



IHI

7<sup>th</sup> Call for proposals

Single-stage call



# TABLE OF CONTENTS

- Introduction.....3
- Topics overview.....4
- Call conditions for single stage and two-stage calls .....5

## 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

<p><b>HORIZON-JU-IHI-2024-07-01-single-stage</b></p> <p><b>Improving clinical management of heart disease from early detection to treatment</b></p>	<p>Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 25 000 000.</p> <p>Applicant consortia must ensure that at least 45% of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.</p>	<p>Research and Innovation Action (RIA)</p> <p>Single-stage submission and evaluation process.</p> <p>Proposals submitted will be evaluated and ranked in one single list. Several proposals might be invited to conclude a Grant Agreement, depending on budget available and their ranking.</p>
<p><b>HORIZON-JU-IHI-2024-07-02-single-stage</b></p> <p><b>User-centric technologies and optimised hospital workflows for a sustainable healthcare workforce</b></p>	<p>Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 25 000 000.</p> <p>Applicant consortia must ensure that at least 45% of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.</p>	<p>Research and Innovation Action (RIA)</p> <p>Single-stage submission and evaluation process.</p> <p>Proposals submitted will be evaluated and ranked in one single list. Several proposals might be invited to conclude a Grant Agreement, depending on budget available and their ranking.</p>
<p><b>HORIZON-JU-IHI-2024-07-03-single-stage</b></p> <p><b>Clinical validation of biomarkers for diagnosis, monitoring disease progression and treatment response</b></p>	<p>Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 45 000 000.</p> <p>Applicant consortia must ensure that at least 45% of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.</p>	<p>Research and Innovation Action (RIA)</p> <p>Single-stage submission and evaluation process.</p> <p>Proposals submitted will be evaluated and ranked in one single list. Several proposals might be invited to conclude a Grant Agreement, depending on budget available and their ranking.</p>

# Call conditions for single stage and two-stage calls

**\*For Call 7 please refer to the conditions relevant to the single-stage call**

**The submission deadline for full proposals (FPs) will be 22/05/2024.**

Scientific evaluation of the single-stage call will take place in Q2 2024. GAP will be completed within 3 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 2023-2024 shall apply *mutatis mutandis* to the calls for proposals covered by this Work Programme. 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

<b><i>Admissibility conditions</i></b>	The conditions are described in General Annex A.
<b><i>Eligibility conditions</i></b>	The conditions are described in General Annex B.
<b><i>Financial and operational capacity and exclusion</i></b>	The conditions are described in General Annex C.
<b><i>Award criteria</i></b>	The criteria are described in General Annex D.
<b><i>Documents</i></b>	The documents are described in General Annex E.
<b><i>Procedure</i></b>	The procedure is described in General Annex F.
<b><i>Legal and financial set-up of the grant agreements</i></b>	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 2023-2024 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 2023-2024 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 2023-2024:

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:
  - One hundred percent (100%) for IHI JU Call 6
  - Twenty percent (20%) for IHI JU Call 7<sup>1</sup>

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<sup>2</sup>.

## 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 2023-2024 shall apply *mutatis mutandis*.

<sup>1</sup> 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.

<sup>2</sup> 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.

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 – 2024,

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 2023-2024 shall apply *mutatis mutandis* for the calls for proposals covered by this Work Programme.

## TECHNOLOGY READINESS LEVELS (TRL)<sup>3</sup>

TRL definitions included in General Annex B ('Eligibility') to Horizon Europe Work Programme 2023-2024 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 2023-2024 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:

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 process, evaluated proposals will be ranked in one single list. 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<sup>4</sup>.

<sup>3</sup> The TRL is not utilised for IHI calls 6 and 7, however, it might be used in future IHI JU calls.

<sup>4</sup> 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.



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.

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 2023-2024 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 2023-2024 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<sup>5</sup>

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<sup>6</sup>.

<sup>5</sup> 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).

<sup>6</sup> 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](https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/temp-form/af/information-on-clinical-studies_he_en.docx)

## SPECIFIC CONDITIONS ON AVAILABILITY, ACCESSIBILITY AND AFFORDABILITY (3A)<sup>7</sup>

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<sup>8</sup> 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<sup>9</sup>, and as part of the Plan for the Dissemination, Exploitation, and Communication Activities ('PDECA') which forms part of the proposal, the applicant consortium 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.<sup>10</sup>
  - b) At the project interim review stage, if relevant<sup>11</sup>, 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.<sup>12</sup>
  - 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<sup>13</sup> 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.

<sup>7</sup> Article 125(3) of the Council Regulation (EU) 2021/2085.

<sup>8</sup> This covers EU Member States and countries that are associated to Horizon Europe at the time of call opening.

<sup>9</sup> As mentioned, 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.

<sup>10</sup> 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.

<sup>11</sup> As discussed, 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.

<sup>12</sup> 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.

<sup>13</sup> Cognisant of IP sensitivities, confidential info, and commercial realities, 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.

## **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 2023-2024 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.

## **COUNTRY SPECIFIC ELIGIBILITY RULES**

Following the Horizon Europe Programme Guide, participation in IHI JU indirect actions will be open but eligibility for funding will be however limited to legal entities established in an EU Member State, Associated Country or Low- and Middle-Income Countries (please consult the list in the Horizon Europe Programme Guide<sup>14</sup>).

Given the invasion of Ukraine by Russia and the involvement of Belarus, legal entities established in Russia, Belarus or in any occupied territory of Ukraine are not eligible to participate in any capacity. Exceptions may be granted on a case-by-case basis for justified reasons, such as for humanitarian purposes, civil society support or people-to-people contacts.

<sup>14</sup> [https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/programme-guide\\_horizon\\_en.pdf](https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/programme-guide_horizon_en.pdf)

# Topic 1: Improving clinical management of heart disease from early detection to treatment

## Expected outcomes

Actions under this topic must contribute to all the following outcomes, ultimately contributing to reducing the burden of heart disease:

- Healthcare systems and patients benefit from the development of integrated solutions for improving critical aspects in the overall care pathway (primary, ambulatory and hospital care) for heart disease.
- Healthcare systems and patients will benefit from the development or optimisation of innovative technologies leading to personalised, patient-centric solutions for the early detection, diagnosis or treatment of heart disease.
- Patients benefit from proposed strategies tailored to their needs for improved outcomes in heart disease.
- Healthcare professionals benefit from the deployment of solutions for improved diagnostic procedures, referral programs or clinical workflows as well as targeted training for relevant clinical staff where appropriate.

## Scope

Heart disease includes structural heart disease (SHD), coronary artery disease (CAD), heart failure (HF) and heart arrhythmias, which are common, devastating, and heterogeneous medical conditions causing a high burden in Europe and worldwide<sup>15</sup> [1][2]. It is estimated that SHD affects 14 million people in Europe alone, while, worldwide, HF affects more than 64 million [1], atrial fibrillation more than 37 million [2] and 244.1 million people were living with CAD in 2020<sup>2</sup>. The impact of these diseases is significant both in terms of the health-related quality of life of patients and caregivers, and the large economic burden, amounting to over EUR 280 billion in the EU for cardiovascular disease (CVD [3]). In Europe, the prevalence of these conditions is expected to rise due to the ageing population and the lifestyle of citizens and, thus, the economic burden will also increase dramatically in the next decades with the costs for health care accounting for the largest part [3][4][5].

However, despite the importance of SHD, CAD, HF and heart arrhythmias, disease management and long-term outcomes remain heterogeneous [6] due to the lack of comprehensive access to detection, diagnosis and care. The care of people with heart disease is also highly complex, with a multitude of diagnostic procedures and multidisciplinary therapeutic approaches available, including pharmaceutical, minimally-invasive and surgical interventions, disease-modifying therapies, and cardiac rehabilitation. Moreover, means for early diagnosis are often suboptimal, thus novel approaches should be explored to provide sustainable and scalable solutions [7].

Critically, improved early detection, diagnosis, referral and patient stratification linked to optimised clinical workflows and clinical decision-making hold the promise of faster, personalised treatments. However, to achieve their successful implementation, there is a need for substantial cross-sectorial research and innovation and better integration of the different steps of care from primary to hospital care for an optimised disease management in more efficient healthcare settings.

Projects funded under this topic should address all or any of the following heart diseases: SHD, CAD, HF, and heart arrhythmias.

<sup>15</sup> [About Structural Heart Diseases | SHD Coalition](#)

<sup>16</sup> [2022 Heart Disease & Stroke Statistical Update Fact Sheet Global Burden of Disease](#)

Applicants are expected to assemble a suitable cross-sectoral public-private partnership to propose activities to address the following objectives in heart disease. In this context, applicants may consider identifying and addressing only some critical aspects of the patients' journey or specific care settings, with the aim of contributing to the overall care pathway improvement.

- Improve the efficiency of primary care, ambulatory or hospital care, considering how to optimise the patient pathway from one to the other and the transition among the teams in each care setting.
- Improve patient outcomes through earlier detection, better diagnosis, monitoring and/or treatment. This may include the development or deployment of innovative technologies or package solutions for early detection and diagnosis, or to seamlessly both treat and monitor (e.g. personalised imaging technologies, personalised sensing technologies, artificial intelligence (AI)-powered clinical decision tools, digital imaging, diagnostic technologies).
- Develop and implement measures and digital tools to enhance efficiency and optimise patient outcomes in primary and hospital care (e.g. reducing hospitalisations, disease burden and/or length of stay), and ensure a continuum between early detection, diagnostic and therapeutic approaches by guiding patients faster to the selection of the best treatment modality. This could be done for example via procedural automation, non-invasive testing, improved access to data, integrated pathways dashboards, and AI-powered clinical decision making.
- Develop personalised, patient-centric solutions in diagnosis and treatment to improve patients' healthcare experience, considering the needs of specific populations such as children, elderly patients, cardio-oncology patients, or patients with co-morbidities.
- Adequate consideration should be given to the sustainability and scalability of the proposed solutions.
- Explore management strategies combining access to medical teams specialising in heart disease and social interventions to address population inequalities in outcomes. Also consider the heterogeneity of the healthcare system in Europe and generate evidence applicable across the diversity of European realities.
- Conduct an initial health economic study (such as cost-effectiveness analyses, budget impact models, etc.) of the proposed interventions on the healthcare system. The health economic study could include, for example, an analysis on whether an optimised management of heart diseases results in avoiding or reducing hospital treatment and the related costs.
- Patients and healthcare professionals should be engaged in all stages of the project from conceptualisation and throughout the implementation (e.g. in raising public awareness, education of patients, helping with the improvement of the referral pathway and the pathway to treatment, developing targeted training for relevant clinical staff).
- 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 regulators in a timely manner (e.g. national competent authorities, the European Medicines Agency (EMA) Innovation Task Force, qualification advice).

Applicants should also reserve resources to synergise with other relevant initiatives, including other projects funded under this topic and those resulting from IHI call 2 topic 1<sup>17</sup> (iCARE4CVD) and IHI call 5 topic 3<sup>18</sup>, as well as with other European research initiatives and infrastructures, such as the European Partnership on Transforming Health and Care Systems (THCS), the Healthier together – EU non-communicable diseases (NCD) initiative, and the European Partnership for Personalised Medicine (EP PerMed) among others.

## Expected impacts

<sup>17</sup> <https://www.ih.europa.eu/apply-funding/ih-call-2>

<sup>18</sup> <https://www.ih.europa.eu/apply-funding/ih-call-5>

Actions under this topic are expected to achieve the following impacts:

- Patients benefit from personalised patient-centred healthcare from early detection to treatment, and improved patient outcomes and experience due to advanced detection, diagnostic, decision-making and disease management throughout the continuum of care.
- Healthcare professionals benefit from novel diagnostic procedures and optimised clinical workflows, which lead to improved clinical outcomes for heart disease.
- Healthcare systems benefit from organisational solutions and an efficient transition through the different stages along the whole continuum of the care pathway for heart disease.
- Companies develop and offer advanced, robust and scalable solutions that leverage innovative technologies, tools and services allowing for integration with other existing workflows to effectively and efficiently support healthcare professionals and health systems in achieving their goals.
- Healthcare professionals benefit from the enhancement of existing clinical management guidelines and the development of new ones as appropriate.

Actions are also expected to contribute to the following EU policies/initiatives:

- European Partnership on Transforming Health and Care Systems (THCS);
- Healthier together – EU non-communicable diseases (NCD) initiative;
- The European Commission proposal for a European Health Data Space (EHDS).

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

The complexity of clinical care for SHD, CAD, HF and heart arrhythmia patients calls for the involvement of different industry sectors involved in diagnosis, data analytics, clinical decision-making, and pharmaceutical and non-pharmaceutical interventions. Beyond industry, it requires bringing together researchers, hospitals, medical staff, patients and patient organisations. The IHI framework provides the ideal setting to create a fruitful collaboration and leveraging of resources and know-how of all these stakeholders and deliver the expected outcomes from this topic.

### **Indicative budget**

Applicant consortia will be competing for the maximum financial contribution from IHI JU of up to EUR 25 000 000.

IHI JU estimates that an IHI JU financial contribution of EUR 12 500 000 would allow a proposal to address these outcomes appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

Applicant consortia must ensure that at least 45% of the action's eligible costs and costs for the action-related additional activities are provided by in-kind contributions to operational activities ('IKOP'), financial contributions ('FC's), or in-kind contributions to additional activities ('IKAA'). While 45% is the threshold for eligibility, applicant consortia are strongly advised to aim for 50% to provide a margin e.g. for unforeseen changes during the project lifetime.

IKOP and FCs may be contributed by the constituent and affiliated entities of both the private members and the contributing partners. IKAA may be contributed by constituent and affiliated entities of the private members only. Contributing partners and their affiliated entities cannot contribute IKAA.

See the call conditions in the annual Work Programme for further information (also in the document "call text" published on the IHI website).

## Indicative duration of the actions

Applicants should propose a project duration that matches the project's activities and expected outcomes and impacts.

## 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' apply.

## References

- [1] Savarese G, Becher PM. Global burden of heart failure: a comprehensive and updated review of epidemiology. *Cardiovasc Res.* 2023 Jan 18;118(17):3272-3287
- [2] Lina Wang, Feng Ze, et al. Trends of global burden of atrial fibrillation/flutter from Global Burden of Disease Study 2017. *Heart* 2021;107:881-887.
- [3] Cardiovascular disease cost the European Union economy €282bn in 2021 — Nuffield Department of Population Health (ox.ac.uk).
- [4] d'Arcy, Joanna L., et al. Large-scale community echocardiographic screening reveals a major burden of undiagnosed valvular heart disease in older people: the OxVALVE Population Cohort Study. *European heart journal* 37.47 (2016): 3515-3522.
- [5] Hessel FP. Overview of the socio-economic consequences of heart failure. *Cardiovasc Diagn Ther.* 2021 Feb; 11(1): 254–262.
- [6] Lawson CA, Zaccardi F, Squire I, et al. 20-year Trends in Cause-Specific Heart Failure Outcomes by Sex, Socioeconomic Status, and Place of Diagnosis: A Population-Based Study. *Lancet Public Health* 2019;4:e406-20. 10.1016/S2468-2667(19)30108-2
- [7] Luise Gaede MD, Marta Sitges MD, Johnson Neil, Eleonara Selvi, William Woan, Richard Derks, Helge Möllmann. European heart health survey 2019. *Clinical Cardiology*, Vol.43, Issue 12.



## Topic 2: User-centric technologies and optimised hospital workflows for a sustainable healthcare workforce

### Expected outcomes

Actions under this topic must contribute to at least three of the following outcomes:

- Healthcare professionals will benefit from assistive technologies that are user-centric, and improved workflows within the hospital setting, resulting in optimised procedures or new capacities, while easing the workload and promoting job satisfaction.
- European healthcare systems will benefit from the automation and improvement of already-existing processes and/or the availability of new technologies. These innovations will provide increased functionality or new capacities.
- Patients will benefit from an improved experience throughout the entire care journey, including increased quality and efficiency of healthcare services derived from the automation or improvement of existing hospital workflows, and/or access to novel treatment modalities.
- Healthcare providers will benefit from new and innovative workflows and/or capabilities for improved cost-effectiveness and efficiency of care delivery, enhancing access to care, and improving the experience of both hospital staff and patients.

### Scope

Due to long-lasting staff shortages and systemic challenges in healthcare systems, which have been exacerbated as a consequence of the COVID-19 pandemic, healthcare professionals are facing increasing workloads and pressures at work, resulting in an increase in burnout and stress as well as short- or long-term absences from work. A high level of clinician and medical staff burnout has many professional ramifications and can result in medical errors and suboptimal patient care as well.

Technical and data-driven solutions have the potential to support the healthcare workforce, but their adoption has faced many challenges such as: a lack of holistic integration in clinical workflows; a lack of proper consideration of the healthcare professionals' input for their design [1][2][3]; the need to enhance the digital skills of health professionals without adding more workload; the lack of real added value for addressing clinically significant problems; and the under- or over- reliance on artificial intelligence (AI) that may compromise clinical outcomes. For example, while the massive growth in medical data and developments in data analytic methods promise better quality of care and health outcomes for patients at a lower cost for health systems, it also fuels the workload of healthcare professionals, due to the high training and documentation burden for clinicians among other things. Similarly, robot-assisted and automation technologies can improve the safety, quality and efficiency of hospital workflows, such as in surgery and other care settings. However, reconciling the tensions that exist between standardisation through automation versus the unpredictable nature of healthcare work remains difficult. In addition, while AI solutions have been suggested to support clinical decision-making, operational optimisation, patient empowerment, healthy lifestyle maintenance and population health management, they require further testing and validation.

The life-critical decision-making in healthcare and the dynamic, stressful work environment require user-centred (that consider the needs, preferences, and experiences of the healthcare workforce) and intuitive tools that support clinicians with reliable diagnostics and planning, as well as the delivery of complex interventions. In addition, better integration of existing solutions and emerging technologies in (optimised) hospital workflows will improve treatment outcomes, ease workloads, and preserve job satisfaction.

The projects funded under this topic should develop or improve innovative medical technology solutions. Through collaborative design approaches incorporating the feedback of end-users, the solutions should



be easy-to-use, clearly identify and tackle any ethical concerns, and aim to be ready for integration into real-world hospital environments. Applicants should also consider the ethical and societal implications of the proposed solutions, involving the perspectives and preferences of patients and their families as the ultimate beneficiaries.

To achieve this aim, applicants must assemble a public-private partnership to ensure successful co-creation of the proposed solution(s), with input of all relevant stakeholders including healthcare professionals and patients, focusing on the following activities.

- Develop and implement solutions to empower the healthcare workforce (for example in diagnostics, management and organisation, planning, delivery of complex interventions, etc.), by supporting and assisting them without introducing additional burdens.
  - Propose solutions (up to a prototype level) that may relate either to the automation of existing workflows, or the adoption and the integration of new capacities and/or the development of trustworthy and autonomous technologies or technology (AI)<sup>19</sup> experiences.
  - These solutions should be data-driven, aiming to improve workflows and assist clinical procedures and/or hospital processes, supporting in planning and creating a more efficient and balanced supply and demand between patient load and staff competencies and healthcare resource consumption.
  - Applicants should take into consideration standardised approaches to data acquisition to allow proper development/training of the technologies.
- Propose and implement a strategy for better integration of existing and/or emerging technologies in different hospital workflows. This may include an analysis of the most critical processes running in hospitals, technological gaps within the hospital environment, ways to optimise workflow(s), and a roadmap of how the proposed technologies can grow, adapt, and innovate to meet the future needs of a healthcare system and its staff.
- Demonstrate potential for deployment through use cases that address wide user groups involving all relevant medical staff categories (nurses, medical staff, specialists, managers, etc.).
- Establish effective training approaches for complex technologies to minimise user burden and operator error, and/or to improve patient outcomes.
- Convincingly demonstrate the scalability and transferability of the approaches across different healthcare professions and different levels of care.
- Demonstrate the feasibility and desirability of the proposed approach(es) or technologies from an economic perspective, analysing the potential impact on patient and staff costs in healthcare institutions, on payers and insurers, and on the healthcare system. Applicants should consider relevant strategies to drive end-user and organisation-wide adoption.
- Where relevant, the proposed solutions should aim at developing and applying relevant standards (e.g. Fast Health Interoperability Resources (FHIR), Health Level Seven International (HL7), Integrating the Healthcare Enterprise (IHE), Logical Observation Identifiers Names and Codes (LOINC), Systemized Nomenclature of Medicine – Clinical Terms (SNOMED CT), Business Process Model and Notation (BPMN)) and ensuring the potential for regulatory approval, taking into consideration the different national regulatory requirements to ensure future implementation in the target markets.
- If relevant, applicants should take into account other dimensions with regulatory implications (for example the prevention and management of shortages, implementation of risk minimisation

<sup>19</sup> If applicable to the proposal, the consortium should consider relevant initiatives on the safe use of AI in the healthcare domain, including references to ISO/SC42, ISO/TC215, and WHO WG on AI4Health.

measures following regulatory decisions, the incorporation of clinical trial design requirements, and collecting real world data (RWD) for regulatory purposes).

- Where applicable, applicants should ensure the proposed solutions take into consideration supporting the secondary use of data generated for research, including by regulators.
- Applicants should also learn from past EU-funded projects (via mapping exercises and desk reviews) and reserve resources to synergise with other relevant ongoing initiatives. These could include other projects funded under this topic, those funded under IHI Call 3<sup>20</sup>, and 'AI for the smart hospital of the future' (DT-ICT-12-2020) or HORIZON-HLTH-2023-CARE-04-02, if relevant.

## Expected impacts

Actions under this topic are expected to achieve the following impacts and contribute to the following EU policies/initiatives:

- development of innovative medical technology that directly contributes to halting the current efflux of medical professionals, fostering sustainable careers in healthcare, and potentially improving clinical outcomes;
- improved patient care through advanced diagnostic and treatment technologies and more efficient clinical workflows, while ensuring the privacy and security of patient data;
- companies develop and offer advanced technological solutions to support healthcare professionals; these solutions should consider workflow integration and reflect end-user needs;
- healthcare systems could improve their capacity and resilience because of more efficient and sustainable solutions.

Actions are also expected to contribute to the following EU policies/initiatives:

- contribute to the 'Comprehensive Approach to Mental Health' of the European Commission by promoting the reduction of psychosocial risks at work in the healthcare sector, and 'a Europe fit for the digital age', by empowering people with a new generation of technologies.

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

Other programmes have previously addressed human-technology interactions in a broad manner, however, IHI JU is best suited to structurally address the specific needs of the healthcare sector. For the successful embedding of technologies in the work of people in healthcare, collaboration between private and public organisations is a basic prerequisite for implementation. This topic, in particular, requires cross-sectoral approaches involving the med-tech and pharmaceutical industries for the effective integration of new technologies in the clinical workflow. Moreover, it is essential to bring together broad user groups involving all relevant medical staff categories (nurses, medical staff, specialists, pharmacists, etc.) with industry partners to ensure the upfront integration of their input.

In addition, a multidisciplinary approach is needed to enable an objective and qualified evaluation of the proposed novel medical technologies, integrating the social sciences and humanities to understand the user preferences and expectations, and ensure acceptance and uptake among users. Where relevant, the evaluation of ethical and technical safety risks may require collaboration with ethicists and regulators.

<sup>20</sup> <https://www.ihj.europa.eu/apply-funding/ihj-call-3>

## Indicative budget

Applicant consortia will be competing for the maximum financial contribution from IHI JU of up to EUR 25 000 000.

IHI JU estimates that an IHI JU financial contribution of EUR 12 500 000 would allow a proposal to address these outcomes appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

Applicant consortia must ensure that at least 45% of the action's eligible costs and costs for the action-related additional activities are provided by in-kind contributions to operational activities ('IKOP'), financial contributions ('FC's), or in-kind contributions to additional activities ('IKAA'). While 45% is the threshold for eligibility, applicant consortia are strongly advised to aim for 50% to provide a margin e.g. for unforeseen changes during the project lifetime.

IKOP and FCs may be contributed by the constituent and affiliated entities of both the private members and the contributing partners. IKAA may be contributed by constituent and affiliated entities of the private members only. Contributing partners and their affiliated entities cannot contribute IKAA.

See the call conditions in the annual Work Programme for further information (also in the document "call text" published on the IHI website).

## Indicative duration of the actions

Applicants should propose a project duration that matches the project's activities and expected outcomes and impacts.

## 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' apply.

## References

- [1] Collier, R., Medical technology often a burden if designed without physician input. *Canadian Medical Association Journal*, E1091–E1092. 2018.
- [2] Lena Petersson et al., Challenges to implementing artificial intelligence in healthcare: a qualitative interview study with healthcare leaders in Sweden, *BMC Health Services Research*, 2022.
- [3] Schlieter H. et al., Scale-up of Digital Innovations in Health Care: Expert Commentary on Enablers and Barriers, *Journal of Medical Internet Research*, 2022.

## Topic 3: Clinical validation of biomarkers for diagnosis, monitoring disease progression and treatment response

### Expected outcomes

Actions under this topic must contribute to all the following expected outcomes:

- Access for healthcare professionals to novel, robust and fit for purpose biomarkers<sup>21</sup> with linked technologies enabling their use in clinical setting and progress towards validation. Biomarkers and linked technologies may be for diagnosis, monitoring disease progression, selecting the optimal therapeutic treatments, or assessing treatment response.
- Availability for researchers of robust and fit-for-purpose biomarkers with linked technologies enabling their clinical use for diagnosing disease, disease monitoring, or monitoring treatment response. This will enable researchers to develop safer and more effective personalised treatments tailored to the individual's characteristics and the stage of their disease. Alternatively, availability for researchers of key technology (e.g. companion diagnostics) that could be essential for the safe and appropriate use and selection of a corresponding drug or biological product or its development.
- Availability for regulators of robust evidence on the suitability of selected biomarkers and their linked technologies to enable regulatory acceptance for a specific use.

### Scope

Biomarker-driven approaches for diagnosis, monitoring disease progression and assessing treatment response have immense potential to help us progress precision medicine. Despite intense research, few biomarkers are subject to rigorous testing in clinical settings and shown to be fit for purpose (clinically validated). In addition, while there are several novel biomarkers that have shown significant promise for a number of use cases, often the technology to make them accessible for clinical use is not mature enough, which hampers their validation for use. Thus, technology development or improvements to existing technologies may be required to progress these biomarkers to clinical validation. For example, there are many novel and highly innovative technologies in development (e.g. imaging, artificial intelligence (AI), omics markers, phage-based diagnostics in multiple formats among others) and their further development and validation would be a necessary element for validating their detected biomarkers in the clinic.

Furthermore, different healthcare actors (e.g. academics, clinicians, patients, health technology developers and regulators) may have different definitions and expectations on the utilities of biomarkers, and there is a need for an aligned methodological framework for scaling up the clinical validation of candidate biomarkers.

To address this challenge, this topic aims:

- to progress candidate biomarkers towards clinical validation and, when relevant, to regulatory acceptance;  
and/or

<sup>21</sup> See definition as in the [IHI JU Strategic Research and Innovation Agenda](#) (Glossary): BIOMARKERS are biological characteristics, which can be molecular, anatomic, physiologic, or biochemical. These characteristics can be measured and evaluated objectively. They act as indicators of a normal or a pathogenic biological process. They allow the assessment of the pharmacological response to a therapeutic intervention. A biomarker shows a specific physical trait or a measurable biologically-produced change in the body that is linked to a disease or a particular health condition. A biomarker may be used to assess or detect a specific disease as early as possible (diagnostic biomarker), the risk of developing a disease (susceptibility/risk biomarker), the evolution of a disease (prognostic biomarker) – but it can also predict response to a given treatment including potential toxicity (predictive biomarker).

- to progress towards clinical validation innovative technologies necessary for making biomarker(s) accessible for clinical use. In proposals focusing uniquely on these technologies, applicants should justify how such progress will enable the validation of the biomarker(s) for use in a clinical context.

Projects funded under this topic should:

- Assemble a cross-sectoral public-private partnership to align and develop a methodological framework and roadmap for progressing selected candidate biomarker(s) and/or linked technologies enabling the clinical use of the biomarker(s) (or a combination thereof) to rigorous clinical validation.
- Provide a justification and clearly demonstrate why the proposal area responds to an unmet public health need<sup>22</sup>.
- Progress biomarker(s) and/or technologies towards clinical and analytical validation in one or more of these areas: diagnosing disease, early treatment path selection, monitoring disease progression, or treatment response assessment:
  - All types of biomarkers including digital, combinations of biomarkers and multimodal biomarkers are in scope. Proposals addressing biomarker(s) intended for specific populations such as the elderly or children are very welcome.
  - The candidate biomarkers can be combined with existing biomarkers for more personalised decision making.
  - All types of technologies for progressing biomarkers to a stage closer to clinical validation, including innovative and novel approaches, are in scope. Some examples could be technologies for the effective collection, preparation, measurement and analysis of samples and biomarkers, or diagnostic equipment, methods, or systems.
  - In their proposal, applicants must clearly identify the candidate biomarker(s) and/or linked technology(ies) and the proposed application in research and development (R&D) and/or clinical practice.
  - Applicants should provide in their proposal sufficient preliminary evidence, including relevant methodology(ies) and high-quality data to demonstrate that the biomarker(s) and/or technology(ies) can be progressed towards clinical validation and, when relevant, to regulatory acceptance.
  - As relevant, applicants must ensure effective collection, preparation, measurement, and analysis of biomarker samples to allow validation in the clinical setting.
- Build on existing solutions to develop a collaborative platform to integrate, analyse and share data (historical or generated de novo) gathered for the validation of biomarker(s) and/or linked technologies during the project, as well as to support future biomarker validation beyond the project duration. Applicants should plan to ensure the future scalability and sustainability of the platform and future data sharing and ensure adherence to FAIR (findable, accessible, interoperable, reusable) principles.
- Develop a regulatory strategy and interaction plan for evidence generation to support the regulatory qualification of the biomarker/s and/or technologies and engage with regulators in a timely manner

<sup>22</sup> See definition in Art 125.1 of the [Council Regulation \(EU\) 2021/2085](#) establishing the Joint Undertakings under Horizon Europe: "An unmet public health need shall be defined as a need currently not addressed by the health care systems for availability or accessibility reasons, for example where there is no satisfactory method of diagnosis, prevention or treatment for a given health condition or if people's access to health care is limited because of cost, distance to health facilities or waiting times."

(e.g. national competent authorities, European Medicines Agency (EMA) Innovation Task Force, qualification advice). Applicants should reserve resources to support these interactions.

- Elaborate a plan for interacting with all the relevant actors in the learning healthcare system (for example clinicians, academic researchers, healthcare professionals, health technology developers, regulators, policy makers, and others as relevant) to align on utilities of the candidate biomarker(s) and/or technologies for clinical use and guide the roadmap.
- Disseminate the results of the project to ensure uptake by relevant stakeholders, including healthcare systems and technology developers.
- Applicants should also reserve resources to synergise with other relevant initiatives, including other projects funded under this topic and those funded under IHI Call 3 topic 1<sup>23</sup> as relevant.

### **Expected impacts to be achieved by this topic**

Actions under this topic are expected to achieve the following impacts:

- New clinically-validated biomarker-driven approaches are available that lead, as relevant, to more precise and effective diagnosis, leaner diagnosis-to-treatment pathways, better treatment path selection, or improved follow-up and treatment response assessment and monitoring.
- A significant reduction in the diagnostic or therapeutic burden for patients (and caregivers) for example by favouring non- or minimally-invasive approaches.
- Validated tools and approaches supporting evidence-based health and care decisions addressing both the needs of patients and of healthcare systems.
- An increase in the competitiveness of European health industries.

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

The clinical validation of biomarkers and the development of their linked technologies is a challenging process. To meet the topic objectives, a collaboration across several industry sectors (including pharmaceutical and medical technology industries) combined with other relevant stakeholders in the healthcare ecosystem is necessary. The IHI framework is the ideal enabler for gathering the necessary significant cross-sectoral expertise, and fostering collaborative open innovation, including from patients, clinicians, statisticians, healthcare professionals, biomarker specialists, machine learning experts, scientists, experts in regulatory affairs, small and medium-sized enterprises (SMEs), pharmaceutical and medical technology industries among others.

### **Indicative budget**

Applicant consortia will be competing for the maximum financial contribution from IHI up to EUR 45 000 000.

IHI estimates that an IHI financial contribution of EUR 15 000 000 would allow a proposal to address these outcomes appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

Applicant consortia must ensure that at least 45% of the action's eligible costs and costs for the action-related additional activities are provided by in-kind contributions to operational activities ('IKOP'), financial contributions ('FC's), or in-kind contributions to additional activities ('IKAA'). While 45% is the threshold for eligibility, applicant consortia are strongly advised to aim for 50% to provide a margin e.g. for unforeseen changes during the project lifetime.

<sup>23</sup> <https://www.ih.europa.eu/apply-funding/ih-call-3>

IKOP and FCs may be contributed by the constituent and affiliated entities of both the private members and the contributing partners. IKAA may be contributed by constituent and affiliated entities of the private members only. Contributing partners and their affiliated entities cannot contribute IKAA. See the call conditions in the annual Work Programme for further information (also in the document “call text” published on the IHI website).

### Indicative duration of the actions

Applicants should propose a project duration that matches the project’s activities and expected outcomes and impacts.

### 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” apply.

### Glossary

Acronym	Meaning
AI	Artificial Intelligence
CAD	Coronary Artery Disease
COVID-19	Coronavirus Disease 2019
EHDS	European Health Data Space
EMA	European Medicines Agency
EU	European Union
FAIR	Findable, Accessible, Interoperable, and Reusable
FC	Financial Contributions
HF	Heart Failure
IHI JU	Innovative Medicines Initiative Joint Undertaking
IKAA	In-Kind Contributions to Additional Activities
IKOP	In-Kind Contributions to Operational Activities
NCD	Non-communicable Diseases
R&D	Research and Development
SHD	Structural Heart Disease
SMEs	Small and Medium-Sized Enterprises
THCS	Transforming Health and Care Systems

