

Webinar on IHI rules and procedures



Outline

- 1. Introducing IHI
- 2. Participation rules
- 3. Funding rules
- 4. Intellectual property rules
- 5. From Call to grant award
- 6. Points to remember
- 7. Call timelines
- 8. Reference documents



Innovative Health Initiative

EU's new partnership in health between:

- the European Union represented by the European Commission
- **Private Members** representing the sectors involved in healthcare, namely:
 - COCIR (medical imaging, radiotherapy, health ICT and electromedical industries);
 - EFPIA, including Vaccines Europe (pharmaceutical industry and vaccine industry);
 - EuropaBio (biotechnology industry);
 - MedTech Europe (medical technology industry).
- Contributing partners that support the objectives of IHI.



IHI's general objectives

IHI's general objectives set out in the legislation creating IHI are to:

- turn health research and innovation into real benefits for patients and society;
- deliver safe, effective health innovations that cover the entire
 spectrum of care from prevention to diagnosis and treatment –
 particularly in areas where there is an unmet public health need;
- make Europe's health industries globally competitive.



Strategic Research & Innovation Agenda

Focus

 Cross-sectoral approaches to facilitate creation of new products and services to prevent, intercept, diagnose, treat and manage diseases and foster recovery more efficiently.

Goal

 Lay foundations for development of safer and more effective health care products or solutions that respond to unmet public health needs and that can be implemented into healthcare systems.



Participation rules



Two types of consortia envisaged (Type of Calls)

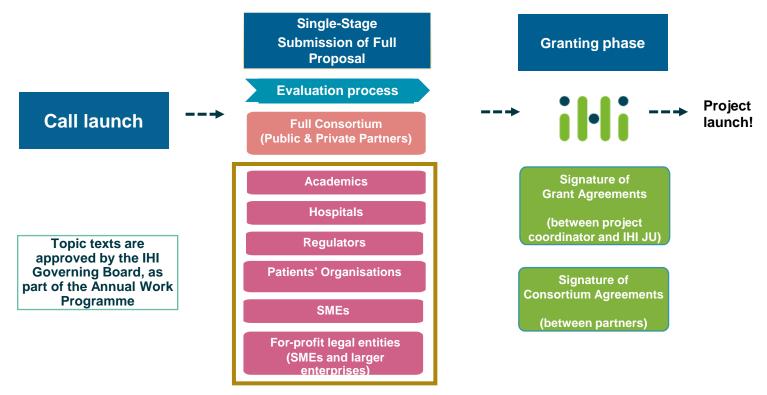
 Single-stage calls – very open – public and private actors self assemble and compete for funding

Two-stage Calls:

- applicant consortia must submit a 'short proposal (SP)' for the stage 1 evaluation.
- SPs must involve all applicant organisations requesting JU funding.
- the 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'.



How does IHI work? single-stage procedure

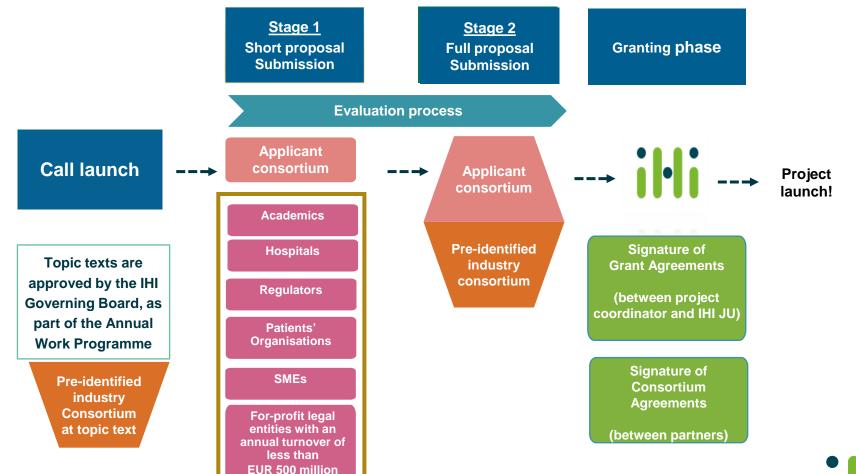


As part of the panel deliberations, IHI JU may organise hearings with the applicants to:

- clarify the proposals and help the panel establish their final assessment and scores, and/or
- improve the experts' understanding of the information presented



How does IHI work? two-stage procedure





Conditions for Call 1 single-stage

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

- Date of Call launch: end June 2022
- Submission deadlines: Deadline Proposal submission: end September 2022
- 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: 50 pages for Full Proposal



Conditions for Call 1 single-stage

Single-stage

- ✓ All evaluated proposals will be ranked in one single list.
- ✓ Proposals above the threshold will be invited in order of ranking to prepare a Grant Agreement within the limits of the available overall budget.
- For topic(s) involve clinical studies, applicants should submit the essential information for clinical studies annex (admissibility condition)
- Indicative contribution: For each topic, the maximum JU contribution is set in the call text
- Plan for Dissemination, Exploitation and Communication Activities (PDECA)
 It must be included in 2nd stage Full proposals



Conditions for Call 2 two-stage

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

- Date of Call launch: end June 2022
- Submission deadlines
- Deadline for Short Proposal submission: end September 2022
- ✓ Deadline for Full Proposal submission: end February 2023
- 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 and 50 pages for Full 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'.



Conditions for Call 2 two-stage

- For topic(s) involve clinical studies, applicants should submit the essential information for clinical studies annex (admissibility condition) in the second stage
- Indicative contribution: For each topic, the maximum JU contribution and the estimated industry contributions are set in the call text
- Hearings: If necessary, at stage 1 hearings might be organised with applicants during panel meetings. After submission deadline, coordinators will be informed about the possible date for the hearing
- Plan for Dissemination, Exploitation and Communication Activities (PDECA): It must be included in 2nd stage Full proposals

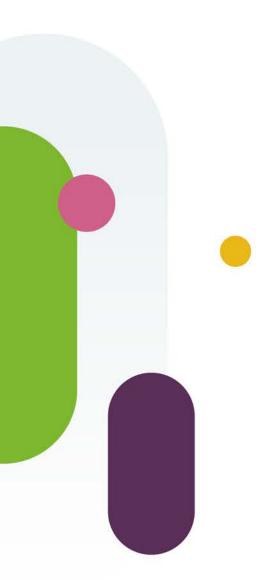
Contacts/discussions about a given topic between potential applicant consortia and members of the pre-identified industry consortium are prohibited throughout the procedure until the results of the first stage evaluation.



Information to the applicants

- Information on the outcome of the evaluation: Maximum 5 months from the submission deadline at the single-stage.
- Indicative date for the signing of grant agreement: Maximum 8 months from the submission deadline.
- For the two-stage Calls, the applicants will be informed of the results of the first stage (SP results) at the latest 6 weeks before the deadline for the second stage submission (FP submission).





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



Entities eligible to Participate

- Any legal entity, regardless of its place of establishment, including legal entities from non associated third countries or international organisations is eligible to participate (whether it is eligible for funding or not)
- A 'legal entity' means any natural or legal person created and recognised as such under national law, EU law or international law, which has legal personnality and which may, acting in its own name, exercise rights and be subject to obligations, or an entity without legal personality.

Open to the world

Beneficiaries and affiliated entities

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)



Consortium Composition



At least 3 independent legal entities established in a different

Member State or Associated Country





1 legal entity should be established in a Member State







Entities eligible for funding



Eligibility for funding: Common principle



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



Common Principles for both single and two-stage Calls



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
 - UK applicants are treated as if the UK is an associated country throughout the process, from admissibility and eligibility to evaluation, up until the preparation of grant agreements. Grant agreements can only be signed if the association has come into force.
 - Legal entities established in Switzerland are currently not covered by the transitional arrangement.
 - Liechtenstein does not intend to associate to Horizon Europe.
- 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





Eligibility for funding in single-stage Calls





For-profit legal entities (both SME and larger enterprises)



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.



Funding rules



IHI JU Funding model

- IHI JU is a PPP, actions are normally co-funded by:
 - IHI funding primarily supports the participation in its projects of organisations like universities, research organisations, patient organisations, small and medium-sized enterprises (SMEs), and mid-sized companies (companies with a turnover below EUR 500 million).
 - larger companies may also be eligible to receive IHI funding.
 - the IHI JU private members (represented by the industry associations COCIR, EFPIA (including Vaccines Europe), EuropaBio and MedTech Europe) and IHI JU Contributing Partners, their constituent entities and affiliated entities (collectively the "industry consortium participants"), shall provide at least 45% of the sum of total project eligible costs plus In-kind contributions to additional activities (IKAA)



IHI JU Specific types of Beneficiaries

Two-Stage Calls: Private members and Contributing Partners

Pre-identified

- ✓ 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

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



IHI JU Specific types of Beneficiaries

Private member

Any legal entity established under public or private law (including constituents and/or affiliates) that is member of one of the Industry Associations.

Constituent entities means the entities that constitute a private member of a joint undertaking, where the private member is an association according to that member's statutes.

Affiliated entity means the entity that has a capital or legal link with a beneficiary (which is in this case a private member or a private member constituent entity)

Contributing Partner legal entities interested in supporting IHI JU's objectives in their specific areas of research, without becoming a member; it participates in the Consortium and provides in kind or financial contributions but is not providing in-kind contributions to additional activities (IKAA)













Industry contributions

In-kind contributions to operational activities (IKOP)

- Eligible costs incurred in implementing the action.
- Non-EU IKOP refers to in kind contribution incurred outside of the 27 EU Member States and Associated countries to Horizon <u>Europe</u>

In-kind contributions to additional activities (IKAA)

Costs for implementing additional activities (not project task and therefore not IKOP)

- √ Programme-specific (i.e. uptake of results from IHI/IMI)
- √ Project-specific (i.e dissemination, sustainability or exploitation of IHI JU project results)

Financial Contribution (FC)

- Financial transfer (cash contributions) by private industry members, their constituent or affiliated entities and by contributing partners to:
 - ✓ project beneficiary(ies) supporting the eligible costs incurred in implementing the IHI projects, or
 - √ the IHI JU <u>directly</u> (to increase a given project funding)



Contribution types

Private members

Contributing Partners

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











IKAA - In-kind contributions to Additional Activities
 Costs for implementing additional activities (NEW, no IKAA in IMI2)

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 ≥ 45% of (Project eligible costs + IKAA)

If the 45% Industry contribution is not secured collectively by the industry consortium participants, 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



One single funding rate per project

One project = One rate

For all beneficiaries and all activities

- 100% of the direct eligible costs
- Indirect costs: 25% flat rate



Types of participants and cost eligibility rules

ТҮРЕ	Works on 'action tasks'?	beneficiary/affiliated	Must be indicated in Annex 1 GA?	Conditions for participation	GA article
Beneficiaries (including private members and contributing partners)	YES	Costs	YES	Must be eligible	Art 7
Affiliated entities (including the ones of private members and contributing partners)	YES	Costs	YES	Must have a capital or legal link with a beneficiary and fulfill the same eligibility conditions	Art 8
Associated partners	YES	1	YES	No specific conditions (APs do not receive funding)	Art 9.1
Third parties contributing to the project	Participate in the action as contributors	Costs	YES	/	Art 9.2
Subcontractors	YES	Invoiced price	NO (only subcontracted tasks must be indicated)	Must be est value for money or lowest price and no conflict of interest	Art 9.3
Third parties receiving financial support	Participate in the action as recipients	Amount of support given	YES	According to the conditions in Annex 1 GA	Art 9.4



Intellectual Property Rights ('IPR') in IHI



Key terms

- 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". For more information, please see the HE Model Grant Agreement and in particular Annex 5.
- 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



Background

- Means any data, know-how or information, including IPR that is:
- held by the beneficiaries before they acceded to the Agreement;
 and
- (2) needed to implement the Action or exploit the results
- The beneficiaries must identify in a written agreement the background as needed for implementing the action or for exploiting its results – normally this is done in the Consortium agreement



Ownership of results

General rule: Results are owned by the beneficiaries that generate them

- Joint ownership: two or more beneficiaries own results jointly if:
 - they have jointly generated them; and
 - it is not possible to: establish the respective contribution of each beneficiary, or - separate them for the purpose of applying for, obtaining or maintaining their protection.
- Joint ownership agreement must be concluded in writing by the joint owners; should define relative contributions, conditions for granting licenses and issues related to costs of protection and sharing of potential revenues



Obligations towards the Results

Obligation to protect:

participants must protect the results — for an appropriate period and with appropriate territorial coverage — if:

- (a) the results can reasonably be expected to be commercially or industrially exploited; and
- (b) protecting them is possible, reasonable and justified (given the circumstances).

Obligation to exploit:

Beneficiaries receiving EU funding must – up to four years after the end of the action – use their best efforts to exploit their results directly or to have them exploited indirectly by another entity, in particular through licensing or transfer.

If, despite a beneficiary's best efforts, the results are not exploited within one year after the end of the action, the beneficiaries must (unless otherwise agreed in writing with the granting authority) use the Horizon Results Platform to find interested parties to exploit the results.



Access Rights*

- to Background and Results of other Beneficiaries:
- o for implementing the action as a rule on royalty-free basis
- for exploitation of results as a rule on fair and reasonable conditions
- Access rights for entities under the same control:
- are granted access to results and background (unless the consortium agreement specifies otherwise) under fair and reasonable conditions
- the entities must be based in the EU or HE associated country



^{*}Additional rights can always be agreed upon in the Consortium Agreement

IPR in IHI compared to IMI2

- 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 V 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.
- 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.

Some notable Access Rights changes from IMI2 JU to IHI JU*

- Access Rights are now consistent with Horizon Europe MGA;
- No third party access rights after project end for research use of results.



^{*} Project IPR specificities to be agreed amongst all parties and detailed in the project Consortium Agreement

From Call to grant award

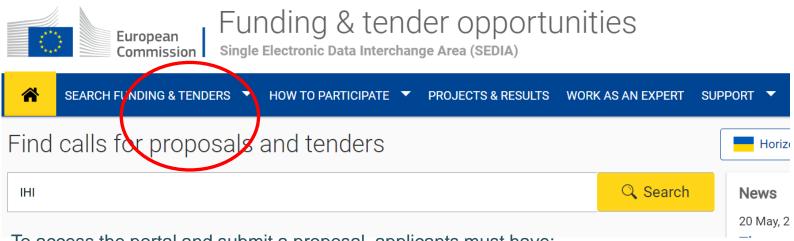




UPDATED

Via the Funding and Tenders Portal

https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/home



To access the portal and submit a proposal, applicants must have:

- An EU Login account (previously, 'ECAS' account)
- Their **organisation registered** on the Participant Portal Beneficiary Register, with a 9-digit **Participant Identification Code (PIC) number**
- If you do not have an EU Login account yet, you can create an EU Login account on the Funding and Tenders Portal, and register your organisation.
- More information: http://ec.europa.eu/research/participants/docs/h2020-funding-guide/user-account-and-roles/ecas-login_en.htm



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



Full 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

Proposal template sections:

- ✓ General information (acronym, proposal title, duration in months)
- Participants (Researchers involved in the proposal, Gender equality plan, etc)
- √ Budget (HE and IHI specificities)
- ✓ Ethics and security (How to Complete your Ethics Self-Assessment).
- √Other questions (proposals including clinical studies)



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 full proposal is maximum 50 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



Annexes

Annex	Description	Compulsory/ Optional
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. 	Compulsory
Declaration of in-kind contribution commitment (IHI specific annex)	The Coordinator on behalf of the consortium confirms compliance with the minimum in kind threshold of 45%	Compulsory
In-kind contributions to additional activities (IKAA) (IHI specific annex)	to IHI private members should fill in the Annex on In-kind contributions to additional activities ('IKAA') of a Project (full) Proposal in Single Calls or in 2nd stage of 2 stage Calls.	Optional
Essential information for clinical studies (HE specific annex)	For proposals that involve clinical studies, project participants must add this document to the application (eligibility condition)	Mandatory for topics involving clinical studies
Ethics (HE specific annex)	Besides the information provided in Part A - participants may include additional information in an annex to proposal part B.	Optional

A single set of evaluation criteria

Thresholds and weighting in the Call documents Minimum of 3 independent experts

Each proposal evaluated 'as it is', not as 'what could be'

Standard criteria

Excellence Impact Quality & efficiency



IHI JU Evaluation criteria

Single and two-stage calls

- Excellence threshold of 3/5
 Please note sub-criteria listed in evaluation form,
- Impact threshold of 3/5
 Please note sub-criteria listed in evaluation form,
- Quality and efficiency of the implementation threshold of 3/5
 Please note sub-criteria listed in evaluation form

Overall threshold is 10/15



Keeping the momentum

Maximum Time To Grant: 8 months from submission of full proposal:

5 months

for informing applicants of scientific evaluation

3 months

for signature of grant agreement

NEW Legal entity validated in parallel



IHI JU Grant Agreement



- The new Horizon Europe Model Grant Agreement includes 44 articles, as well as specific Annexes
- IHI JU follows HE Model Grant Agreement 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

- Contractual arrangement between all participants to set out their rights and obligations, especially governance, liability and IPR
- Shall comply with the HE Model Grant Agreement
- To be agreed before the signature of the GA, IHI JU is not a party
- To be adapted to the specific needs of each IHI2 JU action!







- Eligibility criteria:
 - 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
 The consortium should ensure that 45% Industry contribution is secured
 collectively by the industry consortium participants, otherwise the proposal will
 be declared ineligible and therefore will not be evaluated.





- Read all the call-relevant material:
 - www.ihi.europa.eu
- Begin forming your consortium early
- Carefully read the topic text
- Ensure that all information is explicitly described in order to allow the expert-evaluators to assess against the evaluation subcriteria
- Use the proposal structure / template pay special attention on how to complete your ethics self-assessment.
- Complete accurately the researchers table (Proposal Part A) and ensure a gender balance. This might impact the proposal ranking in case of equal scores



- 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.
- If you plan to be the consortium Coordinator, ensure that you are financially viable otherwise if the your proposal is selected, your organisation should be replaced during the grant preparation phase and this will impact the grant agreement signature timing.
- Finalise and submit your proposal early
- Contact the IHI Office (<u>NOT</u> industry topic writers): <u>infodesk@ihi.europa.eu</u>





Timelines



Call 1 – single stage – Indicative timelines

end-June 2022

Launch of the Call

end-September 2022

 Call Submission Deadline - Full Proposals (FP)

October 2022

Scientific evaluation

end-November 2022

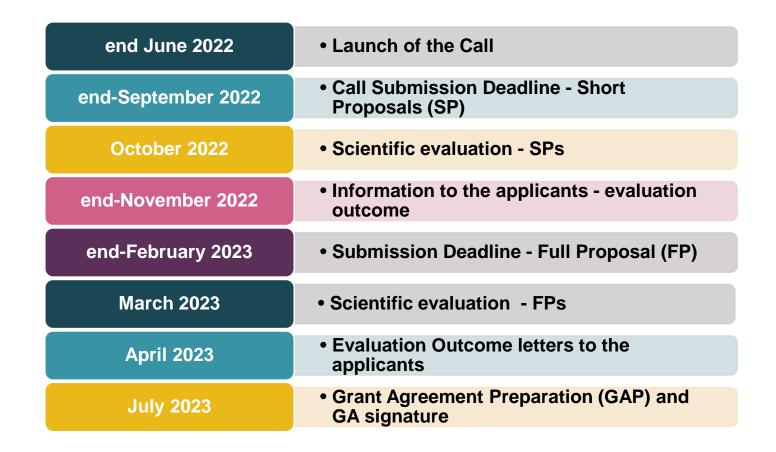
• Information to the applicants - evaluation outcome

March 2023

 Grant Agreement Preparation (GAP) and GA signature



Call 2 - two-stage — Indicative timelines





Reference Documents

- ✓ IHI Specific documents
- <u>SBA</u>
- 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 2021–2022 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 <u>General Model Grant Agreement MGA v1.1 of 15 April 2022</u> (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.



Questions



Questions?

- Raise your hand if you want to ask a question orally or
- Type your question in the chat

After the webinar, send any questions to the **IHI Programme Office**

applicants@ihi.europa.eu



Thank you for your attention

ihi.europa.eu

