



- Call 7
Single 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 next week 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



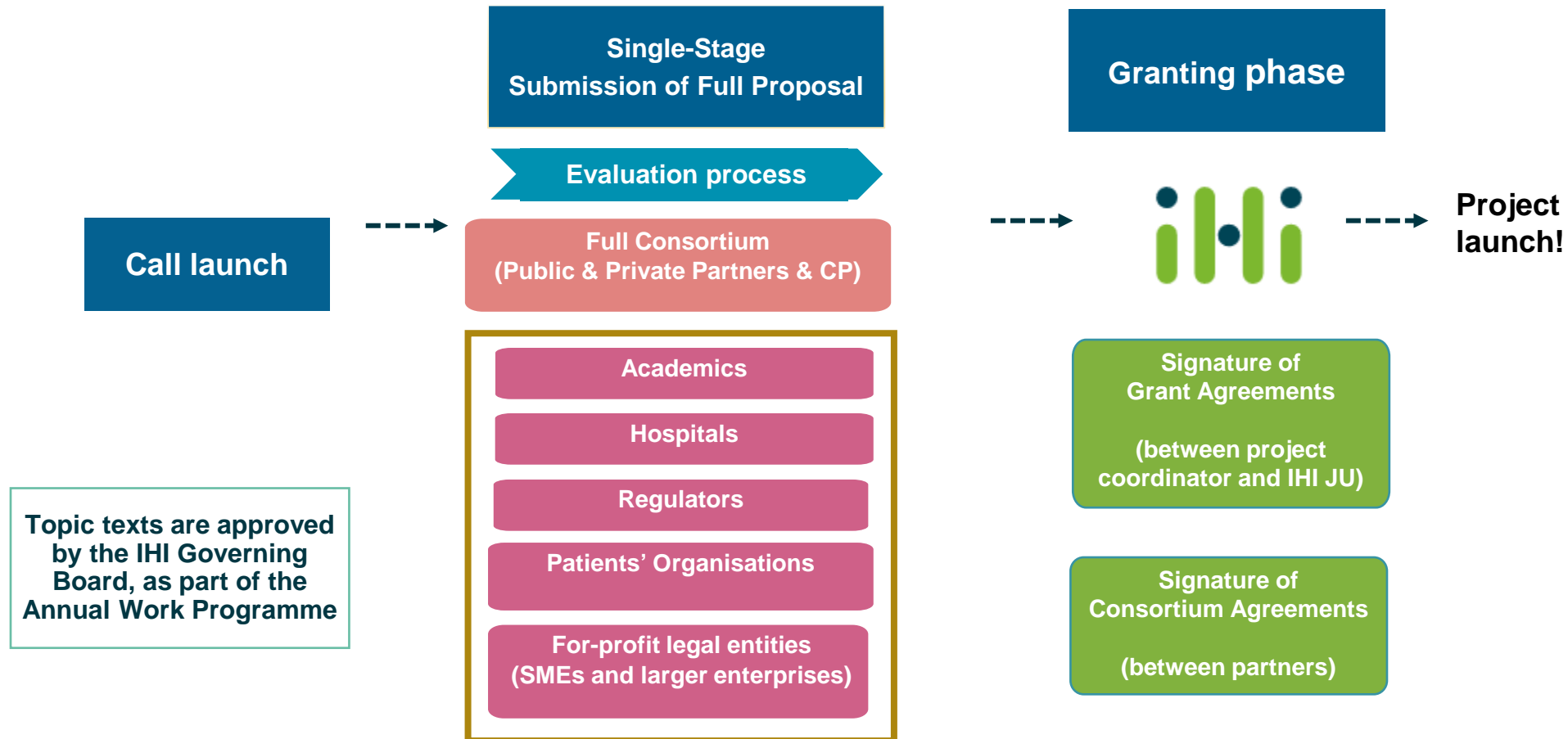
- Participation rules

Call 7

Single-stage

- Open Call - Full Proposals (FP)
 - ✓ public and private actors self-assemble (such as academia, SMEs, large companies, regulators, etc.) and **compete** for funding
 - ✓ applicant consortia will be assessed on the basis of the required expertise to reach the objectives of the submitted proposals (specific requirement described in the call topic text, including the public-private partnership requirement).
 - ✓ applicants might need to involve participants from different health sectors to meet the specific objectives.

How does IHI work? single-stage procedure



Highlights



KEY
POINTS

- The General Annexes of the Horizon Europe Work Programme 2023-2024 shall apply *mutatis mutandis* to the call 7.
- **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



KEY POINTS

Affordability, availability and accessibility of results (applicable to all Call 7 topics)

- Products and services they develop 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”).
- *Call 7: topics with 3A are disclosed in the WP 2024 – check special conditions for every call topic*
- 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 lifetime of the project and for a period of four years after project end, can be found in the IHI Work Programme 2024



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 Horizon Europe (AC)
- Low and middle income countries: See [HE Programme Guide](#).

COUNTRIES ASSOCIATED TO HORIZON EUROPE

- 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 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](#).



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

NEW



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 single-stage Calls





- 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 7

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 for the application letter (please see our CP Guide), 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 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.ihj.europa.eu/shape-our-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.



Contributing partners **should submit a letter to the Governing Board of the IHI JU before the call submission deadline.** Template application letters and more information on contributing partners can be found on the [IHI website](#).

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 can not 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 to build your proposal budget and verify automatically if it reaches 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.

Info session on financial aspects

#IHICallDays

Call 7

Pitches Info sessions

- 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
- 24 Jan 14:30 Optimised hospital workflows
- 25 Jan 14:30 Clinical validation of biomarkers

Register now



Online event



👉 Registration is open now

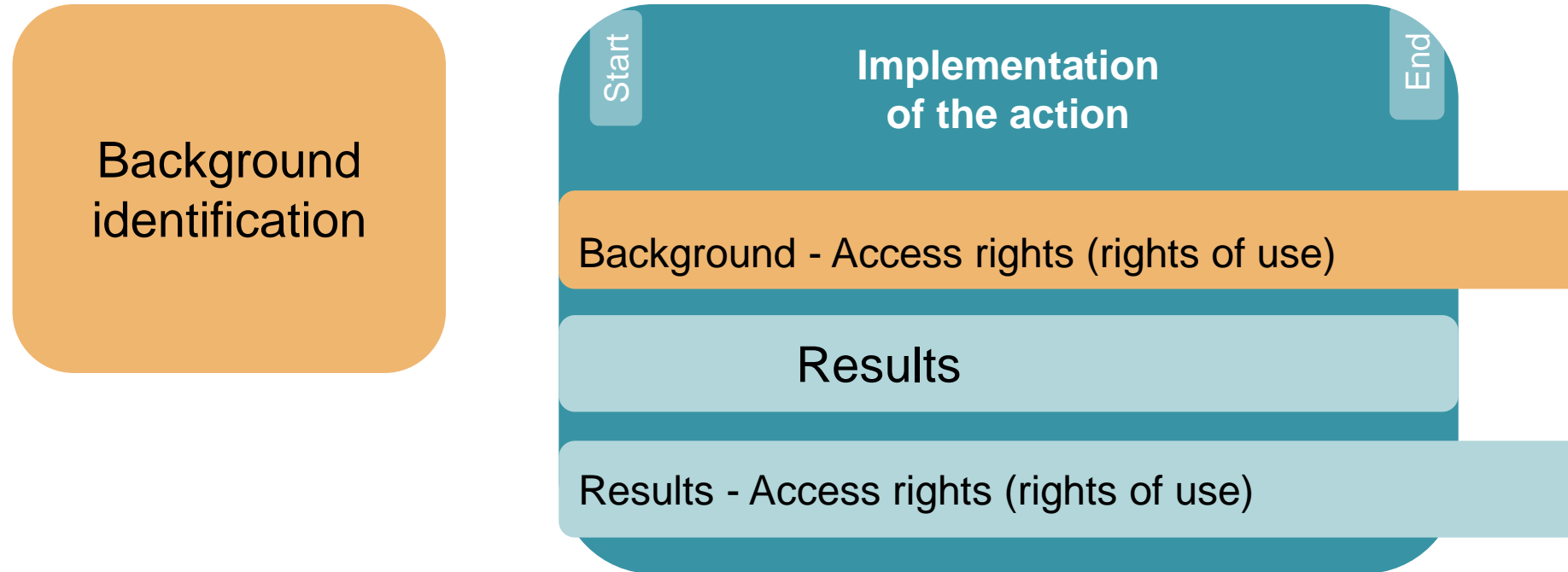
👉 sign up today!

<https://europa.eu/!RTJc7m>
[hashtag#IHICallDays](https://twitter.com/IHICallDays)



- 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

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;
 - 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.
- * Project IPR specificities to be agreed amongst all parties and detailed in the project Consortium Agreement



- 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).
- **Annex: Type of Participants**
- **Annex: Declaration of in-kind contribution commitment**
- **Annex: In-kind contributions to additional activities** - optional annex
- **Annex: Essential information for clinical studies** - compulsory annex
- **Annex: Ethics** (no template) - optional annex – provide more information, if necessary, that goes beyond the ethics self-assessment in Part A
- **Annex: to the budget for the Full Proposal**

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

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.**

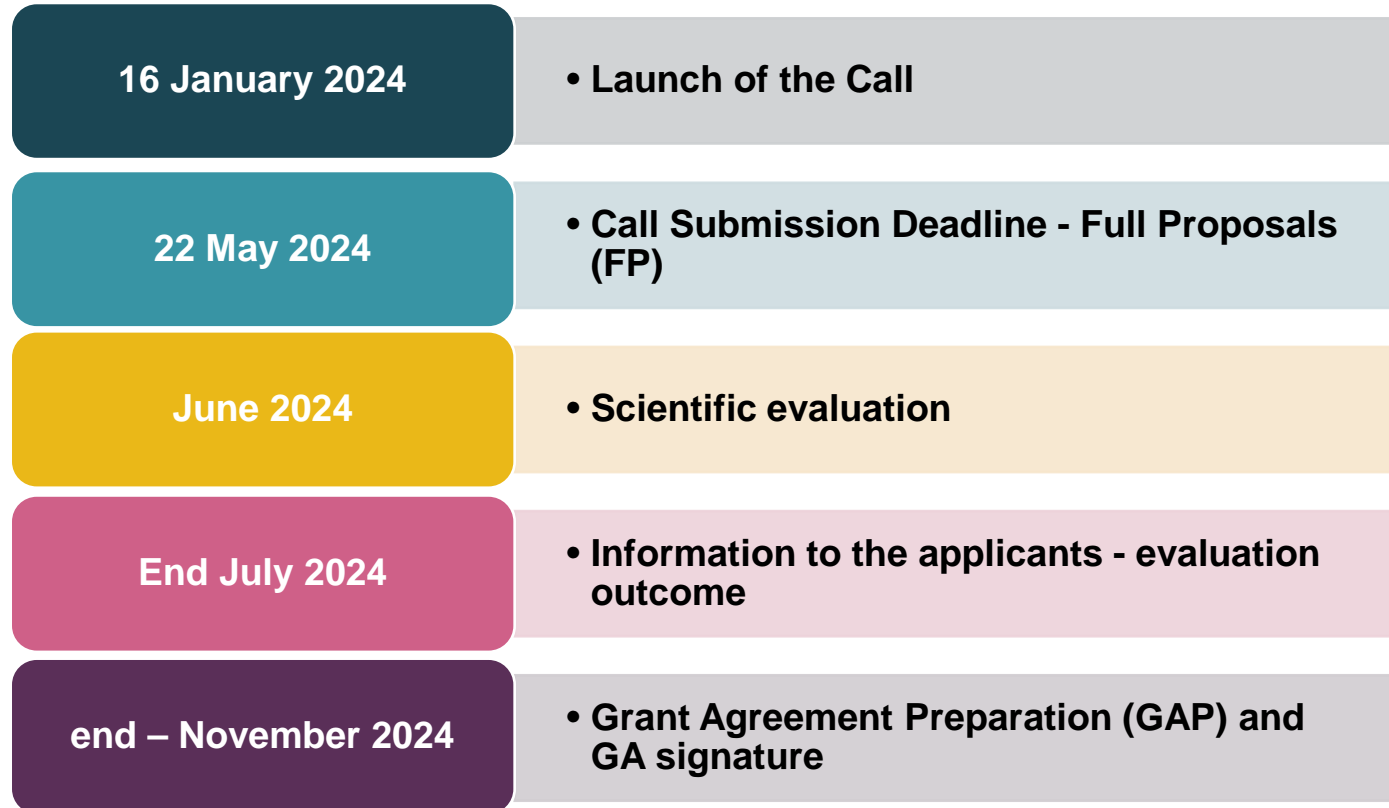
Consortium Agreement for IHI Actions

- 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, DESCA (Development of a Simplified Consortium Agreement)).



● Timelines

Call 7 – single stage – Indicative timelines





Points to remember

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 subcriteria. **Respect the page limit – 50 pages.**
- Use the **proposal structure / template** - pay special attention on how to complete your ethics self-assessment.
- 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 **researchers table** (Proposal Part A) and ensure a gender balance. This might impact the proposal ranking in case of equal scores
- Don't forget the **Gender Equality Plan** (GEP) is an eligibility criterion
- Coordinator must be **financially viable** – check in advance
- Contact the IHI Office (NOT industry topic writers): applicants@ihi.europa.eu

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 experts@ihi.europa.eu mentioning your expert profile number (format EX20XX1234567)



Thank you for your attention

ihi.europa.eu

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

Pitches Info sessions

Call 7

- 10 Jan** **10:30** Management of heart disease
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Join the call 7 pitching sessions

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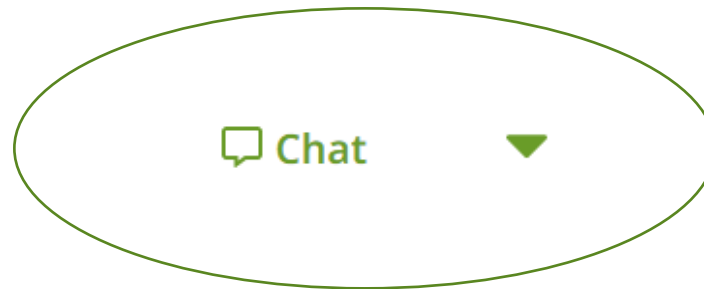
25 Jan 14:30 Clinical validation of biomarkers

Want to pitch?

- ✓ Indicate this in your profile **by 12 January**
- ✓ Register for the pitching session for your topic
- ✓ Create a participant profile and marketplace
- ✓ Download the slide template from the IHI Call Days portal and send us your presentation **by 19 January**

Questions time

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



Marketplace

Marketplace

1

291 Opportunities found

Search

2

PROJECT COOPERATION (291)

CALL TOPICS

3



Call 5 | Improved prediction, detection, and treatment approaches for comprehensive stroke management (36)

PROJECT COOPERATION

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 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

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