MedTech Europe
from diagnosis to cure

The Innovative Health Initiative, a unique opportunity for our industry

Discover how and why to engage in IHI projects

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Disclaimer:
Parts of the text of this booklet are from the EFPIA brochure on IHI and the IHI official website. MedTech Europe expresses its gratitude for the EFPIA concession.

1. About the Innovative Health Initiative (IHI)

The Innovative Health Initiative (IHI) is the world's largest cross-sector public-private partnership between the pharma and medical technology sectors and the European Commission. Its goal is to help create an EU-wide health research and innovation ecosystem that facilitates the translation of scientific knowledge into tangible innovations in prevention, diagnostics, treatment, and disease management.

IHI will contribute to several European policies, most notably Europe's Beating Cancer Plan, the new Industrial Strategy for Europe, the Pharmaceutical Strategy for Europe, the EU digital strategy or the EU Green Deal to name just a few.

Like its predecessors – the Innovative Medicines Initiative (IMI) and the public-private partnership for electronic components and systems (ECSEL) - IHI will bring together diverse stakeholders (companies large and small, universities, patients, health authorities and other health stakeholders) in pre-competitive collaborations (where competitors can share knowledge, assets, data, resources, etc.) to develop, validate, and/or deploy new solutions. However, due to its cross-sectoral nature, in IHI there will be a much greater focus on cross-sectoral projects involving the biopharmaceutical, biotechnology and medical technology sectors, including companies active in the digital area.

The 'public' partner in the partnership is the European Union, represented by the European Commission.

The IHI industry partners are COCIR, EFPIA, EuropaBio, MedTech Europe and Vaccines Europe, but the programme is also open to any company that is not a member of these associations.

In IHI, decisions are made by a Governing Board composed 50/50 of European Commission and Industry representatives. The Board is advised by the States Representatives Group (SRG) and the Science and Innovation Panel (SIP), involving representatives from patients associations, healthcare professionals, regulatory and science communities.

The medical technologies industry will be entitled to receive public funding (EU grants) within IHI, depending on the type of call (see chapter 3). The cost of resources invested in a project (time of experts, samples, studies, consumables, subcontracted work, cash, etc.) or on relevant supporting additional activities – the in-kind contribution to IHI projects - can partially be claimed back. Public partners and Small & Medium Size Enterprises (SMEs) in IHI consortia receive public funding and might be fully compensated depending on their size.

More information:

Industry joint press release

IHI website

MedTech Europe website on IHI

The Innovative Health Initiative (IHI): the future of Research and Innovation in healthcare in Europe - MedTech Europe

2. How can my company benefit from it?

The Innovative Health Initiative has two dimensions:

- Science and business-wise, it offers an unprecedented opportunity to partner at scale with other companies from the pharma and medtech sectors to take advantage of the integration of technologies from research through development to deployment of health interventions, which are currently developed in their silos. It may accelerate with the development of new interventions and their combinations and, through cooperation with healthcare professionals, healthcare authorities, regulators, and patients, prepare the ground for the uptake of new solutions by health systems and medical practice.
- Politically, the Innovative Health Initiative comes to life at a unique momentum of post-pandemic recovery and review or entry into force of some major pieces of legislation governing medical devices, diagnostics, therapeutics, and vaccines.

At the time of writing this booklet, it is impossible to appraise all opportunities fully. Based on outputs from and experience with previous partnerships such as IMI and ECSEL, we anticipate that when using the platform, companies benefit from risk, resource and knowledge sharing in a non-competitive space to accelerate research and reduce time to patients – some examples from IMI include:

- Companies and other investors define project objectives and deliverables; participating companies can align these to their companies' core business objectives.
- By investing a fraction of the total resources, every participant can leverage 10-fold and have access to all results, capabilities, technologies, and data
- New compounds and disease models
- Innovative technologies and analytics
- Faster clinical investigations recruitment (e.g., using electronic health records data standards)
- Joining forces with other companies from different sectors with similar experience and with academic and other public partners such as regulators and HTA bodies creates a critical mass of knowledge and resources to deliver
- Tangible research outputs and productivity tools: candidates, targets, biomarkers, disease models, fast fail cohorts, clinical trials infrastructures, novel trials design
- Intangible outputs: access to networks, capability development, and reputation.

More information:

Thinking of joining an EU project? Read our top tips - MedTech Views

3. How does it work? From concept to project start

Any company can propose an **idea** and gather a group of companies which face similar problems and are ready to collaborate to find a solution. MedTech Europe can also support **fine-tuning and promoting** of these early ideas to all member companies and other partner pharmaceutical and medtech associations. Some of the ideas are **proposed by third parties**. (See also Chapter 4: how to submit a proposal)

The idea takes the form of a **question or problem** that requires resolution. This problem is common to several companies and sectors that cannot be solved simply by joining forces. Therefore, input from other parties – academia, SMEs, regulators, patients, etc. – is needed. This problem statement – and related questions that need to be addressed jointly by the public and private partners – is written up as a **topic (i.e. call for proposals)**. Proposed topics are then discussed between industry associations and the Commission, and with IHI advisory bodies, before alignment between partners and the release in IHI Calls for applications.

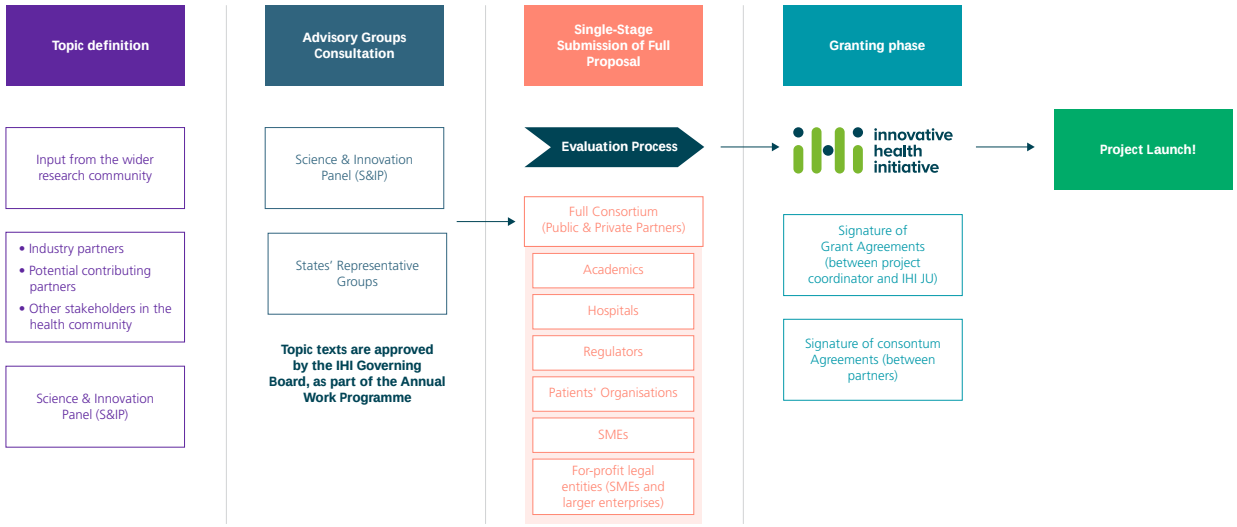
IHI topics should meet five basic criteria:

• EU relevant	• Transformative	• Combining both pharma and MedTech interests	• Need for collaboration (non-/pre-competitive)	• Feasible to implement in reasonable time frame

Single-stage calls

In the single-stage call process, a high-level broad topic text is released by IHI. Public and private partners then form consortia to submit a full proposal together. Consortia may include stakeholders such as academia, SMEs, large companies, regulators, etc. Several projects may be selected and funded per topic. However, in the case of a large number of applications, some projects may not be funded, since funding goes to applications that obtained the highest rank during evaluation. A single-stage submission implies a single submission and evaluation process. The time from idea to project start is shorter than in the two-stage process, and companies can choose their partners without a guarantee of being eventually selected. To meet the eligibility criteria, applicants must ensure already at the proposal stage that the collective in-kind or cash contribution amounts to at least 45 % and preferably 50% of the project budget (*see 6. What is in-kind contribution*). At the same time, companies from the medical technology sector can request partial funding. After the evaluation, the selected proposals within the available budget are invited to complete the grant agreement and related formalities. Only in single-stage calls MedTech Europe members are eligible to receive partial funding for their activities.

Single-stage process



Two-stage calls

In the two-stage call process, industry partners form a **private consortium** and define the call for proposals (the project challenges and goals) to which public consortia will apply. When the challenge, the objectives and the industry contribution are defined, IHI issues a "call". The call for proposals invites consortia populated by public bodies & SMEs only to submit proposals for projects. Essentially, these are all bodies that may benefit from public funding, and industry plays no part in their formation or selection. The proposals from public consortia are then subject to an independent evaluation process organised by the IHI office. All public applications are assessed and only **one winning consortium is selected and merged with the pre-established private consortium** to prepare a joint project proposal. The reviewers again analyse the proposal and recommend the approval or rejection of it. After the approval, the project partners are invited to complete the grant agreement and related formalities. The time from idea to project is longer than in the single stage. Still, this construct is suitable for large standardisation or infrastructure projects which require a critical mass of companies and stakeholders. In two-stage calls, private companies, including members from MedTech Europe, are **not** eligible to receive funding for their activities.

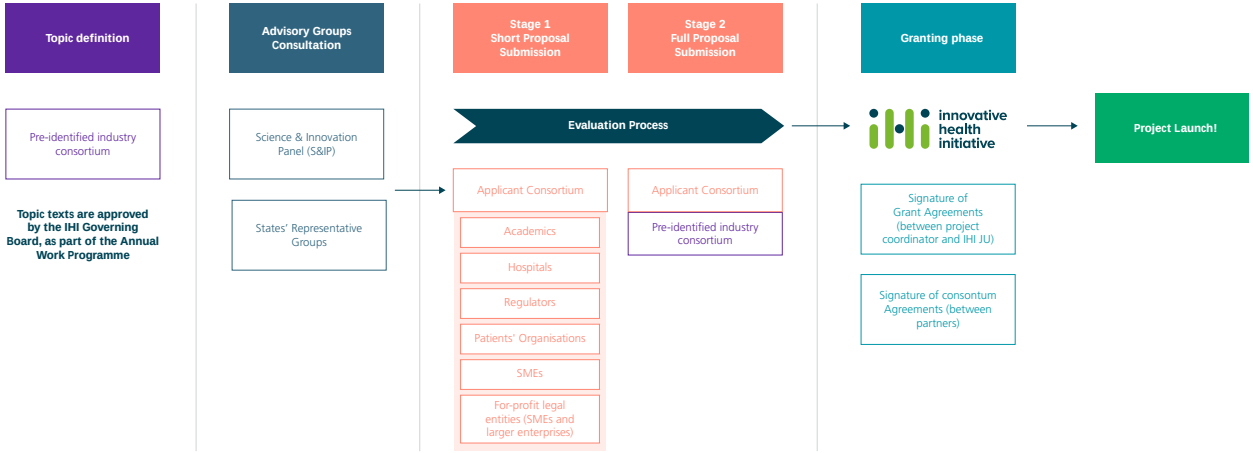
More information:

IHI: How call topics are generated

IHI Guide for applicants

Recording and PowerPoint presentation of the joint Industry Webinar: How to prepare a project proposal - MedTech Europe

Two-stage process



4. Ideation process, submission of a proposal

Any company may propose a topic. Check if the topic is in line with the objectives of the **IHI Strategic Research and Innovation Agenda (SRIA)**

1. Contact your company IHI lead to check if a similar idea has already been discussed. Please get in touch with the MedTech Europe secretariat for further information

2. Check with MedTech Europe if the idea is aligned with/supports the policy goals pursued by your sector. MedTech Europe can help you fine-tune your initial idea to make it IHI-compatible

3. Follow the next three steps from idea to call launch:

- Write a short description of your idea (challenge, outputs, impact)
- Submit the idea to your trade association and, if needed, to other trade associations
- Check other companies' support for your idea and start assemble an industry consortium to prepare a project that will apply to the topic once published by IHI.

NB. Only contact potential public partners for two-stage topics after selecting the winning public consortium. For single-stage topics, you will only be able to formally reach out to potential public partners once the draft call for proposals (or topic text) is published on the IHI website (see Chapter 3).

More information:

IHI Strategic Research and Innovation Agenda (SRIA)

5. How to join an ongoing project

Projects launched under the Innovative Health Initiative (2023 onwards)

Joining an ongoing IHI project without requesting funding requires an agreement of the whole project consortium (public and private partners). If one of the ongoing projects is of interest to your company, and your company is a member of COCIR, EFPIA, EuropaBio, MedTech Europe or Vaccines Europe, please contact your association which will give you contact details of the industry project coordinator.

If you are not a member of one of the five partnering associations, please contact the association whose scope is closest to your activities. Any commercial or non-commercial organisation can also join an IHI project directly as a Contributing Partner (see link). Prior contact with the industry project leads to identifying a joint value proposition, and contributions are necessary in all cases. These options apply only to entities not requesting funding.

More information:

Become an IHI "Contributing Partner"

6. What is in-kind contribution?

The Industry contributes resources in kind, in the form of manpower, data or samples from clinical/ pre-clinical studies (those conducted during the project term), subcontracting, and cash contribution. Industry in-kind resources should match the EU financial resources provided to public consortia. Personnel, the time of staff employed by MedTech Europe companies directly working on IHI projects, is the most common form of in-kind contribution. However, the generation of prospective data and the related cost of prospective studies yield significant contributions. For its in-kind contribution to count, any entity has to be affiliated with one of the five founding industry associations or be an IHI 'Contributing Partner'.

The following **human resources** are required at different stages of project development and execution:

- Scientific/subject matter expertise is necessary for defining call topics, assessing applications, producing the final project and project implementation. This may include communication, regulatory matters, health economics, etc.
- Legal expertise is necessary to write or negotiate agreements with other partners.
- Financial expertise is necessary throughout the process to define in-kind contributions and report them to IMI.
- Project management (for the lead company) is necessary when MedTech Europe and public participants meet to write the joint Project Proposal.

Companies can contribute in kind to IHI via three options:

- In-kind contributions to operational activities (IKOP), contributed directly within projects which can include any relevant costs incurred by companies during a project's lifetime. Up to 20% of these contributions can be incurred outside the EU and Associated Countries*.
- **In-kind contributions to additional activities (IKAA)**: activities outside IHI projects but contributing to the objectives of the Partnership (including the uptake and sustainability of IHI results up to two years after the project's end). These activities have to be incurred in the EU and Associated Countries. This new feature brings opportunities and flexibility for companies' contributions. However, it cannot exceed 40% of the total in-kind contributions from the industry.
- Voluntary cash contributions to public participants are also possible, but this is not mandatory.

What types of activities can we have under the industry in-kind?

Any activity across the industry value chain relevant to the project objectives can be contributed within projects (IKOP). For example:

- Registries in the EU
- Discovery and early research
- Regulatory assessment and health technology assessment
- Pre-clinical and clinical validation
- Manufacturing
- Health outcomes and pharmacovigilance

"Additional activities" (IKAA) can include any of the above. Still, they can also contribute to the sustainability or uptake of a project's results, for instance by setting up a digital platform, maintaining a biobank, setting up a new legal entity, a training programme. IKAA can extend up to two years beyond the timeframe of the consortium.

MedTech Europe has committed to cover its share of the IHI Office costs over the seven years of the IHI partnership. On the decision of the Board of Directors (02 December 2021), each company participating in a successful project will be asked to pay 3% of its in-kind contribution as declared in the approved proposal to MedTech Europe Secretariat, which will make then the payments to IHI Office.

More information:

Recording and PowerPoint presentation of the joint Industry Webinar: How to prepare a project proposal

MedTech Europe IHI JU Guidelines for in-kind contribution to additional activities (IKAA)

** Qualification of EU in-kind is linked to where activities take place, not where a company's headquarters sit. A contribution is considered EU if it is incurred in an activity based in the EU or Associated Country.*

7. Are MedTech companies eligible for funding?

MedTech Companies are eligible for funding in 1-stage proposals, like any other applicant, except pharma companies which opt out.

It's up to MedTech companies to decide the level of EC funding they require, between 0 and 100%. Nevertheless, the higher the grant for medtech companies, the lower budget for public partners in the project. As an indication, 50% seems a reasonable maximum asked by companies.

It is important to note that the in-kind contribution declared by industry should deduce the EC grant the companies they receive.

8. Protection of the company assets

The IHI Intellectual Property (IP) rules derive from the general Horizon Europe (HE) framework: HE IP provisions apply to IHI projects. However, these rules remain flexible and can be adapted to individual projects' and partners' needs.

This can be done in particular via the consortium agreement between partners.

Another critical element of successful negotiations is that IP issues are agreed upon before the project's launch. Project partners can therefore be confident that knowledge developed and shared within the project will be used appropriately.

In brief:

- **Intellectual property rules derive from Horizon Europe:**
    - They are defined in the Horizon Europe Model Grant Agreement
    - The Consortium Agreement negotiated between project partners complements the Grant Agreement and may set out additional rules (as long as they are not contrary to the Grant Agreement).

- **Ownership:**
    - Background: assets and knowledge brought to the project belong to the original owner.
    - Results: results generated within the project are owned by those generating them. Transfer of ownership of results is possible.

- **Access rights:**
    - Access rights for the completion of the project are royalty-free.
    - Access rights for exploitation are negotiated between partners. The model proposed by the industry consortium agreement provides that:
        - Access rights for research use are granted on fair and reasonable terms (preferably royalty-free).
        - Access rights for commercial exploitation are negotiated between partners.

- **On some topics identified upfront, additional exploitation obligations may apply:**
    - IHI has a right to object to the transfer of ownership of project results to non-EU entities. However, companies can request a waiver at the project level before acceding to the grant agreement
    - 3A conditions applicable to specific topics identified upfront to ensure that results are available, accessible and affordable. This requires in particular the applicant consortium to submit and update a "Plan for the Dissemination, Exploitation, and Communication Activities".

    These additional obligations apply only if they are explicitly foreseen in the IHI Call topic text.

More information:

Horizon Europe Model Grant Agreement

Industry Consortium Agreement Template for IHI projects

IHI webinar on IHI rules and procedures: recording / slides 34-40

9. How to report in-kind and financial contributions?

MedTech Europe companies participating in IHI projects report their in-kind and financial contributions as follows:

- **In-kind contributions to operational activities (IKOP)** are reported directly within projects (usually every 18 months) under Horizon Europe rules. For contributions above €430'000, certification is required, based on a Certificate on Financial Statements (CFS).
- **In-kind contributions to additional activities (IKAA)** are reported and certified annually within a specific IHI module under companies' usual accounting practices.

More information:

Horizon Europe Model Grant Agreement

Recording and PowerPoint presentation of the joint Industry Webinar: How to prepare a project proposal - MedTech Europe

Certificate on the Financial Statements template (for IKOP)

IHI JU Guidelines for in-kind contribution to additional activities (IKAA)

10. Sustainability and scaling up

Deployment of IHI results in research, regulatory and medical practice beyond the context of EU-funded projects needs to be properly planned and resourced to achieve the desired impact. This transition to scale often falls outside of the project timelines or objectives. Still, the project design and stakeholders' engagement during the project term will determine the success of future deployment and scale.

One size does not fit all: the "pathway to scale" depends on the result type - standards, infrastructures, or knowledge. The experience of several IMI digital health projects was collected in a field manual with high-level yet actionable guidance. This field manual provides high-level, actionable guidance – combining leading models from both public and private sectors – to help PPPs systematically and strategically chart their scale-up pathway. It is best applied early in a project's life cycle, and encourages an agile approach that adapts to the shifting healthcare landscape.

Under certain conditions, scaling up or deployment of results of past projects can count as IKAA (in kind for additional activities). For more information, please get in touch with your trade association or your company IHI contact person (see Chapter 6).

More information:

Scaling PPP innovation field manual

11. MedTech Europe on your side

Get the support you need MedTech Europe is on your side. The R&I Team of MedTech Europe is here to help you navigate from A to Z along your journey towards IHI. We can provide you with the following:

- Tailored **deep dive webinars**
- On-site or remote **meetings with your teams**
- Valuable **resources and educational materials**
- Support and **guidance** at any time.

12. Where do I find more information?

http://www.ihi.europa.eu

Useful resources:

- Model Grant Agreement
- Model Consortium agreement
- Call Topic text
- Brokerage platform
- Template for ideas
- EC Funding & Tender Portal
- How to prepare a project proposal
- Mutual multiparty confidentiality agreement
- Thinking of joining an EU project? Read our top tips - MedTech Views
- The Innovative Health Initiative (IHI): the future of Research and Innovation in healthcare in Europe -MedTech Europe
- Innovative Health Initiative | IHI Innovative Health Initiative (europa.eu)

Contact

MedTech Europe
Rue Joseph II, 40
B - 1000 Brussels, Belgium
Tel: +32 (0)490 56 1335

Patrick Boisseau
Director General Industry Strategic Initiatives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