

Call 11 Two-Stage call

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.
- IHI call 11 was launched on 17.06.2025 and the final call texts and details of how to apply can be found at: https://www.ihi.europa.eu/apply-funding/ihi-call-11
- If you want to ask a question please use the chat 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

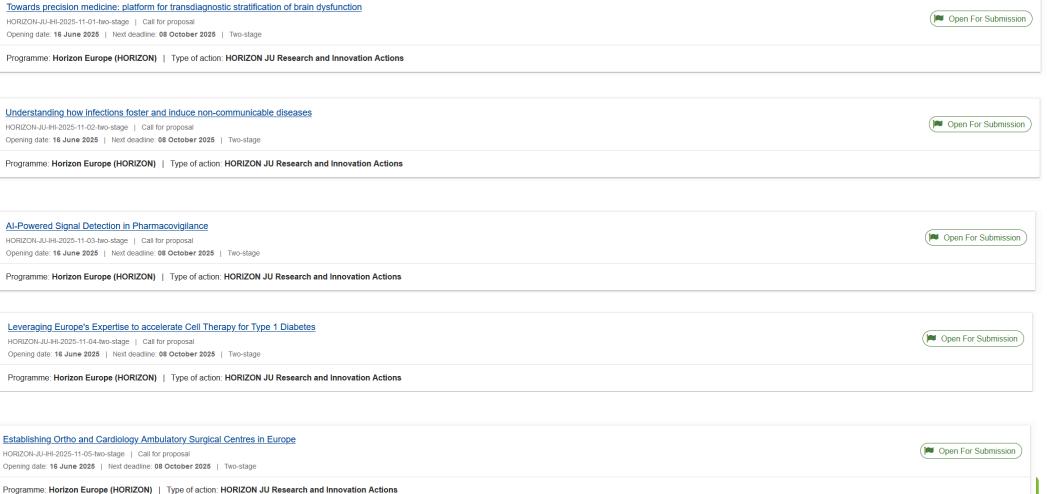
New ideas from **Applicant consortium** (research organisations, patient organisations, SMEs, other healthcare stakeholders etc.) are needed to address the challenge

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 11 - topics





IHI two-stage call 11 - topics



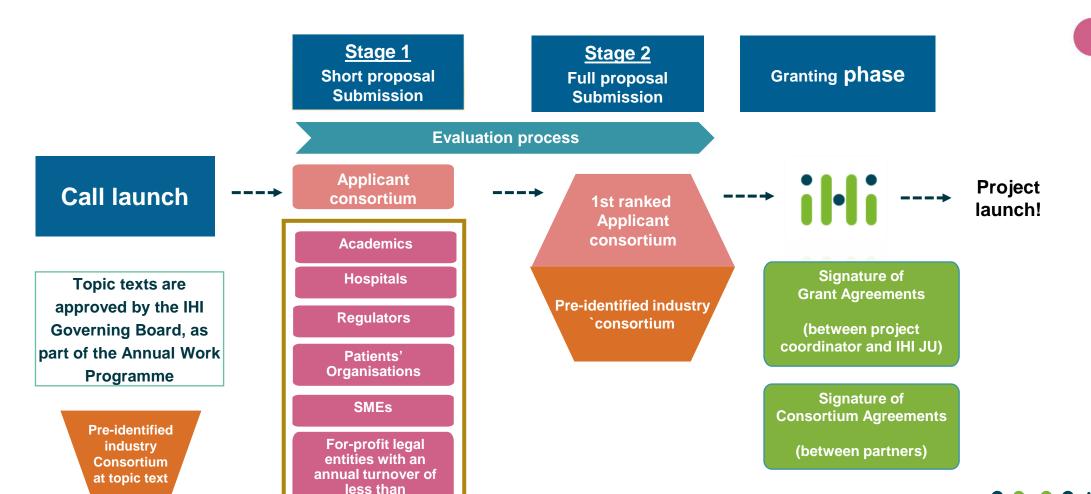








How does IHI two-stage procedure work •



EUR 500 million



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 for: Consortia Participation Funding



Basics of Eligibility for IHI JU Calls

Proposals in IHI JU Calls are submitted by consortia.

Eligible Consortia 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 JU 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?



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 (16)]

How to ensure that an applicant consortium is eligible to participate in IHI JU 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*.



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 to Horizon Europe** ('AC'), or;
- Are established in a Low to Middle Income country ('LMIC').

For Two-Stage calls the following legal entities are <u>not eligible</u> to receive funding:

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



^{*} Eligibility for funding is determined by the type of IHI JU call.

^{**} From 2024 Canada and United Kingdom ['UK'] are considered Associated Countries for IHI JU.

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 under Art. 23 (2) of HE Regulation 2021/695, receive funding from IHI JU when the legal entity's participation is considered essential (for example, access to particular expertise, data etc.)



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.



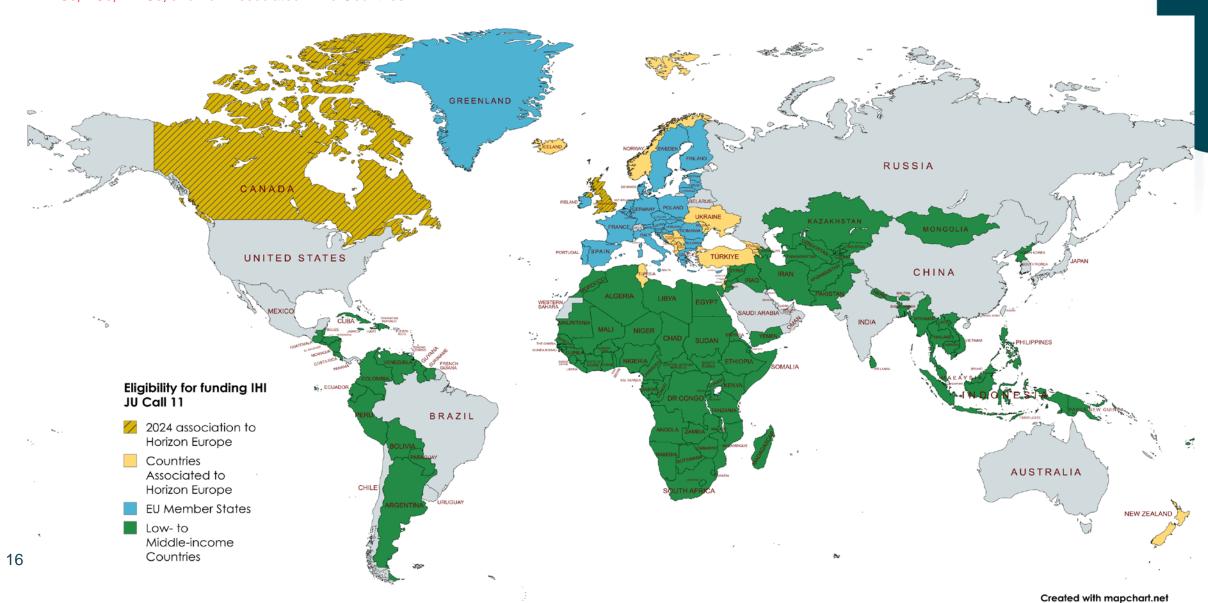
IHI JU Call 11: Eligibility for Funding: UK, Canada, Switzerland, South Korea

Country	<u>Rules</u>
United Kingdom ('UK')	 The agreements whereby UK and CA associate to Horizon Europe are in force from 01 January 2024. Legal entities from UK and CA are eligible to receive funding for Call 11 Topic 01. Call 11 Topics 02 – 05 are funded from carry overs from 2023, therefore legal entities from
Canada ('CA')	 UK and CA are not eligible for funding for those topics. In-kind contributions of legal entities from UK and CA qualify as EU in-kind contributions in Call 11 Topic 01. The legal entities from UK and CA can be beneficiaries and take the role of coordinator for Call 11 Topic 01.
Switzerland ('CH')	Transitional arrangements in place for legal entities from CH and KR starting 01 January 2025. The U.S. Coll 44 Taxing 04 - 05 are fixed at from course from 2023/2024 and legal.
South Korea ('KR')	 IHI JU Call 11 Topics 01 – 05 are funded from carry overs from 2023/2024 and legal entities from CH and KR are not eligible for funding for those topics. Such legal entities that decide to participate for IHI JU Call 11 would still have the possibility to be part of the consortium and take the role of an associated partner (Case A) and thereby participate at their own costs.



IHI JU Call 11: Eligibility

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



IHI JU Call 11: Eligibility for Funding: UK, Canada, Switzerland, South Korea

Eligible/Not Eligible to receive funding in IHI JU Call 11 as follows:

Country	Call 11, Topic 01	Call 11, Topics 02 - 05
United Kingdom ('UK')	Eligible to receive funding	Not Eligible to receive funding
Canada ('CA')	Eligible to receive funding	Not Eligible to receive funding
Switzerland ('CH')	Not Eligible to receive funding	
South Korea ('KR') Not Eligible		to receive funding

Alternative Funding: legal entities from UK, CA, CH, and KR may be able to receive funding from their own governments, Potential applicants should contact their National Contact Point ('NCP') or relevant representative. IHI JU takes no role or responsibility in the application for, or granting of, such funding.

UK applicants: Are requested to contact the UK National Contact Point Ms Jo Frost (ncp-health@iuk.ukri.org) as soon as possible to register for updates, and for advice and assistance regarding UK participation in IHI Call 11.



Intellectual Property Rights ('IPR') in IHI JU



Snapshot of key IP concepts for IHI JU Actions

Background identification

Implementation of the action

Background - Access rights (rights of use)

Results

Results - Access rights (rights of use)

<u>Background:</u> 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".

<u>Results:</u> 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.

innovative health initiative

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

IHI JU: 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 Call: HORIZON-JU-IHI-2025-11-two-stage

(Innovative Health Initiative JU Call 11)

Topic: HORIZON-JU-IHI-2025-11-02-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-211172987

Proposal acronym: test-IHI-call-11-2

Table of contents

Section	Title	Action
1	General information	Show
2	Participants	Show
3	Budget	Show



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)	 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.

In this section you may upload the technical annex of the proposal (in PDF format only) and any other requested attachments Part B * Upload here Type of Participants * Upload here



Call 11 two-stage - Highlight



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 second the stage

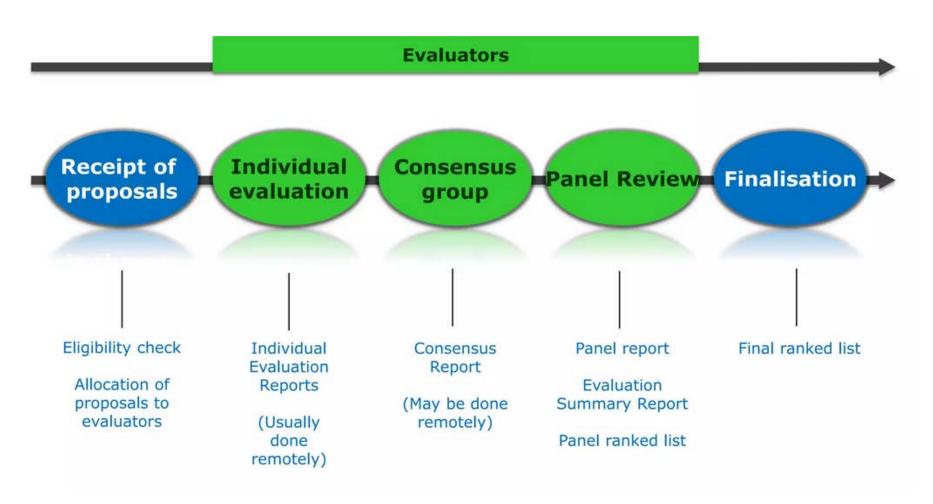
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Essential information for clinical studies

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 (EANT).

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(POUR CONPLETE ACCIDENCE)

AND.

[SECOND PARTY MARIS (the "Connotion Members"), with its address housed at:
(POUR CONTROL ACCIDENCE)

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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 comply 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 (<u>here</u>);
 - Development of a Simplified Consortium Agreement ('DESCA') template.





Timelines



Call 11 - two-stage — Indicative timelines





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 callrelevant material: www.ihi.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



Use the proposal structure / template



Coordinator must be financially viable – check in advance



Contact the IHI Office (<u>NOT</u> 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

