - Topics

Five topics, each focusing on one of the five IHI JU Specific Objectives (SOs)

T1 (SO1): contribute towards a better understanding of the determinants of health and priority disease areas

- T2 (SO2): integrate fragmented health research & innovation efforts bringing together health industry sectors and other stakeholders, focusing on unmet public health needs, to enable the development of tools, data, platforms, technologies & processes for improved prediction, prevention, interception, diagnosis, treatment and management of diseases, meeting the needs of end-users
- T3 (SO3): demonstrate the feasibility of people-centred, integrated healthcare solutions
- T4 (SO4): exploit the full potential of digitalisation and data exchange in healthcare
- T5 (SO5): enable the development of new and improved evaluation methodologies and models for a comprehensive assessment of the added value of innovative and integrated healthcare solutions.

Highlights

- The General Annexes of the Horizon Europe Work Programme 2023-2025 shall apply *mutatis mutandis* to the call 9.
- **Indicative contribution:** For each topic, the maximum JU contribution is set in the call text
- **Applicant consortia must ensure that at least 45%** of the action's eligible costs and costs for additional activities related to the action are provided by contributions (IKOP, FC, IKAA) from private members which are members of IHI JU, their constituent or affiliated entities, and/or from contributing partners;
- **Non-EU IKOP is capped at 20%.** Proposals that exceed such threshold can be funded but during the Grant preparation phase, the non-EU IKOP must be reduced to maximum 20%. This reduction must not affect the fulfilment of 45% contribution (in term of IKOP, IKAA and/or FC paid)*.

Highlights


- For a single-stage call, the **page limit for RIA full proposals is 50 pages**;
- Applicants envisaging including **clinical studies** must provide details of their clinical studies in the dedicated annex using the template provided in the submission system
- Public bodies, research organisations and higher education institutions, from EU Member States and associated countries, **must have a Gender Equality Plan (GEP) or equivalent strategy** in place to be eligible for funding (self-declaration at proposal stage (Part A) and confirmation during the GAP for the successful proposals).
- Plan for Dissemination, Exploitation and Communication Activities (**PDECA**)

Highlights

Affordability, availability and accessibility of results

Products and services developed based or partly based on the results of clinical studies should be **affordable**, **available** and **accessible** to the public at fair and reasonable conditions (the “3A”).

- 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.
- More info on the participants' obligations with regards to the 3A implementation during the life-time of the project and for a period of four years after project end, can be found in the IHI Work Programme 2025

- 
- Eligibility: consortia;
to participate;
to receive funding.

IHI Joint Undertaking: Eligibility

Basics of Eligibility for IHI JU Actions

IHI JU projects are undertaken by consortia.

Consortia in IHI JU projects are composed of *eligible* 'legal entities' drawn from health research and treatment sectors.

Aspects of Eligibility

- What is a 'legal entity'?
- How to ensure that a consortium is eligible to participate in IHI actions?
- When is a legal entity eligible to participate in IHI JU actions?
- When is a legal entity eligible to receive funding in IHI JU actions?

IHI Joint Undertaking: Eligibility

What is a legal entity?

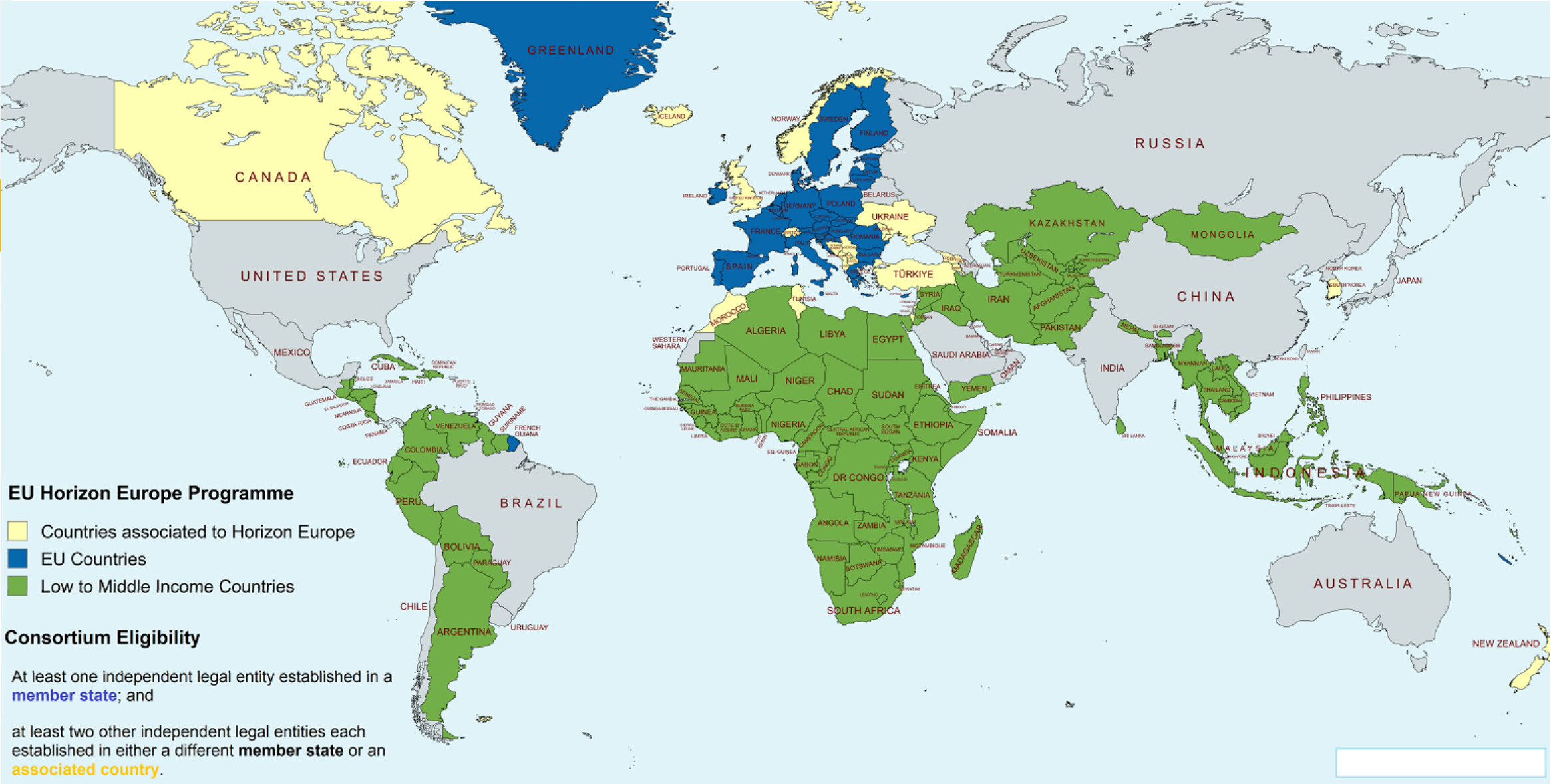
'legal entity' means a natural person, or a legal person created and recognised as such under Union, national or international law, which has legal personality and the capacity to act in its own name, exercise rights and be subject to obligations, or an entity which does not have legal personality as referred to in point (c) of Article 197(2) of the Financial Regulation; [Horizon Europe Regulation, Article 2]

How to ensure that a consortium is eligible to participate in IHI actions?

- 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 a **Horizon Europe Associated Country***.

IHI Joint Undertaking: Eligibility

MSs, ACs, LMICs, and non-Associated Third Countries



IHI Joint Undertaking: Eligibility

Eligibility to Participate

‘Any legal entity, regardless of its place of establishment and including legal entities from non-associated third countries or international organisations, may participate in actions under the Programme...’ [*Horizon Europe Regulation, Article 22.1*]

Eligibility to Receive Funding

In general,* legal entities are entitled to receive funding from IHI JU if they:

- Are established in a Member State of the European Union (‘MS’), or;
- Are established in an Associated Country** (‘AC’), or;
- Are established in a Low to Middle Income country (‘LMIC’).

* Eligibility for funding is determined by the type of IHI JU call

** Canada (from 2023) and United Kingdom [‘UK’] (from 2024) are considered Associated Countries for IHI JU.



IHI Joint Undertaking: Eligibility

Third Countries

Legal entities from non-associated Third Countries do not count towards the above (but these entities are eligible to participate).

Examples of non-associated Third Countries:

- Australia;
- United States of America ('USA').

Exceptional Funding

Legal entities established in non-associated Third Countries may, in exceptional circumstances, receive funding from IHI JU when the legal entity's participation is considered essential (for example, access to particular expertise, data etc.)

IHI Joint Undertaking: Eligibility

Special rules apply for legal entities from certain countries

Ukraine

Given the invasion of Ukraine by Russia and the involvement of Belarus:

- Legal entities established in Russia, Belarus, or in non-government-controlled territories of Ukraine are not eligible to participate in any capacity (*beneficiaries, affiliated entities, associated partners, third parties giving in-kind contributions, subcontractors or recipients of financial support to third parties*)

Hungary

Council Implementing Decision (EU) 2022/2506 on measures for the protection of the Union budget against breaches of the principles of the rule of law in Hungary that took effect on 16 December 2022.

- No European funds are made available, directly or indirectly, to third parties that are public interest trusts established on the basis of the Hungarian Act IX of 2021 or any entity maintained by such a public interest trust. This concerns legal commitments involving Union funding e.g. related to:
 - the purchase of goods, works or services; subcontracting; financial support to third parties; equipment renting or leasing; personnel seconded against payment.

Funding rules



IHI JU Specific types of Participants

Private members (PM) COCIR, EuropaBio, MedTech and EFPIA (including Vaccines Europe):

Constituent entities (CE) are the entities constituting the Industry Associations according to their statutes.

Affiliated entities (AE) are the entities with a capital or legal link with a beneficiary (which is in this case a private member or a private member constituent entity)



Contributing Partners (CP) are legal entities interested in supporting IHI JU's objectives in their specific areas of research, without becoming an IHI member; they participate in the Consortium and provide in-kind to operational activities (IKOP) and/or financial contributions (FC), but not in-kind contributions to additional activities (IKAA), contrary to private members.

Contributing Partners (CPs) in IHI Call 9

Who may apply to become a CP:


Any country, international organisation or legal entity other than a member of IHI JU, which:

- will contribute to the strategic and specific objectives of IHI JU in its specific area of research, on an ad hoc basis,
- will accept the legal framework of IHI JU and submit a letter of application, that details the scope of their engagement in terms of contribution (in-kind and/or cash),
- will observe the deadline and the process for submitting the application letter (please see our CP Guide for detailed information), and
- their application is accepted by the IHI JU Governing Board.

Before you apply to become a CP:

- Make sure that your legal entity is not affiliated directly or via a regional or national or local organisation to an IHI JU private member (COCIR, EFPIA (including Vaccines Europe), EuropaBio and MedTech Europe). For more info visit the websites of the IHI private members.
- Visit the IHI website and read the IHI Guide on CPs and especially the section on '*Applying to become a CP in single-stage calls*':
<https://www.ih.europa.eu/shape-future-research/become-contributing-partner>
- Make sure that your in-kind contribution is eligible in accordance with Article 6 of the Grant Agreement.

In particular, the costs should be actual, recorded in the accounting system of the concerned contributing partner, identifiable and verifiable and incurred during project implementation.

 Prospective contributing partners **must submit their applications as a part of the proposal through the submission portal by the call submission deadline. NEW!**

Contribution types

- **IKOP** - In-kind contributions to operational activities

Eligible costs incurred in implementing an IHI project

Can be Non-EU IKOP or EU IKOP

- **FC** - Financial contributions

Cash contributions to project beneficiary(ies) from the same consortium to support eligible costs for project implementation

- **IKAA** - In-kind contributions to Additional Activities

Costs for implementing additional activities

Private members



Contributing Partners



Private members, their constituents or affiliated entities can contribute IKOP, IKAA and FC.

Contributing partners can contribute IKOP and FC, not IKAA.

45% Eligibility Criterion

- Costs related to contributions (IKOP, IKAA and/or Financial contribution) provided by IHI JU private members and IHI JU Contributing partners, their constituent entities and affiliated entities if any, shall amount to at least **45% of the sum of [total project eligible costs plus IKAA]**.
- **Reminder: Contributing Partners cannot provide IKAA**
- Coordinator of (full) proposal must submit a Declaration to confirm that the required 45% contributions will be provided



(IKOP + IKAA + FC) must be \geq 45% of (Project eligible costs + IKAA)

IHI Annex on Budget and Type of participants
automatically calculates the 45%

If the 45% Industry contribution is not secured collectively by the private members and/or contributing partners, the proposal will be declared ineligible and therefore will not be evaluated

IHI JU office will verify the 45% contributions prior to the GA signature

45% Eligibility Criterion

- 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.

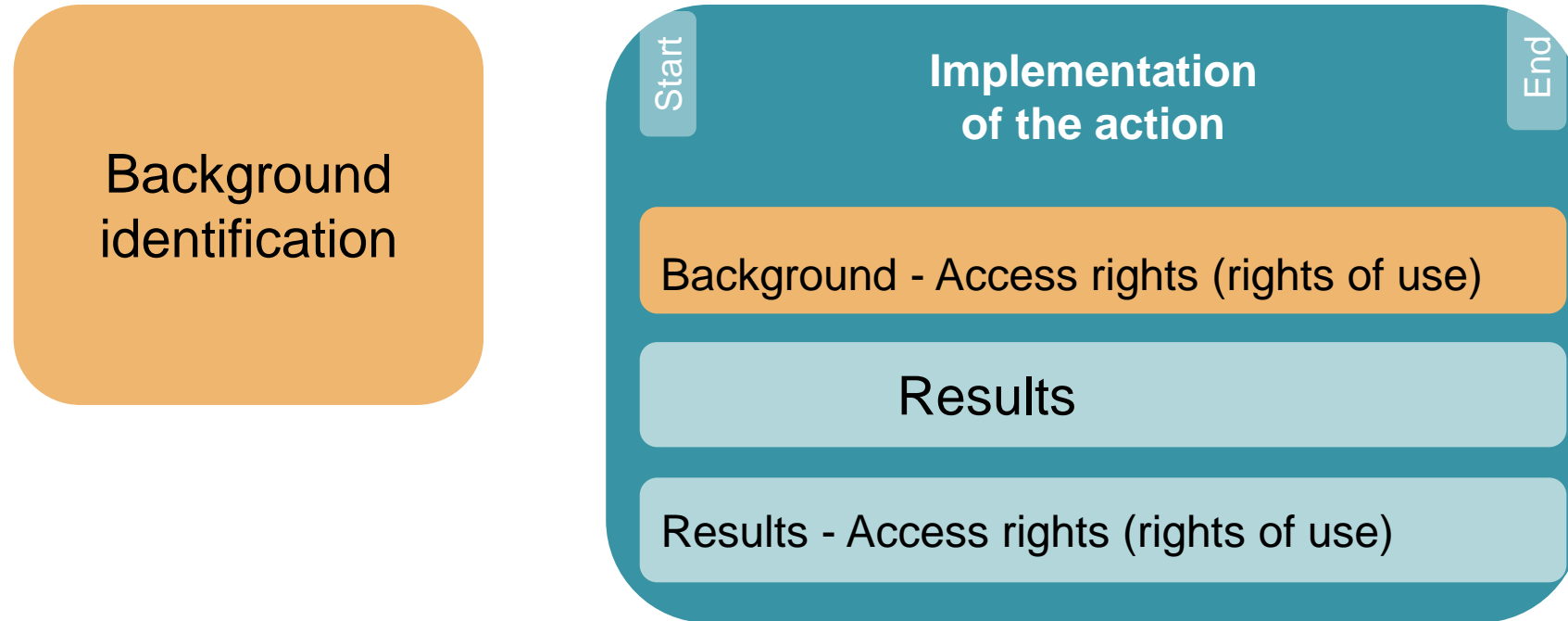


- This prudent approach is to ensure the 45% threshold is maintained during the project implementation (eligibility criterion), despite any possible changes in the consortium composition and/or in the total contributions from IHI private members and/or contributing partners (if any).



- Intellectual Property Rights ('IPR') in IHI

Snapshot of key IP concepts for IHI Actions



Background: As defined in the MGA (Article 16.1), “‘Background’ means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that is:

- (a) held by the beneficiaries before they acceded to the Agreement and
- (b) needed to implement the action or exploit the results”.

Results: any tangible or intangible effect of the action, such as data, know-how or information, whatever its form or nature, whether or not it can be protected, as well as any rights attached to it, including intellectual property rights

Access Rights: define who and when can use Background and Results

IHI Joint Undertaking: Intellectual Property

Points to note on IHI IP*

- IHI IPR rules derived from:
 - Horizon Europe Model Grant Agreement ('MGA') Article 16;
 - supplemented by specific rules identified in HE MGA Annex 5 and;
 - where relevant, the applicable call conditions.
- IHI JU maintains right to object to transfers of ownership of results or to grants of exclusive licences.
- Affordable Access Provisions can, when provided for in the call conditions, introduce additional exploitation obligations for relevant IHI topics;
- Results Ownership List ('ROL') to be submitted at project end as part of final periodic report listing all results and ownership of them (including joint ownership structures).
- Emphasis on Exploitation and Open Science:
 - HE MGA integrates Open Science dissemination model;
 - Unexploited project results can be matched with interested parties via the Horizon Results platform.

From call to grant award



Proposal templates and annexes

Proposal template – Part A (*generated by the IT system - includes information on the proposal, details of the participants, the budget, information on ethics and security, information on clinical studies*).

Proposal template – Part B (narrative part - pdf to be uploaded into the portal) – **compulsory**

Annex: Contributing Partners application/s - optional annex (**NEW**)

Annex: Declaration of in-kind contribution commitment - **compulsory annex**

Annex: In-kind contributions to additional activities - optional annex

Annex: Essential information for clinical studies - **compulsory annex**

Annex: Budget and Type of Participants - **compulsory annex** (**NEW**)

Annex: Ethics (no template) - optional annex –

provide more information, if necessary, that goes beyond the ethics self-assessment in Part A

Evaluation criteria and thresholds

- Minimum of 3 independent experts
- Each proposal evaluated 'as it is', not as 'what could be'
- Sub-criteria listed in evaluation form

Criteria	Threshold
Excellence	3/5
Impact	3/5
Implementation	3/5
TOTAL	10/15

Ex aequo proposals

For proposals with the same score within a single budget envelope the method to establish the priority order is as follows:

Starting with the group achieving the highest score and continuing in descending order:

- 1) Proposals that address aspects of the call that have not otherwise been covered by more highly ranked proposals will be considered to have the highest priority.
- 2) The proposals identified under 1), if any, will themselves be prioritised according to the scores they have been awarded for 'Excellence'. When those scores are equal, priority will be based on scores for 'Impact'.
- 3) Proposals that include the highest number of IHI JU private members and constituent and affiliated entities of the IHI JU private members.
- 4) Proposals that provide the highest percentage of contributions (IKOP, IKAA and financial contributions) from the IHI JU private members and/or contributing partners and the constituent and affiliated entities of both, of the proposal's eligible costs and costs for the related additional activities.
- 5) If necessary, the gender balance among the researchers named in the researchers table in the proposal, will be used as a factor for prioritisation.

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- Grant Agreement & Consortium Agreement

IHI Joint Undertaking: Grant & Consortium Agreements

Grant Agreement ('GA')

- The new Horizon Europe Model Grant Agreement 'HE MGA' includes 44 articles, as well as specific Annexes.
- IHI JU follows HE MGA with IHI JU specificities reflected in Annex 5.
- It is e-signed between IHI JU and Coordinator only. Other beneficiaries e-sign Accession Forms.

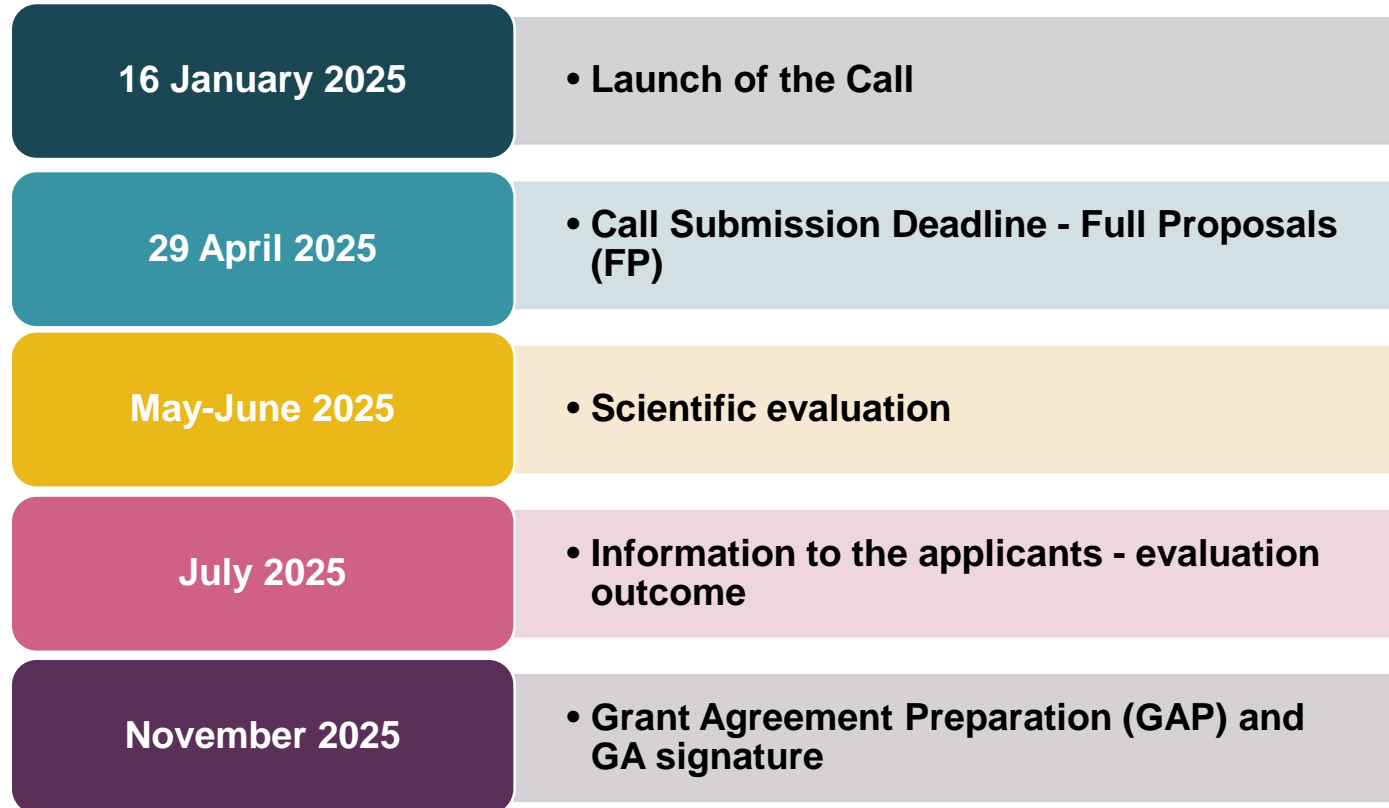
Consortium Agreement ('CA')

- Contractual arrangement between all participants to set out their rights and obligations, especially governance, liability and IPR.
- IHI JU is not a party/signatory to the CA.
- The terms of the CA must with the HE MGA (no conflict/contradictions).
- To be adapted to the specific needs of each IHI JU action.
- To be fully agreed before the signature of the IHI JU action's grant agreement.
- Templates:
 - One template has been prepared by IHI JU private members specifically for IHI projects ([here](#));
 - DESCA (Development of a Simplified Consortium Agreement) ([here](#)), not tailored to IHI specificities.

Timelines



Call 9 – single stage



Points to remember

- Read all the call-relevant material: www.ihl.europa.eu
- Begin forming your consortium early. Read the topic text. Check the IHI website and F&TP.
- Ensure that all information is explicitly described in order to allow the expert-evaluators to assess against the evaluation sub-criteria. **Respect the page limit – 50 pages.**
- Use the **proposal structure / template**
- Plan the **45% In kind contribution and aim at 50%**. This is the responsibility of the entire consortium.
- **Non-EU IKOP is capped at 20%**. Proposals selected for funding that exceed such threshold will be required to reduce non-EU IKOP accordingly in a way to not affect the fulfilment of 45% contribution (in term of IKOP, IKAA and/or FC paid).

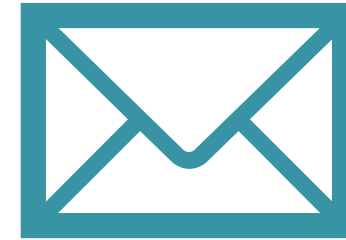
Points to remember

- **Contributing partner:**
 - ✓ **strategic relevance:** demonstrate relevance and potential added value of their proposed contribution for the achievement of the objectives of the IHI JU project
 - ✓ costs incurred by contributing partners in implementing IHI projects fulfil the eligibility criteria as specified in the Article 6.1 of the HE MGA
 - ✓ Make sure that your legal entity is **not affiliated** directly or via a regional or local organisation **to an IHI JU private member** (COCIR, EFPIA (including Vaccines Europe), EuropaBio and MedTech Europe)
- Complete accurately the following since it might impact the final ranking (in case of equal score)
 - ✓ **Budget and Type of Participants**
 - ✓ **Researchers table** (Proposal Part A) and ensure a gender balance.
- Don't forget the **Gender Equality Plan (GEP)** is an eligibility criterion
- Coordinator must be **financially viable** – check in advance

Your contact point



At the IHI Programme Office



General queries:
applicants@ihi.europa.eu

Do you want to be an expert-evaluator?



The screenshot shows the 'EU Funding & Tenders Portal' with a navigation menu including 'Home', 'Funding', 'Procurement', 'Projects & results', 'News & events', 'Work as an expert', and 'Guidance & documents'. The 'Work as an expert' page content includes a search bar, a 'View more details' button, and a list of tasks: 'Assessing applications for EU funding (including prizes and tenders)', 'Monitoring of EU funded projects and contracts', and 'Giving your advice on specific issues'. A red circle highlights the 'Register as expert' button. Below the button, text states: 'As new expert, you will be first requested to create your EU login account and register your profile. Registered experts can update the profile via the 'Expert profile' once signed in. Find out more about the evaluation and monitoring objectives and scope in the terms of reference. If you need further guidance, access the key steps for experts. Calls for expressions of interest for experts'.



- IHI JU (and the whole EU research family) are always looking for new, competent experts in diverse fields
- Create or update your expert profile via <https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/work-as-an-expert>
- E-mail experts@ihi.europa.eu mentioning your expert profile number (format EX20XX1234567)

#IHICallDays

Calls 9 & 10



15 Jan

14:30 Call 10: Secondary use of data in the European Health Data Space

16 Jan

10:30 Call 10: Rules & procedures

Online event

Everything you need to know about IHI contributing partners

Register now

30.01.2025

Online Event





Questions and answers

→ Use the Q&A function