Digital label: one source of comprehensive information for medical technology products

IHI call 10 – topic 1

Angelica VALENTE
7/01/2025 • Online

innovative health initiative

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.

innovative health initiative

Today’s webinar

- **Will cover**:
  - Introduction to IHI programme
  - IHI call 10 topic 1 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

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)

COCIR Advancing Healthcare
efpia
EuropaBio The European Association for Bioindustries
MedTech Europe from diagnosis to cure
Vaccines Europe
Co-funded by the European Union

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**.

innovative health initiative

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, MedTechEurope)
- if relevant, contributions from contributing partners (must be approved by IHI GB)

and

- Public funding via European Commission (Horizon Europe)

innovative health initiative

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

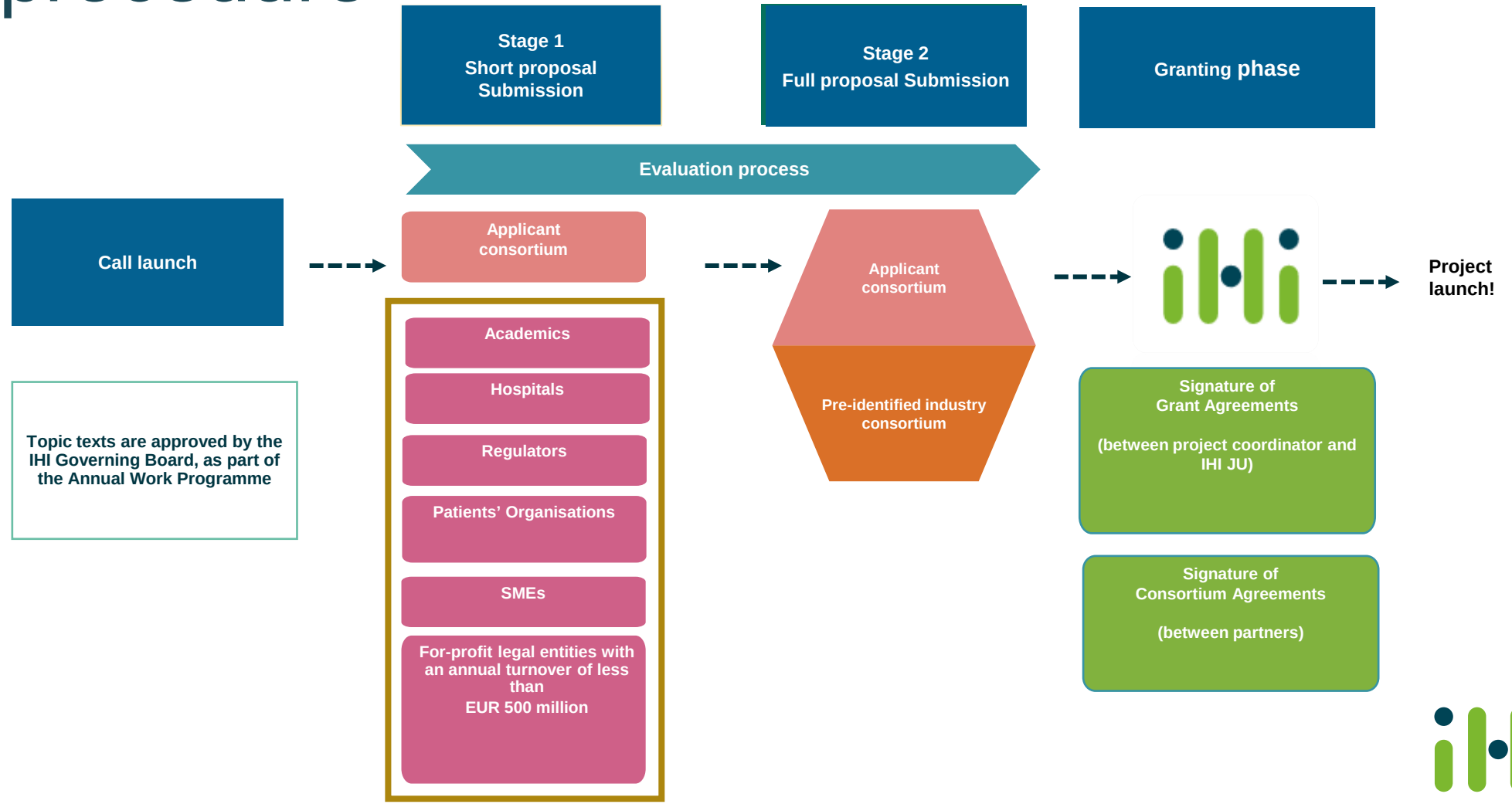
- Lay foundations for development **of safer and more effective health care products or solutions** that respond to **unmet public health needs** and that can be implemented into healthcare systems.

Research supported by IHI should remain at precompetitive level

innovative health initiative

https://www.ihi.europa.eu/about-ihi/research-and-innovation-agenda

How does IHI work? Two-stage procedure



innovative health initiative

Digital label: one source of comprehensive information for medical technology products

IHI call 10 – topic 1

Roger Peterson
07.01.2025

innovative health initiative

Digital label: one source of comprehensive information for medical technology products

Short description of the Idea:

- A form of e-labeling provided as an array of additional elements and topics supporting a medical technology product, which is additional to critical information on the printed label (with a focus on medical device and IVD)
    - Access to the digital label is achieved, for example, through bar codes, 2D Data Matrix, QR codes, etc., which provide a scannable functional link to curated digital landing pages (websites) providing additional information for end users.
    - Note: The term data carrier is synonymous with the ISO 19762 definition of Automatic Identification and Data Capture (AIDC) technologies (e.g., bar codes, smart cards, radiofrequency identification, (RFID), etc.

Conceptual idea

Need for public-private, cross-sector collaboration

Why the expected outcomes can only be achieved by an IHI JU (Joint Undertaking) action

- The digital label is an innovative concept offering benefits to all healthcare stakeholders and society at large. Currently, no regulatory basis exists for the medical technology industry anywhere in the world. Therefore, there is a need to test this concept with users, gather evidence for regulatory decision-making, and build regulators' and users' trust as a basis for a common standard and policy recommendations.

- This new approach of providing information on the label digitally will therefore need all stakeholders (industry, health institutions, healthcare professionals, patients, researchers, including researchers in health literacy, regulators (national competent authorities), and notified bodies to work together in a neutral framework to lay the groundwork for a sustainable and user-centered healthcare information delivery in the EU and ensure its regulatory acceptance.

- **Added value/why an IHI call topic:**
  - ***'Digital label for MedTech based on users' needs & input from all stakeholders***
  - ***To ensure a usable, fit-for-purpose digital label, all stakeholders need to be aligned***

innovative health initiative

Scope of the topic

Digital label: one source of comprehensive information for medical technology products

- Many medical technology products are decreasing in physical size while mandatory requirements for additional product compliance markings, economic operator information, and documents are growing
- The overall aim of this topic is to establish a consensus-based digital label concept applicable to all types and classes of medical devices and IVDs, making use of existing technologies that will be further improved to suit medical technology products specifically

Expected outcomes

Digital label: one source of comprehensive information for medical technology products

- A consensus-based digital label concept/framework for medical devices and in vitro diagnostic medical devices (IVDs) is available to be used by manufacturers that meet end users' requirements and addresses regulators' demands
- Multiple valid and scalable digital label solutions based on a standardized approach are available:
  - All work with the same enabler (label reader) for all medical technology product labels]
  - Serve as an up-to-date single point of access to all information about the specific device;
  - Are interoperable with other EU legislation (such as digital product passport) and national legislation (e.g. language requirements);
  - Consider accepted international standards for data carriers
  - Are acceptable after verification via user testing

innovative health initiative

Expected outcomes

Digital label: one source of comprehensive information for medical technology products

- Evidence-based recommendations are available that may inform the European Commission's and the national competent authorities' policy recommendations
- Training materials on digital labels are available to the end users (healthcare professionals (HCPs) and patients), regulators (national competent authorities), and notified bodies in the EU Member States;
- A basis for future international acceptance is created via:
  - Documentation gathered that would be needed to launch a proposal for a new digital label standard or adaptation of an existing standard under the International Organization for Standardization / International Electrotechnical Commission (ISO/IEC), [e.g., ISO 20417 already offers a segway for the digital label]
  - Awareness raising with other international jurisdictions that consider digital label initiatives

innovative health initiative

Expected impact

Digital label: one source of comprehensive information for medical technology products

- Provide key information as well as additional information that is easily (and more) visible, accessible, and identifiable to end users (HCPs, patients) and health authorities equipped with a simple, smart device (e.g., phone or tablet device);
- Significant reduction of carbon footprint and avoidance of over-labeling, thereby contributing to the European Green Deal
- Improved accessibility of information for users (HCPs and patients) and regulators. All the information that users might need is available in one place in their language of choice, thus increasing equal access of users to medical technologies
- Increased alignment between European MDR, IVDR, and other EU and national legislations
- Increased competitiveness in the EU market thanks to improved supply management and streamlined packaging and labeling operations.

innovative health initiative

Expected contributions of the industry consortium

- Composition of the industry consortium and expected contributions as expertise, resources, activities
  - A wide array of consortium expertise and/or resources will potentially be mobilized to deliver on the topic's expected outcomes, e.g., project management, healthcare medical device engineering and design, legal patient literacy, health literacy, ethical, social science, and medical device regulatory and compliance.
    - Generate metrics-based data
    - Frame historical data

innovative health initiative

Expected contributions of the applicants

Expertise and resources expected to be brought into the project

- The pre-identified industry consortium expects to contribute to the IHI JU project by providing the following expertise and assets:
  - Provision IT infrastructure and IT expertise;
  - Expertise in labeling; regulatory affairs and intelligence; clinical research, marketing, and communications, global supply chain management, project management, etc.;
  - Usability engineering.

innovative health initiative

Key Facts

- Budget:
  - The maximum financial contribution from the IHI JU is up to EUR 3,806,900.
  - The indicative in-kind contribution from industry beneficiaries is EUR 6,156,800.
  - Due to the global nature of the participating industry partners, it is anticipated that some elements of the contributions will be in-kind contributions to operational activities (IKOP) from those countries that are neither part of the EU nor associated with the Horizon Europe program.

- Duration:
  - The indicative duration of the action is 36 months.
  - This duration is indicative only. In the second stage, the consortium selected at the first stage and the predefined industry consortium may jointly agree on a different duration when submitting the full proposal.

innovative health initiative

innovative health initiative

Thank you for your attention

Got questions? Contact applicants@ihi.europa.eu

DO NOT CONTACT THE TOPIC WRITERS

ihi.europa.eu

COCIR Advancing Healthcare

efpia

EuropaBio The European Association for Bioindustries

MedTech Europe from diagnosis to cure

Vaccines Europe

Co-funded by the European Union

Proposal submission & evaluation

innovative health initiative

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

innovative health initiative

Evaluation Criteria (1/2)

- **Excellence**
  - Clarity and pertinence of the proposal'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 call text, and the likely scale and significance of the contributions due to the proposal.

innovative health initiative

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.

innovative health initiative

Tips for applicants

innovative health initiative

Tips for applicants

- Read all the call-relevant material, especially the **topic text**
  - chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.ihi.europa.eu/sites/default/files/uploads/Documents/Calls/IHI_Call10_CallText.pdf (page 13-18)
  - www.ihi.europa.eu/apply-funding/future-opportunities
  - www.ihi.europa.eu/apply-funding/open-calls
- 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

innovative health initiative

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

innovative health initiative

innovative health initiative

Thank you for your attention

ihi.europa.eu

COCIR Advancing Healthcare

efpia

EuropaBio The European Association for Bioindustries

MedTech Europe from diagnosis to cure

Vaccines Europe

Co-funded by the European Union

#IHICallDays

innovative health initiative

Calls 9 & 10

8 Jan	**10:30**	Financial aspects of call 9
9 Jan	**14:30**	Call 10: PFAS exposure, emissions & end-of-life management
14 Jan	**10:30**	Call 9: General information
15 Jan	**10:30**	Call 9: Rules & procedures
15 Jan	**14:30**	Call 10: Secondary use of data in the European Health Data Space
16 Jan	**10:30**	Call 10: Rules & procedures

Online event

COCIR Advancing Healthcare · efpia · EuropaBio · MedTech Europe from diagnosis to cure · Vaccines Europe · Co-funded by the European Union

Questions time

If you want to ask a question, please use the Q&A function on the right corner of your screen

innovative health initiative