

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 pre-competitive research and innovation actions that contribute to addressing the IHI JU's Specific Objectives, as defined in IHI JU's legal basis<sup>1</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 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*", actions to be funded under this call are expected to perform at scale activities that drive concrete and transformational outcomes.

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 pharmaceutical and medical technology industries. In particular, the call welcomes integrated pre-competitive activities, including demonstration pilots, that could accelerate and improve discovery, development and implementation of novel treatments and healthcare solutions.

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<sup>1</sup> Article 115 of the [Council Regulation \(EU\) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe](#)

Proposals submitted under 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.

Proposals that aim to demonstrate feasibility and / or scalability of integrating 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.

To emphasise the people-driven mission and the inclusive objectives of the call, applicants should consider open access to project-generated outputs such as standards, data sets and optimised algorithms.

As proposals can only be submitted under one topic, applicants must carefully consider which 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 SO selected. Considering the complementarity of the 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>2</sup> carefully for full information on the SOs.

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<sup>2</sup> [https://www.ih.europa.eu/sites/default/files/flmngtr/IHI\\_Strategic\\_Research\\_and\\_Innovation\\_Agenda\\_3.pdf](https://www.ih.europa.eu/sites/default/files/flmngtr/IHI_Strategic_Research_and_Innovation_Agenda_3.pdf)

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

**NOTE:** Applicants must also read carefully the section “Introduction to the Call and general elements to be considered for all topics”.

## Expected outcomes

Applicants must define the outcomes expected to be achieved by the project, ensuring that they contribute to at least one of IHI JU’s potential outputs linked to the IHI JU’s Specific Objective 1 “*contribute towards a better understanding of the determinants of health and priority disease areas*”, 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.

The expected outcomes may cover the entire spectrum of care and may be health technologies centred around disease areas and/or key themes such as prevention, personalised medicine, and chronic disease management. They may also include solutions for key enablers such as digital / artificial intelligence (AI) /data, regulatory science, green and sustainability, and implementation science<sup>3</sup>.

## 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 etc. 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, and 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>4</sup> and described in more detail in the IHI JU SRIA<sup>5</sup>.

For example, proposals may aim to deliver new insights into mechanisms of diseases and factors contributing to health status, to identify and validate biomarkers as well as to elucidate potential new mechanisms for therapeutic actions, including innovative methods of data exploitation. Objectives may also cover standardisation activities to facilitate the development of new health technologies, better identify individuals with disease predisposition, predict and monitor disease progression, and assess the efficacy of targeted treatments.

Applicants are encouraged to use the opportunity offered by emerging industrial technologies (e.g. innovative imaging methods, robotics or artificial intelligence) to provide better targets and approaches

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<sup>3</sup> In the context of IHI “Implementation science” refers to the 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, uptake, scale-up, piloting in healthcare).

<sup>4</sup> Article 115 of the [Council Regulation \(EU\) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe](#)

<sup>5</sup> [https://www.ih.europa.eu/sites/default/files/flmng/IHI\\_Strategic\\_Research\\_and\\_Innovation\\_Agenda\\_3.pdf](https://www.ih.europa.eu/sites/default/files/flmng/IHI_Strategic_Research_and_Innovation_Agenda_3.pdf)

to develop new and more precise personalised health innovations for prevention, diagnosis and therapy, as well as facilitating good health while aging.

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 and/or in industrial processes.

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

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 also be given to the Health Data Access Bodies that will be established under the forthcoming European Health Data Space Regulation<sup>6</sup> in the context of secondary use of data.

Applicants should consider relevant existing initiatives/projects to ensure synergies and complementarities and avoid unnecessary overlap and duplication of efforts. The proposal should include a plan on how to synergise with these initiatives.

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

The actions to be funded under this topic are expected to achieve the following:

- a) contribute to one or more of IHI JU's expected impacts linked to 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 benefitting from improved healthcare through regular monitoring of critical parameters using validated tools;

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<sup>6</sup> [https://www.europarl.europa.eu/doceo/document/TA-9-2024-0331\\_EN.pdf](https://www.europarl.europa.eu/doceo/document/TA-9-2024-0331_EN.pdf)

- development of new vaccine strategies targeted to specific sub-populations;
  - increased preparedness of EU healthcare systems for disease outbreaks.
- b) contribute to strengthening 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.

As relevant the actions are expected to contribute to EU programmes, initiatives and policies such as the European Green Deal, Europe's Beating Cancer Plan, the EU Mission on Cancer, the European Virtual Human Twins Initiative, the European Health Emergency Preparedness and Response Authority (HERA), the European Commission's proposal for the European Health Data Space (EHDS), and the EU Artificial Intelligence Act<sup>7</sup>.

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

Science and technologies are changing rapidly, and their successful implementation requires increasing cross-sectoral integration of technologies, know-how, products, services, and workflows for delivering a people-centred healthcare. Laying the groundwork for developing innovative tangible health solutions suitable for end-users therefore 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 charitable foundations/philanthropic organisations with the view to 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. **NB: this amount is indicative and subject to change, pending approval by the IHI Governing Board.**

IHI JU estimates that an IHI JU financial contribution of EUR 5 000 000 to 10 000 000 would allow a proposal to address these outcomes appropriately. **NB: this amount is indicative and subject to change, pending approval by the IHI Governing Board.** 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 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

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<sup>7</sup> [EU Artificial Intelligence Act | Up-to-date developments and analyses of the EU AI Act](#)

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.

INDICATIVE TEXT

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

**NOTE:** Applicants must also read carefully the section “Introduction to the Call and general elements to be considered for all topics”

### Expected outcomes

Applicants must define the outcomes expected to be achieved by the project, ensuring that they contribute to at least one of IHI JU’s potential outputs linked to 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 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.

The expected outcomes may cover the entire spectrum of care and may be health technologies centred around disease areas and/or key themes such as prevention, personalised medicine, and chronic disease management. They may also include solutions for key enablers such as digital / artificial intelligence (AI) /data, regulatory science, green and sustainability, and implementation science<sup>8</sup>.

### 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 etc. 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 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>9</sup> and described in more detail in the IHI JU SRIA<sup>10</sup>:

Proposals could aim, for example, to break down fragmentation between various disciplines of medicine including computational and technological areas to accelerate innovations from early discovery to patient treatment.

Among others, proposals may aim to integrate diverse components (e.g. from focused mission-based research projects, collaborative platforms, databases, AI/ML to diagnostics, medicinal products,

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<sup>8</sup> In the context of IHI “Implementation science” refers to the 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, uptake, scale-up, piloting in healthcare).

<sup>9</sup> Article 115 of the [Council Regulation \(EU\) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe](#)

<sup>10</sup> [https://www.ih.europa.eu/sites/default/files/flmngq/IHI\\_Strategic\\_Research\\_and\\_Innovation\\_Agenda\\_3.pdf](https://www.ih.europa.eu/sites/default/files/flmngq/IHI_Strategic_Research_and_Innovation_Agenda_3.pdf)

medical devices, wearables, digital solutions) in order to foster the development of people-centred, ambitious, large-scale and transformative solutions along the healthcare pathway from beginning to end, including treatment discovery.

Activities may include novel and harmonised approaches to data generation and federation, algorithm optimisation and applicable ML outputs, as well as activities to deliver open-source computational outputs such as machine learning methods for prediction at scale derived from a collaborative, community driven ecosystem.

Other examples are activities that catalyse data-driven AI/ML-influenced discoveries and therapies (e.g. integration of *in vitro*, *in vivo* approaches), (small molecules) screening platforms, manufacturing processes such as mass protein expression, diagnostics and prognostics for early and adapted treatment, including multimodal disease and/or cross-therapy area applications or management approaches. Proposals may address specific target populations, and/or support challenging unmet needs and treatment gaps.

Activities may also address innovations and outcomes within the context of the European Green Deal, so that advances are part of Europe's sustainability goals, supporting the commercial sustainability transition and reducing the overall environmental impact of healthcare.

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 and/or industrial processes.

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

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 also be given to the Health Data Access Bodies that will be established under the forthcoming European Health Data Space Regulation<sup>11</sup> in the context of secondary use of data.

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<sup>11</sup> [https://www.europarl.europa.eu/doceo/document/TA-9-2024-0331\\_EN.pdf](https://www.europarl.europa.eu/doceo/document/TA-9-2024-0331_EN.pdf)



Applicants should consider relevant existing initiatives/projects to ensure synergies and complementarities and avoid unnecessary overlap and duplication of efforts. The proposal should include a plan on how they propose to synergise with these initiatives.

## Expected impacts to be achieved by this topic

The actions to be funded under this topic are expected to achieve the following:

- a) contribute to one or more of IHI JU's expected impacts linked to the 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.
- b) contribute to strengthening 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.

As relevant, the actions are expected to contribute to EU programmes, initiatives and policies such as the European Green Deal, Europe's Beating Cancer Plan, the EU Mission on Cancer, the European Health Emergency Preparedness and Response Authority (HERA), the European Commission's proposal for the European Health Data Space (EHDS), and the EU Artificial Intelligence Act<sup>12</sup>.

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

Science and technologies are changing rapidly, and their successful implementation requires increasing cross-sectoral integration of technologies, know-how, products, services, and workflows for delivering a people-centred healthcare. Laying the groundwork for developing innovative tangible health solutions suitable for end-users therefore, 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

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<sup>12</sup> [EU Artificial Intelligence Act | Up-to-date developments and analyses of the EU AI Act](#)

bodies, payers) as well as charitable foundations/philanthropic organisations with the view to 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 80 000 000. **NB: this amount is indicative and subject to change, pending approval by the IHI Governing Board.**

IHI JU estimates that an IHI JU financial contribution of EUR 8 000 000 to 15 000 000 would allow a proposal to address these outcomes appropriately. **NB: this amount is indicative and subject to change, pending approval by the IHI Governing Board.** 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 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.

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

**NOTE:** Applicants must also carefully read the section “Introduction to the Call and general elements to be considered for all topics”

### Expected outcomes

Applicants must define the outcomes expected to be achieved by the project ensuring that they contribute to at least one of IHI JU’s potential outputs linked to the IHI JU’s Specific Objective 3 “*demonstrate the feasibility of people-centred, integrated healthcare solutions*”, as reflected 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.

The expected outcomes may cover the entire spectrum of care and may be health technologies centred around disease areas and/or key themes such as prevention, personalised medicine, and chronic disease management. They may also include solutions for key enablers such as digital /artificial intelligence (AI)/data, regulatory science, green and sustainability and implementation science<sup>13</sup>.

### 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 etc. 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 capable of directly 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<sup>14</sup> and described in more detail in the IHI JU SRIA<sup>15</sup>:

For example, proposals may aim to foster the development of integrated healthcare solutions, combining different technological areas and taking into account the needs of patients and citizens to, among others: a) facilitate patient contributions to R&I activities; b) support shared decision-making with healthcare professionals; and c) enable self-management of disease and health, *de facto* engaging in social innovation. This may imply, amongst others, the development of harmonised patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs), as well as the development of methods to elicit people’s preferences and digital tools to enable patient involvement.

Applicants should consider the following points in their proposals:

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<sup>13</sup> In the context of IHI “Implementation science” refers to the 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, uptake, scale-up, piloting in healthcare).

<sup>14</sup> Article 115 of the [Council Regulation \(EU\) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe](#)

<sup>15</sup> [https://www.ihj.europa.eu/sites/default/files/flmngq/IHI\\_Strategic\\_Research\\_and\\_Innovation\\_Agenda\\_3.pdf](https://www.ihj.europa.eu/sites/default/files/flmngq/IHI_Strategic_Research_and_Innovation_Agenda_3.pdf)

- 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 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 and/or into industrial processes.

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 also be given to the Health Data Access Bodies that will be established under the forthcoming European Health Data Space Regulation<sup>16</sup> in the context of secondary use of data.

Applicants should consider relevant existing initiatives/projects to ensure synergies and complementarities and avoid unnecessary overlap and duplication of efforts. The proposal should include a plan on how they propose to synergise with these initiatives.

### Expected impacts to be achieved by this topic

The actions to be funded under this topic are expected to achieve the following:

- a) contribute to one or more of the IHI JU's expected impacts linked to the 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 better adapted to their needs through improved diagnostic and monitoring;

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<sup>16</sup> [https://www.europarl.europa.eu/doceo/document/TA-9-2024-0331\\_EN.pdf](https://www.europarl.europa.eu/doceo/document/TA-9-2024-0331_EN.pdf)

- 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;
  - healthcare solutions assessed according to criteria that matter to patients and citizens (in particular, PROMs and PREMs) contributing to achieving people-centred healthcare.
- b) contribute to strengthening 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.

As relevant, the actions are expected to contribute to EU programmes, initiatives and policies such as the European Green Deal, Europe's Beating Cancer Plan, the EU Mission on Cancer, the European Virtual Human Twins Initiative, the European Health Emergency Preparedness and Response Authority (HERA), the European Commission's proposal for the European Health Data Space (EHDS), and the EU Artificial Intelligence Act<sup>17</sup>.

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

Science and technologies are changing rapidly, and their successful implementation requires increasing cross-sectoral integration of technologies, know-how, products, services, and workflows for delivering a people-centred healthcare. Laying the groundwork for developing innovative tangible health solutions suitable for end-users therefore, 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 charitable foundations/philanthropic organisations with the view to 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 30 000 000. **NB: this amount is indicative and subject to change, pending approval by the IHI Governing Board.**

IHI JU estimates that an IHI JU financial contribution of EUR 8 000 000 to 15 000 000 would allow a proposal to address these outcomes appropriately. **NB: this amount is indicative and subject to change, pending approval by the IHI Governing Board.** 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

<sup>17</sup> [EU Artificial Intelligence Act | Up-to-date developments and analyses of the EU AI Act](#)

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

INDICATIVE TEXT

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

**NOTE:** Applicants must also carefully read the section “Introduction to the Call and general elements to be considered for all topics”.

### Expected outcomes

Applicants must define the outcomes expected to be achieved by the project ensuring that they contribute to at least one of IHI JU’s potential outputs linked to the IHI JU’s Specific Objective 4 “*exploit the full potential of digitalisation and data exchange in healthcare*”, as reflected 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.

The expected outcomes may cover the entire spectrum of care and may be health technologies centred around disease areas and/or key themes such as prevention, personalised medicine, and chronic disease management. They may also include solutions for key enablers such as digital /artificial intelligence (AI)/data, regulatory science, green and sustainability, and implementation science<sup>18</sup>.

### 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 etc. 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 capable of directly 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>19</sup> and described in more detail in the IHI JU SRIA<sup>20</sup>:

For example, proposals may aim at supporting the generation, pooling, integration and sharing of high-quality, harmonised, interoperable data (either existing or generated *de novo*), as well as the use of advanced analytical tools (including Artificial Intelligence, computational modelling and simulation or digital twin approaches). They may also support the development of better assistance systems for healthcare professionals to facilitate timely decision-making during disease course, thereby improving patient outcomes.

Applicants should consider the following points in their proposals:

- a) address an unmet public health need based on at least one of the below:

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<sup>18</sup> In the context of IHI “Implementation science” refers to the 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, uptake, scale-up, piloting in healthcare).

<sup>19</sup> Article 115 of the [Council Regulation \(EU\) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe](#)

<sup>20</sup> [https://www.ihj.europa.eu/sites/default/files/flmngqr/IHI\\_Strategic\\_Research\\_and\\_Innovation\\_Agenda\\_3.pdf](https://www.ihj.europa.eu/sites/default/files/flmngqr/IHI_Strategic_Research_and_Innovation_Agenda_3.pdf)

- 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 and/or into industrial processes.

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

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 also be given to the Health Data Access Bodies that will be established under the forthcoming European Health Data Space Regulation<sup>21</sup> in the context of secondary use of data.

Applicants should consider relevant existing initiatives/projects to ensure synergies and complementarities and avoid unnecessary overlap and duplication of efforts. The proposal should include a plan on how to synergise with these initiatives.

### Expected impacts to be achieved by this topic

The actions to be funded under this topic are expected to achieve the following:

- a) contribute to one or more of the IHI JU's expected impacts linked to the 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 a) clinical decision support for increased accuracy of diagnosis and efficacy of treatment; b) shorter times to market; c) wider availability of personalised health interventions to end-users; d) better evidence of the added value from new digital health and artificial intelligence tools, including reduced risk of bias due to improved methodologies.
- b) contribute to strengthening the competitiveness of the EU's health industry via increased economic activity in the development of health technologies, in particular, integrated health

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<sup>21</sup> [https://www.europarl.europa.eu/doceo/document/TA-9-2024-0331\\_EN.pdf](https://www.europarl.europa.eu/doceo/document/TA-9-2024-0331_EN.pdf)



solutions, thus fostering European technological leadership and the digital transformation of our societies.

As relevant, the actions are expected to contribute to EU programmes, initiatives and policies/ such as the European Green Deal, Europe's Beating Cancer Plan, the EU Mission on Cancer, the European Virtual Human Twins Initiative, the European Health Emergency Preparedness and Response Authority (HERA), the European Commission's proposal for the European Health Data Space (EHDS), and the EU Artificial Intelligence Act<sup>22</sup>.

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

Science and technologies are changing rapidly, and their successful implementation requires increasing cross-sectoral integration of technologies, know-how, products, services, and workflows for delivering a people-centred healthcare. Laying the groundwork for developing innovative tangible health solutions suitable for end-users therefore, 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 charitable foundations/philanthropic organisations with the view to 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 30 000 000. **NB: this amount is indicative and subject to change, pending approval by the IHI Governing Board.**

IHI JU estimates that an IHI JU financial contribution of EUR 8 000 000 to 15 000 000 would allow a proposal to address these outcomes appropriately. **NB: this amount is indicative and subject to change, pending approval by the IHI Governing Board.** 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 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

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<sup>22</sup> [EU Artificial Intelligence Act | Up-to-date developments and analyses of the EU AI Act](#)

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.

INDICATIVE TEXT

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

**NOTE:** Applicants must also read carefully the section “Introduction to the Call and general elements to be considered for all topics”

### Expected outcomes

Applicants must define the outcomes expected to be achieved by the project ensuring that they contribute to at least one of IHI JU’s potential outputs linked to 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 reflected 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.

The expected outcomes may cover the entire spectrum of care and may be health technologies centred around disease areas and/or key themes such as prevention, personalised medicine, and chronic disease management. They may also include solutions for key enablers such as digital/AI/data, regulatory science, green and sustainability, and implementation science<sup>23</sup>.

### 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 etc. 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 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>24</sup> and described in more detail in the IHI JU SRIA<sup>25</sup>:

For example, proposals may aim to develop methods and tools to assess the added value of emerging and converging health technologies, taking into consideration different stakeholders’ value dimensions, to support harmonised approaches for evidence generation.

Applicants should consider the following points in their proposals:

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<sup>23</sup> In the context of IHI “Implementation science” refers to the 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, uptake, scale-up, piloting in healthcare).

<sup>24</sup> Article 115 of the [Council Regulation \(EU\) 2021/2085 of 19 November 2021 establishing the Joint Undertakings under Horizon Europe](#)

<sup>25</sup> [https://www.ihj.europa.eu/sites/default/files/flmngqr/IHI\\_Strategic\\_Research\\_and\\_Innovation\\_Agenda\\_3.pdf](https://www.ihj.europa.eu/sites/default/files/flmngqr/IHI_Strategic_Research_and_Innovation_Agenda_3.pdf)

- 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 and/or into industrial processes.

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

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 also be given to the Health Data Access Bodies that will be established under the forthcoming European Health Data Space Regulation<sup>26</sup> in the context of secondary use of data.

Applicants should consider relevant existing initiatives/projects to ensure synergies and complementarities and avoid unnecessary overlap and duplication of efforts. The proposal should include a plan on how they propose to synergise with these initiatives.

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

The actions to be funded under this topic are expected to achieve the following:

- a) contribute to one or more of the expected impacts linked to the IHI JU's specific objective 5 as reflected in the IHI JU SRIA, i.e.:
- 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.

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<sup>26</sup> [https://www.europarl.europa.eu/doceo/document/TA-9-2024-0331\\_EN.pdf](https://www.europarl.europa.eu/doceo/document/TA-9-2024-0331_EN.pdf)

- b) contribute to strengthening 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.

As relevant, the actions are expected to contribute to EU programmes, initiatives and policies such as the European Green Deal, Europe's Beating Cancer Plan, the EU Mission on Cancer, the European Virtual Twins Initiatives, the European Health Emergency Preparedness and Response Authority (HERA), the European Commission's proposal for the European Health Data Space (EHDS), and the EU Artificial Intelligence Act<sup>27</sup>.

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

Science and technologies are changing rapidly, and their successful implementation requires increasing cross-sectoral integration of technologies, know-how, products, services, and workflows for delivering a people-centred healthcare. Laying the groundwork for developing innovative tangible health solutions suitable for end-users, therefore, 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 charitable foundations/philanthropic organisations with the view to 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. **NB: this amount is indicative and subject to change, pending approval by the IHI Governing Board.**

IHI JU estimates that an IHI JU financial contribution of EUR 5 000 000 to 10 000 000 would allow a proposal to address these outcomes appropriately. **NB: this amount is indicative and subject to change, pending approval by the IHI Governing Board.** 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 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).

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<sup>27</sup> [EU Artificial Intelligence Act | Up-to-date developments and analyses of the EU AI Act](#)

### **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.

INDICATIVE TEXT