

Call 6 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 and B2Match platform.
- We will also publish the presentation slides.
- The call will be officially launched tomorrow and all links and details
 of how to apply will be published on the IHI website and the
 Funding and Tenders Portal.



Outline

- 1. Participation rules
- 2. Funding rules
- 3. Intellectual property rules
- 4. From Call to grant award
- 5. Call timelines
- 6. 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

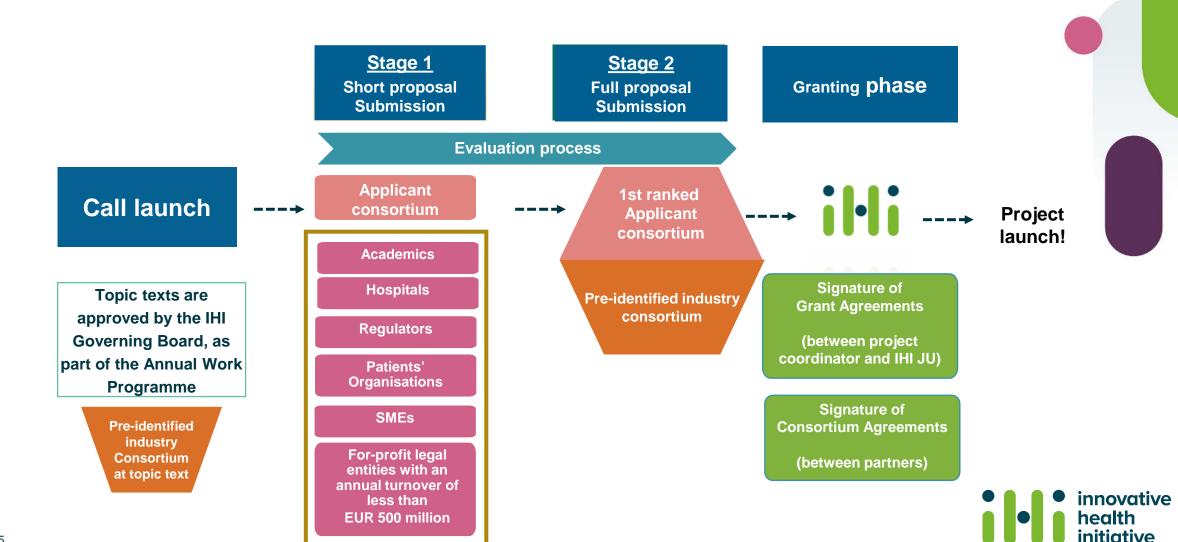
New ideas from **Applicant consortium** (research organisations, patient organisations, SMEs, other healthcare stakeholders etc.) are needed to address the challenge

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 endusers 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



Call 6 two-stage Highlights

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

- Date of Call launch: 16 January 2024
- Submission deadlines
- ✓ Deadline for Short Proposal submission: 16 April 2024
- Deadline for Full Proposal submission: 10 October 2024
- 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
- 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'.



Call 6 two-stage Highlights

- Indicative contribution: For each topic, the maximum 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) involve clinical studies, applicants should submit the essential information for clinical studies annex (admissibility condition) in the second stage

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.





Entities eligible to participate



Attracting stakeholders

Any legal entity, regardless its place of establishment, carrying out work relevant to the Call objectives may be part of applicant consortia

But... not all participating entities are eligible for funding



Eligibility

Consortium composition (collaborative projects)

- at least one independent legal entity established in a Member State, and
- at least two other independent legal entities each established either in a different Member State or an Associated Country.

EU COUNTRIES

- Member States (MS)
 including their outermost
 regions
- The Overseas Countries and Territories (OCTs) linked to the MS.

NON-EU COUNTRIES

- Countries associated to Horizor Europe (AC)
- Low and middle income countries: See <u>HE Programme</u> <u>Guide</u>.

COUNTRIES ASSOCIATED TO HORIZON EUROPE

- Countries associated to Horizon Association agreements produce legal effects
 - Transitional arrangements
 - •UK is treated as an Associated Country
 - •Switzerland is a third country.





EU restrictive measures Special rules apply for entities from certain countries

- 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)
- 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 <u>Hungary</u> 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 <u>link</u>.





Entities eligible for funding



Eligibility rules: funding



Any legal entity established in a Member State, Associated Country or Low and Middle Income Countries

See Horizon Europe programme guide





Third country to Horizon Europe legal entities are normally not eligible for receiving IHI funding

exceptional funding (recommended by experts evaluators) when it considers that their participation is essential





Eligibility rules: funding



Any legal entity established in a Member State, Associated Country or Low and Middle Income Countries

See Horizon Europe programme guide

- the Member States of the European Union, including their outermost regions;
- the Overseas Countries and Territories (OCTs) linked to the Member States;
- eligible non-EU countries:
 - countries associated to Horizon Europe
 - The association agreements produce legal effects
 - transitional arrangements
- low- and middle-income countries identified in the Horizon Europe



Third country to Horizon Europe legal entities are normally not eligible for receiving IHI funding

exceptional funding (recommended by experts evaluators) when it considers that their participation is essential







Eligibility for funding in two-stage Calls



Non-profit organisations

For-profit legal entities
(SME and larger enterprises with an annual turnover of less than EUR 500 million)



NOT eligible for funding:

- Pre-identified Industry Consortium
- For-profit company:



- (a) with an annual turnover of EUR 500 million or more
- (b) directly or indirectly controlling/or being controlled by for profit legal entities with an annual turnover of EUR 500 million or more.

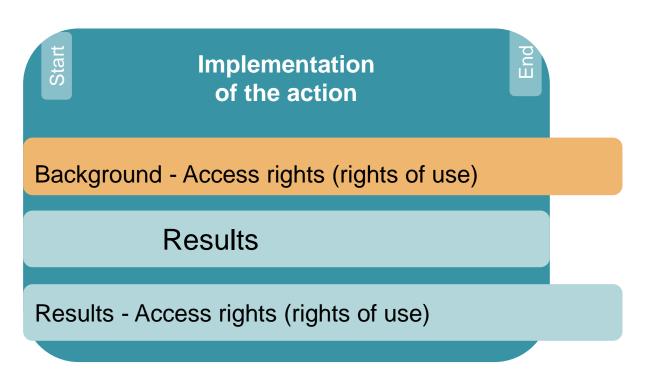


Intellectual Property Rights ('IPR') in IHI



Snapshot of key IP concepts for IHI Actions

Background identification



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

IPR in IHI

- Horizon Europe ('HE') legal basis applies (no specific derogations for IHI JU, unlike IMI2).
- IHI IPR rules derived from:
 - Horizon Europe Model Grant Agreement ('MGA') Article 16;
 - supplemented by specific rules identified in HE MGA Annex 5 and;
 - o where relevant, the applicable call conditions.
- IHI JU maintains right to object to transfers of ownership of results or to grants of exclusive licences.
- 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;
 - Affordable Access Provisions can, when provided for in the call conditions, introduce additional exploitation obligations for relevant IHI topics;
 - Unexploited project results can be matched with interested parties via the Horizon Results platform.
- * Project IPR specificities to be agreed amongst all parties and detailed in the project Consortium Agreement



From Call to grant award



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





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.

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



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.

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



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



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.



Agreements for IHI Actions



IHI Grant Agreement

- 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 for IHI Actions

- Contractual arrangement between all participants to set out their rights and obligations, especially governance, liability and IPR.
- IHI JU is not a party/signatory.
- Shall comply with the HE MGA.
- To be fully agreed before the signature of the GA.
- To be adapted to the specific needs of each IHI JU action
- Templates are available in the IHI website (templates provided by private members, health initiative DESCA (Development of a Simplified Consortium Agreement)).

Points to remember



Points to remember

- Read all the call-relevant material: <u>www.ihi.europa.eu</u>
- 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 (<u>NOT</u> industry topic writers): <u>applicants@ihi.europa.eu</u>





Timelines



Call 6 - two-stage — Indicative timelines





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
- Horizon Europe Main Work Programme 2023–2024 13. General Annexes
- Horizon Europe Programme Guide^[1]
- 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

State Representative Group (SRG)

The main States Representatives appointed to IHI JU SRG (the main delegates, but not the alternates) are on our website here:

https://www.ihi.europa.eu/about-ihi/who-we-are/states-representatives-group.



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



Thank you for your attention

ihi.europa.eu



#IHICallDays



Call 6

15 Jan 14:30 Rules & procedures: two-stage calls

16 Jan 10:30 RWD / RWE in decision-making

16 Jan 14:30 Treatment persistency

Call 7

10 Jan 10:30 Management of heart disease

10 Jan 14:30 Optimised hospital workflows

11 Jan 10:30 Rules & procedures: single-stage calls

11 Jan 14:30 Clinical validation of biomarkers

12 Jan 14:30 Single-stage calls: financial aspects

23 Jan 14:30 Management of heart disease

14:30 Optimised hospital workflows

14:30 Clinical validation of biomarkers











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Questions time

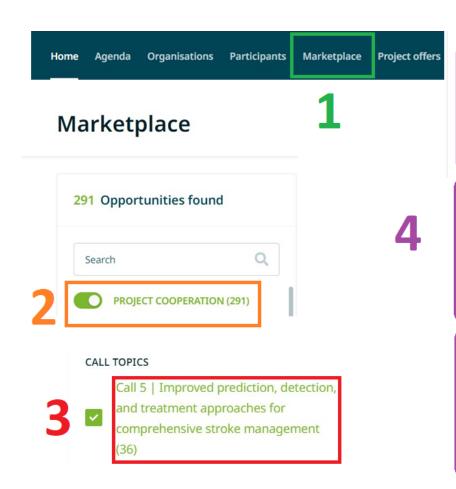
If you want to ask a question please use the chat function on the right corner of your





screen

Marketplace





Updated on June 21, 2023

EEG based Triage of Stroke Patients

What type of organisation are you looking for? (Question for consortium/coordinator seeking partners)

What kind of expertise are you looking for? (Question for consortium/coordinator seeking partners)

PROJECT COOPERATION

Updated on June 21, 2023

Medical image analysis and segmentation

We would like to join a consortium and can contribute the following expertise:

Medical image data are used in a variety of ways for diagnosis, treatment planning, monitoring of interventions, observation of condition changes and documentation. Common image modalities range from

PROJECT COOPERATION

Updated on June 21, 2023

Remote vital functions monitoring, evaluation and smart interventions

Our research center focuses on the collection, remote monitoring, and evaluation of vital data.

What do we bring to the consortium?



How to book your meetings via the B2Match platform

Book your meetings in 4 easy steps

- 1. Make yourself available
- 2. Look for partner on the participants or organisation tab
- 3. Select date, time, attendees (up to eight per meeting), add message
- 4. Send the meeting request and wait for the reply

Step by Step guide on how to book meetings: https://europa.eu/!FkjV9n



Questions time

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





