All information regarding future IHI Call topics is indicative and subject to change. Final information about future IHI Calls will be communicated after approval by the IHI Governing Board.

Topic 1: Digital label: one source of comprehensive information for medical technology products

Expected outcomes

The action under this topic must contribute to all of the following outcomes:

1. 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 meets end users' requirements and addresses regulators' demands.
2. Multiple valid and scalable digital label solutions based on a standardised approach are available and they:
    a. all work with the same enabler (label reader) for all medical technology product labels (all medical devices and IVDs, all types, all classes). This topic does not cover pharmaceutical products as such. Combination products that fall into the scope of regulations on medical devices and *in vitro* diagnostic medical devices (MDR/IVDR) are, therefore, regulated as devices and are considered to be part of this topic;
    b. serve as an up-to-date single point of access to all information about the specific device;
    c. are interoperable with other EU legislations (such as digital passport);
    d. consider accepted international standards for data carriers;
    e. are acceptable after verification via user testing.
3. Evidence-based recommendations are available that may inform European Commission and National Competent Authorities policy recommendations.
4. 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.
5. Basis towards future international acceptance is created via:
    - documentation gathered that would be needed to launch under the International Organisation for Standardisation/International Electrotechnical Commission (ISO/IEC) a proposal for a new digital label standard or adaptation of an existing standard[1] (development of a standard itself is not planned during the lifetime of the project);
    - awareness raising with other international jurisdictions that consider digital label initiatives.

Scope

A digital label is a form of e-labelling provided as an array of elements supporting a medical technology product, which is additional to critical information on the printed label (identification & traceability of the device, warnings and precautions, handling and use information). Access to the digital label is achieved,

[1] e.g ISO 20417 already offers a segway for digital label. This standard is also foreseen for harmonisation with MDR.

for example in the form of barcodes, 2D data matrix, QR codes, etc., which provides a scannable link to curated digital landing pages (websites) where the additional information will be displayed.

Under the current Regulations on medical devices and *in vitro* diagnostic medical devices (MDR/IVDR: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical) both critical information as well as additional information have to be included on the product's printed label.

While many medical technology products are decreasing in physical size, mandatory requirements for additional product compliance information are growing, which leads to various problems. Users might find it difficult to locate the desired information on the label due to the extensive text and small print. Manufacturers have to update their entire physical label if they change an economic operator. Such label changes have an impact on the environment, product availability and inventory and they cause inefficiencies and ultimately raise costs. Local requirements for the label regarding device disposal are increasing and lead to increased amounts of packaging (and therefore later increased amounts of waste). In case of new environmental legislation, the physical label needs also to be updated during the device's lifetime.

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.

Note that this topic does not cover medicinal products, except combination products that fall into the scope of MDR/IVDR Regulations and are, therefore, regulated as devices. Furthermore, this topic does not directly address the electronic provision of IFU (instructions for use) as this is already allowed for certain medical devices and IVDs in the EU. Access to eIFU through the digital label is only an additional benefit to facilitate access to all relevant information in one place (on top of the means of delivery allowed currently by MDR/IVDR). Finally, the scope of this topic does not address post market surveillance aspects.

To fulfil the overall aim, the action funded under this topic must:

- deliver a framework for:
    - mapping of data elements that must be physically present on the label and those that the manufacturer can provide digitally. The framework will consider the requirements of EU Regulations (MDR General Safety and Performance Requirement (GSPR) 23.1, IVDR GSPR 20.1; the Packaging and Packaging Waste (PPWD) Directive; Digital Product passport, waste & packaging, battery, etc.) and is meant to also support future EU legislation (or transposition thereof in Member States).
    - a standardised concept in providing digital content and structure for the medtech manufacturers.
- define and make publicly available key performance indicators (KPIs) (e.g. trends of access and digital content type) or other measures to assess the acceptability and workability of the potential digital label solution(s), provided by manufacturers, and to be tested with end users (HCPs & patients).
- generate evidence on the acceptability and usability of digital label solutions through testing in a variety of use environments that will be defined by the full consortium. This will include user feedback on behaviour changes in a variety of use environments. The action should also make the results of testing, analysis and conclusions public.
- engage with all relevant stakeholders (e.g. HCPs, patients, National Competent Authorities, Notified Bodies) throughout the project lifetime to get robust input through consultations, surveys, workshops and testing in order to:

- maximise end user adoption (and understanding) of digital labels
- ensure that concerns and demands of end users and regulators are met

- based on the results of testing and body of evidence gathered, develop recommendations on digital labels to inform relevant stakeholders, regulators, policy makers, and the relevant ISO/IEC bodies for the possible development of IEC/ISO standard for digital label for medical devices and IVDs (or for the update of an existing standard) (the standard itself will NOT be developed during the lifetime of the project).
- ensure appropriate knowledge dissemination via:
  - developing training materials
  - subsequently finetuning training material for deployment to the public at large in all EU national languages: end users (HCPs, patients)/regulators (National Competent Authorities)/Notified Bodies in the EU Member States and any other relevant stakeholders
  - facilitating awareness and communication with other global jurisdictions' digital label initiatives

Applicants should develop a strategy and plan for generating appropriate evidence as well as for engaging and formally consulting with regulators (e.g. national competent authorities).

Expected impacts

The action to be funded under this topic is expected to achieve the following impacts:

1. Streamlined and 'green' delivery of information
   a. Key information as well as additional information is easily (and more) visible, accessible and identifiable to users (HCPs, patients) and health authorities equipped with a simple smart phone;
   b. Significant reduction of carbon footprint and avoidance of over-labelling, hereby contributing to the European Green Deal.
2. 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.
   a. Targeted information based on user location: in the EU, summary of safety and clinical performance (SSCP), the European database for medical devices (EUDAMED) modules when available[2]; globally, electronic instructions for use (eIFU));
   b. Crucial information from the printed label is additionally visible upon scanning (e.g. expiry date);
   c. Connection to technical support in case of problems;
   d. Reducing risk of use errors;
   e. Real time updates;
   f. Avoidance of cluttered labels.
3. Increased alignment between MDR and other EU legislation & streamlined compliance for all. The one digital carrier will directly link the user with the up-to-date information required by the Digital

[2] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=OJ:L_202401860

Product passport in multiple languages (EU Packaging and Packaging Waste Regulation EU Battery regulation, information on spare parts, etc.), hereby contributing to the European Green Deal.

4. Increased competitiveness in the EU market thanks to improved supply management and streamlined packaging and labelling operations.
5. Driving acceptance through (voluntary) adoption of digital labels by medical devices manufacturers and their use by end users, Notified Bodies, National Competent Authorities in the European market, supported by the developed training material. Digital label is considered an additional tool to requirements in current legislation (MDR, IVDR).

Why the expected outcomes can only be achieved by an IHI JU action

The digital label is an innovative concept offering benefits to all healthcare stakeholders and society at large. Currently, for the medical technology industry no regulatory basis exists anywhere in the world. There is therefore a need to test this concept with users, gather evidence for regulatory decision making and build regulators' as well as 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 centred healthcare information delivery in the EU and ensure its regulatory acceptance.

An aligned multistakeholder approach to the digital label will ensure the speedy success of this concept.

Pre-identified industry consortium

In the spirit of partnership, and to reflect how IHI JU two-stage call topics are built upon identified scientific priorities agreed together with a number of proposing industry beneficiaries (i.e. beneficiaries who are constituent or affiliated entities of a private member of IHI JU), it is envisaged that IHI JU proposals and actions may allocate a leading role within the consortium to an industry beneficiary. Within an applicant consortium discussing the full proposal to be submitted for stage 2, it is expected that one of the industry beneficiaries may become the project leader. Therefore, to facilitate the formation of the final consortium, all beneficiaries, affiliated entities, and associated partners are encouraged to discuss the weighting of responsibilities and priorities regarding such leadership roles. Until the role is formalised by execution of the Grant Agreement, one of the proposing industry beneficiaries shall, as project leader, facilitate an efficient drafting and negotiation of project content and required agreements.

Indicative budget

- The maximum financial contribution from the IHI JU is up to EUR 3 960 000. ***NB: this amount is indicative and subject to change, pending approval by the IHI Governing Board.***
- The indicative in-kind contribution from industry beneficiaries is EUR 6 156 800. ***NB: this amount is indicative and subject to change, pending approval by the IHI Governing Board.***

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 to the Horizon Europe programme.

The indicative in-kind contribution from industry beneficiaries may include in-kind contributions to additional activities (IKAA).

Indicative duration of the action

The indicative duration of the action is 36 months.

This duration is indicative only. At 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.

Contribution of the pre-identified industry consortium

The pre-identified industry consortium expects to contribute to the IHI JU project by providing the following expertise and assets:

- IT infrastructure provision and IT expertise;
- Expertise in labelling; regulatory affairs & intelligence; clinical research, marketing and communications, global supply chain management, project management etc.;
- Usability engineering.

Applicant consortium

The first stage applicant consortium is expected, in the short proposal, to address the scope and deliver on the expected outcomes of the topic, taking into account the expected contribution from the pre-identified industry consortium.

This may require mobilising the following expertise and/or resources:

- project management experience in running multi-stakeholder, cross-sectoral projects;
- digital labels for medical devices;
- healthcare, medical device engineering and design, as well as medical device regulation and compliance;
- demonstrated experience in interacting with regulators, citizens and/or patient representatives, health care professionals;
- data standards and interoperability;
- software and digital health;
- legal, patient literacy, health literacy, ethical, social science.

At the second stage, the consortium selected at the first stage and the predefined industry consortium will form the full consortium. The full consortium will develop the full proposal in partnership, including the overall structure of the work plan and the work packages, based upon the short proposal selected at the first stage.

Dissemination and exploitation obligations

The specific obligations described in the conditions of the calls and call management rules under ‘Specific conditions on availability, accessibility and affordability’ do not apply.