innovative health initiative

IHI

10th Call for proposals

Two-stage call

COCIR Advancing Healthcare · efpia · EuropaBio The European Association for Bioindustries · MedTech Europe from diagnosis to cure · Vaccines Europe

Co-funded by the European Union

TABLE OF CONTENTS

Introduction

The Innovative Health Initiative Joint Undertaking (IHI JU) is a partnership between the European Union and industry associations representing the sectors involved in healthcare, namely COCIR (medical imaging, radiotherapy, health ICT and electromedical industries); EFPIA, including Vaccines Europe (pharmaceutical industry and vaccine industry); EuropaBio (biotechnology industry); and MedTech Europe (medical technology industry).

IHI JU aims to pioneer a new, more integrated approach to health research and builds on the experience gained from the Innovative Medicine Initiative 2 Joint Undertaking (IMI2 JU).

IHI JU aims to translate health research and innovation into real benefits for patients and society, and ensure that Europe remains at the cutting edge of interdisciplinary, sustainable, patient-centric health research. Health research and care increasingly involve diverse sectors. By supporting projects that bring these sectors together, IHI JU will pave the way for a more integrated approach to health care, covering prevention, diagnosis, treatment, and disease management.

As current health challenges and threats are global, IHI JU should be open to participation by international academic, industrial and regulatory actors, in order to benefit from wider access to data and expertise, to respond to emerging health threats and to achieve the necessary societal impact, in particular improved health outcomes for Union citizens.

Topics Overview

HORIZON-JU-IHI-2025-10-01 **Digital label: one source of comprehensive information for medical technology products**	The maximum financial contribution from IHI JU is up to EUR 3 806 900. The indicative in-kind contribution from industry partners is EUR 6 156 800. The indicative in-kind contribution from industry partners may include in-kind contributions to additional activities.	Research and Innovation Action (RIA). Two-stage submission and evaluation process. Only the applicant consortium whose proposal is ranked first at the first stage is invited for the second stage.
HORIZON-JU-IHI-2025-10-02 **Enabling and safeguarding innovation in secondary use of health data in the European Health Data Space (EHDS)**	The maximum financial contribution from IHI JU is up to EUR 6 043 000. The indicative in-kind contribution from industry partners is EUR 5 772 500. The indicative in-kind contribution from IHI JU contributing partners is EUR 70 500. The indicative in-kind contribution from industry partners may include in-kind contributions to additional activities.	Research and Innovation Action (RIA). Two-stage submission and evaluation process. Only the applicant consortium whose proposal is ranked first at the first stage is invited for the second stage.
HORIZON-JU-IHI-2025-10-03 **Per- and Poly-fluoroalkyl substance (PFAS) exposure, emissions, and end of life management in the healthcare sector**	The maximum financial contribution from IHI JU is up to EUR 24 000 000. The indicative in-kind and financial contribution from industry partners is EUR 23 902 900. The indicative in-kind contribution from industry partners may include in-kind contributions to additional activities.	Research and Innovation Action (RIA). Two-stage submission and evaluation process. Only the applicant consortium whose proposal is ranked first at the first stage is invited for the second stage.

Call conditions for single stage and two-stage calls

For Call 10 please refer to the conditions relevant to the two-stage call

The submission deadline for short proposals (SPs) will be 23/04/2025 and the full proposals (FPs) submission deadline will be 14/10/2025.

Scientific evaluation of the SPs and FPs under the two-stage call will be completed by 2025. Grant Agreement Preparation (GAP) will be completed within 3 (three) months from the notification to applicants of the evaluation results of the full proposal, and maximum eight months from the final date of submission of the FPs, in line with the applicable time to grant (TTG).

Conditions of the calls and call management rules

For call management, IHI JU will utilise the EC IT infrastructure available under Funding & Tender opportunities – Single Electronic Data Interchange Area (SEDIA).

The General Annexes of the Horizon Europe Work Programme 2023-2025 shall apply *mutatis mutandis* to the calls for proposals covered by this Work Programme, including the "Restrictions for the protection of European communication networks" under General Annex B. In accordance with Article 5(2)(a) of the Council Regulation (EU) 2021/2085, in duly justified cases, derogations related to the specificities for IHI JU may be introduced in the relevant Work Programme. Where necessary, this will be done when the topic texts are identified in this Work Programme.

To maximise the efficiency of the calls management, IHI JU will continuously explore and implement simplifications and improve its processes while maintaining the highest standards of the evaluation process, in line with the applicable Horizon Europe rules.

All proposals must conform to the conditions set out in Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination.

GENERAL CONDITIONS RELATING TO THE IHI JU CALLS	
Admissibility conditions	The conditions are described in General Annex A.
Eligibility conditions	The conditions are described in General Annex B.
Financial and operational capacity and exclusion	The conditions are described in General Annex C.
Award criteria	The criteria are described in General Annex D.
Documents	The documents are described in General Annex E.
Procedure	The procedure is described in General Annex F.

Legal and financial set-up of the grant agreements	The conditions are described in General Annex G.

Any specificity for IHI JU is highlighted in the below sections:

STANDARD ADMISSIBILITY CONDITIONS, PAGE LIMITS AND SUPPORTING DOCUMENTS

General Annex A ('Admissibility') to the Horizon Europe Work Programme 2023-2025 shall apply *mutatis mutandis* for the calls for proposals covered by this Work Programme.

In addition, page limits will apply to proposals as follows:

- for a single-stage call, the limit for RIA full proposals is 50 pages;
- at the first stage of a two-stage call, the limit for RIA short proposals is 20 pages;
- at the second stage of a two-stage call, the limit for RIA full proposals is 50 pages.

STANDARD ELIGIBILITY CONDITIONS

General Annex B to the Horizon Europe Work Programme 2023-2025 shall apply *mutatis mutandis* for the calls for proposals covered by this Work Programme unless otherwise provided in this Work Programme.

Per the above and by way of derogation from General Annex B of the Horizon Europe Work Programme 2023-2025:

According to Article 119 of the Council Regulation (EU) 2021/2085, for indirect actions selected under calls for proposals covered by this Work Programme:

- applicant consortia must ensure that at least 45% of the action's eligible costs and costs for additional activities related to the action are provided by contributions (IKOP, FC, IKAA) from private members which are members of IHI JU, their constituent or affiliated entities, and contributing partners;
- While the constituent or affiliated entities of the members other than the union of IHI JU can contribute any of those contribution types, contributing partners can only contribute IKOP and FC, not IKAA;
- further to the above, the applicant consortium must submit a self-declaration that the required percentage of 45% contributions will be provided;
- the eligibility condition above and the self-declaration requirement do not apply to the first stage of a two-stage application;
- at project level, the maximum amount of non-EU IKOP is set to:
  - Twenty percent (20%) for IHI JU Call 9[1]
  - One hundred percent (100%) for IHI JU Call 10

This is justified as a means to ensure the achievement of project objectives based on Article 119(5) of Council Regulation (EU) 2021/2085, and to ensure full openness to non-EU IKOP in these calls[2].

[1] Even if this threshold of 20% is not intended as an eligibility condition *per se*, proposals recommended for funding that will feature a non-EU IKOP amount higher than the 20% of IKOP, will be requested to remove the exceeding part. If this is the case, this non-EU IKOP reduction exercise will need to comply with eligibility criteria whereby at least 45% of the action's eligible costs and costs for additional activities related to the action are provided by contributions (IKOP, FC, IKAA) from private members which are members of IHI JU, their constituent or affiliated entities, and contributing partners.

[2] It has to be noted that, pursuant to Article 119(4) of Council Regulation (EU) 2021/2085, at the level of the IHI JU programme, non-EU IKOP must not exceed 20% of in-kind contributions to operational costs provided by private members which are IHI JU members, their constituent or affiliated entities, and contributing partners. Furthermore, at the level of the IHI JU programme, IKAA shall not constitute more than 40% of in-kind contributions provided by private members which are IHI JU members.

ENTITIES ELIGIBLE FOR FUNDING

In relation to the single-stage calls for proposals covered by this Work Programme, the relevant provisions of the General Annex B to the Horizon Europe Work Programme 2023-2025 shall apply *mutatis mutandis*.

By way of derogation, in relation to the two-stage calls for proposals covered by this Work Programme, the following provisions shall apply:

- Legal entities identified in the topic text of the call for proposals shall not be eligible for funding from IHI JU. Nevertheless:

- These entities will be entitled to provide contributions as IHI JU members other than Union or contributing partners or as constituent or affiliated entities of either.

- Legal entities participating in indirect actions selected under this type of calls for proposals shall not be eligible for funding where:

    a) they are for-profit legal entities with an annual turnover of EUR 500 million or more;

    b) they are under the direct or indirect control of a legal entity described in point (a), or under the same direct or indirect control as a legal entity described in point (a);

    c) they are directly or indirectly controlling a legal entity referred to in point (a).

In line with Article 5(2)(a) (additional conditions in duly justified cases) and Article 119(3) (private contributions to amount of at least 45% of an indirect action's eligible costs and costs of its related additional activities) of the Council Regulation (EU) 2021/2085, under two-stage submission procedures, the following additional condition applies:

- The applicants which are IHI JU members other than the Union, or their constituent entities and affiliated entities, and contributing partners and that are pre-identified in the topics – under the section 'Industry consortium' – of a call for proposals shall not apply at the first stage of the call. The applicant consortium selected at the first stage shall, in preparation for the proposal submission at the second stage, merge with the pre-identified industry consortium.

- In addition, in line with Articles 11 and 119(1) and (3) of the Council Regulation (EU) 2021/2085, legal entities providing in-kind contributions as constituent entities or affiliated entities of IHI JU private members or as contributing partners that are:

    - Not eligible for funding in two-stage calls for proposals; or

    - Not established in a country generally eligible for funding in accordance with Part B of the General Annexes to the Horizon Europe Work Programme 2023 – 2025,

may exceptionally sign the grant agreement.

This is subject to the following conditions:

- Their participation is considered essential for implementing the action by the granting authority; and
- They participate without requesting any funding.

The essentiality of non-EU legal entities for implementing the action shall be ascertained by the granting authority.

LIST OF COUNTRIES AND APPLICABLE RULES FOR FUNDING

With reference to Article 23 of the Council Regulation (EU) 2021/2085, the eligibility of participants in a proposal submitted to a call for proposals for any of the topics in this Work Programme will take into

account any application of Art 22(5) of the Horizon Europe Regulation as well as Union legislation and guidance relevant for its application triggered for topics from other Horizon Europe Work Programmes for proposals with similar scope.

TYPES OF ACTION: SPECIFIC PROVISIONS AND FUNDING RATES

General Annex B ('Eligibility') to the Horizon Europe Work Programme 2023-2025 shall apply *mutatis mutandis* for the calls for proposals covered by this Work Programme.

EVALUATION RULES

General Annex D ('Award Criteria') to the Horizon Europe Work Programme 2023-2025 shall apply *mutatis mutandis* for the calls for proposals covered by this Work Programme with the following additions: The relevant calls for proposals launched under this Work Programme shall specify whether the call for proposals is a single-stage or two-stage call, and the predefined submission deadline.

Award criteria and scores:

Experts will evaluate the proposals on the basis of criteria of 'Excellence', 'Impact' and 'Quality and efficiency of the implementation' according to the type of action, as follows:

	Excellence Aspects to be taken into account to the extent that the proposed work corresponds to the topic description in the work programme:	**Impact** Aspects to be taken into account to the extent that the proposed work corresponds to the topic description in the work programme:	**Quality and efficiency of the implementation** Aspects to be taken into account to the extent that the proposed work corresponds to the topic description in the work programme:
First stage evaluation of two-stage procedure	• 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 overall methodology.	• 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.	• Quality and effectiveness of the outline of the work plan. • Capacity of each participant, and extent to which the consortium as a whole brings together the necessary expertise.
Single-stage and second stage of two-stage procedure	• 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, including the underlying concepts, models, assumptions, interdisciplinary approaches, appropriate consideration of the gender dimension in research and	• 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. • Suitability and quality of the measures to maximise expected outcomes and impacts, as set out in the dissemination and exploitation plan, including communication activities.	• Quality and effectiveness of the work plan, assessment of risks (including risk of falling below 45% contribution threshold), appropriateness of the effort assigned to work packages, and the resources overall. • Capacity and role of each participant, and extent to which the consortium as a whole establishes a public-private collaboration and brings together the necessary expertise. If relevant capacity and role of the contributing partner(s) to the consortium. • Clearly defined and effective integration of in-kind and

	innovation content, and the quality of open science practices, including sharing and management of research outputs and engagement of citizens, civil society and end users where appropriate.		financial contributions of IHI JU private members, their constituent or affiliated entities to enable a successful public-private partnership. If relevant clearly defined and effective integration of in-kind and financial contribution of contributing partner(s).

For all evaluated proposals, each criterion will be scored out of 5. Half marks may be given.

For the evaluation of proposals under both single-stage and two-stage submission procedures:

- the threshold for individual criteria will be 3;
- the overall threshold, applying to the sum of the three individual scores, will be 10;
- proposals that pass individual thresholds and the overall threshold will be considered for funding, within the limits of the available budget. Proposals that do not pass these thresholds will be rejected.

Under the single-stage evaluation procedure, evaluated proposals will be ranked in one single list. With the exception of those provisions herein for establishing priority order for proposals with the same score within the same budget envelope, General Annex F ('Procedure') to the Horizon Europe Work Programme 2023-2025 shall apply *mutatis mutandis.*

For proposals with the same score within a single budget envelope (with the exception of the first stage of two-stage submissions) the method to establish the **priority order** is as follows:

Starting with the group achieving the highest score and continuing in descending order:

1) Proposals that address aspects of the call that have not otherwise been covered by more highly ranked proposals will be considered to have the highest priority.
2) The proposals identified under 1), if any, will themselves be prioritised according to the scores they have been awarded for 'Excellence'. When those scores are equal, priority will be based on scores for 'Impact'.
3) Proposals that include the highest number of IHI JU private members and constituent and affiliated entities of the IHI JU private members.
4) Proposals that provide the highest percentage of contributions (IKOP, IKAA and financial contributions) from the IHI JU private members and contributing partners and the constituent and affiliated entities of both, of the proposal's eligible costs and costs for the related additional activities.
5) If necessary, the gender balance among the researchers named in the researchers table in the proposal, will be used as a factor for prioritisation.
6) If necessary, any further prioritisation will be based on geographical diversity, defined as the number of Member States or Associated Countries represented in the proposal, not otherwise receiving funds from projects higher up the ranking list (and if equal in number, then by budget).
7) If a distinction still cannot be made, the panel may decide to further prioritise by considering other factors related to the objectives of the call, or to IHI JU in general. These may include, for example, enhancing the quality of the project portfolio through synergies between projects or, where relevant and feasible, involving SMEs. These factors will be documented in the panel report.
8) The method described in 1) to 6) will then be applied to the remaining equally ranked proposals in the group.

The highest ranked proposals, within the framework of the available budget, will be invited to prepare a Grant Agreement.

Under the two-stage evaluation procedure, and on the basis of the outcome of the first stage evaluation, the applicant consortium of the highest ranked short proposal (first stage) for each topic will be invited to discuss with the relevant industry consortium the feasibility of jointly developing a full proposal (second stage).

If the first-ranked consortium and industry consortium decide that the preparation of a joint full proposal is not feasible, they must formally notify IHI JU within 30 days from the invitation to submit the second stage proposal. This notification must be accompanied by a joint report clearly stating the reasons why a second stage proposal is considered not feasible. In the absence of a joint notification within the deadline, it is deemed that the first ranked applicant consortium and the industry consortium are going to submit the joint second stage proposal. Accordingly, the second and third-ranked short proposals will be formally rejected.

If the preliminary discussions with the higher ranked proposal and the industry consortium fail, the applicant consortia of the second and third-ranked short proposals (first stage) for each topic may be invited by IHI JU, in priority order, for preliminary discussions with the industry consortium. The decision to invite lower-ranked consortia to enter into discussions with the industry consortium will take into account the content of the report from the joint report from the first-ranked consortium and industry consortium.

Under the two-stage evaluation procedure, contacts or discussions about a given topic between potential applicant consortia (or any of their members) and any member of the relevant industry consortium are prohibited throughout the procedure until the results of the first stage evaluation are communicated to the applicants[3].

As part of the panel deliberations, IHI JU may organise hearings with the applicants to:

1) clarify the proposals and help the panel establish their final assessment and scores, and/or;

2) improve the experts' understanding of the information presented.

In cases clearly identified in the relevant call for proposals where a given topic is composed of two or more sub-topics, one short proposal per sub-topic will be invited.

The IHI JU evaluation procedure is confidential.

The members of the applicant consortia shall avoid taking any actions that could jeopardise confidentiality.

Following each evaluation stage, applicants will receive an ESR (evaluation summary report) regarding their proposal.

INDICATIVE TIMETABLE FOR EVALUATION AND GRANT AGREEMENT PREPARATION

Information on the outcome of the evaluation (single-stage, or first stage of a two-stage):

- Single-stage: Maximum 5 months from the submission deadline at the single-stage.
- Two-stage: Maximum 5 months from the submission deadline at the first stage.

[3] Failure to observe this restriction may result in IHI JU rejecting either the breaching participant or the full proposal per Article 141 point 1, letter (c) of the REGULATION (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision.

Information on the outcome of the evaluation (second stage of a two-stage):

- Maximum 5 months from the submission deadline at the second stage.

Indicative date for the signing of grant agreement:

- Single-stage: Maximum 8 months from the submission deadline.
- Two-stage: Maximum 8 months from the submission deadline at the second stage.

General Annex G ('Legal and Financial setup of the Grant Agreements') to the Horizon Europe Work Programme 2023-2025 shall apply *mutatis mutandis* for the calls for proposals covered by this Work Programme.

BUDGET FLEXIBILITY

General Annex F to the Horizon Europe Work Programme 2023-2025 shall apply *mutatis mutandis* to the calls for proposals covered by this Work Programme.

SUBMISSION TOOL

Proposals in response to a topic of an IHI JU call for proposals must be submitted online, before the call deadline, by the coordinator via the Submission Service section of the relevant topic page available under Funding & Tender opportunities – Single Electronic Data Interchange Area (SEDIA). No other means of submission will be accepted.

PROPOSALS INCLUDING CLINICAL STUDIES[4]

Under the single-stage submission procedures and for the second stage of the two-stage submission procedures: Applicants envisaging including clinical studies must provide details of their clinical studies in the dedicated annex using the template provided in the submission system[5].

SPECIFIC CONDITIONS ON AVAILABILITY, ACCESSIBILITY AND AFFORDABILITY (3A)[6]

When the specific topic condition so requires, the following conditions shall apply:

- The participants must, during the lifetime of the project and for a period of four years after project end, use their best efforts to ensure that those products or services that are developed by any of the participants and are totally or partly based on the results of clinical studies performed as part of the activities of the selected project, will be broadly[7] available and accessible, at fair and reasonable conditions.

- In particular, and always to the extent permitted by applicable competition law:

  a) At the proposal stage[8], and as part of the Plan for the Dissemination, Exploitation, and Communication Activities ('PDECA') which forms part of the proposal, the applicant consortium

[4] Clinical study covers clinical studies/trials/investigations/cohorts and means, for the purpose of this document, any systematic prospective or retrospective collection and analysis of health data obtained from individual patients or healthy persons in order to address scientific questions related to the understanding, prevention, diagnosis, monitoring or treatment of a disease, mental illness, or physical condition. It includes but is not limited to clinical studies as defined by Regulation 536/2014 (on medicinal products), clinical investigation and clinical evaluation as defined by Regulation 2017/745 (on medical devices), performance study and performance evaluation as defined by Regulation 2017/746 (on *in vitro* diagnostic medical devices).

[5] Template for providing essential information in proposals involving clinical studies - https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/temp-form/af/information-on-clinical-studies_he_en.docx

[6] Article 125(3) of the Council Regulation (EU) 2021/2085.

[7] This covers EU Member States and countries that are associated to Horizon Europe at the time of call opening.

[8] For those 3A specific projects, the 3A content in the PDECA will be checked during the evaluation stage. Omission/inadequate treatment of 3A would be identified as a shortcoming. The content however, once considered adequate, will not be utilised for positive scoring and will not contribute towards any evaluation criteria.

must identify potential and expected project results that may be subject to the 3A conditions and broadly outline their strategy to achieve the above objectives.[9]

b) At the project interim review stage, if relevant[10], the PDECA should be updated with a revised 3A strategy. This update should be based on the progress of the clinical studies conducted or to be conducted as part of the project and include any pertinent action to be implemented both during the project and over the four years after project end.

c) At the end of the project, the PDECA should be updated, to provide the expected planning for further product development and (if already scheduled) product launch, within the timeframe of four years after the project end and in order to meet those objectives laid out under point 1 above.[11]

d) Within 12 months from the project end date, and on a yearly basis thereafter for a period of 3 years (totalling four years from project end), a confidential report[12] must be submitted to IHI JU by the owner of the project result describing the status of the development of the product and of any other exploitation actions, planned or undertaken, concerning the products/services.

JU RIGHT TO OBJECT TO TRANSFER/EXCLUSIVE LICENSING

According to the Horizon Europe rules, and in order to protect Union interests, the right for IHI JU to object to transfers of ownership of results or to grants of an exclusive licence regarding results should apply to participants. Therefore, the provisions set out in General Annex G to the Horizon Europe Work Programme 2023-2025 on the right to object apply generally. It should be noted that in accordance with the Council Regulation (EU) 2021/2085 and the Horizon Europe model Grant Agreement, the right to object applies also to participants that have not received funding from IHI JU and for the periods set therein. In choosing whether to exercise the right to object, IHI JU will, on a case-by-case basis, make a reasoned decision in compliance with the legal basis.

FINANCIAL SUPPORT TO THIRD PARTIES

Financial support for third parties in IHI projects is allowed for the call(s) covered by this work programme. The additional conditions contained in General Annex B to the Horizon Europe Work Programme 2023-2025 for Financial Support to Third Parties shall apply *mutatis mutandis.*

[9] Suggested components would be 1) Identification of planned clinical studies that might generate results for which the provisions are relevant; 2) Confirmation that the consortium members are aware of the provisions and will consider them accordingly. 3)Tentatively identifying markets/areas where the product/service could be made affordable, accessible, available. These points could be checked at the evaluation stage.

[10] This interim point allows a realistic appraisal of the 3A possibilities during the project lifetime, particularly as to the viability of specific expected 3A results.

[11] Per the Model Grant Agreement ('MGA') Article 16, the beneficiaries must complete the Results Ownership List ('ROL') which identifies each result generated in the project and the owner thereof. The ROL should inform on the relevant results for which owners implement the 3A strategy in the PDECA for the four years following the project.

[12] Cognisant of IP sensitivities, confidential info, and commercial realties, the IHI JU suggests that the confidential report PDECA could, if needed, be composed of two parts:

1. **A high-level abstract**, to be made publicly available (not containing confidential information), comprising:
   a) Broad summary of the result's development to this point, including a detailed description of the result and the potential product or service that could incorporate or partly incorporate the result;
   b) Broad description of expected downstream actions (including product and service applications);
   c) broad assessment of expected impact of the above downstream actions towards ensuring affordability, availability, and accessibility.
2. **A Confidential Annex** in which:
   a) The owning beneficiary explains if the result is a product or service (or is expected to become one within 4 years) or not, and if yes, further confirms:
      i. The planned measures to be taken to effect the 3A obligations;
      ii. That the owning beneficiary will undertake all necessary actions to adhere to the 3A provisions to the best of its capacity;
      iii. That the owing beneficiary will keep the IHI JU updated on a yearly basis on the progress.

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 under 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 legislation (such as digital product passport) and national legislation (e.g. language requirements);
    d. consider accepted international standards for data carriers[13];
    e. are acceptable after verification via user testing.
3. Evidence-based recommendations are available that may inform the European Commission's and the 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. A basis towards 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[14] under the International Organisation for Standardisation / International Electrotechnical Commission (ISO/IEC) – note that 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 and traceability of the device, warnings and precautions, handling and use information). Access to the digital label is achieved, 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.

[13] 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, radio frequency identification, (RFID), etc.

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

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 rising 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 under 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 and 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 taking into account the different device types.
- 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 and 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.
    - conducting usability studies will support end-user age demographics and capture metrics on the acceptability/usability of end-user participants' potential disabilities related to interacting with digital technologies.
- 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 ISO/ IEC standards for digital labelling for medical devices and IVDs (or for the update of an existing standard) – note that 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 device (e.g., phone or tablet device);
    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[15]; 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 and national legislations and streamlined compliance for all. One digital carrier will directly link the user with the up-to-date information required by the Digital

[15] 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 device 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, no regulatory basis exists for the medical technology industry 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

The pre-identified industry consortium that will contribute to this cross-sectoral IHI JU project is composed of the following medical technology industry beneficiaries ('constituent or affiliated entities of private members'):

- Arthrex (lead)
- bioMérieux
- Johnson & Johnson
- Terumo
- Thermo Fisher Scientific

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 3 806 900.

- 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 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 and 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 pre-defined 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.

Topic 2 : Enabling and safeguarding innovation in secondary use of health data in the European Health Data Space (EHDS)

Expected outcomes

The European Health Data Space (EHDS) is a key initiative under the European Strategy for Data and the European Health Union that enables the secondary use of health data for various purposes, including research and innovation. The outcomes of this topic will lead to the identification of pathways for enabling innovation through the EHDS while safeguarding intellectual property, Regulatory Data Protection (RDP)[16], and trade secrets in health data.

This topic must contribute to all of the following outcomes:

- comprehensive frameworks, processes, policies and guidelines are available to support the procedural and operational aspects of the EHDS from an innovation perspective;
- recommendations to inform EHDS governance are available to address the needs of a broad set of stakeholders, including citizens, hospitals, public institutions and the healthcare industry. The right balance must be struck between the need for an EHDS that enables efficient data sharing for the secondary use of health data to promote research and innovation in healthcare, and the need for maintaining a strong Intellectual Property (IP) system[17] while preserving confidential information within health research data;
- recommendations are available for enabling dialogues between health data holders (HDHs), health data users (HDUs) and health data access bodies (HDABs) to address issues around innovation, as well as dealing with IP, RDP, and Trade Secrets, utilising the EHDS and the operationalisation of the EHDS; and
- materials, guidance, recommendations, training and other support tools are available to educate interested parties about innovation and data sharing under the EHDS.

The target groups for all the outcomes are:

- those establishing the EHDS and the EHDS infrastructure, through which health data will be made available for secondary purposes;
- member state agencies involved with the establishment and functioning of HDABs;
- HDHs making IP, RDP and trade secret protected data, which may include sensitive and confidential data, available through the EHDS for secondary use; and
- HDUs intending to access IP, RDP and trade secret protected data for secondary use.

Scope

The background to this topic arises from the EU regulation for an EHDS. This topic focuses on the secondary use aspects of the regulation establishing the EHDS and recognises that, to be successful, there is a need to consider both the societal benefits of data-driven advancements in healthcare and the legitimate interests of public and private sector innovators for a strong IP system and an efficient means of supporting the secondary use aspect of the EHDS.

The specific challenges/problems addressed by the topic include:

[16] 'RDP': regulatory data protection rights, i.e. Article 10(1) of Directive 2001/83/EC, and Article 14(11) of Regulation (EC) 726/2004

[17] 'IP System': the set of legal and regulatory measures established within the EU for the protection of IP rights, including RDP and Trade Secrets

- balancing the societal benefits of data-driven innovation in healthcare against the legitimate interests of public and private sector innovators to safeguard relevant legal and regulatory rights related to their data (e.g., copyright, (*sui generis*) database rights, CCI (Confidential Commercial Information), trade secrets, RDP (Regulatory Data Protection)**,** patents, etc.);

- empowering HDHs and HDUs to engage with and use the EHDS for data-driven healthcare innovation by providing them with knowledge and tools, e.g., contractual agreements between HDHs and HDUs for data sharing or other potential legal, organisational or technical measures, to operationalise secondary data sharing and to safeguard intellectual property rights, trade secrets and regulatory data protections;
- developing robust frameworks and guidelines to support the implementation of the EHDS to enable harmonised and efficient sharing of IP-protected data (including in the context of cross-over with data anonymisation considerations) across all member states while safeguarding IP and trade secrets in support of innovation; and
- exploring concerns regarding commercial and competition-sensitive data and the risk of unauthorised disclosures.

The topic objectives are to:

- build trust and confidence in the EHDS: respecting and keeping proprietary information confidential, creating trust and confidence among stakeholders and promoting their active participation in the EHDS to enable responsible and timely data sharing;
- propose implementation practices that will support the efficient inclusion of health data in the EHDS for secondary research purposes and support the procedural and operational aspects of the EHDS;
- support innovators' competitiveness by safeguarding valuable IP and trade secrets data whilst fostering further research and innovation;
- advance data governance and confidentiality practices within the EHDS to ensure appropriate protection of IP and trade secrets;
- ensure data governance throughout the whole product life cycle, from development to post market monitoring and update;
- minimise the administrative burden for HDABs, HDHs and HDUs impacted by the EHDS;
- ensure that relevant legal and regulatory rights of innovators are respected and timely preserved to minimise uncertainty and maximise opportunities for innovation under the EHDS;
- support an EHDS implementation that facilitates data sharing, innovation, and research to advance healthcare for EU citizens, and uses processes that take advantage of existing practices in industry and health authorities and are resource efficient.

Applicants should envisage the following activities as part of their proposal:

<u>With regards to the outcome supporting the procedural and operational aspects of the EHDS:</u>

- conduct research into data strategy, management and governance;
- conduct comparative reviews of existing data exchanges and the need for transparency, interoperability and standardisation of data;
- conduct comparative reviews with work developed in the context of national data spaces;
- through elaborate use cases, explore the procedural and operational aspects of the EHDS from various perspectives, including:

    - assessing data sharing platforms and technologies, such as data security measures like encryption technologies, access control mechanisms, black boxes, federated learning, and their implications on the data sharing and IP system;
    - investigating the sharing of different types of data covered by the EHDS, which include trade secrets and/or data protected by IP or RDP as well as complex data (for example, imaging data), for secondary use. This will help to address different scenarios regarding purpose, time of sharing, and territorial scope, potentially leveraging test environments to evaluate operational and practical aspects of data sharing and data usability under the EHDS.
- identify best practices, guidelines, standards, and tools for intellectual property, trade secret, and opt-in/out management that can be used and advanced within the EHDS frameworks;
- develop proposals for comprehensive frameworks, processes, policies and guidelines balancing the needs of HDHs to safeguard the IP system and minimise the administrative burden while facilitating data sharing and collaboration;
- develop mechanisms and technologies for IPR-aware data manipulation, including reviewing best practices in anonymisation / pseudonymisation techniques and synthetic data generation, with the goal of facilitating the reuse of electronic health data that is subject to IP protection;
- prepare recommendations for technical standards for access controls, data minimisation, secure data storage, anonymisation techniques, handling of evolving data sets, etc., which might benefit innovation related to trade secrets and IP protected data covered by the EHDS.

<u>With regards to the outcome striking the appropriate balance:</u>

- evaluate and comparatively study laws, including trade secret laws and other laws of the EU Strategy for Data and of the EU Member States, to identify common and differentiating features and legal bases in order to propose recommendations for Member State implementation of HDABs and to develop guidance for IP and regulatory data protection covering areas such as dataset descriptions, data sharing policies and agreements, access controls, and governance practices and data use;
- conduct comprehensive research into the interplay between IP, transparency, regulatory data protection, state aid, competition laws, international treaties, the need for openness, and the potential risk for misuse of data under the EHDS;
- conduct research exploring compatibility and gaps of the EHDS versus existing laws around data and data sharing, IP, including protection of confidential information and trade secrets, and related laws, such as privacy, the EU data governance act, the EU data act, the EU AI act and regulatory data protection;
- propose guidelines and frameworks regarding data sharing and data use to support the balance of the societal benefits of data-driven healthcare research and innovation under the EHDS against the legitimate interests of public and private sector innovators for a strong IP system, including, for example, a classification of data into categories depending on IP sensitivity;
- develop guidance on responsible use and mechanisms to hold irresponsible / misusing HDUs accountable and prevent misuse;
- develop clear rules for data ownership and IP ownership determination for all kinds of newly generated data using EHDS;
- propose a harmonisation framework including standard agreements for IP ownership to enable secondary use of data provided via the EHDS for research purposes;

- analyse and provide recommendations on exploitation and publication of results by HDU and impact on HDHs with IP and trade secret protected data.

With regards to the outcome establishing frameworks for dialogues:

- engage public and private innovators in the European Health Data Space 2 (EHDS2) Stakeholder Engagement initiative to shape the definition of responsible secondary use of data for research and innovative purposes under the EHDS, including territorial considerations;
- prepare recommendations to develop a framework for dialogues between innovators and HDABs to address issues around innovation and operationalisation under the EHDS, balancing all the relevant stakeholders' legitimate interests. This engagement should, where possible, leverage and complement the action providing support to stakeholders on secondary use of data within the European Health Data Space[18].

With regards to the outcome educational aspects:

- develop training packages, including educational materials, guidance, recommendations, and other support tools to educate stakeholders about innovation, data sharing and the IP system under the EHDS. Training packages developed as part of this action should, where possible, leverage and complement outputs from the action developing capacity building for secondary uses of health data for the European Health Data Space[19];
- educate stakeholders about using the EHDS for innovative purposes.

Applicants are expected to consider the potential regulatory impact of the results and, as relevant, develop a regulatory strategy and interaction plan for generating appropriate evidence as well as engaging with relevant regulators in a timely manner.

Applicants should consider as relevant existing infrastructures/networks/collaborations to ensure synergies and complementarities.

Expected impacts

The action contributes to all the general objectives of IHI JU, particularly to specific objective 4 '*exploit the full potential of digitalisation and data exchange in health care'*.

The action under this topic is expected to achieve all of the following impacts:

- 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; and
- Increased industry confidence in the EHDS.

The action will also contribute to several European policies/initiatives, which include:

- The European Health Data Space;

[18] https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/tender-details/31fb9b46-36be-42ba-9b7a-9dea85c4abb7-CN

[19] https://hadea.ec.europa.eu/calls-tenders/capacity-building-secondary-uses-health-data-european-health-data-space_en

- The European Commission's Pharmaceutical Strategy for Europe, specifically the pillar on competitiveness, innovation, and sustainability;
- Related measures under the ongoing revision of the pharmaceutical legislation;
- The Trade Secret Directive;
- The European Strategy for Data, incl. GDPR, Data Act, Data Governance Act, AI Act;
- The Digital Strategy; and
- The Digital Single Market Strategy.

Overall, these expected impacts aim to create a secure, collaborative, and innovative ecosystem within the EHDS, which will increase trust and confidence among stakeholders, optimise data utilisation, enhance protection of intellectual property, and facilitate advancements in healthcare research and innovation.

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

The Intellectual Property ('IP') system exists to support innovation and is a key driver for all healthcare industries operating in EU. Thus, understanding how the EHDS interacts with, and might impact, the IP system will be key to its success and that of the European innovation landscape.

Public and private partners will be Health Data Holders (HDHs) and Health Data Users (HDUs) who may simultaneously be innovators. Thus, combining the strengths and expertise of private and public partners is essential to develop holistic solutions balancing the protection of IP (including trade secrets) with an EHDS that facilitates data sharing and utilisation for research and innovation.

Industry partners bring expertise in secondary use of health data, IP and trade secret management, which can be leveraged to develop effective strategies for protecting innovation whilst also facilitating health data sharing. They also understand the concerns of industry in protecting innovation with IP.

Public partners bring their knowledge of and insights into the healthcare sector, and expertise in health data management as well as technology transfer. Public partners will provide insights into the needs of the healthcare system and societal considerations for sharing health data for secondary use.

The proposed public-private collaboration is essential to develop robust frameworks, policies, and processes addressing the complex challenges posed by the EHDS. A close collaboration is necessary for the implementation of an EHDS that facilitates secondary use of data whilst also respecting the needs of innovators for a strong IP system. The collaboration will enable the EHDS to exploit the full potential of digitalisation and data exchange in health care.

The relevant stakeholders for this topic are those involved with the establishment of the EHDS for secondary use purposes and those who will provide and access data utilising the EHDS, which include, amongst others:

- HDHs and HDUs, including healthcare providers, pharmaceutical companies, and medical technology companies;
- Patient organisations and other Non-Governmental Organisations in the health research space;
- Universities and institutions or other organisations with an interest in health data;
- EU and Member State authorities responsible under the EHDS to handle and protect data of HDHs; and
- EU and Member State authorities who will establish federated data networks, HDABs and secure processing environments under the regulation for the EHDS.

Pre-identified industry consortium and contributing partners

The pre-identified industry consortium that will contribute to this cross-sectoral IHI JU project is composed of the following medical technology industry beneficiaries ('constituent or affiliated entities of private members'):

- AbbVie
- Astra Zeneca
- Bayer
- bioMérieux
- Boehringer Ingelheim
- GSK
- Johnson & Johnson (Lead)
- Merck
- MSD
- Novartis
- Novo Nordisk
- Pfizer
- Sanofi (Co-lead)
- UCB

In addition, the following contributing partners will participate to the IHI project:

- Brightinsight
- Clarivate

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, it is envisaged that IHI JU proposals and actions may allocate a leading role within the consortium to a constituent or affiliated entity of a private member.

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 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.

Due to the global nature of the participating industry beneficiaries, 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 pre-identified industry consortium and contributing partner(s) may jointly agree on a different duration when submitting the full proposal.

Contribution of the pre-identified industry consortium and contributing partners

The pre-identified industry consortium and contributing partner(s) expect to contribute to the IHI JU project by providing the following expertise and assets:

- Legal, paralegal experts and advisors/consultants specialised in IP & trade secrets protection in the digital and medical environments;
- Governmental affairs and policy experts;
- ISRM (Information Security & Risk Management) experts;
- Data strategy and governance experts;
- Communication expertise for webinars & workshops;
- Data privacy experts;
- Public affairs experts.

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 and contributing partner(s).

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

- Academic and/or research organisations involved in innovation and competition with particular expertise in legal and IP;
- ISRM (Information Security & Risk Management) experts;
- Hospital networks/HDHs/HDUs (clinical research units);
- Implementers of large digital healthcare infrastructures for primary and secondary data use (i.e., which make use of the EU policies mentioned in the expected impact section) from across the EU;
- Project management expertise related to qualitative market research and public relations;
- Project management organisations with project management expertise of large multi-stakeholder European public-private partnerships;
- Legal expertise and, in particular, privacy and regulatory data protection expertise;

- Experts from, or with connections to country ministries, involved with implementing and operating Health Data Access Bodies;
- Publicly accessible datasets.

At the second stage, the applicant consortium selected at the first stage and the pre-identified industry consortium and contributing partner(s) 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.

Topic 3: Per- and Poly-fluoroalkyl substance (PFAS) exposure, emissions, and end of life management in the healthcare sector

Expected outcomes

Per- and Poly-fluoroalkyl substances (PFAS) are a broad range of materials which have many uses within the scope of healthcare products, including as components of medicines, vaccines, medical devices, and diagnostics. These substances are currently critical to product quality, safety, and efficacy and essential to their manufacture and safe storage. PFAS make up a large group of persistent anthropogenic chemicals which are difficult to degrade and/or dispose of in an environmentally respectful manner. This IHI topic prioritises phasing-out PFAS of concern *(specified below)* as much as possible by using alternatives that maintain at least the same level of patient safety and product performance. Additionally, where it is not feasible to replace the use of PFAS, e.g. for technical or toxicological reasons, applicants should investigate how their use can be minimised / adequately controlled with respect to environmental exposure. The current knowledge needed to address these challenges is fragmented and incomplete.

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

- replace PFAS: new environmentally sustainable materials as alternatives to PFAS that maintain patient safety are developed for the benefit of the healthcare industry and the citizens;
- reduce / re-use PFAS: improved usage of PFAS materials and minimised exposure is achieved for the benefit of the environment and therefore citizens and society;
- a mapping of the types and applications of PFAS throughout the supply chain is available for healthcare technologies and products, including collaborating with upstream suppliers;
- a database of alternatives to PFAS is available;
- new disposal processes of PFAS are available for the benefit of the environment and therefore citizens and society.

Scope

To replace PFAS in medical technologies without risking human health, input from supply chain actors, scientists, and engineers is crucial. This includes assessing material availability, feasibility, and testing. Where current technology falls short, understanding PFAS environmental exposure and mitigation must improve. Standardised testing protocols and quantification methodologies are needed to measure exposure accurately. Effective mitigation requires knowledge of exposure routes and environmentally sensitive disposal methods. A scientific, data-driven approach that aligns with the safe and sustainable by design (SSbD[20]) framework is essential for lifecycle exposure management and ensuring alternative materials are safe and effective. Collaboration among scientists, policymakers, regulators, healthcare providers, chemical manufacturers, patient groups and trade associations and waste managers is vital to address technical, legal, and practical considerations. Proper scientific assessment of alternatives is necessary to maintain safety and quality.

The key challenges in the field include:

- obtaining information on PFAS uses in healthcare due to a complex global supply chain and limited data sharing;

[20] https://publications.jrc.ec.europa.eu/repository/handle/JRC128591

- many specific use requirements and potential exposure routes exist due to the ubiquitous nature of PFAS use in the healthcare sector, including in production equipment, consumables, packaging, delivery devices, medical devices, complex machinery and cleaning agents;
- identifying alternatives for high-performing PFAS like polytetrafluoroethylene (PTFE) while ensuring product quality and safety;
- end-of-life management of healthcare products is underdeveloped, with inconsistent approaches to multi-component waste management;
- current wastewater treatment technologies struggle to eliminate complex PFAS;
- consideration of PFAS guidelines and regional policy disparities that may impact the global utility of this study.

The overall aim of this IHI JU topic is to provide world-leading, fully integrated and globally applicable solutions to address PFAS emission and exposure concerns, for example by substitution.

To fulfil the IHI JU's topic aim, the applicant should address the following objectives:

Objective 1: Cross-sector solutions to develop PFAS alternatives

- **Activities:**
  - Establish public-private collaboration to increase knowledge about PFAS applications and alternatives with a focus on prioritised PFAS chemicals listed in Table 1;
  - Document key performance characteristics for PFAS used in healthcare products, manufacture, and testing;
  - Exploit industry, academic and manufacturing collaborations, incorporating skills such as chemical synthesis, material sciences and analytics to develop PFAS alternatives;
  - Test and validate PFAS alternatives generated by this project and, in addition, PFAS alternatives developed through research external to this project against performance characteristics and applications.
- **Outputs:**
  - Reporting system to label PFAS-containing raw materials or medical device components;
  - Technology on optimised materials capable of replacing PFAS in specific applications;
  - Reliable data on alternative materials that could replace PFAS and corresponding design and performance characteristics;
  - Technology for replacing PFAS chemicals in chemical synthesis or excipients in drug manufacturing;
  - Replacements for trifluoroacetic acid (TFA) in chromatography and other analytical methods;
  - Development of PFAS-free process aids (tubing, gaskets, fittings);
  - Searchable database of validated PFAS alternatives.

Objective 2: Understanding PFAS in the medtech sector

- **Activities:**
  - Identify and map PFAS types and applications in the medtech sector and align with those already identified in previous mappings of PFAS in the pharmaceutical industry;
  - Develop a methodology for risk-benefit analysis of PFAS use;

- Establish public-private collaboration to gain knowledge about PFAS applications, alternatives, risks, and risk management options;
- Identify suppliers to raise awareness of PFAS alternatives and secure continuous supplies of raw materials and parts;
- Collect data on PFAS materials used in the supply chain, emissions, and mitigation options.

- **Outputs:**
  - Increased knowledge of PFAS types and applications throughout the medtech and diagnostic process supply chain;
  - Robust evaluation of PFAS alternatives;
  - Enhanced stakeholder information sharing between medtech and the manufacturers of equipment, devices, disposables, PPE manufacturers and other activities identified by this mapping exercise.

Objective 3: Sector-specific solutions to reduce and reuse PFAS materials

- **Activities:**
  - Map and calculate PFAS exposure from different categories of applications;
  - Develop end-of-life management options across the sector in line with the SSbD framework;
  - Evaluate and leverage PFAS removal technologies;
  - Evaluation of sector specific circular economy principles for applications where removal is not yet possible;
  - Evaluate sector-specific solutions to minimise PFAS exposure in partnership with healthcare facilities and waste management companies.
- **Outputs:**
  - End-of-life management guidelines for PFAS components/chemicals, including circularity aspects and waste treatment;
  - PFAS-specific removal, decontamination or environmentally responsible disposal technologies for TFA from wastewaters.

PFAS application	PFAS materials
Films/plastics (primary contact material) for final drug product sterile packaging: • Cap or stopper coatings/liners • Vial stoppers • Syringe stoppers • Seal linings • Blister packs	ETFE (cap or stopper liners) Other coatings (proprietary) e.g., OmniFlex stopper coatings PTFE (coating for vial and syringe stoppers and seal linings)
Films/plastics (primary contact material) in manufacture and containment of drug intermediates (drug substance): • Containers/films/bottles • Single-use processing bags • Single-use bioreactors • Probes/inserts • Sterile liquid filtration membranes • Liquid filtration – virus clearance • Vent and/or gas filtration (of bioreactors/carboys) – filter membranes • Devices • PTFE thread sealing tape in engineering systems	PVDF PTFE PTFE bottles FEB bags/bottles

• Biopharma drug cryostorage bags and cell culture cryostorage bags • Support filters (e.g., HEPA/HVAC air purification)	
Films/plastics (primary contact material) for final drug product non-sterile packaging – blister packs	PCTFE
• Analytical HPLC methods • Intermediate, raw material or ancillary material used in manufacture or purification of protein-based drugs	Use TFA in the mobile phase PTFE filters PTFE seals
Tubing and tube fittings (manufacturing engineering systems and transfer of drug material intermediates and final product) incl. gaskets and O-rings Hardware systems (lined pipes, TFF cassette seals/components/solvent exchange systems/lined valves/gaskets Pumps and components (diaphragm)	PVDF (tubings and fittings), PTFE, FKM (tubing/O-rings/gaskets), FEP, PFA
Heat and/or chemical resistant components, nonreactive coatings/insulation/lubricants/refrigerants	Additive of ABS Additive in polycarbonates
ETFE: Ethylene tetrafluoroethylene; PTFE: Polytetrafluoroethylene; PVDF: Polyvinylidene fluoride; FEP: Fluorinated ethylene propylene; PCTFE: Polychlorotrifluoroethylene; TFA: Trifluoroacetic acid Table adapted from EFPIA response to the ECHA consultation on the proposal for a universal ban on PFAS, Annex 3: ISPE_Industrial Use of Fluoropolymers & Fluoroelastomers in Pharmaceutical Manufacturing Facilities	

Table 1 – Types of PFAS in use in healthcare industry. The project scope includes exploring alternatives to the PFAS materials listed here. (Table adapted from EFPIA response to the ECHA consultation on the proposal for a universal ban on PFAS, Annex 3: ISPE_Industrial Use of Fluoropolymers & Fluoro-Elastomers in Pharmaceutical Manufacturing Facilities).

In addition to the critical uses in Table 1, the following high-priority PFAS use cases in the healthcare sector are core to this project's scope:

- production equipment and consumables (filters, tubing, seals/gaskets);
- primary and secondary packaging;
- medical devices (with and without patient contact) e.g. catheters, implants, needles, contact lenses; *in vitro* diagnostics (IVD), device handles;
- medical technology processing aids;
- complex machinery (diagnostic, imaging, research equipment);
- healthcare cleaning agents;
- healthcare consumables (surgical drapes, gowns, packaging, tapes, sutures, wound dressings, personal protective equipment (PPE));
- wastewater treatment.

The proposal should aim to collaborate with the following actors and initiatives:

- Industry associations and task forces with PFAS focus, such as EFPIA PFAS task force, Biophorum PFAS response team, Innovative Quality (Pharma) Consortium, American Chemical Society ACS) Green Chemistry Institute Pharmaceutical Roundtable, Pharmaceutical Supply Chain Initiative (PSCI), Animal Health Europe (AhE);
- IMI/IMI2 JU and IHI JU consortia (past and ongoing), including Prioritisation and Risk Evaluation of Medicines in the EnviRonment (PREMIER) and Intelligent Assessment of Pharmaceuticals in the Environment (iPiE) (on waste treatment), and the project resulting from IHI Call 4 topic 5 *Safe & sustainable by design (SSbD) packaging and single use device solutions for healthcare products*;
- Ongoing Horizon 2020 projects and future Horizon Europe calls comprising a PFAS focus;
- The Partnership for the Assessment of Risk from Chemicals (PARC);
- Regulators (to inform, align expectations, assess impact on regulatory pathways and ensure data and results produced will be fit-for-purpose); for the pharmaceutical and medical device industries including the European Medicines Agency (EMA), European Directorate for the Quality of

Medicines & HealthCare (EDQM) & Official Medicines Control Laboratory (OMCL) network as well as additional national competent authorities. In the scope of this specific topic, engagement with the European Chemicals Agency (ECHA) should also be included.

Applicants should consider developing and implementing a strategy and plan to support relevant regulatory interactions.

Expected impacts

This IHI JU topic will enable and directly contribute to the EU health priorities, initiatives, and policies. Healthcare products containing PFAS are often essential for the health of citizens in Europe and worldwide. The proposed IHI JU topic would strengthen collaboration between healthcare system stakeholders to reduce emissions of, and exposure to PFAS, evaluate alternatives and therefore, contribute to the EU Chemicals Strategy for Sustainability of the EU Green Deal.

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

1. contribute to IHI JU SRIA objectives, driving cross-sectoral health innovation for a competitive European health industry. Contribute to the objectives of the Industrial Strategy for Europe and Pharmaceutical Strategy for Europe;
2. understanding human health and environmental risks from PFAS in healthcare from a life cycle perspective, i.e. mapping where PFAS is introduced in the healthcare industry and removal, where possible;
3. manage PFAS risks with novel mitigation measures, including safe disposal, reuse, and recycling;
4. develop methodologies and solutions for PFAS replacement that meet regulatory requirements without compromising efficacy, quality, safety, or environmental performance;
5. position the EU as a leader in safe, sustainable PFAS alternatives through industry-academia collaboration; foster medicine supply in the EU, avoid non-EU dependencies, and keep R&D activities in Europe for active substances to address societal and political needs;
6. strengthen stakeholder collaboration to reduce emissions and exposure until alternatives are found;
7. share industry knowledge and best practices to inform future PFAS policy;
8. improve business planning certainty for medical technology manufacturers, ensuring long-term sustainability and patient access.

Possible target groups: medical technology and medicines manufacturers and their supply chains, stakeholders involved in regulatory approval process (i.e., notified bodies, policy makers); waste management companies; hospitals and other healthcare settings and providers.

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

Addressing widespread PFAS use in medical technologies, medicinal products and vaccines requires cross-sector collaboration, involving industry (the pharmaceutical and vaccines development and manufacturing industry, as well as the medical technology development and manufacturing industry (medical devices, *in vitro* diagnostic devices (IVDs), imaging devices, drug-device combination products, etc.), plus academia, healthcare professionals, patients, health authorities, manufacturers, and IHI JU's partners. Mapping, risk assessments, and understanding performance characteristics need expertise from chemistry, environmental science, healthcare, and engineering. Resource sharing through a public-private partnership is essential for funding, research facilities, and data. Engaging diverse stakeholders ensures comprehensive and accepted solutions.

Pre-identified industry consortium

The pre-identified industry consortium that will contribute to this cross-sectoral IHI JU project is composed of the following pharmaceutical and medical technology industry beneficiaries ('constituent or affiliated entities of private members'):

- Abbott
- Abbvie
- AstraZeneca
- Bayer
- Biotronic
- Boehringer Ingelheim
- BSCI
- Gilead
- GSK
- Johnson & Johnson
- LabCorp
- Edwards Lifesciences
- Eli Lilly
- Ion Beam Applications
- Karl Storz
- Merck KGaA
- Novartis
- Novo Nordisk
- Olympus
- Pfizer
- Roche
- Sanofi
- Servier
- Stryker
- Terumo
- UCB (lead)

In the spirit of partnership, and to reflect how IHI JU two-stage call topics are built upon identified scientific priorities agreed together with several 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 in the second stage, it is expected that one of the industry beneficiaries may become the project leader. Therefore, to facilitate the formation of the full 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 24 000 000.
- The indicative in-kind and financial contribution from industry beneficiaries is EUR 23 902 900.

Due to the global nature of the participating industry beneficiaries, 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 allocation of the EUR 567 500 financial contribution (FC) from industry beneficiaries will be decided by the full consortium at the second stage when preparing the full proposal.

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 60 months.

This duration is indicative only. At the second stage, the applicant consortium selected at the first stage and the pre-identified 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 will provide the following expertise:

- chemical synthesis and active pharmaceutical ingredient (AP)I/drug product manufacturing;
- medical device manufacturing and assembly, packaging, distribution, medical supply chain management and quality control;
- regulatory affairs topics, occupational safety;
- standardised analytical methods and in process controls;
- use of process aids, their procurement and quality assurance aspects (e.g. qualification);
- management of chemical/biotechnology waste and decontamination of waste water;
- circular economy expertise;
- safe and sustainable by design methodologies;
- activities, results and insights from existing pilots and studies (these may include historical data generated outside of the project timelines that will not constitute part of the in-kind contribution);
- publication support and data dissemination.

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:

- academic centres and research organisations:
    - expertise in PFAS analytics, chemical synthesis, material sciences, coatings, and biodegradation;
    - researchers working on PFAS alternatives and optimising existing materials.
- manufacturers:
    - PFAS materials (e.g., films, spare parts, equipment, implants, foils);
    - Medical manufacturing, critical technologies, medicinal products, and vaccines;
    - Drug substance manufacturing/vaccines targeting PFAS excipient replacements/reductions.
- analytical methods experts: replace TFA in chromatography and other technologies;
- standards organisations: develop and update analytical standards/testing methodologies;
- process aids development experts: replace PFAS-containing process aids (tubing, gaskets, fittings) with PFAS-free alternatives;
- circular economy experts: establish PFAS-specific collection and recycling systems;
- “Safe and sustainable by design” experts;
- Healthcare waste management organisations;
- Urban wastewater treatment management organisations;
- Healthcare sector consultants: provide input and test solutions;
- project management:
    - coordinate communication, meetings, and risk management;
    - grant administration, financial management, and reporting;
    - digital/IT development and implementation to support data governance and management;
    - coordinate internal and external networking and stakeholder engagement.

At the second stage, the consortium selected at the first stage and the pre-identified 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.

Glossary

Topic 1

Acronym	Meaning
IVDs	*in vitro* diagnostic medical devices
MDR	regulations on medical devices
IVDR	regulations on *in vitro* diagnostic medical devices
HCPs	healthcare professionals
ISO	International Organisation for Standardisation
IEC	International Electrotechnical Commission
eIFU	electronic instructions for use
GSPR	General Safety and Performance Requirement
PPWD	Packaging and Packaging Waste
SSCP	safety and clinical performance
EUDAMED	European database for medical devices

Topic 2

Acronym	Meaning
EHDS	European Health Data Space
HDHs	health data holders
EHDS2	European Health Data Space 2
HDUs	health data users
HDABs	health data access bodies
CCI	Confidential Commercial Information
RDP	Regulatory Data Protection
IPR-aware	Intellectual Property Awareness

Topic 3

Acronym	Meaning
PFAS	Per- and Poly-fluoroalkyl substance
SSbD	safe and sustainable by design
PTFE	polytetrafluoroethylene
TFA	Trifluoroacetic
ISPE	International Society for Pharmaceutical Engineering
ECHA	European Chemicals Agency
IVD	in-vitro diagnostics
PPE	Personal protective equipment
ACS	American Chemical Society
PSCI	Pharmaceutical Supply Chain Initiative (PSCI)
AhE	Animal Health Europe
PARC	Assessment of Risk from Chemicals
EDQM	European Directorate for the Quality of Medicines & HealthCare
OMCL	Official Medicines Control Laboratory
TFA	Trifluoroacetic acid