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

### Boosting innovation for a competitive European health ecosystem

### Introduction to the Call and general elements to be considered for all topics.

This call aims to fund <u>pre-competitive</u><sup>1</sup> Research and Innovation Actions (RIA) <sup>2</sup> that contribute to addressing the IHI JU's Specific Objectives, as defined in IHI JU's legal basis<sup>3</sup> and described in more detail in the IHI JU Strategic Research and Innovation Agenda (SRIA).

The call contains five topics, each focusing on one of the five IHI JU Specific Objectives (SOs):

- **Topic 1 (SO1)**: contribute towards a better understanding of the determinants of health and priority disease areas;
- Topic 2 (SO2): integrate fragmented health research and innovation efforts bringing together
  health industry sectors and other stakeholders, focussing on unmet public health needs, to
  enable the development of tools, data, platforms, technologies and processes for improved
  prediction, prevention, interception, diagnosis, treatment and management of diseases,
  meeting the needs of end-users;
- Topic 3 (SO3): demonstrate the feasibility of people-centred, integrated healthcare solutions:
- Topic 4 (SO4): exploit the full potential of digitalisation and data exchange in healthcare;
- Topic 5 (SO5): enable the development of new and improved evaluation methodologies and models for a comprehensive assessment of the added value of innovative and integrated healthcare solutions.

The scope of each of the topics is broad in order to harness new science and technologies that will foster the development of health innovations to prevent, intercept, diagnose, treat and manage diseases and enable recovery more efficiently, and that could ultimately be integrated/implemented into the healthcare ecosystem for the benefit of patients and society.

In line with the first IHI JU general objective 'to contribute towards the creation of an EU-wide health research and innovation ecosystem that facilitates translation of scientific knowledge into innovations, notably by launching at least 30 large-scale, cross-sectoral projects, focussing on health innovations',

<sup>&</sup>lt;sup>1</sup> In the context of IHI, pre-competitive refers to collaborative research among potential competitors addressing common challenges, building knowledge and developing foundational technologies or standards that benefit all the actors in that research space, rather individual companies.

<sup>&</sup>lt;sup>2</sup> Research and innovation actions (RIA) — Activities that aim primarily to establish new knowledge or to explore the feasibility of a new or improved technology, product, process, service or solution. This may include basic and applied research, technology development and integration, testing, demonstration and validation of a small-scale prototype in a laboratory or simulated environment (see General Annex B ('Eligibility') to the Horizon Europe Work Programme 2026-2027)

<sup>&</sup>lt;sup>3</sup> Article 115 of the Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe

actions to be funded under this call are expected to perform activities at scale that drive novel, concrete and transformational outcomes.

Furthermore, actions to be funded under this call should address unmet public health needs in line with the second IHI JU general objective of delivering safe, effective health innovations that cover the entire spectrum of care – from prevention to diagnosis and treatment – particularly in areas where there is an unmet public health need.

Unmet public health needs are needs that are currently not addressed by the healthcare systems for various reasons; for example, if no health technologies<sup>4</sup> are known to tackle a disease effectively, or because of a general overload on health care systems that challenges the capacity to deliver the right care at the right time.

In this context applicants should consider at least one of the below points:

- the high burden of the disease for patients and/or society due to its severity and/or the number of people affected by it;
- the high economic impact of the disease for patients and society;
- the transformational nature of the potential results on innovation processes where projects are not focussed on individual disease areas (e.g. health data analytics).

Most activities are expected to be cross-sectoral, reflecting the integrative nature of IHI as a public-private partnership, and to consider the different innovation cycles of the pharmaceutical and medical technology industries. In particular, the call welcomes integrated pre-competitive activities, including demonstration pilots, that could accelerate and improve the discovery, development, deployment and user uptake of novel treatments and healthcare solutions.

Proposals that aim to demonstrate the feasibility and/or scalability of integrating novel solutions into global, national, or regional healthcare systems and/or of innovations are welcomed. However, the research supported by this call for proposals should remain at the pre-competitive level and should translate into solutions that can be applied by all players in the ecosystem.

Proposals submitted under the topics of this call may cover activities over the whole health innovation chain including, but not limited to:

- discovery of new molecules, mechanisms of action, processes, technologies;
- development and testing of these discoveries;
- development of methodologies for assessment of safety, health outcomes or health-economic evaluation;
- standardisation activities;
- contribution to regulatory science;
- pilots/proofs of feasibility including in-silico trials.

As proposals can only be submitted under one topic, applicants must carefully consider which IHI JU Specific Objective is the most relevant to the primary focus of their proposal and submit it only under the corresponding topic. Applicants must clearly justify the alignment of the objectives of their proposed work with the IHI JU Specific Objective selected. Considering the complementarity of the

<sup>&</sup>lt;sup>4</sup> Health technology means a medicinal product, a medical device or medical and surgical procedures as well as measures for disease prevention, diagnosis or treatment used in health care.

IHI JU Specific Objectives, proposals may also cover aspects related to other Specific Objective(s). If so, applicants should also highlight this in their proposal.

Applicants are therefore encouraged to read the IHI JU SRIA<sup>5</sup> carefully for full information on the IHI JU Specific Objectives. Furthermore, applicants should carry out a landscape analysis of the relevant existing initiatives/projects to avoid unnecessary overlap and duplication of efforts.



<sup>&</sup>lt;sup>5</sup> https://www.ihi.europa.eu/sites/default/files/flmngr/IHI Strategic Research and Innovation Agenda 3.pdf

## Topic 1: Boosting innovation for a better understanding of the determinants of health

<u>NOTE</u>: Applicants must also read the section 'Introduction to the Call and general elements to be considered for all topics' carefully.

### **Expected outcomes**

Applicants must define the outcomes expected to be achieved by their proposal, ensuring that they add novel contributions to a better understanding of the determinants of health and priority disease areas, in line with the IHI JU's Specific Objective 1 as set out in the IHI JU Strategic Research and Innovation Agenda (SRIA).

Actions (projects) to be funded under this topic must deliver outcomes that address public health needs and support the development of future health innovations that are safe, people-centred, effective, cost-effective and affordable for patients and for health care systems. These outcomes are also expected to benefit the relevant stakeholders in the healthcare ecosystem.

The expected outcomes may cover the entire spectrum of care from prevention to disease management and may be centred around disease areas, key themes or approaches such as prevention, precision diagnostics, personalised medicine, and chronic disease management. They may also include enabling solutions for digitalisation, artificial intelligence (AI), regulatory science, greener and more sustainable healthcare and the deployment and use of these solutions into practice.

### Scope

With a view to harnessing new science and technologies, this topic aims to fund pre-competitive research and innovation for novel tools, methods and technologies that will foster the development of health innovations to prevent, intercept, diagnose, treat, and manage diseases and enable recovery more efficiently.

Accordingly, applicants must assemble a collaborative public-private partnership consortium reflecting the integrative and cross-sectoral nature of IHI JU, that is capable of addressing the challenge(s) and scope of the IHI JU Specific Objective 1 'contribute towards a better understanding of the determinants of health and priority disease areas', as defined in IHI JU's legal basis<sup>6</sup> and described in more detail in the IHI JU SRIA<sup>7</sup>.

<sup>&</sup>lt;sup>6</sup> Article 115 of the <u>Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe</u>

<sup>&</sup>lt;sup>7</sup> https://www.ihi.europa.eu/sites/default/files/flmngr/IHI Strategic Research and Innovation Agenda 3.pdf

Applicants should consider the following points in their proposals:

- a) address an unmet public health need based on at least one of the below:
  - the high burden of the disease for patients and/or society due to its severity and/or the number of people affected by it;
  - the high economic impact of the disease for patients and society;
  - the transformational nature of the potential results on innovation processes where projects are not focussed on individual disease areas (e.g. health data analytics);
- demonstrate the ability to translate research into innovative solutions that can be integrated/implemented into the healthcare ecosystem (taking into consideration the fragmented nature of European healthcare systems) and/or in industrial processes;
- c) carry out a landscape analysis to avoid unnecessary overlap and duplication of efforts with existing initiatives/projects and to identify potential synergies and complementarities with the relevant ones. The proposal should include a plan on how to synergise with these identified initiatives.

When applicable, proposals should consider relevant aspects of patient-centricity, with the help of the most suitable health technologies and/or social innovations, taking demographic trends into account as relevant.

In their proposals, applicants are expected to perform activities at scale that consider the different innovation cycles of the pharmaceutical and medical technology industries and drive concrete and transformational outcomes, in line with the first IHI JU General Objective<sup>8</sup>. In particular, the topic welcomes integrated pre-competitive activities, including demonstration pilots, that could accelerate and improve the discovery, development and piloting of methods and strategies that facilitate the uptake of evidence-based practice and research outcomes into regular use (e.g. translation of results, deployment, uptake and piloting use in healthcare of novel treatments and healthcare solutions).

If applicable, applicants are expected to consider the potential regulatory impact of the anticipated project's outputs, and, as relevant, develop a regulatory strategy and interaction plan for generating appropriate evidence and for engaging with regulators and other bodies in a timely manner, e.g. EU national competent authorities, notified bodies for medical devices and *in-vitro* diagnostic devices, health technology assessment (HTA) agencies, and the European Medicines Agency (EMA) through existing opportunities for regulatory support services, such as the Innovation Task Force and qualification advice.

As relevant, consideration should be given to the Health Data Access Bodies established under the European Health Data Space Regulation<sup>9</sup> in the context of secondary use of data.

Applicants are strongly encouraged to consider relevant measures to provide open access to project generated outputs such as standards, data sets and other research results and, if relevant, share evidence on their clinical utility and economic aspects (efficiency).

<sup>&</sup>lt;sup>8</sup> 'to contribute towards the creation of an EU-wide health research and innovation ecosystem that facilitates translation of scientific knowledge into innovations, notably by launching at least 30 large-scale, cross-sectoral projects, focussing on health innovations'

<sup>&</sup>lt;sup>9</sup> https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L 202500327

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

Applicants are expected to define the expected impacts to be achieved by their proposal that will contribute to one or more of the expected impacts linked to IHI JU's Specific Objective 1 as set out in the IHI JU SRIA, i.e.:

- patients benefit from preventive treatment or early disease intervention before onset of symptoms;
- prevention and early diagnosis of disease combined with better understanding of the mechanisms involved, leading to the development of more cost-effective strategies;
- patients benefit from improved healthcare through regular monitoring of critical parameters using validated tools;
- development of new vaccine strategies targeted to specific sub-populations;
- increased preparedness of EU healthcare systems for disease outbreaks.

Furthermore, the actions to be funded under this topic are expected to contribute to:

- a) the strengthening of the competitiveness of the EU's health industry, via increased economic activity in the development of health technologies, in particular integrated health solutions, thus fostering European technological leadership and the digital transformation of our societies.
- b) the implementation of the EU's Life Sciences Strategy<sup>10</sup> and its specific aims such as:
  - i) reinforcing European R&I e.g. through the translation of new knowledge to innovative health solutions;
  - ii) promoting a holistic approach to the life sciences (e.g. One Health approach among others).

The actions are expected also to consider and contribute to EU programmes, initiatives and policies such as the European Green Deal, Europe's Beating Cancer Plan, the EU Mission on Cancer, the Apply AI Strategy, the European Virtual Human Twins Initiative, the 1+ Million Genomes Initiative, the preparedness and response to health emergencies, the upcoming EU Biotech Act, the Regulation on the European Health Data Space (EHDS), and the EU Artificial Intelligence Act, where relevant.

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

Science and technologies are changing rapidly, and their successful implementation requires increased cross-sectoral integration of technologies, know-how, products, services, and workflows for delivering people-centred healthcare. Laying the groundwork for the development of innovative tangible health solutions that are suitable for end-users requires expertise, resources, and knowledge from all stakeholders in the innovation value chain.

IHI JU provides a unique framework to stimulate a co-creation/co-ideation approach, bringing together the private (pharma and medical technology industry sectors) and public partners (academia, healthcare professionals and providers, patients and carers, regulators, health technology assessment bodies, payers) as well as small and medium-sized enterprises (SMEs), charitable foundations / philanthropic organisations, with a view towards ensuring that the developed solutions are comprehensive, evidence-based, and aligned with public health needs whilst offering new market opportunities to companies.

<sup>&</sup>lt;sup>10</sup> https://research-and-innovation.ec.europa.eu/document/download/411698e8-6062-41af-96e5-af54474d70f5 en

### **Indicative budget**

Applicant consortia will be competing for the maximum financial contribution from IHI JU of up to EUR 30 000 000.

IHI JU estimates that an IHI JU financial contribution of at least EUR 8 000 000 would allow a proposal to address the outcomes appropriately and achieve the expected impacts. Nonetheless, this does not preclude the 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'). However, while 45% is the threshold for eligibility, applicant consortia are strongly advised to aim for 50% to adequately support the ambition of the research in question and reflect the true public-private dimension, as well as to provide a margin e.g. for unforeseen changes during the project lifetime.

IKOP and FCs may be contributed by the constituent and/or affiliated entities of both the private members<sup>11</sup> and the contributing partners. IKAA may be contributed by constituent and/or affiliated entities of the private members only. Contributing partners and/or 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 proposed 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.

<sup>&</sup>lt;sup>11</sup> The IHI JU private members are the 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)

### Topic 2: Boosting innovation through better integration of fragmented health R&I efforts

<u>NOTE</u>: Applicants must also read the section 'Introduction to the Call and general elements to be considered for all topics' carefully.

### **Expected outcomes**

Applicants must define the outcomes expected to be achieved by their proposal, ensuring that they contribute to the integration of fragmented health R&I efforts to enable development of tools, data, platforms, technologies and processes for improved prediction, prevention, interception, diagnosis, treatment and management of diseases, meeting the needs of end-users in line with the IHI JU's Specific Objective 2 as set out in the IHI JU Strategic Research and Innovation Agenda (SRIA).

Actions (projects) to be funded under this topic must deliver results that address public health needs and support the development of future health innovations that are safe, people-centred, effective, cost-effective and affordable for patients and for health care systems. These outcomes are also expected to benefit the relevant stakeholders in the healthcare ecosystem.

The expected outcomes may cover the entire spectrum of care from prevention to disease management and may be centred around disease areas, key themes or approaches such as prevention, precision diagnostics, personalised medicine, and chronic disease management. They may also include enabling solutions for digitalisation, artificial intelligence (AI), regulatory science, greener and more sustainable healthcare and the deployment and use of these solutions into practice.

### Scope

With a view to harnessing new science and technologies, this topic aims to fund pre-competitive research and innovation for novel tools, methods, technologies that will foster the development of health innovations to prevent, intercept, diagnose, treat, and manage diseases and enable recovery more efficiently.

Accordingly, applicants must assemble a collaborative public-private partnership consortium reflecting the integrative and cross-sectoral nature of IHI JU, that is capable of addressing the challenge(s) and scope of the IHI JU Specific Objective 2 'integrate fragmented health research and innovation efforts bringing together health industry sectors and other stakeholders, focussing on unmet public health needs, to enable the development of tools, data, platforms, technologies and processes for improved prediction, prevention, interception, diagnosis, treatment and management of diseases, meeting the needs of end-users' as defined in IHI JU's legal basis<sup>12</sup> and described in more detail in the IHI JU SRIA<sup>13</sup>:

<sup>&</sup>lt;sup>12</sup> Article 115 of the Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe

<sup>13</sup> https://www.ihi.europa.eu/sites/default/files/flmngr/IHI Strategic Research and Innovation Agenda 3.pdf

Applicants should consider the following points in their proposals:

- a) address an unmet public health need based on at least one of the below:
  - the high burden of the disease for patients and/or society due to its severity and/or the number of people affected by it;
  - the high economic impact of the disease for patients and society;
  - the transformational nature of the potential results on innovation processes where projects are not focussed on individual disease areas (e.g. health data analytics).
- b) demonstrate the ability to translate research into innovative solutions that can be integrated/implemented into the healthcare ecosystem (taking into consideration the fragmented nature of European healthcare systems) and/or industrial processes.
- c) carry out a landscape analysis to avoid unnecessary overlap and duplication of efforts with existing initiatives/projects and to identify potential synergies and complementarities with the relevant ones. The proposal should include a plan on how to synergise with these identified initiatives.

When applicable, proposals should consider relevant aspects of patient-centricity, with the help of the most suitable health technologies and/or social innovations, taking demographic trends into account as relevant.

Proposals may address specific target populations, underserved communities or areas with limited resources, and/or support challenging unmet needs and diagnostic or treatment gaps.

In their proposal, applicants are expected to perform activities at scale that consider the different innovation cycles of the pharmaceutical and medical technology industries and drive concrete and transformational outcomes, in line with the first IHI JU General Objective<sup>14</sup>. In particular, the topic welcomes integrated pre-competitive activities, including demonstration pilots, that could accelerate and improve the discovery, development and piloting of methods and strategies that facilitate the uptake of evidence-based practice and research outcomes into regular use (e.g. translation of results, scale-up, uptake and piloting use in healthcare of novel treatments and healthcare solutions).

If applicable, applicants are expected to consider the potential regulatory impact of the anticipated project's outputs and, as relevant, develop a regulatory strategy and interaction plan for generating appropriate evidence and for engaging with regulators and other bodies in a timely manner, e.g. EU national competent authorities, notified bodies for medical devices and *in vitro* diagnostic devices, health technologies assessment (HTA) agencies and the European Medicines Agency (EMA) through existing opportunities for regulatory support services such as the Innovation Task Force and qualification advice.

As relevant, consideration should be given to the Health Data Access Bodies established under the European Health Data Space Regulation<sup>15</sup> in the context of secondary use of data.

Applicants are strongly encouraged to consider relevant measures to provide open access to project generated outputs such as standards, data sets and other research results and, if relevant, share evidence on their clinical utility and economic aspects (efficiency).

<sup>&</sup>lt;sup>14</sup> 'to contribute towards the creation of an EU-wide health research and innovation ecosystem that facilitates translation of scientific knowledge into innovations, notably by launching at least 30 large-scale, cross-sectoral projects, focussing on health innovations'

<sup>&</sup>lt;sup>15</sup> https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L 202500327

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

Applicants are expected to define the expected impacts to be achieved by their proposal that will contribute to one or more of the expected impacts linked to IHI JU's Specific Objective 2, as set out in the IHI JU SRIA, i.e.:

- breaking down fragmentation between various disciplines of medicine and technological areas in order to conceive and develop technologically and socially innovative, people-centred, integrated healthcare solutions that can seamlessly be introduced in healthcare systems;
- fostering development of safe and effective innovative health technologies and their combinations thanks to new and harmonised approaches to data generation;
- better and faster integration of future products, services and tools along the healthcare pathway (including health promotion and disease prevention), responding to patients' specific needs and leading to improved health outcomes and patient well-being;
- patients and industry benefit from innovative manufacturing processes such as 3D printing, on-demand small-scale good manufacturing practice (GMP) synthesis, on-site portable production systems etc.;
- green transition enabled across all aspects of healthcare, both in the delivery of healthcare
  to patients, and in the technologies and products that emerge from a competitive
  European industry.

Furthermore, the actions to be funded under this topic are expected to contribute to:

- a) the strengthening of the competitiveness of the EU's health industry, via increased economic activity in the development of health technologies, in particular, integrated health solutions, thus fostering European technological leadership and the digital transformation of our societies.
- b) the implementation of the EU's Life Sciences Strategy and its specific aims such as:
  - reinforcing European R&I e.g. through the translation of new knowledge to innovative health solutions; biotechnology innovation; bringing together fragmented efforts into dynamic and connected R&I ecosystems;
  - ii) driving industrial innovation and sustainability (e.g. improving processes to green European industrial health industry, novel tools such as new approach methodologies (NAMs), or others).

The actions are expected also to consider and contribute to EU programmes, initiatives and policies such as the European Green Deal, Europe's Beating Cancer Plan, the EU Mission on Cancer, the upcoming Cardiovascular Plan, the Apply AI Strategy, the European Virtual Human Twins Initiative, the 1+ Million Genomes Initiative, the preparedness and response to health emergencies, the upcoming EU Biotech Act, the Regulation on the European Health Data Space (EHDS), and the EU Artificial Intelligence Act, where relevant.

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

Science and technologies are changing rapidly, and their successful implementation requires increased cross-sectoral integration of technologies, know-how, products, services, and workflows for

delivering people-centred healthcare. Laying the groundwork for the development of innovative tangible health solutions that are suitable for end-users requires expertise, resources, and knowledge from all stakeholders in the innovation value chain.

IHI JU provides a unique framework to stimulate a co-creation/co-ideation approach, bringing together the private (pharma and medical technology industry sectors) and public partners (academia, healthcare professionals and providers, patients and carers, regulators, health technology assessment bodies, payers) as well as small and medium-sized enterprises (SMEs), charitable foundations / philanthropic organisations, with a view towards ensuring that the developed solutions are comprehensive, evidence-based, and aligned with public health needs whilst offering new market opportunities to companies.

### **Indicative budget**

Applicant consortia will be competing for the maximum financial contribution from IHI JU of up to EUR 60 000 000.

IHI JU estimates that an IHI JU financial contribution of at least EUR 15 000 000 would allow a proposal to address the outcomes appropriately and achieve the expected impacts. Nonetheless, this does not preclude the 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'). However, while 45% is the threshold for eligibility, applicant consortia are strongly advised to aim for 50% to adequately support the ambition of the research in question and reflect the true public-private dimension as well as to provide a margin e.g. for unforeseen changes during the project lifetime.

IKOP and FCs may be contributed by the constituent and/or affiliated entities of both the private members <sup>16</sup> and/or the contributing partners (if any). IKAA may be contributed by constituent and/or affiliated entities of the private members only. Contributing partners and/or 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 proposed 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.

<sup>&</sup>lt;sup>16</sup> The IHI JU private members are the 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)

## **Topic 3: Boosting innovation for people-centred integrated healthcare solutions**

<u>NOTE</u>: Applicants must also read the section 'Introduction to the Call and general elements to be considered for all topics' carefully.

### **Expected outcomes**

Applicants must define the outcomes expected to be achieved by their proposal, ensuring that they contribute to the feasibility of people-centred, integrated healthcare solutions in line with the IHI JU's Specific Objective 3 as set out in the IHI JU Strategic Research and Innovation Agenda (SRIA).

Actions (projects) to be funded under this topic must deliver results that address public health needs and support the development of future health innovations that are safe, people-centred, effective, cost-effective and affordable for patients and for health care systems. These outcomes are also expected to benefit the relevant stakeholders in the healthcare ecosystem.

The expected outcomes may cover the entire spectrum of care from prevention to diseases management and may be centred around disease areas, key themes or approaches such as prevention, precision diagnostics, personalised medicine, and chronic disease management. They may also include enabling solutions for digitalisation, artificial intelligence (AI), regulatory science, greener and more sustainable healthcare and the deployment and use of these solutions into practice.

### Scope

With a view to harnessing new science and technologies, this topic aims to fund pre-competitive research and innovation for novel tools, methods, technologies that will foster the development of health innovations to prevent, intercept, diagnose, treat and manage diseases, and enable recovery more efficiently.

Accordingly, applicants must assemble a collaborative public-private partnership consortium reflecting the integrative and cross-sectoral nature of IHI JU that is capable of addressing the challenge(s) and scope of the IHI JU's Specific Objective 3 'demonstrate the feasibility of people-centred, integrated healthcare solutions', as defined in IHI JU's legal basis 17 and described in more detail in the IHI JU SRIA 18.

<sup>&</sup>lt;sup>17</sup> Article 115 of the <u>Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe</u>

<sup>18</sup> https://www.ihi.europa.eu/sites/default/files/flmngr/IHI Strategic Research and Innovation Agenda 3.pdf

Applicants should consider the following points in their proposals:

- a) address an unmet public health need based on at least one of the below:
  - the high burden of the disease for patients and/or society due to its severity and/or the number of people affected by it;
  - the high economic impact of the disease for patients and society;
  - the transformational nature of the potential results on innovation processes where projects are not focussed on individual disease areas (e.g. health data analytics).
- b) have people-centric, rather than product- and pathology-centric, approaches the focus being on the patient and citizen journey through health care, with the help of most suitable health technologies and social innovations and taking account of demographic trends;
- c) demonstrate the ability to translate research into innovative solutions that can be integrated/implemented into the healthcare ecosystem (taking into consideration the fragmented nature of European healthcare systems) and/or into industrial processes.
- d) carry out a landscape analysis to avoid unnecessary overlap and duplication of efforts with existing initiatives/projects and to identify potential synergies and complementarities with the relevant ones. The proposal should include a plan on how to synergise with these identified initiatives.

In their proposal, applicants are expected to perform activities at scale that consider the different innovation cycles of the pharmaceutical and medical technology industries and drive concrete and transformational outcomes, in line with the first IHI JU General Objective<sup>19</sup>. In particular, the topic welcomes integrated pre-competitive activities, including demonstration pilots, that could accelerate and improve the discovery, development and piloting of methods and strategies that facilitate the uptake of evidence-based practice and research outcomes into regular use (e.g. translation of results, deployment, uptake and piloting use in healthcare of novel treatments and healthcare solutions).

If applicable, applicants are expected to consider the potential regulatory impact of the anticipated project's outputs and, as relevant, develop a regulatory strategy and interaction plan for generating appropriate evidence and for engaging with regulators and other bodies in a timely manner, e.g. EU national competent authorities, notified bodies for medical devices and *in vitro* diagnostic devices, health technologies assessment (HTA) agencies, and the European Medicines Agency (EMA) through existing opportunities for regulatory support services such as the Innovation Task Force and qualification advice.

As relevant, consideration should be given to the Health Data Access Bodies established under the European Health Data Space Regulation<sup>20</sup> in the context of secondary use of data.

Applicants are strongly encouraged to consider relevant measures to provide open access to project generated outputs such as standards, data sets and other research results and, if relevant, share evidence on their clinical utility and economic aspects (efficiency).

<sup>&</sup>lt;sup>19</sup> 'to contribute towards the creation of an EU-wide health research and innovation ecosystem that facilitates translation of scientific knowledge into innovations, notably by launching at least 30 large-scale, cross-sectoral projects, focussing on health innovations'

<sup>&</sup>lt;sup>20</sup> https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L 202500327

### Expected impacts to be achieved by this topic

Applicants are expected to define the expected impacts to be achieved by their proposal that will contribute to one or more of the expected impacts linked to IHI JU's Specific Objective 3, as set out in the IHI JU SRIA, i.e.:

- raised awareness among citizens and patients on their own role in managing their health;
- improved patient adherence to prevention programmes and medical interventions;
- people, including vulnerable populations (e.g. elderly and children as well as their carers and/or representatives), are better able to make informed decisions with their healthcare professionals about prevention, treatment interventions and disease management;
- increased frequency and quality of cooperation between patients, citizens and industrial stakeholders in the development of healthcare solutions, in particular integrated care solutions;
- patients benefit from prevention and treatment that is better adapted to their needs through improved diagnostic and monitoring;
- integrated healthcare solutions, including those based on the use of digital solutions, better responding to the needs and preferences of patients and citizens, supporting an inclusive approach;
- successful implementation of digital solutions supporting people-centred care;
- facilitated introduction of innovative solutions for improved home care of patients;

Furthermore, the actions to be funded under this topic are expected to contribute to:

- a) the strengthening of the competitiveness of the EU's health industry via increased economic activity in the development of health technologies, in particular, integrated health solutions, thus fostering European technological leadership and the digital transformation of our societies.
- b) the implementation of the <u>EU's Life Sciences Strategy</u> and its specific aims such as reinforcing European R&I e.g. through the translation of new knowledge to innovative health solutions; better means to engage with citizens to work closer with end-users to ensure adequate solutions for their specific needs and to beat disinformation and build trust.

The actions are expected also to consider and contribute to EU programmes, initiatives and policies such as the European Green Deal, Europe's Beating Cancer Plan, the EU Mission on Cancer, the Apply AI Strategy, the European Virtual Human Twins Initiative, the 1+ Million Genomes Initiative, the preparedness and response to health emergencies, the upcoming EU Biotech Act, the Regulation on the European Health Data Space (EHDS), and the EU Artificial Intelligence Act, where relevant.

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

Science and technologies are changing rapidly, and their successful implementation requires increased cross-sectoral integration of technologies, know-how, products, services, and workflows for delivering people-centred healthcare. Laying the groundwork for the development of innovative tangible health solutions that are suitable for end-users requires expertise, resources, and knowledge from all stakeholders in the innovation value chain.

IHI JU provides a unique framework to stimulate a co-creation/co-ideation approach, bringing together the private (pharma and medical technology industry sectors) and public partners (academia, healthcare professionals and providers, patients and carers, regulators, health technology

assessment bodies, payers) as well as small and medium-sized enterprises (SMEs), charitable foundations / philanthropic organisations, with a view towards ensuring that the developed solutions are comprehensive, evidence-based, and aligned with public health needs whilst offering new market opportunities to companies.

### **Indicative budget**

Applicant consortia will be competing for the maximum financial contribution from IHI JU of up to EUR 20 000 000.

IHI JU estimates that an IHI JU financial contribution of at least EUR 8 000 000 would allow a proposal to address the outcomes appropriately and achieve the expected impacts. Nonetheless, this does not preclude the 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'). However, while 45% is the threshold for eligibility, applicant consortia are strongly advised to aim for 50% to adequately support the ambition of the research in question and reflect the true public-private dimension as well as to provide a margin, e.g. for unforeseen changes during the project lifetime.

IKOP and FCs may be contributed by the constituent and/or affiliated entities of both the private members<sup>21</sup> and/or the contributing partners, if relevant. IKAA may be contributed by constituent and/or affiliated entities of the private members only. Contributing partners and/or 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.

<sup>&</sup>lt;sup>21</sup> The IHI JU private members are the 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)

## Topic 4: Boosting innovation through exploitation of digitalisation and data exchange in healthcare

<u>NOTE</u>: Applicants must also read the section 'Introduction to the Call and general elements to be considered for all topics' carefully.

### **Expected outcomes**

Applicants must define the outcomes expected to be achieved by their proposal, ensuring that they contribute to the digitalisation and data exchange in healthcare in line with the IHI JU's Specific Objective 4 as set out in the IHI JU Strategic Research and Innovation Agenda (SRIA).

Actions (projects) to be funded under this topic must deliver results that address public health needs and support the development of future health innovations that are safe, people-centred, effective, cost-effective and affordable for patients and for health care systems. These outcomes are also expected to benefit the relevant stakeholders in the healthcare ecosystem.

The expected outcomes may cover the entire spectrum of care from prevention to disease management and may be centred around disease areas, key themes or approaches such as prevention, precision diagnostics, personalised medicine, and chronic disease management. They may also include enabling solutions for digitalisation, artificial intelligence (AI), regulatory science, greener and more sustainable healthcare and the deployment and use of these solutions into practice.

### Scope

With a view to harnessing new science and technologies, this topic aims to fund pre-competitive research and innovation for novel tools, methods, technologies that will foster the development of health innovations to prevent, intercept, diagnose, treat and manage diseases and enable recovery more efficiently.

Accordingly, applicants must assemble a collaborative public-private partnership consortium reflecting the integrative and cross-sectoral nature of IHI JU that is capable of addressing the challenge(s) and scope of the IHI JU Specific Objective 4 'exploit the full potential of digitalisation and data exchange in healthcare', as defined in IHI JU's legal basis<sup>22</sup> and described in more detail in the IHI JU SRIA<sup>23</sup>.

Applicants should consider the following points in their proposals:

- a) address an unmet public health need based on at least one of the below:
  - the high burden of the disease for patients and/or society due to its severity and/or the number of people affected by it;
  - the high economic impact of the disease for patients and society;
  - the transformational nature of the potential results on innovation processes where projects are not focussed on individual disease areas (e.g. health data analytics).

<sup>&</sup>lt;sup>22</sup> Article 115 of the Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe

<sup>&</sup>lt;sup>23</sup> https://www.ihi.europa.eu/sites/default/files/flmngr/IHI Strategic Research and Innovation Agenda 3.pdf

- b) demonstrate the ability to translate research into innovative solutions that can be integrated/implemented into the healthcare ecosystem (taking into consideration the fragmented nature of European healthcare systems) and/or into industrial processes.
- c) carry out a landscape analysis to avoid unnecessary overlap and duplication of efforts with existing initiatives/projects and to identify potential synergies and complementarities with the relevant ones. The proposal should include a plan on how to synergise with these identified initiatives.

When applicable, proposals should consider relevant aspects of patient-centricity, with the help of the most suitable health technologies and/or social innovations, taking demographic trends into account as relevant.

In their proposal, applicants are expected to perform at scale activities that consider the different innovation cycles of the pharmaceutical and medical technology industries and drive concrete and transformational outcomes, in line with the first IHI JU General Objective<sup>24</sup>. In particular, the topic welcomes integrated pre-competitive activities, including demonstration pilots, that could accelerate and improve the discovery, development and piloting of methods and strategies that facilitate the uptake of evidence-based practice and research outcomes into regular use (e.g. translation of results, deployment, uptake and piloting use in healthcare of novel treatments and healthcare solutions).

If applicable, applicants are expected to consider the potential regulatory impact of the anticipated project's outputs, and, as relevant, develop a regulatory strategy and interaction plan for generating appropriate evidence and for engaging with regulators and other bodies in a timely manner, e.g. EU national competent authorities, notified bodies for medical devices and *in vitro* diagnostic devices, health technologies assessment (HTA) agencies, and the European Medicines Agency (EMA), through existing opportunities for regulatory support services such as the Innovation Task Force and qualification advice.

As relevant, consideration should be given to the Health Data Access Bodies established under the European Health Data Space Regulation<sup>25</sup> in the context of secondary use of data.

Applicants are strongly encouraged to consider relevant measures to provide open access to project generated outputs such as standards, data sets and other research results and, if relevant, share evidence on their clinical utility and economic aspects (efficiency).

### Expected impacts to be achieved by this topic

Applicants are expected to define the expected impacts to be achieved by their proposal that will contribute to one or more of the expected impacts linked to IHI JU's Specific Objective 4, as reflected in the IHI JU SRIA, i.e.:

- wider availability of interoperable, quality data, respecting FAIR (findable, accessible, interoperable, reusable) principles, facilitating research and the development of integrated products and services;
- improved insight into the real-life behaviour and challenges of patients with complex, chronic diseases and co-morbidities thanks to m-health and e-health technologies;
- advanced analytics / artificial intelligence supporting health R&I, resulting in:

<sup>&</sup>lt;sup>24</sup> 'to contribute towards the creation of an EU-wide health research and innovation ecosystem that facilitates translation of scientific knowledge into innovations, notably by launching at least 30 large-scale, cross-sectoral projects, focussing on health innovations'

<sup>&</sup>lt;sup>25</sup> https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L 202500327

- clinical decision support for increased accuracy of diagnosis and efficacy of treatment;
- ii) shorter times to market;
- iii) wider availability of personalised health interventions to end-users;
- iv) better evidence of the added value from new digital health and artificial intelligence tools, including reduced risk of bias due to improved methodologies.

Furthermore, the actions to be funded under this topic are expected to contribute to:

- a) the strengthening of the competitiveness of the EU's health industry via increased economic activity in the development of health technologies, in particular, integrated health solutions, thus fostering European technological leadership and the digital transformation of our societies.
- b) the implementation of the <u>EU's Life Sciences Strategy</u> and its specific aims such as unlocking the power of new knowledge, data and Al for breakthrough innovation.

The actions are expected also to consider and contribute to EU programmes, initiatives and policies such as the European Green Deal, Europe's Beating Cancer Plan, the EU Mission on Cancer, the Apply AI Strategy, the European Virtual Human Twins Initiative, the 1+ Million Genomes Initiative, the preparedness and response to health emergencies, the upcoming EU Biotech Act, the Regulation on the European Health Data Space (EHDS), and the EU Artificial Intelligence Act, where relevant.

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

Science and technologies are changing rapidly, and their successful implementation requires increased cross-sectoral integration of technologies, know-how, products, services, and workflows for delivering people-centred healthcare. Laying the groundwork for the development of innovative tangible health solutions that are suitable for end-users requires expertise, resources, and knowledge from all stakeholders in the innovation value chain.

IHI JU provides a unique framework to stimulate a co-creation/co-ideation approach, bringing together the private (pharma and medical technology industry sectors) and public partners (academia, healthcare professionals and providers, patients and carers, regulators, health technology assessment bodies, payers) as well as small and medium-sized enterprises (SMEs), charitable foundations / philanthropic organisations, with a view towards ensuring that the developed solutions are comprehensive, evidence-based, and aligned with public health needs whilst offering new market opportunities to companies.

### **Indicative budget**

Applicant consortia will be competing for the maximum financial contribution from IHI JU of up to EUR 43 300 000.

IHI JU estimates that an IHI JU financial contribution of at least EUR 8 000 000 would allow a proposal to address the outcomes appropriately and achieve the expected impacts. Nonetheless, this does not preclude the 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'). However, while 45% is the threshold for eligibility, applicant consortia are strongly advised to aim for 50% to adequately support the ambition of the research in question and reflect the true public-private dimension as well as to provide a margin e.g. for unforeseen changes during the project lifetime.

IKOP and FCs may be contributed by the constituent and/or affiliated entities of both the private members<sup>26</sup> and/or the contributing partners, if relevant. IKAA may be contributed by constituent and/or 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 proposed 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.

### Legal entities established in the UK

According to the conditions of the calls and call management rules under 'Entities eligible for funding', legal entities participating in this topic and established in the UK are not eligible to receive funding.

### Legal entities established in Canada

According to the conditions of the calls and call management rules under 'Entities eligible for funding', legal entities participating in this topic and established in Canada are not eligible to receive funding.

#### Legal entities established in the Republic of Korea

According to the conditions of the calls and call management rules under 'Entities eligible for funding', legal entities participating in this topic and established in the Republic of Korea are not eligible to receive funding.

### Legal entities established in Switzerland

According to the conditions of the calls and call management rules under 'Entities eligible for funding', legal entities participating in this topic and established in Switzerland are not eligible to receive funding.

<sup>&</sup>lt;sup>26</sup> The IHI JU private members are the 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)

# Topic 5: Boosting innovation for better assessment of the added value of innovative integrated healthcare solutions

<u>NOTE</u>: Applicants must also read the section 'Introduction to the Call and general elements to be considered for all topics' carefully.

### **Expected outcomes**

Applicants must define the outcomes expected to be achieved by their proposal, ensuring that they contribute to new and improved methodologies and models for a comprehensive assessment of the added value of innovative and integrated healthcare solutions in line with the IHI JU's specific objective 5 as set out in the IHI JU Strategic Research and Innovation Agenda (SRIA).

Actions (projects) to be funded under this topic must deliver results that address public health needs and support the development of future health innovations that are safe, people-centred, effective, cost-effective and affordable for patients and for health care systems. These outcomes are also expected to benefit the relevant stakeholders in the healthcare ecosystem.

The expected outcomes may cover the entire spectrum of care from prevention to disease management and may be centred around disease areas, key themes such as prevention, precision diagnostics, personalised medicine, and chronic disease management. They may also include enabling solutions for digitalisation, artificial intelligence (AI), regulatory science, greener and more sustainable healthcare and the deployment and use of these solutions into practice.

#### Scope

With a view to harnessing new science and technologies, this topic aims to fund pre-competitive research and innovation for novel tools, methods, technologies that will foster the development of health innovations to prevent, intercept, diagnose, treat, and manage diseases and enable recovery more efficiently.

Accordingly, applicants must assemble a collaborative public-private partnership consortium reflecting the integrative and cross-sectoral nature of IHI JU that is capable of addressing challenge(s) and scope of the IHI JU's Specific Objective 5 'enable the development of new and improved methodologies and models for a comprehensive assessment of the added value of innovative and integrated healthcare solutions'; as defined in IHI JU's legal basis<sup>27</sup> and described in more detail in the IHI JU SRIA<sup>28</sup>.

Applicants should consider the following points in their proposals:

- a) address an unmet public health need based on at least one of the below:
  - the high burden of the disease for patients and/or society due to its severity and/or the number of people affected by it;

<sup>&</sup>lt;sup>27</sup> Article 115 of the Council Regulation (EU) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe

<sup>28</sup> https://www.ihi.europa.eu/sites/default/files/filmngr/IHI Strategic Research and Innovation Agenda 3.pdf

- the high economic impact of the disease for patients and society;
- the transformational nature of the potential results on innovation processes where projects are not focussed on individual disease areas (e.g. health data analytics).
- b) inform innovation-responsive guidance and regulatory science approaches;
- c) demonstrate the ability to translate research into innovative solutions that can be integrated/implemented into the healthcare ecosystem (taking into consideration the fragmented nature of European healthcare systems) and/or into industrial processes.
- d) carry out a landscape analysis to avoid unnecessary overlap and duplication of efforts with existing initiatives/projects and to identify potential synergies and complementarities with the relevant ones. The proposal should include a plan on how to synergise with these identified initiatives.

When applicable, proposals should consider relevant aspects of patient-centricity, with the help of the most suitable health technologies and/or social innovations, taking demographic trends into account as relevant.

In their proposal, applicants are expected to perform at scale activities that consider the different innovation cycles of the pharmaceutical and medical technology industries and drive concrete and transformational outcomes, in line with the first IHI JU General Objective<sup>29</sup>. In particular, the topic welcomes integrated pre-competitive activities, including demonstration pilots, that could accelerate and improve the discovery, development and piloting of methods and strategies that facilitate the uptake of evidence-based practice and research outcomes into regular use (e.g. translation of results, deployment, uptake and piloting use in healthcare of novel treatments and healthcare solutions).

If applicable, applicants are expected to consider the potential regulatory impact of the anticipated project's outputs, and as relevant, develop a regulatory strategy and interaction plan for generating appropriate evidence and for engaging with regulators and other bodies in a timely manner, e.g. EU national competent authorities, notified bodies for medical devices and *in vitro* diagnostic devices, health technology assessment (HTA) agencies, and the European Medicines Agency (EMA) through existing opportunities for regulatory support services such as the Innovation Task Force and qualification advice.

As relevant, consideration should be given to the Health Data Access Bodies that are established under the European Health Data Space Regulation<sup>30</sup> in the context of secondary use of data.

Applicants are strongly encouraged to consider relevant measures to provide open access to project-generated outputs such as standards, data sets and other research results and, if relevant, share evidence on their clinical utility and economic aspects (efficiency).

### Expected impacts to be achieved by this topic

Applicants are expected to define the expected impacts to be achieved by their proposal that will contribute to one or more of the expected impacts linked to IHI JU's Specific Objective 5 as reflected in the IHI JU SRIA, i.e.:

<sup>&</sup>lt;sup>29</sup> 'to contribute towards the creation of an EU-wide health research and innovation ecosystem that facilitates translation of scientific knowledge into innovations, notably by launching at least 30 large-scale, cross-sectoral projects, focussing on health innovations'

<sup>30</sup>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L 202500327

- seamless and successful implementation in healthcare settings of cross-sectoral innovations, integrated products and services delivering proven benefits to patients, healthcare systems and society as a whole;
- patients have improved access to innovations that meet their needs and those of the healthcare systems;
- better informed decision-making at different levels of the healthcare system (authorities, organisations), that will in turn contribute to a better allocation of resources towards cost-effective innovations;
- faster entry to the market of cost-effective innovative solutions developed by industry, which could translate to a positive effect on their R&I investments.

Furthermore, the actions to be funded under this topic are expected to contribute to:

- a) the strengthening of the competitiveness of the EU's health industry, via increased economic activity in the development of health technologies, in particular integrated health solutions, and thus fostering European technological leadership and the digital transformation of our societies.
- b) the implementation of the <u>EU's Life Sciences Strategy</u> and its specific aims such as:
  - i) reinforcing European R&I e.g. supporting multinational clinical trials and improving the clinical research ecosystem;
  - providing smooth and rapid market access for life science innovations e.g. through promoting innovation-responsive regulation to ensure timely real value delivery of innovations to people;
- c) the improvement of the health technology assessment (HTA) methodology for instance through:
  - development and uptake of innovative HTA approaches tailored to meet the demands of HTA organisations, policy makers, and industry, including aspects such as usability, integration into care pathways, and patient experience. This also covers novel methods for assessment of added value of combined technologies;
  - ii) crafting and deploying dissemination and educational programs to ensure unified HTA expertise throughout the EU, covering both medical technology and pharmaceutical innovations;
  - iii) uptake of innovative medical devices and in-vitro diagnostics.

The actions are expected also to consider and contribute to EU programmes, initiatives and policies such as the European Green Deal, Europe's Beating Cancer Plan, the EU Mission on Cancer, the Apply AI Strategy, the European Virtual Human Twins Initiative, the 1+ Million Genomes Initiative, preparedness and response to health emergencies, the upcoming EU Biotech Act, the Regulation on the European Health Data Space (EHDS), and the EU Artificial Intelligence Act, where relevant.

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

Science and technologies are changing rapidly, and their successful implementation requires increased cross-sectoral integration of technologies, know-how, products, services, and workflows for delivering people-centred healthcare. Laying the groundwork for the development of innovative

tangible health solutions that are suitable for end-users requires expertise, resources, and knowledge from all stakeholders in the innovation value chain.

IHI JU provides a unique framework to stimulate a co-creation/co-ideation approach, bringing together the private (pharma and medical technology industry sectors) and public partners (academia, healthcare professionals and providers, patients and carers, regulators, health technology assessment bodies, tax payers) as well as small and medium-sized enterprises (SMEs), charitable foundations / philanthropic organisations, with a view towards ensuring that the developed solutions are comprehensive, evidence-based, and aligned with public health needs whilst offering new market opportunities to companies.

### **Indicative budget**

Applicant consortia will be competing for the maximum financial contribution from IHI JU of up to EUR 9 800 000.

IHI JU estimates that an IHI JU financial contribution of at least EUR 4 900 000 would allow a proposal to address the outcomes appropriately and achieve the expected impacts. Nonetheless, this does not preclude the 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'). However, while 45% is the threshold for eligibility, applicant consortia are strongly advised to aim for 50% to adequately support the ambition of the research in question and reflect the true public-private dimension as well as to provide a margin e.g. for unforeseen changes during the project lifetime.

IKOP and FCs may be contributed by the constituent and/or affiliated entities of both the private members<sup>31</sup> and/or the contributing partners, if relevant. IKAA may be contributed by constituent and/or 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 proposed 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.

#### Legal entities established in the Republic of Korea

According to the conditions of the calls and call management rules under 'Entities eligible for funding', legal entities participating in this topic and established in the Republic of Korea are not eligible to receive funding.

<sup>&</sup>lt;sup>31</sup> The IHI JU private members are the 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)

### Legal entities established in Switzerland

According to the conditions of the calls and call management rules under 'Entities eligible for funding', legal entities participating in this topic and established in Switzerland are not eligible to receive funding.



HORIZON-JU-IHI-2026-12-SINGLE- STAGE-01 Boosting innovation for a better understanding of the determinants of health	Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 30 000 000.  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.	Research and Innovation Action (RIA) Single-stage submission and evaluation process.  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.
HORIZON-JU-IHI-2026-12- SINGLE- STAGE-02 Boosting innovation through better integration of fragmented health R&I efforts	Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 60 000 000.  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.	Research and Innovation Action (RIA) Single-stage submission and evaluation process.  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.
HORIZON-JU-IHI-2026-12- SINGLE-STAGE-03  Boosting innovation for people-centred integrated healthcare solutions	Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 20 000 000.  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.	Research and Innovation Action (RIA)  Single-stage submission and evaluation process.  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.
HORIZON-JU-IHI-2026-12- SINGLE-STAGE-04  Boosting innovation through exploitation of digitalisation and data exchange in healthcare	Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 43 300 000.  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.	Research and Innovation Action (RIA) Single-stage submission and evaluation process.  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.
HORIZON-JU-IHI-2026-12- SINGLE-STAGE-05  Boosting innovation for better assessment of the added value of innovative integrated healthcare solutions	Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 9 800 000.  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	Research and Innovation Action (RIA)  Single-stage submission and evaluation process.  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.

contributing partners.