Some key elements to consider when preparing to apply to IHI Call 12



• If you remember only one thing - READ

- Read the topic text
- Read the IHI call-related guidance
- Understand IHI's rules and requirements
- Understand what you are applying for





IHI Call 12

- New applicant-driven Call, taking into account experience from pilot Call 9.
- Create additional research opportunities and harness new science and technologies through a broad scope.
- Be attractive to innovative proposals and to a range of new stakeholders including smaller players, private members that might be not already involved in IHI activities.
- Provide opportunities for new cross sectoral collaborations in line with IHI's general and specific objectives.
- Enhance openness and co-creation of research ideas to projects.

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.





IHI Call 12

Boosting innovation for a competitive European health ecosystem



- IHI Call 12 comprises 5 topics, each focusing on one of the five IHI Specific Objectives (SOs)
- The call contains an introduction and general elements to be considered for all topics
- The overall aim is to fund pre-competitive research and innovation actions that are in line with the general objectives of IHI and address at least one of IHI SOs as set out in the IHI <u>Strategic Research and Innovation Agenda</u> (<u>SRIA</u>)

It is important to read carefully the introduction to the Call and general elements to be considered for all topics

NB - In the context of IHI, pre-competitive refers to collaborative research among potential competitors addressing common challenges, building knowledge and developing foundational technologies or standards that benefit all the actors in that research space, rather that individual companies.



IHI Call 12 - Topics

Five topics (T), each focusing on one of the five IHI Specific Objectives (SOs)

T1: contribute towards a better understanding of the determinants of health and priority disease areas;



T2: integrate fragmented health research & innovation efforts bringing together health industry sectors and other stakeholders, focusing on unmet public health needs, to enable the development of tools, data, platforms, technologies & processes for improved prediction, prevention, interception diagnosis, treatment and management of diseases, meeting the needs of end-users;



T3: demonstrate the feasibility of people-centred, integrated healthcare solutions;



T4: exploit the full potential of digitalisation and data exchange in healthcare;



T5: 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.







General elements to be considered for all topics

- Most activities are expected to be cross-sectoral, and may cover the whole health innovation chain including but not limited to:
 - discovery of new molecules, mechanisms of action, processes, technologies;
 - development and testing of these discoveries;
 - development of methodologies for assessment of safety, health outcomes or healtheconomic evaluation;
 - standardisation activities;
 - contribution to regulatory science;
 - pilots/proofs of feasibility including in-silico trials.





General elements to be considered for all topics

- Proposals that aim to demonstrate the feasibility and/or scalability of integrating solutions into national or regional healthcare systems and/or of innovations are welcomed.
 - Remember: Research should remain at the pre-competitive level and translate into solutions that can be applied by all players in the ecosystem.
- Proposals can <u>ONLY</u> be submitted under one topic, so please consider which Specific Objective is the most relevant to the primary focus of your proposal.
- Applicants must clearly justify the alignment of the objectives of their proposed work with the Specific Objective selected. Considering the complementarity of the IHI JU Specific Objectives, proposals may also cover aspects related to other Specific Objective(s). If so, applicants should also highlight this in their proposal





IHI Call 12 - Scope for each topic

Assemble a **collaborative public-private partnership consortium** reflecting the integrative and cross-sectoral nature of IHI that is capable of addressing the challenge(s) and scope of the selected IHI Specific Objective.

Applicants should consider the following points in their proposals:

- a) Address an unmet public health need based on at least one of the below:
 - high burden of disease for patients and/or society
 - high economic impact of the disease for patients and society;
 - transformational nature of the potential results on innovation processes





IHI Call 12 - Scope for each topic

- b) Demonstrate the ability to translate research into innovative solutions that can be integrated/implemented into the healthcare ecosystem and/or in industrial processes.
- c) Carry out a landscape analysis to avoid unnecessary overlap and duplication of efforts with existing initiatives/projects and to identify potential synergies and complementarities with the relevant ones. The proposal should include a plan on how to synergise with these identified initiatives.

When applicable, relevant aspects of patient-centricity to be considered







What should you think about?

To be good fit to IHI, your proposal should be:

- Precompetitive
- Contribute directly to IHI's objectives and address specific objectives
- Address an unmet public health need
- Cross sectoral
- Public private in nature, leveraging contributions from:
 - industries part of the IHI industry associations (EFPIA –including Vaccine Europe-, COCIR, MedTech Europe and EuropaBio)
 - EU public funding Horizon Europe
 - if relevant, also from Contributing Partners (upon approval by IHI Governing Board)
- Innovative and ambitious and will deliver clearly-described impacts on society, science, competitiveness of the EU's health industry and implementation of the <u>EU's Life Sciences</u> <u>Strategy</u>



A standard, single-stage IHI call

You need to build / join a public-private partnership

Read our:

Guide for Applicants
and other
key call documents

Consortium size

At least 1 organisation established in an EU Member State + 2 organisations established in the EU or a country associated to Horizon Europe.

Entities eligible for funding

Restrictions regarding eligibility for funding for entities based in countries recently associated to Horizon Europe.

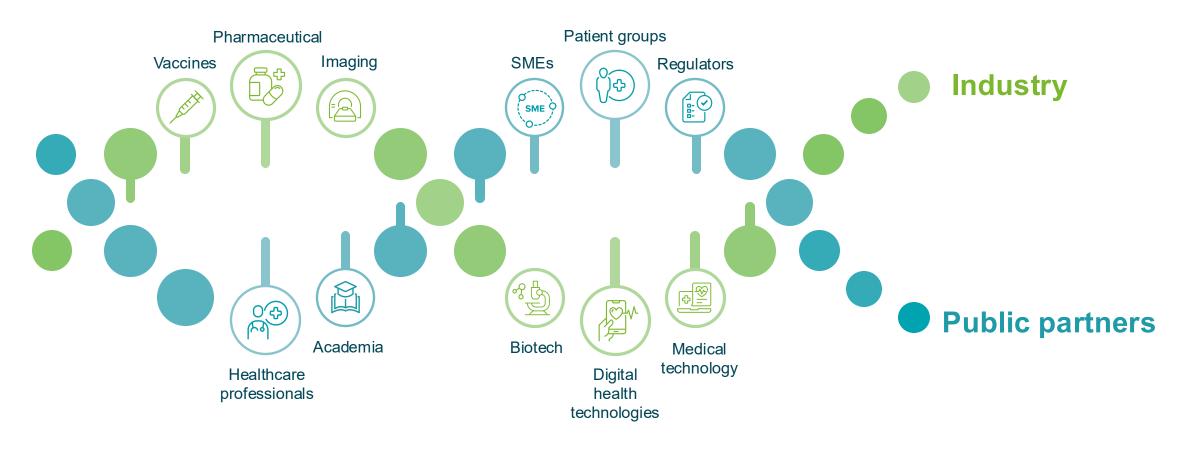


Read carefully the call topics

Funding

Half (minimum 45%) of the project's costs must come via contributions from IHI industry members and (if relevant) contributing partners.

Consortium Composition



Collaboration is part of our DNA





IHI Joint Undertaking: Consortium Eligibility

How to ensure that a consortium is eligible to participate in IHI actions?

- at least one independent legal entity established in an EU Member State, and
- at least two other independent legal entities each established either in a different EU Member State or a Horizon Europe Associated Country.
- This is the legal minimum on average IHI projects have 25 partners
- Please remember the composition of the consortium is your key to success, each partner should have a clearly defined role and contribution to the project – avoid duplications and redundancy





IHI Joint Undertaking: Eligibility

Eligibility to Participate

'Any legal entity, regardless of its place of establishment and including legal entities from non-associated third countries or international organisations, may participate in actions under the Programme...'

Eligibility to Receive Funding

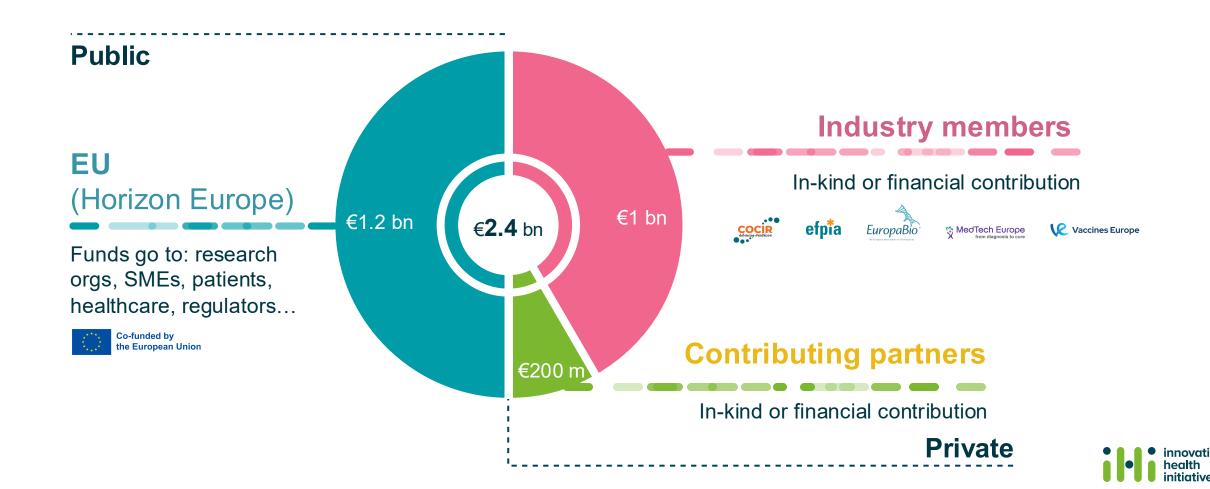
In general, legal entities are entitled to receive funding from IHI JU if they:

- Are established in a Member State of the European Union ('MS'), or;
- Are established in an Associated Country** ('AC'), or;
- Are established in a Low to Middle Income country ('LMIC').

Please check the call text carefully to understand if restrictions on availability of funding apply



We are a public-private partnership...



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 (CPs) in IHI Call 12

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 and the process for submitting the application letter (please see our CP Guide for detailed information), and
- their application is accepted by the IHI JU Governing Board.





Before you apply to become a CP:

- Check that your legal entity is <u>not affiliated</u> directly or via a regional or national or local organisation to an IHI JU private member (COCIR, EFPIA (including Vaccines Europe), EuropaBio and MedTech Europe).
- Visit the IHI website and read the IHI Guide on CPs:
 - https://www.ihi.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:
 - o i.e., the costs should be actual, recorded in the accounting system of the concerned contributing partner, identifiable and verifiable and incurred during project implementation.

Prospective contributing partners must submit their applications as a part of the proposal through the submission portal by the call submission deadline.





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





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, 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 shall amount to at least 45% of the sum of [total project eligible costs plus 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 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





We recommend that industry contributions should be 50% of total project costs

Consortia are strongly encouraged to aim at having <u>50%</u> of the action's eligible costs and costs for action-related additional activities provided by the industry consortium participants.

This eligibility criterion applies not only at the evaluation stage but applies for the project's duration



Spotlight on type 1 diabetes - EDENT1FI

IHI Call 3 - Topic 1: Screening platform and biomarkers for prediction and prevention of diseases of unmet public health need

Some 9 million people worldwide have type 1 diabetes (T1D). 90% of those diagnosed have no family history of T1D and so are not picked up by these efforts.

- The aim of EDENT1FI is to improve the early detection of T1D by setting up a pan-European open platform to screen 200 000 children and adolescents for T1D;
- Assess the psychosocial, medical and economic impacts of screening for T1D in different health systems and populations;
- Refine the biomarkers used to determine a person's risk of developing T1D;
- Design clinical trials of novel treatments that could stop the disease.

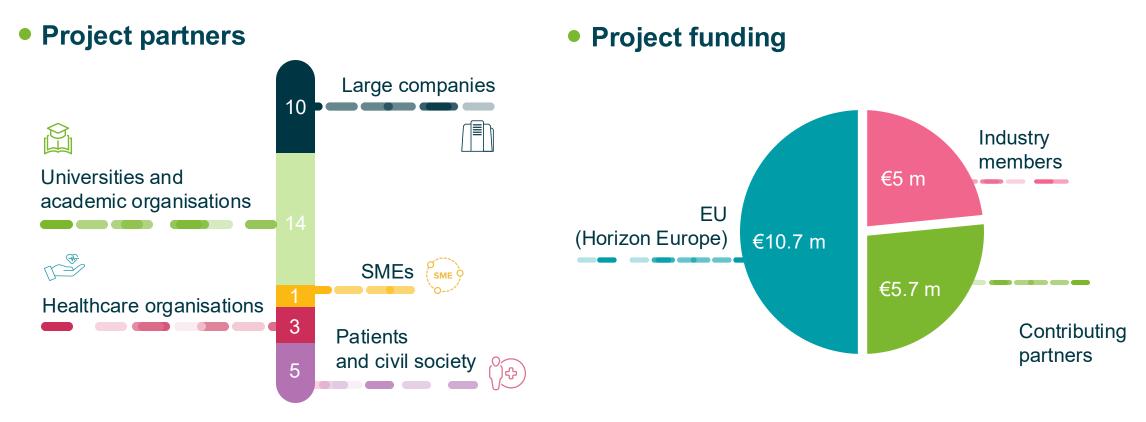
Ultimately, EDENT1FI hopes to pioneer a new approach to T1D diagnosis and care, with a much stronger focus on early detection and prevention of the disease. In the long term, learnings from the project could also be applied to other childhood diseases.





Spotlight on type 1 diabetes – EDENT1FI

The EDENT1FI project aims to improve our ability to detect type 1 diabetes in children and adolescents before the body's insulin-producing cells have been badly damaged.







Points to remember

- Read all the call-relevant material: www.ihi.europa.eu
- We expect strong competition: high quality of proposal is a must.
- Ensure that all information is explicitly described in order to allow the expertevaluators to assess against the evaluation sub-criteria. Respect the page limit – 50 pages.
- Use the proposal structure / template
- Plan the 45% In kind contribution and aim at 50%.
- Non-EU IKOP is capped at 20%.





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 <u>projects fulfil the eligibility</u> <u>criteria</u>
 - ✓ Make sure that your legal entity is not affiliated directly or via a regional or local organisation to an IHI JU private member
- Complete accurately the following since it might impact the final ranking (in case of equal score)
 - **✓** Budget and Type of Participants
 - ✓ Researchers table (Proposal Part A) and ensure a gender balance.

Coordinator must be financially viable – check in advance





Plan for success

- Create a strong public-private partnership aiming to include all relevant stakeholders
- Brilliant science is not enough, a well designed and effective workplan is equally important
- Impact at system level, not only for the benefit of an individual actor/company
- Consider as relevant deployment/scaling up

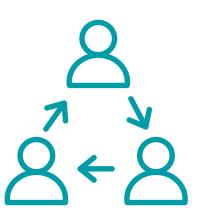




Webinars for applicants at Call launch

- Call 12 topic webinar
- Rules and procedures of the evaluation and granting process
- Understanding IHI's financial rules

Call 12 is expected to be launched in January 2026





Your contact point









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Thank you for your attention

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