

- Enabling and safeguarding innovation in secondary use of health data in the European Health Data Space (EHDS)

IHI call 10 – topic 2

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15.01.2025 • Online

Before we start...

- We are recording this session and it will be published on the IHI website. We will also publish the presentation slides.
- The call will be launched shortly and all links and details of how to apply will be published on the IHI website and the Funding and Tenders Portal.
- If you want to ask a question please use the Q&A function on the right corner of your screen.

Today's webinar

- **Will cover:**

- Introduction to IHI programme
- IHI call 10 topic 2 presented by lead of the pre-identified industry consortium
- Proposal submission & evaluation
- Tips for writing a successful proposal

- **Will not cover**

- Rules and procedures

Innovative Health Initiative

EU partnership in health between:

- the **European Union** represented by the European Commission &
- **Healthcare industry associations:**
 - **COCIR** (medical imaging, radiotherapy, health ICT and electromedical industries)
 - **EFPIA**, including **Vaccines Europe** (pharmaceutical and vaccine industries)
 - **EuropaBio** (biotechnology industry)
 - **MedTech Europe** (medical technology industry)



IHI's general objectives

- 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**.

IHI projects are...

Created via open and competitive calls for proposals

Cross sectorial public private partnerships leveraging:

- Contributions from industrial partners from the IHI industry associations (COCIR, EFPIA including Vaccines Europe, EuropaBio, MedTech Europe)
- if relevant, contributions from contributing partners (must be approved by IHI GB)

and

- Public funding via European Commission (Horizon Europe)

Strategic Research & Innovation Agenda

Focus

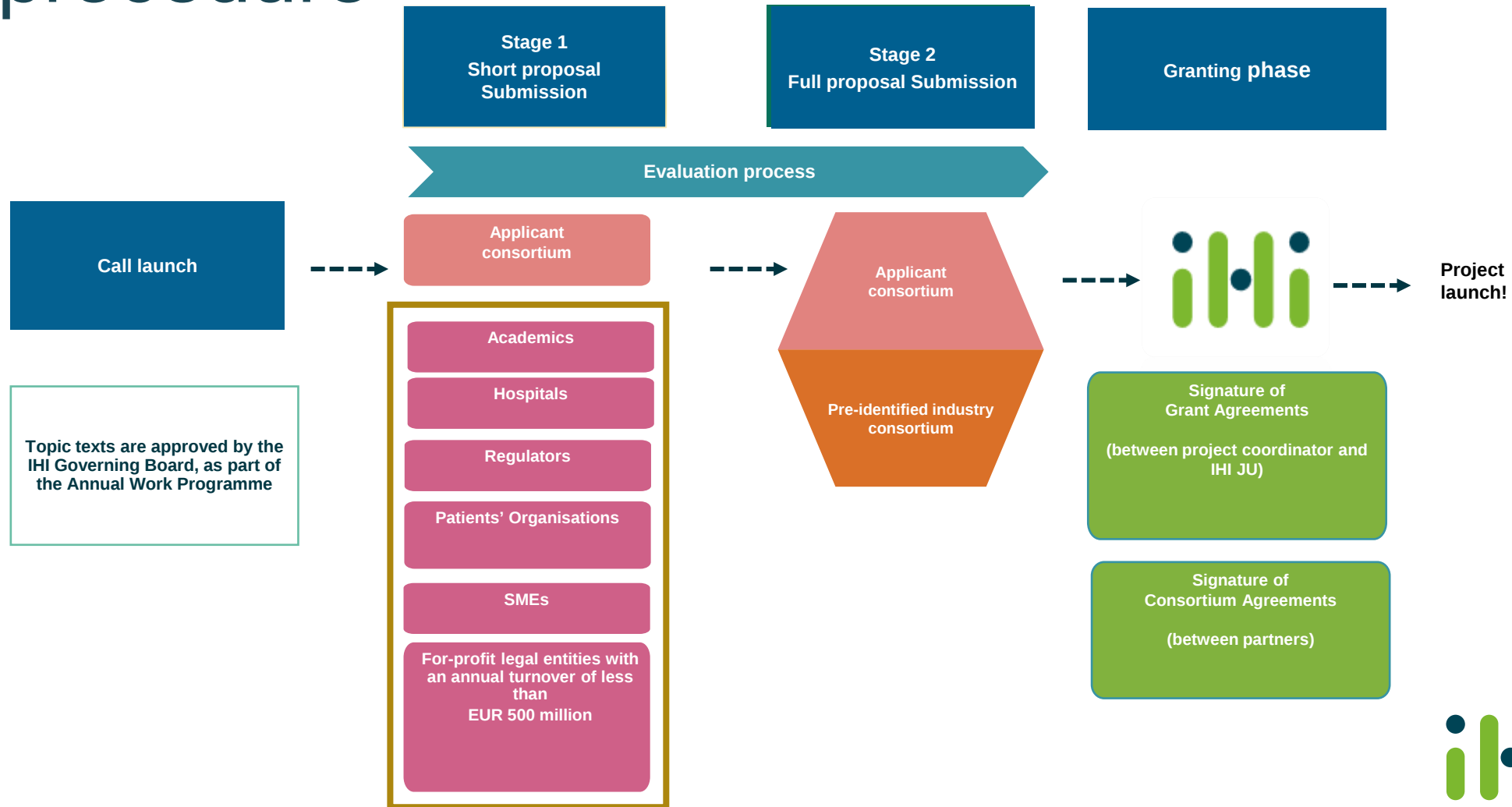
- **Cross-sectoral approaches** to facilitate creation of new products and services to **prevent, intercept, diagnose, treat and manage diseases** and foster recovery more efficiently.

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.

Research supported by IHI should remain at precompetitive level

How does IHI work? Two-stage procedure

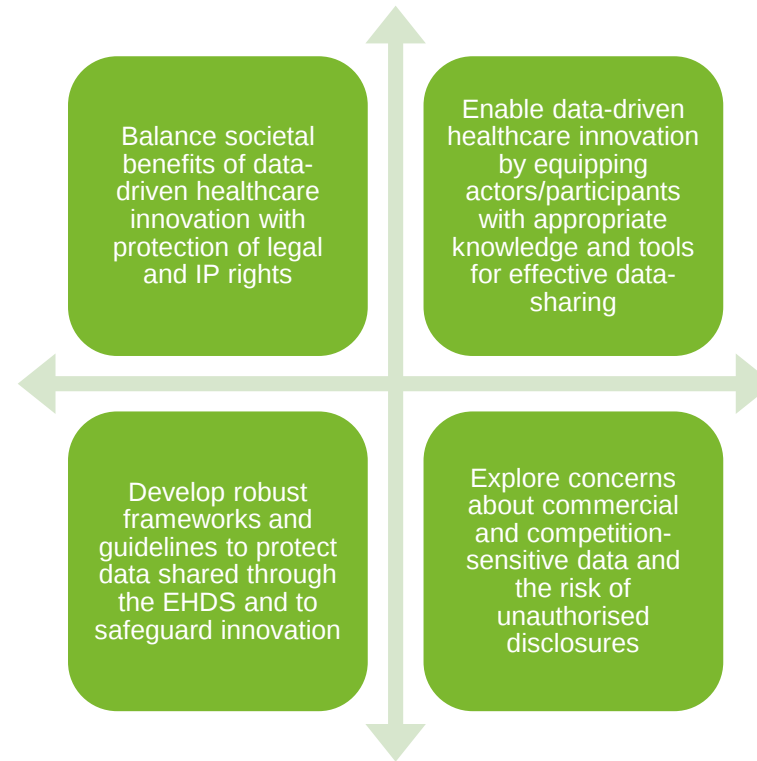




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The challenge



Need for public-private, cross-sector collaboration

- Health Data Holders (HDHs), Health Data Users (HDUs), Health Data Access Bodies and providers of secure processing environments form the backbone of the European Health Data Space (EHDS)
- The public and private sector from across all aspects of the healthcare sector will provide that backbone
- Collaboration is essential
 - For creating solutions balancing IP protection with data sharing and utilization for research and innovation
 - To develop effective frameworks, policies, and procedures for safeguarding innovation for everyone with the EHDS
 - To build trust and confidence in the system

Scope of the topic

- Empowering the societal benefits of data-driven healthcare innovation and preserving the legitimate interests of public and private sector innovators for a strong IP system to enable safeguarding of innovation through secondary use of health data in the European Health Data Space (EHDS)

Expected outcomes

- Comprehensive frameworks, processes, policies and guidelines to support the procedural and operational aspects of the EHDS from an innovation perspective
- Recommendations to inform EHDS governance striking a balance between efficient data sharing for healthcare research & innovation and the need for maintaining a strong Intellectual Property (IP) system
- Enabling dialogues between health data holders (HDHs), health data users (HDUs) and health data access bodies (HDABs) to address issues around innovation
- Education of interested parties about innovation and data sharing under the EHDS

Expected impact

- Fostering data-driven research and innovation advancing healthcare in the EU
- A world-leading approach to IP protection of data
- Improved balance between data utilisation and access control rights
- Best practices for data sharing, data security and prevention of unauthorised disclosure
- Recommendations for legal and ethical standards
- Increased confidence in the EHDS

Expected contributions of the industry consortium

Industry consortium

- AbbVie
- Astra Zeneca
- Bayer
- bioMérieux
- Boehringer Ingelheim
- GSK
- Johnson & Johnson
- Merck
- MSD
- Novartis
- Novo Nordisk
- Pfizer
- Sanofi
- UCB
- Brightinsight
- Clarivate

Expected Contributions

- Expertise in:
 - Secondary use of health data
 - IP and trade secret management
 - Protecting innovation with IP and Trade Secrets

Expected contributions of the applicants

Expertise and resources expected to be brought into the project

- Academic and/or research organisations involved in innovation and competition with expertise in legal and IP
- Information Security & Risk Management experts
- Hospital networks/health data holders/ health data users (clinical research units)
- Implementers of large digital healthcare infrastructures for primary and secondary data use
- Project management expertise and organisations of large multistakeholder European public-private partnerships
- Legal expertise and, in particular, privacy and data protection expertise
- Experts from, or with connections to country ministries, involved with implementing and operating Health Data Access Bodies
- Publicly accessible datasets

Key Facts

- Budget
 - Maximum financial contribution from the IHI JU is up to EUR 6 043 000
 - The indicative in-kind contribution from industry beneficiaries is EUR 5 772 500
 - The indicative in-kind contribution from IHI JU contributing partners is EUR 70 500.
- Duration is 36 months



Thank you for your attention

Got questions? Contact applicants@ihi.europa.eu

DO NOT CONTACT THE TOPIC WRITERS

ihi.europa.eu





Proposal submission & evaluation

Proposal Template - Parts A, B & Annexes

- **Part A** of the proposal is **administrative data** that is entered in webforms through the Funding & Tenders Portal.
- **Part B** of the proposal is the **narrative part** that includes three sections:
 - Excellence
 - Impact
 - Quality and efficiency of the implementation
- **Read instructions** in proposal template **very carefully**
- **Annex:**
 - Participant type

Evaluation Criteria (1/2)

- **Excellence**

- Clarity and pertinence of the project's objectives, and the extent to which the proposed work is ambitious, and goes beyond the state of the art.
- Soundness of the proposed methodology

- **Impact**

- Credibility of the pathways to achieve the expected outcomes and impacts specified in the work programme, and the likely scale and significance of the contributions due to the project.

Evaluation Criteria (2/2)

- **Quality and efficiency of the implementation**
 - Quality and effectiveness of the outline of the work plan
 - Capacity and role of each participant, and extent to which the consortium as a whole brings together the necessary expertise.

- Tips for applicants

Tips for applicants

- Read all the call-relevant material, especially the **topic text**
 - www.ih.europa.eu/apply-funding/open-calls
 - www.ih.europa.eu/apply-funding/future-opportunities
 - https://www.ih.europa.eu/sites/default/files/uploads/Documents/Calls/IHI_Call10_CallText.pdf
- Form your consortium **early**
 - Already think “public-private partnership”
- Ensure that **all information requested in the call text and proposal template** is provided to allow the evaluation experts to easily assess your proposal against the evaluation criteria
- Consider & plan for the potential **regulatory impact** of results

Finding project partners

You'll need to build or join a consortium!

- Use EU Funding & Tenders portal **partner search tool**:
 - <https://europa.eu/!QU87Nx>
- Get in touch with your **IHI national contact point**:
 - <https://europa.eu/!D7jyMy>
- Network on social media:
 - be.linkedin.com/company/innovative-health-initiative

#IHICallDays

Calls 9 & 10



16 Jan

10:30 Call 10: Rules & procedures

Online event

Everything you need to know about IHI contributing partners

Register now

30.01.2025

Online Event





Questions and answers

→ Use the Q&A function