



# Call 8

## Two-Stage calls rules and procedures

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# 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 chat function on the right corner of your screen.

# Outline

1. Participation rules
2. Funding rules
3. Intellectual property rules
4. Proposal template and evaluation criteria
5. Grant Agreement & Consortium Agreement
6. Call timelines
7. Points to remember

# IHI two-stage procedure – key concepts

**Pre-identified industry consortium** (including contributing partners if any) align themselves around a real challenge in health care agree to work together (across sectors) and commit resources

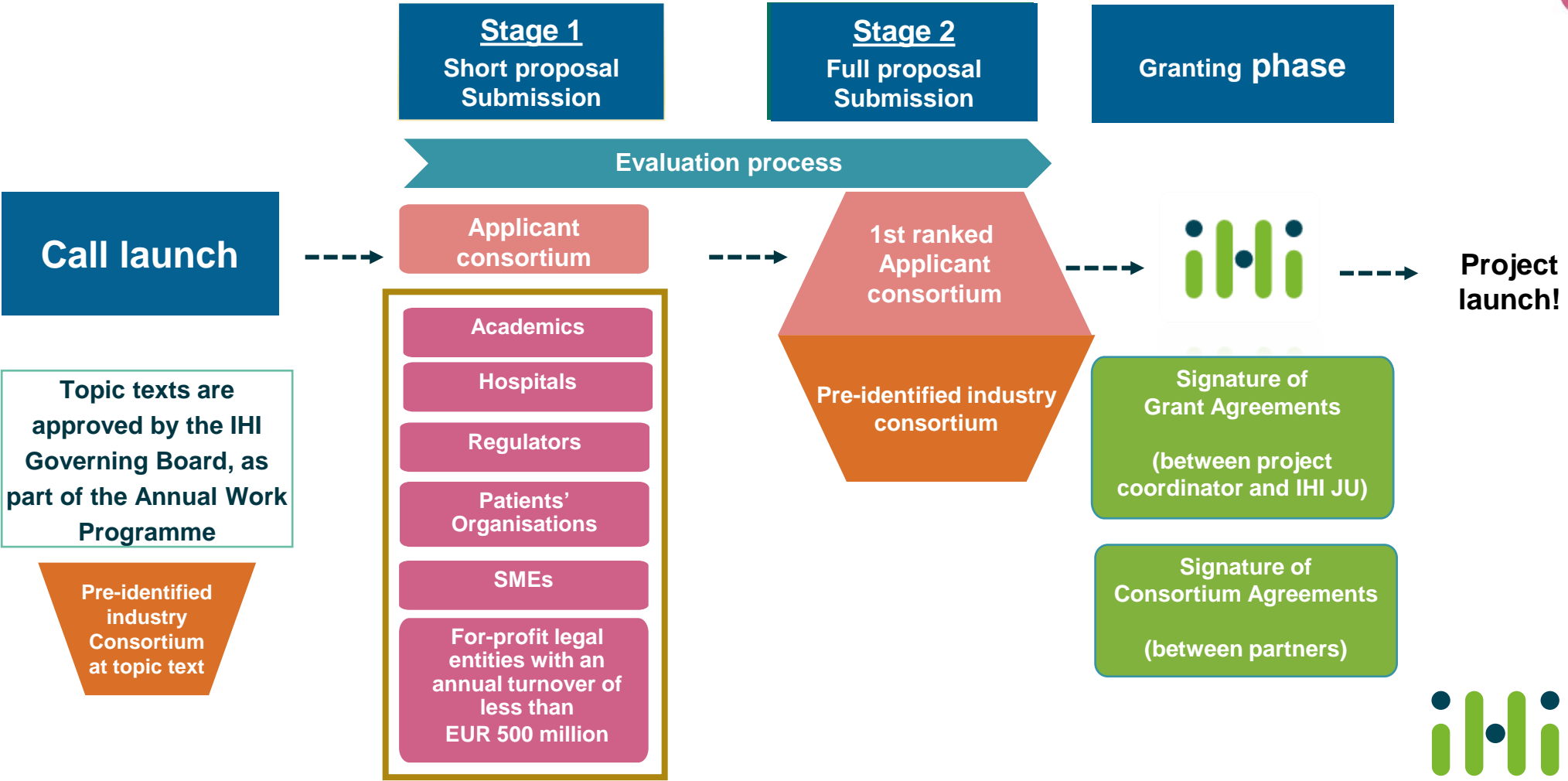
New ideas from **Applicant consortium** (research organisations, patient organisations, SMEs, other healthcare stakeholders etc.) are needed to address the challenge

Scale is a key to success and is provided by the leveraging of IHI funding with industry contributions in the **Full consortium** (Public Private Partnership)

Outcomes should be transformative for healthcare and meet end-users needs



# How does IHI two-stage procedure work



# IHI JU Specific types of Beneficiaries

## Two-Stage Calls: Private members and Contributing Partners

### Pre-identified - responsible for the 45% in-kind contribution

- ✓ main drivers of the topic definition
- ✓ identify their in-kind contributions through expertise and assets
- ✓ listed in the topic text (overall contribution and not per partner)
- ✓ not eligible for funding
- ✓ can not participate with the applicant consortium

### Not pre-identified

- ✓ any other participant that is part of the applicant consortium during the stage 1
- ✓ not involved in the topic definition
- ✓ they could join the consortium afterwards (i.e GAP or during the project implementation via amendment)
- ✓ can be eligible for funding
- ✓ do not contact the pre-identified industry consortium during the application process



- Eligibility: rules to participate and to receive funding.

# IHI JU 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 JU 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 JU Eligibility

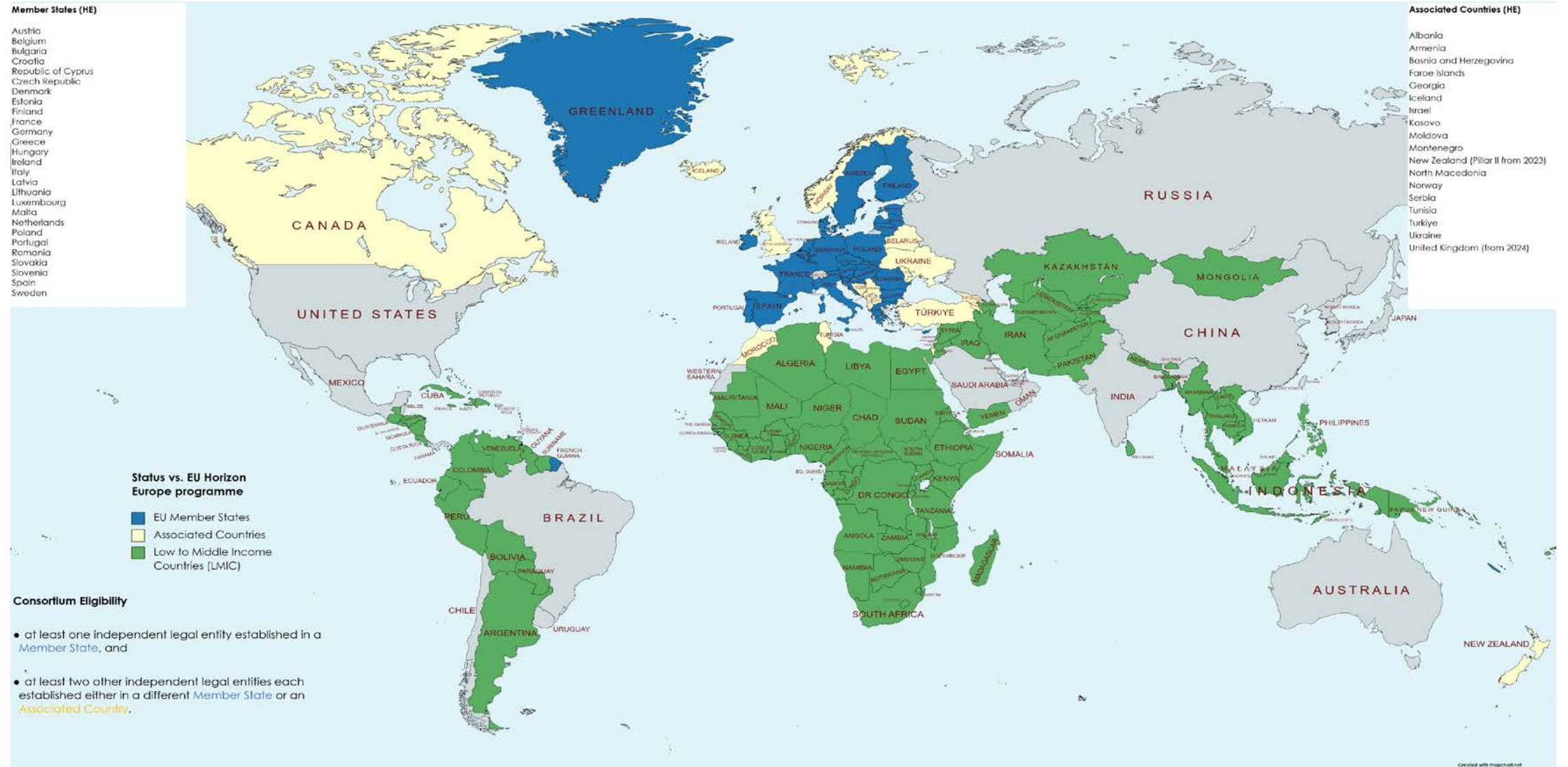
## MSs, ACs, LMICs, and non-Associated Third Countries

### Member States (HE)

Austria  
Belgium  
Bulgaria  
Croatia  
Republic of Cyprus  
Czech Republic  
Denmark  
Estonia  
Finland  
France  
Germany  
Greece  
Hungary  
Ireland  
Italy  
Latvia  
Lithuania  
Luxembourg  
Malta  
Netherlands  
Poland  
Portugal  
Romania  
Slovakia  
Slovenia  
Spain  
Sweden

### Associated Countries (HE)

Albania  
Armenia  
Bosnia and Herzegovina  
Faroe Islands  
Georgia  
Iceland  
Israel  
Kosovo  
Moldova  
Montenegro  
New Zealand (Pillar II from 2023)  
North Macedonia  
Norway  
Serbia  
Tunisia  
Turkiye  
Ukraine  
United Kingdom (from 2024)



# IHI JU 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 JU 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:

- Switzerland\*;
- 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.)

\* Swiss entities participate at their own cost and normally apply for funding from the Swiss government.

# IHI JU Eligibility: restrictive measures

## Special rules apply for legal entities from certain countries

### Russia, Belarus

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:

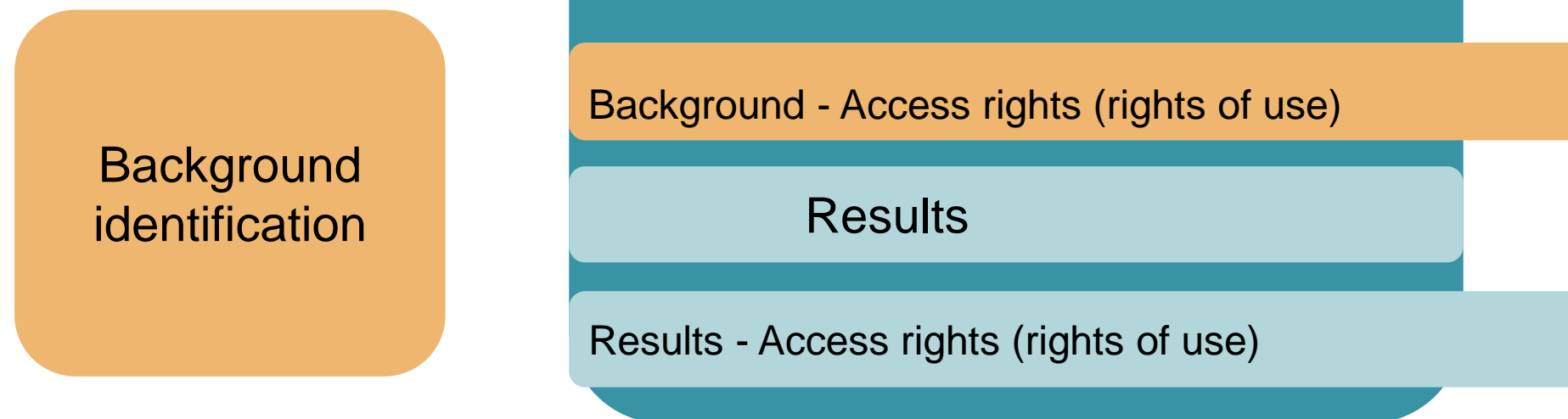
- the purchase of goods, works or services; subcontracting; financial support to third parties; equipment renting or leasing; personnel seconded against payment.

You can find an indicative – non –exhaustive - list of affected entities (i.e. public interest trusts and entities maintained by them) under this [link](#).



# 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 JU Intellectual Property Rights

## Points to note on IHI IPR\*

- 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.



All templates are available in IHI Website and in the submission environment

# Proposal template and evaluation criteria

# Short Proposal Proposal Template - Part A

**Part A** of the proposal is generated by the IT system. It is based on the information entered by the participants through the submission system in the Funding & Tenders Portal.

The participants can update the information in the submission system at any time before final submission

- **General information (acronym, proposal title, duration in months)**
- **Participants**
- **Budget**

3 – Budget for the proposal	
TOTAL Requested EU contribution to eligible costs (Requested grant amount) - EUR	

# Proposal Template - Part B

- **Part B** of the proposal is the narrative part that includes three sections that each correspond to an evaluation criterion.
  - Excellence
  - Impact
  - Quality and efficiency of the implementation
- RIA short proposal is maximum **20 pages**.
- The proposal should respect the page limit set out in the application form. Excess pages will be automatically made illegible and will not be taken into consideration by the evaluators.

# Annex

Annex	Description
Type of Participants (IHI specific annex)	<ul style="list-style-type: none"><li>• This annex enables IHI to meet its reporting obligations on the type of participants.</li><li>• Even though this annex will not be part of the evaluation by the independent experts, applicants will not be able to finalise their submission without uploading this Annex in the Submission Tool.</li></ul>

# Call 8 two-stage. Highlight

- **Indicative contribution:** For each topic, the maximum IHI JU contribution and the estimated industry contributions are set in the call text
- **Plan for Dissemination, Exploitation and Communication Activities (PDECA):** It must be included in 2nd stage full proposals
- For topic(s) involving clinical studies, applicants should submit the **essential information for clinical studies** annex (admissibility condition) **in the second stage**

# 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
<b>TOTAL</b>	<b>10/15</b>

# Evaluation criteria – Tips

## Excellence

- Address all the objectives of the topic text (unless written otherwise). You should not pick and choose, or you will be penalized.
- Clearly describe how your methodology has incorporated knowledge from various stakeholders. This is NOT about the consortium composition but about the knowledge build into the methodology

## Impact

- Please provide meaningful and MEASURABLE estimates when it comes to your project's contribution to impacts. We often see unrealistic impacts with no justification

## Implementation

- Prepare clear graphs, do not list deliverables at this stage, focus on the overall structure of your project, your WPs and their overall objectives.
- Reflect and leave some space to describe how your consortium will fit with the industry consortium: read the topic text and what the industry is bringing to the project and show you have taken this into consideration, and you are aware that you are not on your own.

- 
- Grant Agreement & Consortium Agreement



# IHI JU 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 are available online:
  - Private Members' prepared template for IHI JU actions (links on the IHI website);
  - Development of a Simplified Consortium Agreement ('DESCA') template.



● Timelines

# Call 8 - two-stage – Indicative timelines

June 2024	• Launch of the Call
mid-October 2024	• Call Submission Deadline - Short Proposals (SP)
October-November 2024	• Scientific evaluation - SPs
mid-December 2024	• Information to the applicants - evaluation outcome
end of April 2025	• Submission Deadline - Full Proposal (FP)
May 2025	• Scientific evaluation - FPs
mid-June 2025	• Evaluation Outcome letters to the applicants
end of September 2025	• Grant Agreement Preparation (GAP) and GA signature



# Points to remember

# Points to remember

Horizon Europe Rules for participation apply to IHI JU Call for Proposals and Actions except where specifically derogated

- **Minimum conditions**

**Only RIA:** At least 3 independent legal entities established in a different Member State or Associated Country

IMPORTANT! 1 legal entity should be established in a Member State

- **Page limit: 20 pages for Short Proposal**

- Contacts/discussions about a given topic between potential applicant consortia and members of the pre-identified industry consortium **are prohibited throughout the procedure** until the results of the first stage evaluation.

- First ranked applicant consortium will be invited to prepare and submit a 'full proposal (FP)' for the stage 2 evaluation together with the 'pre-identified industry consortium'.

# Points to remember

- Read all the call-relevant material: [www.ihl.europa.eu](http://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 subcriteria.
- **Respect the page limit**
- Use the proposal structure / template
- Coordinator must be financially viable – check in advance
- Contact the IHI Office (NOT industry topic writers):  
[applicants@ihl.europa.eu](mailto:applicants@ihl.europa.eu)

# Reference Documents

All call related documents will be available by the Call launch in IHI website and in the Funding and Tenders portal

## IHI Specific documents

- [SBA](#)
- [Strategic Research and Innovation Agenda \(SRIA\)](#)

## Horizon Europe Reference documents

- [Horizon Europe Main Work Programme 2023–2024 – 13. General Annexes](#)
- [Horizon Europe Programme Guide<sup>\[1\]</sup>](#)
- [Horizon Europe Framework Programme and Rules for Participation Regulation 2021/695](#)
- [Horizon Europe Specific Programme Decision 2021/764](#)
- [EU Financial Regulation](#)
- [Rules for Legal Entity Validation, LEAR Appointment and Financial Capacity Assessment](#)
- [Funding & Tenders Portal Online Manual](#)
- [Funding & Tenders Portal Terms and Conditions](#)
- [Funding & Tenders Portal Privacy Statement](#)
- Horizon Europe [General Model Grant Agreement MGA v1.1 of 15 April 2022](#) (or subsequent versions).





# More information



# Your contact points

## At the IHI Programme Office

General queries: [applicants@ihi.europa.eu](mailto:applicants@ihi.europa.eu)

## State Representative Group (SRG)

The States Representatives appointed to IHI JU SRG are on our website here: [ihi.europa.eu/about-ihi/who-we-are/states-representatives-group](https://ihi.europa.eu/about-ihi/who-we-are/states-representatives-group).

## National Contact Points

You can find out here more about your national health NCPs [ec.europa.eu/info/funding-tenders/opportunities/portal/screen/support/ncp](https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/support/ncp)

# Do you want to be an expert-evaluator?



- 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 [ec.europa.eu/info/funding-tenders/opportunities/portal/screen/work-as-an-expert](https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/work-as-an-expert)
- E-mail [experts@ihi.europa.eu](mailto:experts@ihi.europa.eu) mentioning your expert profile number (format EX20XX1234567)

# #IHICallDays

## Call 8



## Online event

18 June

**10:30-11:30** A city-based approach to reducing cardiovascular mortality in Europe

20 June

**10:30-11:30** Novel endpoints for osteoarthritis by applying big data analytics

20 June

**14:30-15:30** Modelling regulatory sandbox mechanisms and enabling their deployment

21 June

**15:30-16:30** Patient-centred clinical-study endpoints derived using digital health technologies



**Register now**





- Thank you for your attention

[ihi.europa.eu](http://ihi.europa.eu)

# Questions time

If you want to ask a question please use the chat function on the right corner of your screen

