

FAQs on IHI call 9

About this document

This document was prepared to address the most frequently asked questions received during the info session on IHI call 9 held on 10 October 2024. Readers should note that at the time of writing, IHI call 9 is still under development and so the information presented should be considered indicative and subject to change. Final information about the future IHI calls will be communicated after the IHI Governing Board's approval.

To stay up to date on IHI call 9 as well as other IHI calls and activities, sign up for our $\underline{\text{monthly newsletter}}$, and/or follow us on social media – $\underline{\text{LinkedIn}}$ – $\underline{\text{X}}$ – $\underline{\text{Mastodon}}$.

Contents

| Questions on IHI call 9 | 2 |
|--|----|
| Scope – subject areas and activities | 2 |
| Funding and timelines | 4 |
| Miscellaneous | 5 |
| Questions on the brokerage platform and event | 6 |
| Proposals | 6 |
| Miscellaneous | 6 |
| Questions on IHI's rules and procedures | 8 |
| Eligibility to participate / receive funding / funding rates | 8 |
| Contribution of industry partners / contributing partners | 9 |
| Consortium size / composition rules | 10 |
| Miscellaneous | 10 |
| General questions about IHI | 11 |













Questions on IHI call 9

Scope – subject areas and activities

Q: Can you please clarify 'pre-competitive'? Is it linked to a specific technology readiness level (TRL)? How is this reflected in IP?

The work supported by IHI should be pre-competitive, meaning it will not deliver products or services directly into healthcare systems or the market. The are no specific requirements regarding TRL. IP rules in IHI projects are defined under the Horizon Europe General Model Grant Agreement (article 16 and Annex 5). The consortium agreement may also include provisions on IP, but these must not conflict with the rules of the grant agreement. Please note that IHI cannot advise on the wording of consortium agreement.

Q: Are there any requirements regarding how far the results of projects in call 9 are from the market? For example, do the services or products that are developed need to reach a certain TRL level at the end of the project?

The are no specific requirements regarding TRL. Please remember that the type of projects funded are research and innovation actions and not innovation actions. The work supported by IHI should be precompetitive, meaning it will not deliver products or services directly into healthcare systems or the market. Note: Horizon Europe funds different types of collaborative projects including, for example:

- Research and innovation actions (RIA) that establish new knowledge and/or explore a new or improved technology, product, process, service or solution. EU funding covers up to 100% of the project costs.
- Innovation actions (IA) that produce plans or designs for new or improved products, processes or services including prototyping, testing, demonstrating, piloting, large-scale product validation and market replication. EU funding covers up to 70% of the project costs.

Q: Can you please specify the priority disease areas (SO1)? Would the following disease areas be in scope: neurodevelopmental disorders (e.g. autism) behavioural (i.e. non-pharmacological) treatment; rare diseases; AMR; epilepsy; obesity, longevity and ability to work?

The Innovative Health Initiative has been conceived to encompass disease areas focussing on unmet public health needs and therefore there is no defined list. As mentioned in the IHI Strategic Research and Innovation Agenda, to identify focused areas for the partnership's activities, three criteria will be considered: (1) the high burden of the disease for patients and/or society due to its severity and/or the number of people affected by it; (2) the high economic impact of the disease for patients and society; (3) the transformational nature of the potential results on innovation processes where projects are not focussed on individual diseases (e.g. health data analytics).

Q: Would it be of interest to target one disease area or is it better to target more than one disease area?

This will depend on the objectives of the proposal.

Q: Would the following be in scope: leveraging academic innovations for a translational platform for the benefit of patients / clinical trials / social interventions and quality assurance interventions?

This will depend on the objectives of the proposal.

Q: Could you please specify what 'implementation science' includes?

In the context of IHI, 'Implementation science' refers to the development and piloting of methods and strategies that facilitate the uptake of evidence-based practice and research outcomes into regular use (e.g. translation of results, scale-up and piloting in healthcare).

Q: Does the grant cover very high-risk, state-of-the-art research? Does it also cover innovative (new) and challenging work, but that is less high-risk?

This will depend on the objectives of the proposal.

Q: What are the topics for this call?

The topics for this call match the five specific objectives of the <u>Strategic Research and Innovation Agenda</u> and are:

- Topic 1 (SO1): Contribute towards a better understanding of the determinants of health and priority disease areas
- Topic 2 (SO2): Integrate fragmented health research and innovation efforts bringing together health industry sectors and other stakeholders, focussing on unmet public health needs, to enable the development of tools, data, platforms, technologies and processes for improved prediction, prevention, interception, diagnosis, treatment and management of diseases, meeting the needs of end-users
- Topic 3 (SO3): Demonstrate the feasibility of people-centred, integrated healthcare solutions
- Topic 4 (SO4): Exploit the full potential of digitalisation and data exchange in healthcare
- Topic 5 (SO5): Enable the development of new and improved evaluation methodologies and models for a comprehensive assessment of the added value of innovative and integrated healthcare solutions.

The draft call text is available on the **IHI** website.

Note that unless stated otherwise, all information regarding future IHI call topics is indicative and subject to change. Final information about future IHI calls is communicated after approval by the IHI Governing Board.

Q: The strategic objectives overlap, and in fact, the majority of the running IHI projects cover different objectives. If a project addresses more than one objective, will this face a better evaluation? Do you have any additional tips on clustering/shaping a project under only one objective?

While there is complementarity of the IHI JU Specific Objectives, proposals can only be submitted under one topic. Therefore applicants must carefully consider which Specific Objective is the most relevant to the primary focus of their proposal and submit it only under the corresponding topic. Applicants must clearly justify the alignment of the objectives of their proposed work with the SO selected. If proposals cover also aspects related to other Specific Objective(s), applicants should also highlight this in their proposal. Applicants are therefore encouraged to read the IHI SRIA carefully for full information on the SOs.

Q: How does the IHI call differ from the Health Cluster 1 calls?

IHI is a public-private partnership under Health Cluster 1. However as a partnership, we have <u>objectives</u> as set out in the legislation creating IHI, including making Europe's health industries globally competitive.

Furthermore, applicants must assemble a collaborative public-private partnership consortium reflecting the integrative and cross-sectoral nature of IHI JU, leveraging at least 45% contribution from the IHI private members and, if relevant, from contributing partners.

Q: Would you consider the development (not discovery) of a drug in this call?

The work supported by IHI should be pre-competitive, meaning it will not deliver products or services directly into healthcare systems or the market.

Q: If there are too many excellent proposals, will there be areas with priorities?

Further information will be provided in the call conditions at the time of call launch.

Q: What do you mean by 'unmet needs'?

As mentioned in the <u>IHI SRIA</u>, 'unmet public health needs' are needs currently not addressed by the healthcare systems for various reasons, for example if no medicines are known to treat a disease. Areas of public health importance are those where the burden of disease is high for patients and society due to the severity of the disease (in terms of mortality, physical and functional impairment, comorbidities, loss of quality of life ...), and/or the number of people affected by it. For example, Alzheimer's disease.

Q: On the aspect of integrating health research and innovation, can the innovation be a digital transformation?

In principle yes, as long as it addresses the objectives of the selected topic.

Q: Is it expected to launch a product to the market, or is it ok to make steps towards this direction?

Please note that the work supported by IHI should be pre-competitive, meaning it will not deliver products or services directly into healthcare systems or the market.

Q: Is the development of commercialisation opportunities, business models etc for industry partners of interest and within scope for the funding, despite the pre-competitive research focus?

For this call, IHI will fund pre-competitive research and innovation actions that contribute to addressing IHI JU's Specific Objectives, as defined in IHI JU's legal basis and described in more detail in the IHI Strategic Research and Innovation Agenda (SRIA). According to Horizon Europe, research and innovation actions (RIA) establish new knowledge and/or explore a new or improved technology, product, process, service or solution.

Funding and timelines

Q: What is the overall budget of the call? What is the estimated budget per project? Will the overall budget of the call be divided in the different topics/SOs, or will all proposals be competing among them?

Indicative information on budgets can be found in the draft text published on the <u>IHI website</u>. Note that the text is still undergoing review, so this information may change. Final information will be published following Governing Board approval of the call text.

Q: When the call will be launched?

The call will be launched in early 2025.

Q: Is there an estimated proposal submission deadline for the call?

The deadline will be published when the call is launched.

Q: What is recommended duration of the projects?

Applicants should propose a project duration that matches the project's activities and expected outcomes and impacts.

Q: How many projects will be funded per topic?

This is not predefined. Nevertheless for each topic applicant consortia will be competing for a maximum financial contribution from IHI JU.

For each topic, IHI JU will provide an estimate for an IHI JU financial contribution that would allow a proposal to address the outcomes appropriately, although this would not preclude the submission and selection of a proposal requesting different amounts.

Q: Will there be a possibility for in-kind contribution to additional activities like in previous calls?

Yes, it will be possible. But please note that in-kind contributions to additional activities (IKAA) are contributions which may only be incurred by the constituent or affiliated entities of the IHI JU private members and consist of costs for implementing additional activities. More information can be found in our guidelines on IKAA.

Q: The call will be launched in early 2025, but will the work programme be published earlier?

Yes, we will publish the Work Programme once it has been approved by the IHI Governing Board.

Miscellaneous

Q: If an IHI proposal was unsuccessful in a previous round, can it be resubmitted for this round, with changes to address reviewer concerns, if it addresses one of the core questions?

This is an applicant-driven call. All proposals that address the objectives of a specific topic can be submitted.

Q: Next to the bottom-up call, will there also be top-down calls in call 9?

No, IHI call 9 is a single-stage call that is purely applicant driven. IHI is also working on a two-stage call, IHI call 10, which will be launched at the same time. Information on the draft topics can be found here.

Questions on the brokerage platform and event

Proposals

Q: Can you make the proposal visible only to the people you want to be part of it?

No – once a proposal is made visible on the platform, it will be visible to everyone who has registered.

Q: Can I submit a proposal idea even if I'm not a coordinator?

Yes.

Q: Can one company submit more than one proposal?

Yes.

Q: Is there some sort of NDA or protection in place for information shared on the platform?

Any proposal published on the platform will be visible to other registered users, so you should not include any confidential information.

Q: If our proposal is not accepted for a pitch at the brokerage event, can we still submit our proposal in the EC portal?

Yes.

Q: Can the proposal template in the platform be used for an activity that should fit to a broader proposal (is it meant for coordinators or also for partners that may provide support to specific aspects)?

It is primarily for people with proposals for an entire project. Organisations that want to showcase their specific expertise should do so via their profile.

Q: Do we have to publish the idea on the platform if we already know who we would like to partner with?

No.

Q: The platform is only a tool to prepare right? The official way to submit a proposal will follow later, or is that also through the platform?

Yes – our platform is there to help you get your idea out there and start building a consortium. Formally submitting a proposal in response to this call will only be possible via the <u>EU Funding and Tenders portal</u> – the portal links relating to IHI call 9 will be published on the IHI website when the call is launched.

Miscellaneous

Q: What is the link to the brokerage platform?

https://ihicalldays2024.converve.io/

Q: Will there be additional brokerage events after Nov 12-13?

IHI will not be organising additional brokerage events on call 9. However, the platform will remain open until the call deadline, so you can and should keep using it after the event to find partners and share and search for proposal ideas. We would also recommend potential applicants to use their contacts and other events to network around this call.

Q: Do we really need to attend the face-to-face brokerage or online event for submitting proposals to the call?

No, but it will be a very good opportunity to find other people who are interested in this call.

Q: So, do I understand it correctly - you can attend the brokerage event with a premature consortium and ditto proposal?

Yes – the idea is to come with early-stage ideas for a proposal so that you can meet other people who will help you refine it and develop it further.

Q: Are the pitch and poster compulsory to apply for the call?

No.

Q: You say that the event is online on November 14th. But you also say it will be online up until the call. Could you elaborate?

The networking platform will remain open until the call deadline, and it will be possible to find, contact and meet people one-on-one until then. On 14 November, we will additionally open virtual lounges where several people will be able to meet to discuss project proposals, for example.

Q: How can we identify and contact private partners that belong to the IHI partnership, both in the platform and at the event?

You can find people from the industry in the platform as follows:

- In the left-hand menu, select 'People'.
- At the top of the page, there are several filters one is marked 'Member Industry Associations'. If you
 select one or all or the associations listed, you should see people who are members of or work for the IHI
 industry partners.
- If you see someone you want to contact, click on their profile and then click on 'send message'.
- To see who will be at the event, go to the filter marked 'Type' and select 'Onsite Attendee'.

Q: What would be the best approach to pitch our idea to IHI industry members to explore if they are interested in being involved?

We provide general advice on how to network and approach partners on our <u>website</u>. In addition, HNN3.0 has developed a comprehensive guide on this subject – the latest version is available <u>here</u>.

Q: Can SMEs (not affiliated to the IHI members) also join the networking platform?

Any organisation can join the networking platform. IHI projects bring together diverse organisation types, and we hope the platform participants will reflect that!

Q: Do we need to start by contacting the IHI industry associations to be sure that one is interested?

This is a competitive call, so you will need to approach industry representatives to gauge their interest. It is up to you if you go via the associations or directly to someone working in a company.

Questions on IHI's rules and procedures

General note – the answers to many of these questions can be found in the following documents:

- Guide for Applicants
- FAQ

In addition, we will organise online info sessions on the rules and procedures for single-stage calls and the financial aspects of single-stage proposals. These will be held around the time of the call launch, in early 2025. Details will be announced on the IHI website, in the IHI newsletter, and via our social media channels.

Eligibility to participate / receive funding / funding rates

Q: Where can I find information on the eligibility of organisations from different countries (e.g. Switzerland, UK, US, Canada, South Korea...) to participate in IHI projects and receive funding?

Guide for Applicants Section 2.3

FAQ Questions 3, 4, 5

Q: As this is a single-stage call, half of the project costs (minimum 45%) should come from IHI industry members and (if relevant) contributing partners. If an academic unit is leading/involved in the project, do they also need to co-finance with 40%?

The 45% rule applies to the project as a whole and this is an eligibility criterion. The funding rate for participants that are eligible to receive funding is 100% of direct costs plus a flat rate of 25% for indirect costs.

Please see FAQ Questions 3, 4, 5 on who is eligible to receive funding.

Q: How do you define an SME?

Guide for Applicants Section 2.3.3

Q: Is a joint venture company considered as a large company if it is controlled by a large pharmaceuticals company?

IHI JU refers to annual turnover rather than company being large. See FAQ Questions 4 & 5.

Q: Are private healthcare organisations eligible to apply?

Guide for Applicants Section 2.2

FAQ Questions 3, 4, 5

Q: How do you define a public institution?

Guide for Applicants Section 2.3.3

Contribution of industry partners / contributing partners

Q: Is it mandatory to include IHI industry members in your consortia, or can you include other industry partners?

As we are a public-private partnership between the EU and specific industry associations, we do expect consortia to include members of those industry associations.

Q: So 50% of the cost should be covered by the industry partners and 50% by the IHI?

FAQ Question 10

Q: Should industry contributions be in kind? What sorts of in-kind contribution would you accept?

Guide for Applicants Section 3.2.1.3

Q: Should industry partners be already involved in the project proposals?

Yes, in single-stage calls like IHI call 9, industry partners should be involved in the proposals as half of the project costs (45% minimum) must be covered by industry partners, and if relevant, IHI contributing partners.

Q: Is a foundation eligible to provide in-kind contribution?

If an entity is not an IHI private member, it may contribute in-kind only if that foundation applies to become an IHI contributing partner and the IHI Governing Board accepts its application.

Q: Can data from previous projects relevant to the new proposal be considered as in-kind contributions?

All in-kind contributions must be eligible in the meaning of Article 6.1 of the <u>Grant Agreement</u>. Data that are pre-existing the start of the project and for which the entity does not incur costs anymore during the project implementation are not eligible. Only actual costs incurred during project implementation for those data (e.g., harmonisation costs, transfer costs) can be valorised as IKOP (in-kind contributions to operational activities).

See FAQ Question 24

Q: Can industry partners be based outside Europe?

It is possible that an IHI private member is based outside of Europe. Nevertheless, please note that there is cap on the percentage of the non-EU contributions in the projects – this will be specified in the final version of the call text.

Q: Do all industry members of a consortium need to be a member of IHI industry partner organisation?

In order to be considered an IHI private member and contribute towards the eligibility criterion of 45% of the total project costs as in-kind contributions, an entity must be a member of:

 a. one of the IHI private members, which are the European life science industry, represented by the industry associations COCIR, EFPIA (including Vaccines Europe), EuropaBio and MedTech Europe. Please visit: https://www.ihi.europa.eu/about-ihi/who-we-are/partners

- b. member of these industry trade associations (listed in point a above); or
- c. an affiliated entity of one of the above categories.

Q: How many industry partners should be involved?

There is no minimum or maximum number of IHI industry partners. What does matter is that they contribute half (minimum 45%) of the project costs.

Consortium size / composition rules

Q: Just to be completely clear, as a private company from country A, we should form a consortium with at a minimum one partner from the IHI industry bodies from country B, and one public institution from country C, is that correct?

This is not entirely correct. Please read in detail FAQ Question 2.

Q: The minimum 3 organisations from EC member/associated states must be from 3 DIFFERENT countries or could be from same country? and does it mean minimum 3 PUBLIC organisations or public and/or private from 3 different countries?

FAQ Question 2.

Q: As a private company, do I understand correctly that we need to find one or more public institutions as partners in order to qualify as a consortium?

FAQ Question 2.

Q: Can you apply as part of more than one consortium?

Yes.

Miscellaneous

Q: What about IP and ownership?

Information on this can be found in the <u>Grant Agreement</u> (article 16 and Annex 5). The consortium agreement may also include provisions on IP, but they may not conflict with the rules of the grant agreement. Please note that IHI may not advise on the wording of consortium agreement.

Q: If the project is based on unpublished data, who ensures that the shared information remains confidential and is not used by others?

Please consult the wording of the <u>Grant Agreement</u> on confidentiality. The consortium agreement may also include provisions on confidentiality, but they may not conflict with the rules of the grant agreement. Please note that IHI may not advise on the wording of consortium agreement.

Q: Is the funding a grant or a loan?

IHI funding is a grant, not a loan.

Q: Which profile is expected to be the leader of the consortium? Public research or private industry?

FAQ Question 17.

Q: When evaluating the proposals, will you follow the same procedure/important points as in previous calls or will there be something new? Is the evaluation performed similar to Horizon Europe proposals? (independent evaluation, consensus, ranking)

The evaluation form is available <u>here</u>. Note that we are making a small update to this form so please check the version published around the time of the call launch.

Guide for Applicants chapter 5.

Q: Will the proposal template be changed?

The proposal template will be updated for this call – it will be published here.

General questions about IHI

Q: Who funds IHI?

The total budget for IHI for the period 2021-2027 is €2.4 billion.

- €1.2 billion comes from Horizon Europe, the EU's framework programme for research and innovation.
- €1 billion will come from the IHI industry partners
- €200 million will come from other life science industries or associations that decide to contribute to IHI as contributing partners.

More details can be found <u>here</u>.

Q: Where can I find the list of IHI industry members?

On our website <u>here</u>.