



- Call 10
Two-Stage call

Rules and Procedures

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16 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 has been launched this morning and all links and details on how to apply are published on the Funding and Tenders Portal and the IHI website.
- Final approved call 10 text already available [here](#).
- 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



Proposal template and evaluation criteria



Grant Agreement & Consortium Agreement



Call timelines



Points to remember

IHI two-stage calls

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



IHI two-stage call 10 - topics

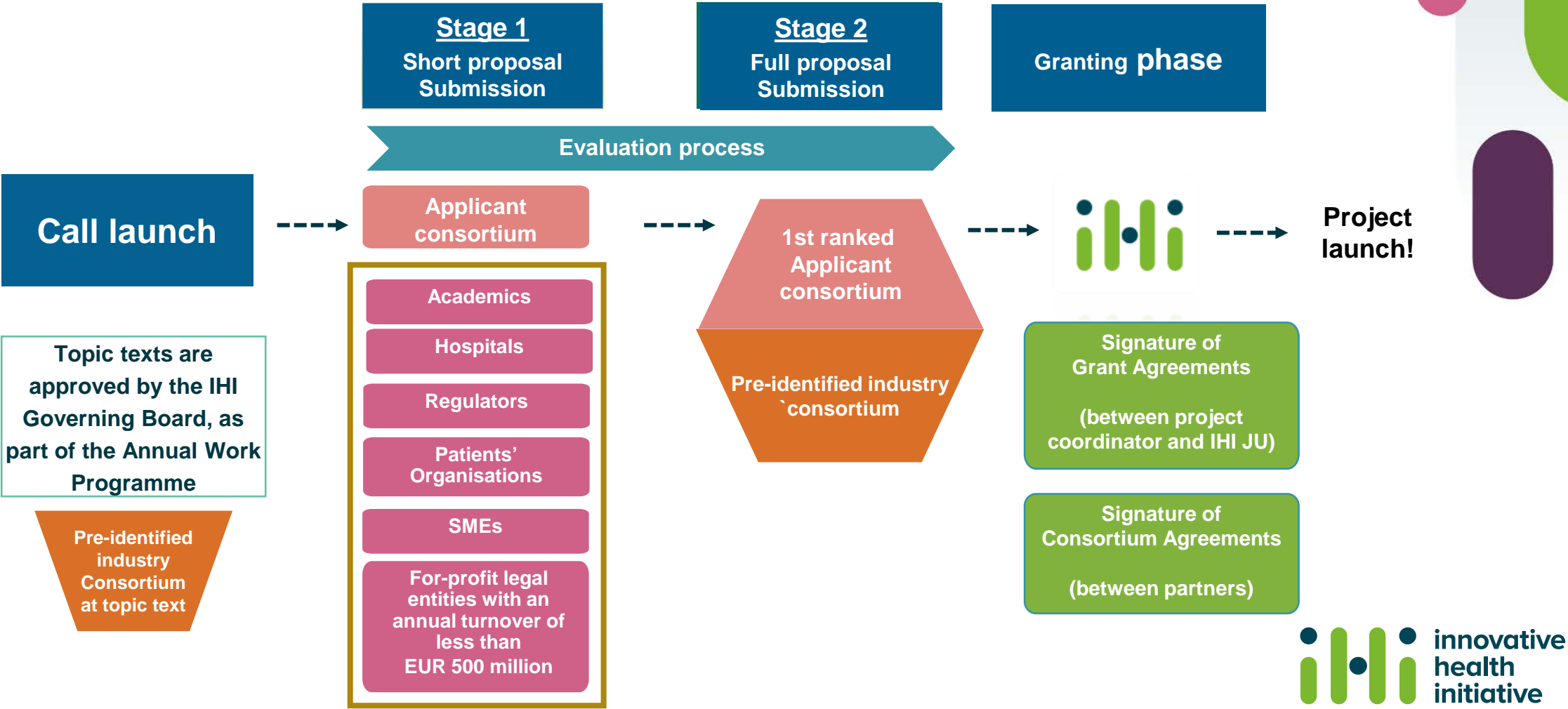
Digital label: one source of comprehensive information for medical technology products

Enabling and safeguarding innovation in secondary use of health data in the European Health Data Space (EHDS)

Per- and Poly-fluoroalkyl substance (PFAS) exposure, emissions, and end of life management in the healthcare sector



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: 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?

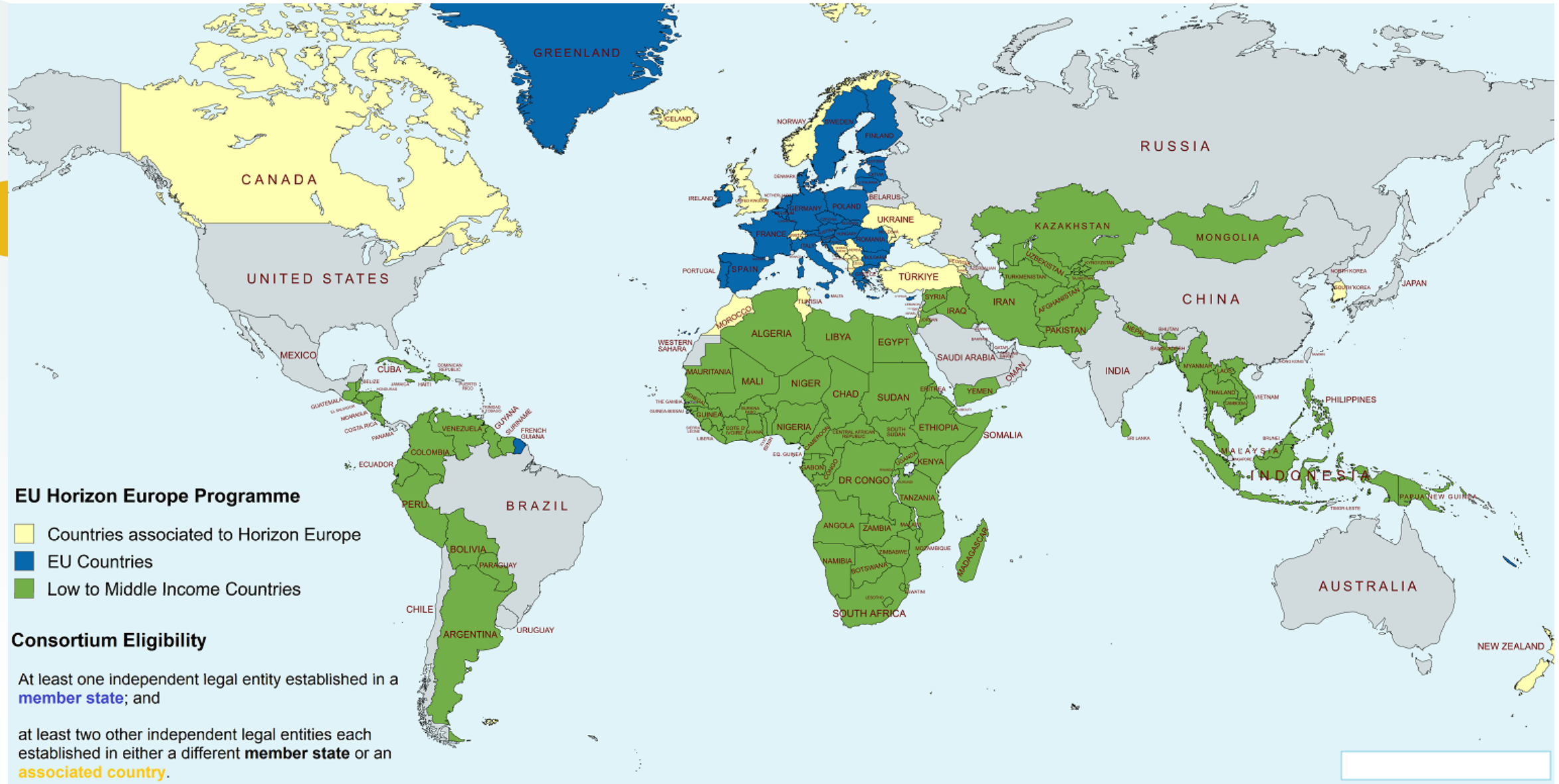
'legal entity' means a natural person, or a legal person created and recognised as such under Union, national or international law, which has legal personality and the capacity to act in its own name, exercise rights and be subject to obligations, or an entity which does not have legal personality as 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’).

For **Two-Stage** calls the following legal entities are not eligible to receive funding:

- Legal entities in the pre-identified industry consortium in the topic text;
- Legal Entities with an annual turnover of EUR 500million or more.

* 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:

- 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.)



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

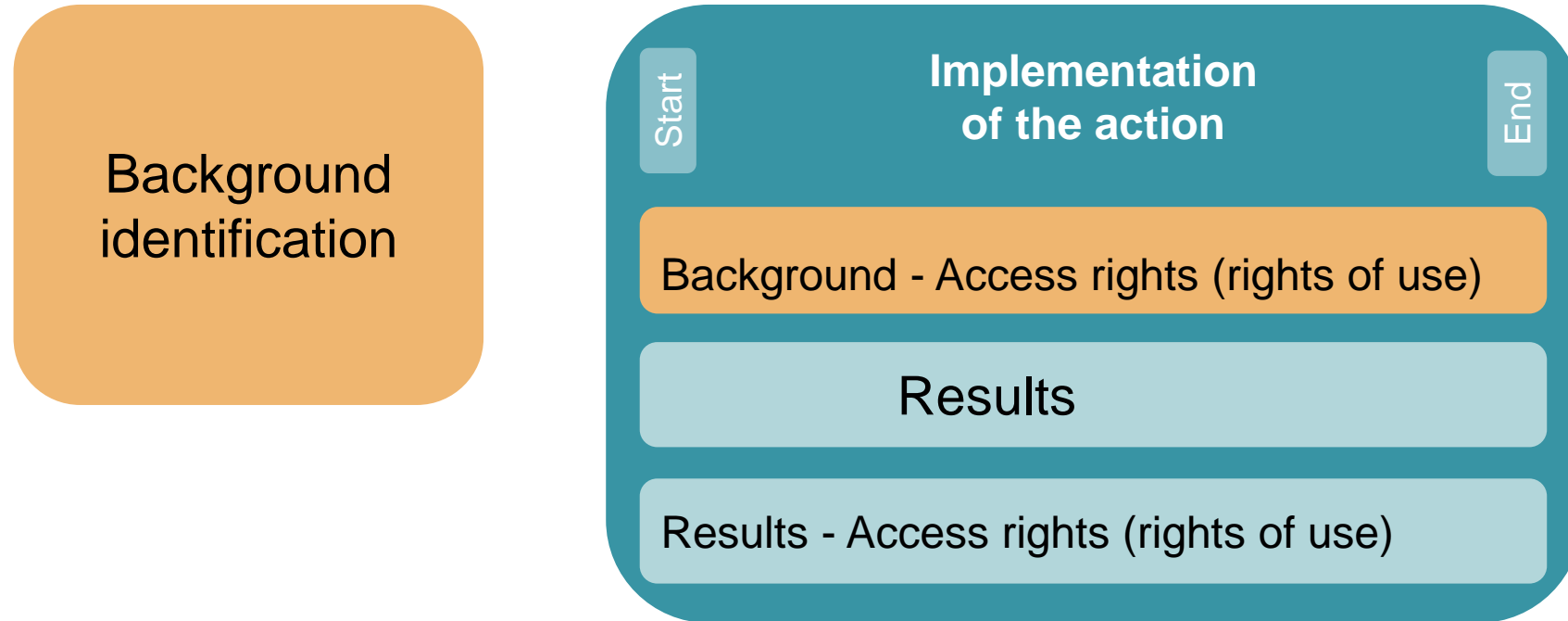
Council Implementing Decision (EU) 2022/2506 on measures for the protection of the Union budget against breaches of the principles of the rule of law in **Hungary** that took effect on 16 December 2022.

- 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.



- 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.



Proposal template and evaluation criteria

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

Application forms

Call: HORIZON-JU-IHI-2025-10-two-stage
(Innovative Health Initiative JU Call 10)

Topic: HORIZON-JU-IHI-2025-10-03-two-stage

Type of action: HORIZON-JU-RIA
(HORIZON JU Research and Innovation Actions)

**Type of Model Grant Agreement: HORIZON Action Grant
Budget-Based**

Proposal number: SEP-211119953

Proposal acronym: Test-AC-8-3

Table of contents

Section	Title	Action
1	General information	
2	Participants	
3	Budget	

Proposal Template - Part B

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



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">• This annex enables IHI to meet its reporting obligations on the type of participants.• 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.

Part B and Annexes

In this section you may upload the technical annex of the proposal (in PDF format only) and any other requested attachment:

Part B * Upload here

Type of Participants * Upload here

Call 10 two-stage - Highlight

1

Indicative contribution

For each topic, the maximum JU contribution and the estimated industry contributions are set in the call text

2

Plan for Dissemination, Exploitation and Communication Activities (PDECA)

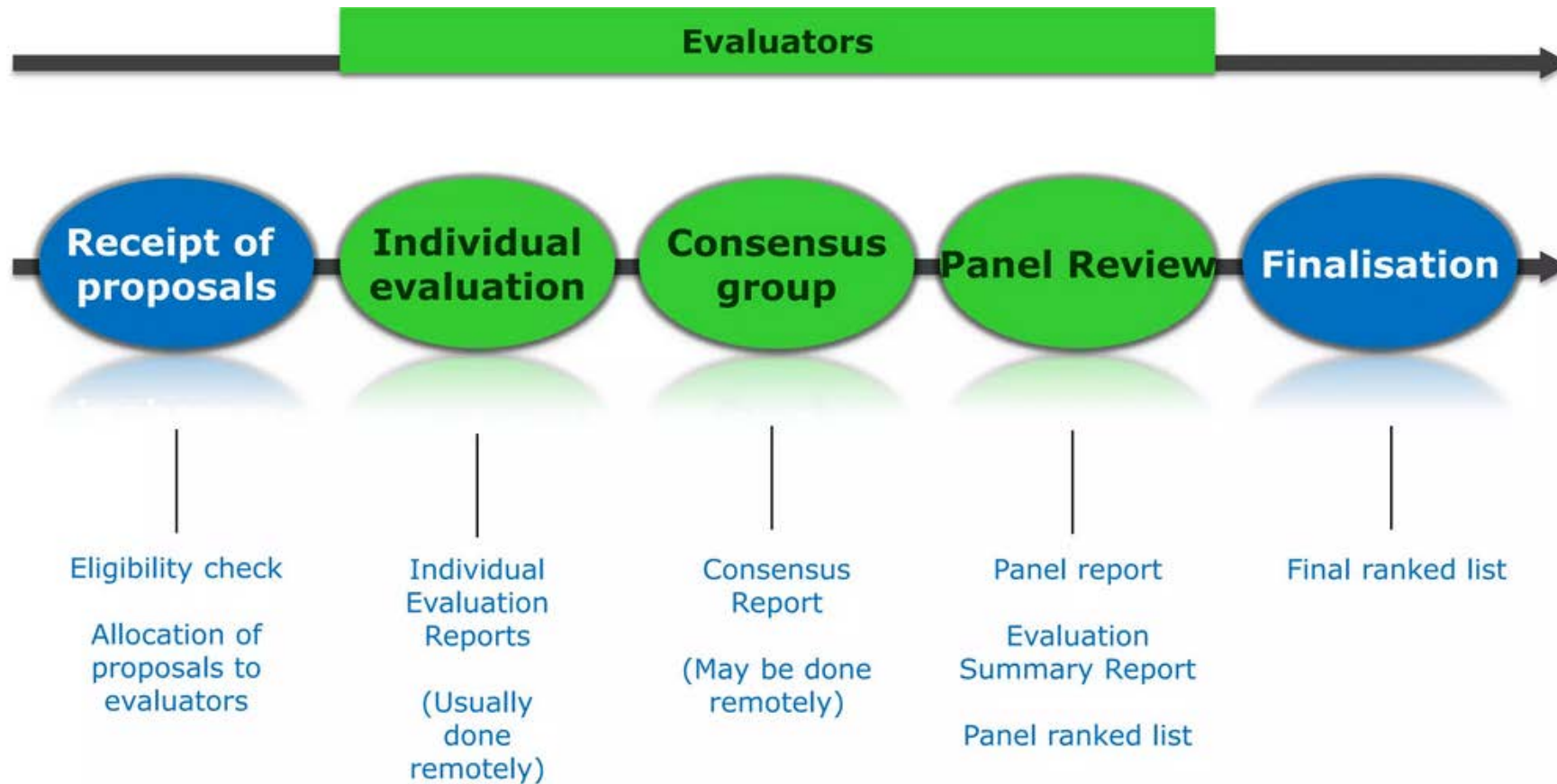
It must be included **in the second stage**

3

Essential information for clinical studies

For topic(s) involve clinical studies, applicants should submit the annex (admissibility condition) **in the second stage**

Evaluation flow and thresholds



Evaluation flow 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

Evaluation – 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



CONSORTIUM AGREEMENT

This Agreement (the "Agreement") is effective [DATE].

BETWEEN: [FIRST PARTY NAME] (the "Founder"), with its address located at:
[YOUR COMPLETE ADDRESS]

AND: [SECOND PARTY NAME] (the "Consortium Member"), with its address located at:
[COMPLETE ADDRESS]

WHEREAS, the Consortium Members propose to form a consortium (the "Consortium") to undertake a project with respect to _____ (the "Project");

WHEREAS, in accordance with the terms of this Agreement, the Consortium Members will cooperate and work towards the development of the Project;

NOW THEREFORE, in consideration of the premises and of the mutual agreements contained in this Agreement, the Parties hereto agree as follows:

1. OBJECT

1.1 The object of this Agreement is for the Parties hereto to arrive at a strategic understanding with each other to pool their resources, cooperate with each other and jointly prepare Project Reports and carry out the Project as described in "Annexure A."

2. EXCLUSIVITY

2.1 The Parties hereto agree that no Party shall, subsequent to the signing of the present Agreement, withdraw from this Agreement during the execution of the Project in connection with the purpose of the Project as outlined for any reason whatsoever.

3. PROJECT MANAGEMENT

3.1 Identification

3.1.1 The Parties agree that the Project lead site is: _____

3.1.2 The Parties agree that the Project will be managed by _____ ("Project Manager").

Consortium Agreement Page 1 of 4

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 are available online:
 - Private Members' prepared template for IHI JU actions ([here](#));
 - Development of a Simplified Consortium Agreement ('DESCA') [template](#).



● Timelines

Call 10 - two-stage – Indicative timelines

16 January 2025	• Launch of the Call
23 April 2025	• Call Submission Deadline - Short Proposals (SP)
May-June 2025	• Scientific evaluation - SPs
End June 2025	• Information to the applicants - evaluation outcome
14 October 2025	• Submission Deadline - Full Proposal (FP)
October-November 2025	• Scientific evaluation - FPs
December 2025	• Evaluation Outcome letters to the applicants
March 2026	• 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

1

Read all the call-relevant material:
www.ihl.europa.eu

2

Begin forming your consortium early. Read the topic text. Check the IHI website and F&TP.

3

Ensure that all information is explicitly described in order to allow the expert evaluators to assess

4

Use the proposal structure / template

5

Coordinator must be financially viable – check in advance

6

Contact the IHI Office (NOT industry topic writers)

Reference Documents

✓ IHI Specific documents

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

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

✓ Horizon Europe Reference documents

- [HE Main Work Programme 2023–2025 – 13. General Annexes](#)
- [HE Programme Guide](#)
- [HE Framework Programme 2021/695](#)
- [HE Specific Programme Decision 2021/764](#)
- [EU Financial Regulation 2018/1046](#)
- [Rules for Legal Entity Validation, LEAR Appointment and Financial Capacity Assessment](#)
- [EU Grants AGA — Annotated Model Grant Agreement](#)
- [Funding & Tenders Portal Online Manual](#)
- [Funding & Tenders Portal Terms and Conditions](#)
- [Funding & Tenders Portal Privacy Statement](#)
- [General Model Grant Agreement MGA v1.2](#)

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 contains the following text:

Home > Work as an expert

Work as an expert

We need experts for:

- Assessing applications for EU funding (including prizes and tenders),
- Monitoring of EU funded projects and contracts,
- Giving your advice on specific issues.

Experts act in their individual capacity to assist the EU services with the implementation of EU funding & tenders managed through the Portal.

Do you have an extensive professional experience & proven domain-knowledge?

[Register as expert](#)

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

The 'Register as expert' button is circled in red in the original image.



- 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



Online event

- 7 Jan** **10:30** Call 10: Digital labelling
- 8 Jan** **10:30** Financial aspects of call 9
- 9 Jan** **14:30** Call 10: PFAS exposure, emissions & end-of-life management
- 14 Jan** **10:30** Call 9: General information
- 15 Jan** **10:30** Call 9: Rules & procedures
- 15 Jan** **14:30** Call 10: Secondary use of data in the European Health Data Space
- 16 Jan** **10:30** Call 10: Rules & procedures

Everything you need to know about IHI contributing partners

Register now

30.01.2025

Online Event





Questions and answers

→ Use the Q&A function