



# IHI

## 3<sup>rd</sup> Call for proposals



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## Introduction

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

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

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

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

## Topics Overview

<p><b>HORIZON-JU-IHI-2022-03-01</b></p> <p><b>Screening platform and biomarkers for prediction and prevention of diseases of unmet public health need</b></p>	<p>Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 30 000 000.</p> <p>Applicant consortia must ensure that at least 45 % of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.</p>	<p>Research and Innovation Action (RIA)</p> <p>Single-stage submission and evaluation process.</p> <p>Proposals submitted will be evaluated and ranked in one single list. Several proposals might be invited to conclude a Grant Agreement, depending on the budget availability and their ranking.</p>
<p><b>HORIZON-JU-IHI-2022-03-02</b></p> <p><b>Patient-generated evidence to improve outcomes, support decision making, and accelerate innovation</b></p>	<p>Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 24 000 000.</p> <p>Applicant consortia must ensure that at least 45 % of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.</p>	<p>Research and Innovation Action (RIA)</p> <p>Single-stage submission and evaluation process.</p> <p>Proposals submitted will be evaluated and ranked in one single list. Several proposals might be invited to conclude a Grant Agreement, depending on the budget availability and their ranking..</p>
<p><b>HORIZON-JU-IHI-2022-03-03</b></p> <p><b>Combining hospital interventional approaches to improve patient outcomes and increase hospital efficiency</b></p>	<p>Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 30 000 000.</p> <p>Applicant consortia must ensure that at least 45 % of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.</p>	<p>Research and Innovation Action (RIA)</p> <p>Single-stage submission and evaluation process.</p> <p>Proposals submitted will be evaluated and ranked in one single list. Several proposals might be invited to conclude a Grant Agreement, depending on the budget availability and their ranking.</p>

<p><b>HORIZON-JU-IHI-2022-03-04</b></p> <p><b>Strengthening the European translational research ecosystem for advanced therapy medicinal products (ATMPs) for rare diseases</b></p>	<p>Applicant consortia will be competing for the maximum financial contribution from IHI up to EUR 30 000 000.</p> <p>Applicant consortia must ensure that at least 45 % of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.</p>	<p>Research and Innovation Action (RIA)</p> <p>Single-stage submission and evaluation process.</p> <p>Proposals submitted will be evaluated and ranked in one single list. Several proposals might be invited to conclude a Grant Agreement, depending on the budget availability and their ranking.</p>
<p><b>HORIZON-JU-IHI-2022-03-05</b></p> <p><b>Digital health technologies for the prevention and personalised management of mental disorders and their long-term health consequences</b></p>	<p>Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 24 000 000.</p> <p>Applicant consortia must ensure that at least 45 % of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.</p>	<p>Research and Innovation Action (RIA)</p> <p>Single-stage submission and evaluation process.</p> <p>Proposals submitted will be evaluated and ranked in one single list. Several proposals might be invited to conclude a Grant Agreement, depending on the budget</p>

# Call Conditions

## Conditions of the calls for proposals and call management rules

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

The General Annexes of the Horizon Europe Work Programme 2021-2022 shall apply *mutatis mutandis* to the calls for proposals covered by the second amended Work Programme. In accordance with Article 5(2)(a) of the Council Regulation (EU) 2021/2085, in duly justified cases, derogations related to the specificities for IHI JU may be introduced in the relevant Work Programme. Where necessary, this will be done when the topic texts are identified in the second amended Work Programme.

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

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

The General Annexes of the Horizon Europe Work Programme 2021 – 2022 shall apply to the calls for proposals covered by the second amended Work Programme. Any specificity for IHI JU is highlighted in the sections below.

## General conditions relating to the IHI JU Calls

<b>ADMISSIBILITY CONDITIONS</b>	<b>THE CONDITIONS ARE DESCRIBED IN GENERAL ANNEX A.</b>
<b>Eligibility conditions</b>	The conditions are described in General Annex B.
<b>Financial and operational capacity and exclusion</b>	Annex C.
<b>Award criteria</b>	The criteria are described in General Annex D.
<b>Documents</b>	The documents are described in General Annex E.
<b>Procedure</b>	The procedure is described in General Annex F.

## Standard admissibility conditions, pages limits and supporting documents

Part A ('Admissibility') of the General Annexes to the Horizon Europe Work Programme 2021-2022 shall apply *mutatis mutandis* for the calls for proposals covered by the second amended Work Programme.

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

- for a single-stage call, the limit for RIA full proposals is 50 pages;

## Standard eligibility conditions

Part B of the General Annexes to the Horizon Europe Work Programme 2021-2022 shall apply *mutatis mutandis* for the call for proposals covered by the second amended Work Programme unless otherwise provided in the second amended Work Programme.

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

- Applicant consortia must ensure that at least 45% of the action's eligible costs and costs for action-related additional activities are provided by contributions (IKOP, FC, IKAA) from private members, their constituent or affiliated entities, and contributing partners.
- While private members can contribute any of those contribution types, contributing partners can only contribute IKOP and FC, not IKAA.
- Further to the above, the applicant consortium must submit a self-declaration that the required percentage of 45% contributions will be provided.
- At the level of the IHI JU programme, non-EU IKOP must not exceed 20% of in-kind contributions to operational costs provided by private members which are IHI JU members, their constituent or affiliated entities, and contributing partners.
- At project level, the maximum amount of non-EU IKOP is set to one hundred percent (100%). This is justified as a means to ensure the achievement of project objectives based on Article 119(4) and 119(5) of Council Regulation (EU) 2021/2085, and to ensure full openness to non-EU IKOP in these calls.
- Furthermore, at the level of the IHI JU programme, IKAA shall not constitute more than 40% of in-kind contributions provided by private members which are IHI JU members.

## Entities eligible for funding

In relation to the single-stage calls for proposals covered by the second amended Work Programme the relevant provisions of the Part B of the General Annexes to the Horizon Europe Work Programme 2021-2022 shall apply *mutatis mutandis*.

## List of countries and applicable rules for funding

With reference to Article 23 of the Council Regulation (EU) 2021/2085, eligibility of participants in a proposal submitted to a call for proposals for any of the topics in the second amended Work Programme will take into account any application of Art 22(5) of the Horizon Europe Regulation triggered for topics from other Horizon Europe Work Programmes for proposals with similar scope.

## Types of action: specific provisions and funding rates

Part B ('Eligibility') of the General Annexes to the Horizon Europe Work Programme 2021-2022 shall apply *mutatis mutandis* for the calls for proposals covered by the second amended Work Programme.

## Technology readiness Levels (Trl)<sup>1</sup>

TRL definitions included in Part B ('Eligibility') of the General Annexes to Horizon Europe Work Programme 2021-2022 shall apply *mutatis mutandis* for the calls for proposals covered by this amended Work Programme.

<sup>1</sup> The TRL is not utilised for IHI call 1, call 2 and call 3, however, it is anticipated to be used in future IHI calls



## Evaluation Rules

Part D ('Award Criteria') of the General Annexes to the Horizon Europe Work Programme 2021-2022 shall apply *mutatis mutandis* for the calls for proposals covered by the second amended Work Programme with the following additions:

### Award criteria and scores:

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

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

For the evaluation of proposals under single-stage:

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

Under the single-stage evaluation process, evaluated proposals will be ranked in one single list. The best ranked proposals, in the framework of the available budget, will be invited to prepare a Grant Agreement.

The IHI JU evaluation procedure is confidential.

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

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

### Indicative timetable for evaluation and grant agreement preparation

Information on the outcome of the evaluation for a single stage call is maximum 5 months from the submission deadline.

The Indicative date for the signing of grant agreement for a single stage is maximum 8 months from the submission deadline.

Part G ('Legal and Financial setup of the Grant Agreements') of the General Annexes to the Horizon Europe Work Programme 2021-2022 shall apply *mutatis mutandis* for the calls for proposals covered by the second amended Work Programme.

### Budget Flexibility

Part F of the General Annexes to the Horizon Europe Work Programme 2021-2022 shall apply *mutatis mutandis* to the calls for proposals covered by the second amended Work Programme.

### Submission Tool

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

## Proposals including clinical studies<sup>2</sup>

Applicants envisaging including clinical studies must provide details of their clinical studies in the dedicated annex using the template provided in the submission system.

### Specific conditions on availability, accessibility and affordability (3A)

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

- The participants must, during the lifetime of the project and for a period of four years after project end, use their best efforts to ensure that those products or services that are developed by any of the participants and are totally or partly based on the results of clinical studies performed as part of the activities of the selected project, will be broadly<sup>3</sup> available and accessible, at fair and reasonable conditions.
- In particular, and always to the extent permitted by applicable competition law:
  - a) At the proposal stage<sup>4</sup>, and as part of the Plan for the Dissemination, Exploitation, and Communication Activities ('PDECA') which forms part of the proposal, the applicant consortium must identify potential and expected project results that may be subject to the 3A conditions and broadly outline their strategy to achieve the above objectives.<sup>5</sup>
  - b) At the project interim review stage, if relevant<sup>6</sup>, the PDECA should be updated with a revised 3A strategy. This update should be based on the progress of the clinical studies conducted or to be conducted as part of the project and include any pertinent action to be implemented both during the project and over the four years after project end.
  - c) At the end of the project, the PDECA should be updated, to provide the expected planning for further product development and (if already scheduled) product launch, within the timeframe of four years after the project end and in order to meet those objectives laid out under point 1 above.<sup>7</sup>
  - d) Within 12 months from the project end date, and on a yearly basis thereafter for a period of 3 years (in total 4 years from project end), a confidential report<sup>8</sup> must be submitted to

<sup>2</sup> Clinical study covers clinical studies/trials/investigations/cohorts and means, for the purpose of this document, any systematic prospective or retrospective collection and analysis of health data obtained from individual patients or healthy persons in order to address scientific questions related to the understanding, prevention, diagnosis, monitoring or treatment of a disease, mental illness, or physical condition. It includes but it is not limited to clinical studies as defined by Regulation 536/2014 (on medicinal products), clinical investigation and clinical evaluation as defined by Regulation 2017/745 (on medical devices), performance study and performance evaluation as defined by Regulation 2017/746 (on in vitro diagnostic medical devices).

<sup>3</sup> This covers EU Member States and Countries that are Associated to Horizon Europe at the time of call opening.

<sup>4</sup> As mentioned, for those 3A specific projects, the 3A content in the PDECA will be checked during the evaluation stage. Omission/inadequate treatment of 3A would be identified as a shortcoming. The content however, once considered adequate, will not be utilised for positive scoring and will not contribute towards any evaluation criteria.

<sup>5</sup> Suggested components would be 1) Identification of planned clinical studies that might generate results for which the provisions are relevant; 2) Confirmation that the consortium members are aware of the provisions and will consider them accordingly. 3) Tentatively identifying markets/areas where the product/service could be made affordable, accessible, available. These points could be checked at the evaluation stage.

<sup>6</sup> As discussed, this interim point allows a realistic appraisal of the 3A possibilities during the project lifetime, particularly as to the viability of specific expected 3A results.

<sup>7</sup> Per the Model Grant Agreement ('MGA') Article 16, the beneficiaries must complete the Results Ownership List ('ROL') which identifies each result generated in the project and the owner thereof. The ROL should inform on the relevant results for which owners implement the 3A strategy in the PDECA for the four years following the project.

<sup>8</sup> Cognizant of IP sensitivities, confidential info, and commercial realities, the IHI JU suggests that the confidential report PDECA could, if needed, be composed of two parts:

1. **A high-level abstract**, to be made publicly available (not containing confidential information), comprising:
  - a) Broad summary of the result's development to this point, including a detailed description of the result and the potential product or service that could incorporate or partly incorporate the result;
  - b) Broad description of expected downstream actions (including product and service applications);
  - c) Broad assessment of expected impact of the above downstream actions towards ensuring Affordability, Availability, and Accessibility.

IHI JU by the owner of the project result describing the status of the development of the product and of any other exploitation actions, planned or undertaken, concerning the products/services.

## **JU right to object to transfer/exclusive licensing**

According to the Horizon Europe rules, and in order to protect Union interests, the right for IHI JU to object to transfers of ownership of results or to grants of an exclusive licence regarding results should apply to participants. Therefore, the provisions set out in General Annex G to the Horizon Europe Work Programme 2021-2022 on the right to object apply generally. It should be noted that in accordance with the Council Regulation (EU) 2021/2085 and the Horizon Europe model Grant Agreement, the right to object applies also to participants that have not received funding from IHI JU and for the periods set therein. In choosing whether to exercise the right to object, IHI JU will, on a case-by-case basis, make a reasoned decision in compliance with the legal basis.

**2. A Confidential Annex** in which:

- a) The owning beneficiary explains if the result is a product or service (or is expected to become one within 4 years) or not, and if yes, further confirms:
- i. The planned measures to be taken to effect the 3A obligations;
  - ii. That the owning beneficiary will undertake all necessary actions to adhere to the 3A provisions to the best of its capacity;
  - iii. That the owing beneficiary will keep the IHI JU updated on a yearly basis on the progress.

# Topic 1: Screening platform and biomarkers for prediction and prevention of diseases of unmet public health need

## Expected impacts to be achieved by this topic

The following impacts are expected:

- 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 interventions and strategies.
- Increased availability of validated biomarkers for disease interception and diagnosis, tested in real-world settings.
- Advanced analytics/artificial intelligence supporting health research and innovation (R&I), resulting in wider availability of personalised health interventions to end-users.

## Expected outcomes

R&I actions (projects) to be supported under this topic should aim to deliver results that contribute to all of the following expected outcomes for disease(s) of high unmet public health need selected by the applicants<sup>9</sup>:

- Patients will receive more timely personalised interventions (prevention, early treatment to avoid complications, etc) to reduce morbidity and mortality from major diseases, improving the lives of citizens.
- Healthcare professionals have access to a screening platform and clinically validated biomarkers for identifying people at risk of disease to facilitate the selection of the most appropriate preventative action.
- Researchers have new biomarkers for prediction and prevention to allow for the development of safer and more effective personalised interventions tailored to the individual's characteristics.
- Healthcare systems will benefit from reliable evidence to target effective, preventative therapeutic interventions to those citizens who will benefit most from them.

## Scope

As the population of the European Union ages, the rising burden of disease is a major challenge to the sustainability and resilience of healthcare systems. The identification of individuals at risk of developing an illness so that they can receive an appropriate treatment before the disease develops is an important factor to address this problem. However, for many health conditions, we lack full understanding of the underlying mechanisms, including the predisposition to disease and how environmental and genetic factors affect the occurrence of the disease.

<sup>9</sup> **Unmet public health needs** are needs currently not addressed by healthcare systems for various reasons, for example if no medicines are known to treat a disease. Areas of public health importance are those where the burden of disease is high for patients and society due to the severity of the disease (in terms of mortality, physical and functional impairment, comorbidities, loss of quality of life...) and/or the number of people affected by it. For example, Alzheimer's disease.

Projects funded under this topic should address this challenge by developing an open platform for screening individuals with the aim of identifying people at risk of disease. Applicants should clearly identify a disease(s) of unmet public health need, and specify the initial biomarkers to identify people at risk that will be used within the project (e.g. genetic, metabolic, digital and imaging biomarkers, lifestyle/environmental, family inherited disease, and/or combinations of these) and explain their choices with relevant evidence where possible. By the end of the project, the screening platform should be able to be used for population screening and decision-making including selection of the most appropriate intervention(s) and new technology development.

In particular, for the selected disease(s), the project(s) funded under this topic are expected to:

- Set up a comprehensive interdisciplinary collaboration of the clinical research, industrial, public health, and health technologies communities to develop the screening platform and generate the evidence base for general population screening. This platform should be built to operate in an open-source environment allowing interoperability with applications from different providers, and build on clearly identified existing initiatives where relevant, while aiming at facilitating reusability (for example, a modular structure to enable flexibility and customisation to support new developments). The ethics considerations of operating such a platform must be considered and relevant guidelines for digital biomarker design and development should be followed as appropriate.
- Clinically validate and assess the utility of the screening platform and biomarkers<sup>10</sup> to identify people at risk by designing and implementing a large-scale general population cohort screening study in several representative European countries.
- Design and clinically validate innovative assay technologies for disease risk identification, including digital technologies with data capture/analysis.
- Deliver digital tools for more effective and efficient management and execution of screening programmes and improved disease prevention. Artificial intelligence (AI) tools should be robust and explainable where relevant.
- Publish the relevant methods, standard operating procedures (SOPs), algorithms, standards and guidelines to allow the platform to be used more broadly and for diagnostics and therapies to be developed.
- Develop a plan/roadmap based on solid evidence to facilitate the regulatory qualification of the biomarkers identified and used within the project, and seek engagement with regulators where relevant (e.g. through the EMA Innovation Task Force, scientific advice).
- Develop and optimise relevant clinical practice guidelines through systematic evidence and outcome review, while addressing factors influencing uptake of these biomarkers in clinical practice.
- Raise awareness of disease prevention and provide training and education to relevant healthcare professionals, patients and family members. These training materials should be made available for use after the project ends.

A key objective is to facilitate changing healthcare practice, so applicants will need to demonstrate that their outputs can be taken up by healthcare systems and take steps to facilitate this.

<sup>10</sup> Biomarkers are biological characteristics, which can be molecular, anatomical, physiological, or biochemical. These characteristics can be measured and evaluated objectively. They act as indicators of a normal or a pathogenic biological process. They allow the assessment of the pharmacological response to a therapeutic intervention. A biomarker shows a specific physical trait or a measurable biologically-produced change in the body that is linked to a disease or a particular health condition. A biomarker may be used to assess or detect a specific disease as early as possible (diagnostic biomarker), the risk of developing a disease (susceptibility/risk biomarker), the evolution of a disease (prognostic biomarker) – but it can also predict response to a given treatment including potential toxicity (predictive biomarker).

Applicants are expected to consider allocating appropriate resources to explore synergies with other relevant initiatives and projects.

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

To develop novel biomarker combinations and implement them in a broadly applicable screening platform requires significant cross-sectoral expertise including from patients, healthcare professionals, biomarker specialists, machine learning experts, academic researchers, SMEs, and the pharmaceutical and medical technology industries. These different public and private stakeholders will need to work closely together in the collaborative environment provided by an IHI project to achieve the objectives of this topic.

### **Indicative budget**

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

IHI estimates that an IHI financial contribution of between EUR 10 000 000 and EUR 15 000 000 would allow a proposal to address these outcomes appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

Applicant consortia must ensure that at least 45 % of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.

Additional activities from industry members and their constituent or affiliated entities may also contribute towards this 45 % threshold, providing these activities are related to the project. Contributing partners do not contribute additional activities.

### **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 calls management rules under "Specific conditions on availability, accessibility and affordability" apply<sup>11</sup>.

<sup>11</sup> See section 4.2.3.2 of the second amended Work Programme

## Topic 2: Patient-generated evidence to improve outcomes, support decision making, and accelerate innovation

### Expected impacts to be achieved by this topic

The following impacts are expected:

- Enable the added value of people-centred integrated healthcare solutions<sup>12</sup> to be assessed according to criteria that matter to patients and citizens, using patient-reported outcome measures (PROMs), patient preference information (PPI), and patient-reported experience measures (PREMs).
- Facilitate the development and implementation of integrated healthcare solutions based on patient input including PROMs, PPI, and PREMs. These solutions should better respond to the needs and preferences of patients and citizens and support an inclusive approach.
- Enable the smart use of patient input and patient-generated evidence to facilitate the faster market entry of patient-centric and cost-effective advanced integrated healthcare solutions<sup>12</sup>, and also spur further innovation by improving return on research and innovation investments.
- Use patient input gathered via m-health, e-health and other technologies to gain improved insights into the real-life behaviour of, and challenges faced by, patients of all ages with complex, chronic diseases and co-morbidities.

### Expected outcomes

Research and innovation (R&I) actions (projects) to be supported under this topic should aim to deliver results that contribute to all of the following expected outcomes for the use cases selected:

- Decision makers have new methods for the integration of PROMs, PPI, and PREMs and other people-generated information into regulatory and health technology assessment (HTA) evaluation processes for integrated healthcare solutions.
- Patients of all ages have access to novel integrated healthcare solutions<sup>12</sup> that are developed using structured patient input and better respond to their needs and preferences.
- Researchers have new methodological approaches to elicit and integrate patient preferences into the conception, development, and implementation of integrated healthcare solutions<sup>12</sup>.
- Researchers have wider access to interoperable, quality patient input and patient-generated data, respecting the FAIR (findable, accessible, interoperable, reusable) principles, facilitating the research and development of integrated healthcare solutions.
- Researchers are provided with new outcomes, outcome measures and the time horizon over which value should be assessed to develop appropriate tools and methods for the collection and analysis of PROMs, PPI, and PREMs.

<sup>12</sup> Integrated healthcare solutions are innovative solutions integrating various technologies, coupled with complementary tools and services.

## Scope

The amount of health data generated by citizens themselves is rapidly increasing. Such data includes patient-reported outcome measures (PROMs), patient preference information (PPI), and patient-reported experience measures (PREMs), as well as other digital health data/digital biomarkers. While the potential for these data to be harnessed to improve individual healthcare is enormous, these data are often fragmented among multiple providers, so that neither the citizen, nor the healthcare ecosystem have a comprehensive overview, and therefore it is very challenging to fully use these data to provide reliable evidence for decision-makers, and to improve health outcomes.

Research and innovation (R&I) actions to be supported under this topic will aim to address this challenge by:

- Developing a framework to integrate patient input and patient-generated data for use in decision making (regulatory, health economic evaluation, reimbursement, healthcare programme design, tailored prescription of therapies, and technology development), benefit-risk evaluation and value assessment of integrated healthcare solutions.<sup>12</sup> Applicants should build on existing frameworks where appropriate and appropriately address ethics considerations.
- Implement several use cases to support and demonstrate the use of the framework, focusing on using patient input and patient-generated evidence to address challenges that are not adequately addressed by other initiatives. These use cases should demonstrate the value of using patient input (PROMs, PPI, PREMs) and patient generated data (digital health data/digital biomarkers) along the healthcare continuum, including showcasing improvements to data interoperability, healthcare workflows and processes, disease prevention, and care, including home-based care. These use cases should also act as examples of best practice for future use of the framework.
- Facilitating multi-stakeholder access to patient inputs and patient-generated health data such that actionable harmonised data can be used for quality decision making.
- Comparing/contrasting the properties of the three types of patient input (PROMs, PPI, PREMs), identify differences and opportunities for integrated/complementary use.
- Developing an approach or approaches to integrating PROMs, PPI, and PREMs data into the design of core outcomes sets, end-to-end patient treatment pathways, clinical decision support systems, and treatment guidelines. The core outcome sets used within the project should be made available more widely where possible.

Applicants are expected to seek engagement with regulators where relevant (e.g. through the EMA Innovation Task Force, scientific advice) and consider allocating appropriate resources to explore synergies with other relevant initiatives and projects.

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

As the cost of healthcare continues to rise, integrated healthcare solutions<sup>12</sup> offer possibilities for delivering better patient outcomes more efficiently. However, the infrastructure for developing effective solutions at scale and for evaluating novel 'high-value' care products, programmes, and services is fragmented.

While patient input is critical to developing these person-centred integrated care solutions, to date, coordination among different types of product and service providers has been mostly on an as-needed basis. There has been little incentive for these diverse research disciplines and different types of product and service providers to coordinate their efforts to develop systematic approaches to the use of patient-generated data.



Such patient input can be derived from multiple sources, which have different theoretical foundations and are at different levels of methodological maturity. Different types of patient input, although complementary, require different skill sets that are often not found within a single institution. Only a pre-competitive collaboration that brings together patients, healthcare professionals, industry sponsors, researchers, programme designers, and programme evaluators, can ensure the effective implementation of patient input in the design, evaluation, and implementation of effective innovated integrated care strategies.

### **Indicative budget**

Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 24 000 000.

IHI estimates that an IHI financial contribution of between EUR 10 000 000 and EUR 14 000 000 would allow a proposal to address these outcomes appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

Applicant consortia must ensure that at least 45 % of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.

Additional activities from industry members and their constituent or affiliated entities may also contribute towards this 45 % threshold, providing these activities are related to the project. Contributing partners do not contribute additional activities.

### **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 calls management rules under "Specific conditions on availability, accessibility and affordability" do not apply<sup>13</sup>.

<sup>13</sup> See section 4.2.3.2 of the second amended Work Programme.

## Topic 3: Combining hospital interventional approaches to improve patient outcomes and increase hospital efficiency

### Expected impacts to be achieved by this topic

The following impacts are expected:

- Improve patient outcomes of hospital care and foster faster recovery by overcoming issues of fragmentation through combining innovative interventional approaches.
- Seamless and successful implementation in hospital settings of cross-sectoral innovations, integrated products and services delivering proven benefits to patients, healthcare systems (including hospital staffing), and society as a whole.
- Advanced analytics/artificial intelligence (AI) supporting health research and innovation, resulting in improved clinical decision support for increased efficacy of treatment.

### Expected outcomes

Research and innovation (R&I) actions (projects) to be supported under this topic should aim to deliver results that contribute to all of the following expected outcomes:

- Patients will be offered improved, evidence-based, innovative hospital treatment combinations that lead to better outcomes.
- Healthcare professionals will have access to improved clinical decision support systems that will recommend personalised treatments using patient-specific datasets collected in the hospital setting.
- Healthcare systems will have better evidence on cost-effective combinations of interventions and how these combinations can increase hospital efficiency.
- Researchers will have improved information on treatment combinations to facilitate the development of improved interventions.

### Scope

Patients admitted to hospital to undergo elective or non-elective procedures typically require recovery and rehabilitation to get back to normal life. New treatment approaches such as minimally invasive surgical approaches, locoregional interventions, novel imaging and diagnostic techniques, clinical decision support systems, and robotics have the potential to reduce complications, facilitate faster recovery, and help increase hospital efficiencies. However, due to limitations in interoperability, reliable evidence and suitable guidelines, these innovative approaches, treatment options and clinical decision support systems are not being optimally combined to provide the best patient care.

Projects funded under this topic should address this challenge by showcasing how existing hospital interventions, treatment approaches and technologies can be optimally combined to improve patient outcomes, enhance patient pathways, generate efficiency gains, reduce hospital staffing challenges, help to lower costs, and decrease societal burden.

In particular, projects should:

- Access and integrate clinical data routinely generated using existing technologies during the patient journey (e.g. medical history profile of patients, diagnosis achieved, for example, by medical imaging and *in-vitro* diagnostic (IVD) tests, digital information generated during the hospital procedure, vital signs and anaesthesia management, electronic healthcare record systems (EHRs), and drug prescriptions such as analgesics). The interoperability of these data should be addressed as appropriate. Suitable, secure IT infrastructure to support edge and cloud computing in compliance

with the general data protection regulation (GDPR) and other data privacy policies at national and local levels should be utilised.

- Train and clinically validate explainable AI algorithms to support the development of training programmes, procedure planning and intraoperative assistance solutions, including clinical decision support systems.
- Demonstrate, via use cases using these data & algorithms, how combinations of and/or synergies between the above-mentioned tools, technologies, and therapeutic approaches can be harnessed to improve patient care. This should include comparing the combination of innovative interventional approaches and clinical decision support systems (CDSS) versus limited or no systematic combination of these innovative interventional approaches and CDSS.
- Implement tools to confirm successful treatment during or after the procedure and monitor therapy response and disease regression.
- Develop and implement new methodologies to assess and demonstrate the added value of combining innovative interventional approaches and clinical decision support systems to all relevant stakeholders.
- Encourage the uptake of the results of the project through a strong communication and outreach plan, including the publication of a gap assessment in order to guide future research in this field.

Applicants are expected to consider allocating appropriate resources to explore synergies with other relevant initiatives and projects including any projects resulting from Horizon Europe Cluster 1 Health topics, and, where relevant, seek engagement with regulators (e.g. through the EMA Innovation Task Force, scientific advice).

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

To achieve the transformation outlined above, a broad cross-sectoral collaboration is needed including healthcare professionals to give insights on their experience with the current technology utilisation and act as champions for the new developments, academic researchers, health economists, hospital management, public procurers, technology developers and vendors, and patients, who will benefit from the solutions. Integrating data from multiple origins/sources requires the cooperation of data holders, both public and private, in a non-competitive, neutral setting like an IHI project.

### **Indicative budget**

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

IHI estimates that an IHI financial contribution of between EUR 8 000 000 and EUR 10 000 000 would allow a proposal to address these outcomes appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

Applicant consortia must ensure that at least 45 % of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.

Additional activities from industry members and their constituent or affiliated entities may also contribute towards this 45 % threshold, providing these activities are related to the project. Contributing partners do not contribute additional activities.

### **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 calls management rules under "Specific conditions on availability, accessibility and affordability" do not apply<sup>14</sup>.

<sup>14</sup> See section 4.2.3.2 of the second amended Work Programme.

## Topic 4: Strengthening the European translational research ecosystem for advanced therapy medicinal products (ATMPs) for rare diseases

### Expected impacts to be achieved by this topic

- Benefits for patients both with rare and ultra-rare diseases and who may gain from effective and safe advanced therapy medicinal products (ATMPs) and other related innovative therapeutic modalities.
- A better and more cost-effective development of ATMPs and other related innovative therapeutic modalities due to improved scientific and technological processes. This is applicable especially to those ATMPs intended both for the treatment of rare diseases and those that are currently underserved by current therapies (the latter often being of genetic origin).
- Europe to become more attractive for developing ATMPs due to the availability of sustained, interconnected networks of technological and scientific centres of excellence. Although their current focus is on translational research, linkages to clinical networks, including the European reference networks (ERNs) on rare diseases will enhance their activities. The same is true for synergies to be developed with the European Joint Programme on Rare Diseases and the future European partnership on rare diseases. This would set out a more efficient and effective pathway for the development of treatment modalities for patients with rare diseases in Europe.
- Benefits for a broader range of disorders beyond the rare disease domain due to a more robust development of ATMPs and other related innovative therapeutic modalities as well as knowledge transfer across actors in ATMP development.

### Expected outcomes

Research and innovation (R&I) actions to be supported under this topic must work towards results that contribute to all the following expected outcomes.

- A sustainable network of centres of excellence, that should:
  - i. advance the most promising, impactful, translatable, quality-controlled technologies that address the bottlenecks in the development of ATMPs and other related innovative therapeutic modalities such as the use of messenger RNA (mRNA), or nucleic acids and nanoparticle (NPs) delivery for gene editing;
  - ii. make these technologies accessible to all actors involved in the development of ATMPs and other related innovative therapeutic modalities, including the research community, academia, clinics, small to medium-sized enterprises (SMEs), healthcare professionals, biotech, medical technology and pharmaceutical companies, and patients;
  - iii. share information, processes and methods, and build capacity in science and technology, and regulatory awareness of ATMPs, including the ability to assist industrial and academic developers of ATMPs in their translational research.
- Consensus reached on quality standards (e.g. of analytical methods) and translation process by the ATMP community at large that support the timely and robust development of ATMPs and other related innovative therapeutic modalities.
- Strengthened interactions with regulators to enable a more streamlined and transparent regulatory pathway that will optimise and speed up the development and delivery of ATMPs and other innovative therapeutic modalities for rare diseases for the benefit of patients, carers, healthcare systems and society.

- Improved technologies/processes, analytic tools, methods including non-clinical methods, and assays useful for the development of ATMPs and other related innovative therapeutic modalities, beyond those targeting rare and ultra-rare diseases.

## Scope

There are over 7 000 rare diseases resulting in 30 million patients<sup>15</sup> in Europe with a rare disease. Globally more than 300 million patients<sup>16</sup> are affected. In Europe, less than 10 % of rare disease patients receive treatment and only 1 % are managed using an approved treatment. ATMPs such as gene and cell therapies and other related innovative therapeutic modalities, are very promising to treat patients with rare diseases, especially ultra-rare diseases. However, ATMPs rely on complex technologies where the development process is hampered by a lack of standardisation, scalability and reproducibility.

The overall aim of this topic is to optimise and streamline the future development of ATMPs and other related innovative therapeutic modalities for rare diseases by strengthening the ecosystem that facilitates the transition of early pre-clinical proof-of-concept research to clinical development. This topic focuses on the scientific, technological and regulatory barriers that are limiting translational research into rapid and cost-effective development of ATMPs and other related innovative therapeutic modalities for rare diseases.

To fulfil this aim, the proposals should:

1. Establish a network of scientific and technical centres of excellence (new and/or existing laboratories/institutions) complementing each other to enable translational research in ATMPs or other related innovative therapeutic modalities relevant to the future treatment of genetically defined diseases. These scientific and technical centres are expected to provide access and advance translatable, quality-controlled technologies, share data, and build capacity to assist industrial and academic developers of ATMPs. They are also expected to explore the establishment of connections with clinical networks, including the ERNs on rare diseases.
2. Develop tools and methods and define key characteristics of ATMPs, and quality standards that are critical to later stages of development of ATMPs and other related innovative therapeutic modalities, in particular those targeting rare diseases with no approved treatment option. Relevant therapeutic modalities must include appropriate vector systems and innovative modalities such as messenger RNA (mRNA) and nanoparticles (NPs) for therapeutics. Technology areas of interest could include targeted delivery (e.g. methods to target distribution), stability (e.g. methods to increase the stability of RNA), transgene expression, advanced redosing technology approaches/reduced immunogenicity of gene delivery platforms, and other underlying biology relevant to the specific therapeutic modality enabling accelerated translation to clinical development and manufacturing.
3. Develop and support the uptake of standardised analytical assays, methods and technological platforms, other non-clinical methods and design strategies as well as translation processes for:
  - i. reducing the timeframe and costs and improving the future development of ATMPs and other related innovative therapeutic modalities and/or;
  - ii. optimising manufacturing processes to maintain product quality while ensuring broad accessibility of critical manufacturing materials and demonstrating the economy of scale for ATMPs or other related innovative therapeutic modalities.

<sup>15</sup> <https://www.eurordis.org/information-support/what-is-a-rare-disease/>

<sup>16</sup> <https://www.nature.com/articles/s41431-019-0508-0>

4. Demonstrate the translatability, scalability, and robustness of technologies suitable for the development of subsequent ATMPs and other related innovative therapeutic modalities. This may include process development, mRNA and NPs scale-up and stability, vector production, increasing the throughput of the systematic assessment of the biological and mechanistic features and product characterisation, and ensuring broad accessibility of critical manufacturing materials such as cell lines and producer plasmids.
5. Assess the methods and technological platforms developed for their translational and regulatory validity/utility. Define a regulatory pathway to support the fit-for-purpose development of ATMPs, taking into account an evolving regulatory environment and the interplay between all applicable legislation. Ensure early engagement with the regulators so that the methods and data generated support regulatory needs.
6. Validate the performance of the methods and technologies developed and demonstrate their higher performance in comparison to existing methods for addressing the bottlenecks in the development and manufacturing cycles of ATMPs and other related innovative therapeutic modalities. In addition, test the functionality of the centres of excellence and demonstrate their capability and performance to support translational research through use cases.  
To achieve this, the submitted proposals must plan for an open expression of interest / call process to invite third parties, external to the initially established consortium, to submit use cases at least twice during the lifetime of the project. These use cases must:
  - showcase the utility and validity of the methods and technologies developed and verify that they are fit for purpose in the context of the scientific, technological or regulatory challenges; and
  - measure and help adjust the capability and performance of centres and networks of excellence in assisting industrial and academic developers of ATMPs in their translational research.

For the use cases, clinical validation of technological solutions developed would be in the scope of this topic (within the framework of the above objectives). While conducting full randomised controlled trials are out of scope for this topic, other forms of clinical studies are in scope under the use cases, which may include pilot clinical studies, observational studies, real world data studies etc., depending on the needs of proponents of the use cases.

7. Contribute to strengthening the European rare disease ecosystem by engaging all relevant stakeholders, especially patients and patients' representatives for rare diseases, carers, clinicians, and regulators.
8. Define relevant metrics and measure the use of centres of excellence by relevant stakeholders for the development of their assets or novel technological solutions/therapies.
9. Define a plan for sustainability beyond the lifetime of the project, including consideration for potential expansion to additional promising technological areas.

Applicant consortia should take stock of the state-of-the-art methods and technologies delivered by other EU and global initiatives on rare diseases (e.g. the Accelerating Medicines Partnership Bespoke Gene Therapy Consortium, the Innovative Medicines Initiative (IMI) project ARDAT, the European Joint Programme on Rare Diseases and the future European partnership on rare diseases, or other EU-funded consortia). Proposals should plan for synergies and collaborations to ensure complementarity while avoiding duplication.

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

A cross-sectorial and multidisciplinary public-private collaboration driving innovative science and technology solutions is needed to deliver on the outcomes and impacts of this topic, fostering a trusted collaborative environment where the end-users integrate from day one with the innovation developers to ensure projects generate useful and usable outputs that will be sustained for longer term impact. There is a need to remove key technical bottlenecks, facilitate cooperation and sharing information and processes and bring together all relevant stakeholders in order to streamline the translation of early research into development of potential ATMPs. This will enable accessibility to world-leading solutions that would otherwise limit or delay progression through development and towards effective treatment for patients. Therefore, collaboration and synergies between the research institutions, clinics who often conduct the early research and biotech, SMEs, pharmaceutical and medical technology companies is critical to ensure that the approaches can be translated. Bringing on board the unique expertise of patients and advocates in rare diseases in this effort is essential. Early engagement with regulators is fundamental to maximising the impact of these technologies on public health and ensuring they are fit for purpose. Finally, connections with clinicians and rare diseases networks are needed to ensure an integrated development pathway for ATMPs for rare diseases.

## Indicative budget

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

IHI estimates that an IHI financial contribution of between EUR 20 000 000 and EUR 30 000 000 would allow a proposal to address these outcomes appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

Applicant consortia must ensure that at least 45 % of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.

Additional activities from industry members and their constituent or affiliated entities may also contribute towards this 45 % threshold, providing these activities are related to the project. Contributing partners do not contribute additional activities.

## 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 calls management rules under "Specific conditions on availability, accessibility and affordability" apply<sup>17</sup>.

<sup>17</sup> See section 4.2.3.2 of the amended Work Programme.



## Topic 5: Digital health technologies for the prevention and personalised management of mental disorders and their long-term health consequences

### Expected impacts to be achieved by this topic

#### The following impacts are expected:

- Enhanced cross-sectoral collaboration between healthcare industries, academia and all other relevant actors of the healthcare ecosystem. This will be achieved keeping the people with mental disorders in the centre, outreaching to the social and educational system as relevant to foster sustained and patient-centric innovation in digital health technologies (DHT) for mental health care.
- Preparedness of the healthcare system for the implementation and integration of DHT with existing clinical care strategies thereby also decreasing the burden on staff.
- Prevention (primary and secondary, relapses, chronification, long-term health consequences), earlier and more precise diagnosis, more clinically effective interventions and monitoring, better patient adherence, and reduced hospitalisation (reduction in re-admission/period of hospitalisation).
- Demonstration of the added value of DHT for better management and care and improved experience of people with mental disorders and their families/caregivers, paving the way for a broader and sustained application of DHT in healthcare.
- More cost-effective care pathway management for people with mental disorders.
- Contribute to the upcoming 'European Health Data Space' by promoting better exchange of and access to different types of health data and data generated by DHT and other medical health technologies (using standards in data, technologies...).
- Knowledge and learnings on mental disorders' long-term impact on physiology and physical health. This will contribute to the better overall health & well-being of the population, especially for people with mental health disorders.

### Expected outcomes

R&I actions (projects) to be supported under this topic must contribute to all of the following outcomes:

- Robust evidence on the feasibility, acceptability, adherence, and personal satisfaction with digital health technologies (DHT) in people with mental disorders. People with mental disorders and their families/caregivers should be included in evidence generation. This includes pathways to maximise motivation and engagement with DHT of all relevant end-users and healthcare actors. This includes patient-centric selection of potential application features, measurement technologies and digital endpoints. Proper attention should be given to the issues of vulnerability, stigma and difficulties related to limited digital/eHealth literacy. Consideration should be given to ethical, cultural, gender and age-specific (e.g. adolescents') needs and preferences to ensure continued use of the DHT.
- A flexible, interoperable, and reusable digital platform that can be used across numerous conditions and scenarios (various mental disorders, comorbidities, long-term health consequences and other disease areas) to collect, analyse and integrate diverse multimodal clinical and patient data, including patient reported outcome measures (PROMs) and patient reported experience measures (PREMs), with an emphasis on those generated by DHT. Variability across countries should be addressed, as digital infrastructures and the availability of digital tools may differ. Mapping of the specific links between digital infrastructures and types of digital health technology (e.g. concepts, data types, standards, technological approaches) should be included. Consideration must be given to ethical, social, and legal aspects and to the FAIR (findable, accessible, interoperable, reusable) principles.

- Effective and agreed guidelines for the development and implementation of DHT in clinical research and as a part of everyday health and care, enabling the development of more patient-centric treatments, optimised health and care interventions and better disease prevention. Evidence from quantitative studies on potential favourable/unfavourable effects of the technologies on care, and on their impact on changing clinical research and clinical trials should be included. Relevant organisational and work processes, policy and regulatory aspects should be addressed to foster the sustained integration of DHT in real world practice.
- Robust knowledge for better understanding of mental disorders, their change over time and how all this relates to clinical outcomes including the remission, relapse, and recurrence of the conditions, long-term health conditions and mortality and/or surrogate outcome measures when relevant. Socioeconomic outcomes and family/caregiver burden should be addressed. Better insights into other aspects like patient adherence to therapy and adverse drug reactions should be gained.
- A robust body of data to enable the development of digital tools that optimise the engagement of people with mental disorders, caregivers and other relevant actors (healthcare professionals, social workers etc.) adapted to the needs of the patient population and age-specific needs, tackling the issues of stigma, vulnerability, lack of treatment seeking and overall poor adherence to treatment (including lifestyle related). Consideration should be given to providing intuitive equipment and user interfaces and easy troubleshooting.
- Enhanced and more reliable tools and methods (e.g. analytical tools and algorithms) able to provide (near) real time feedback on the DHT, including on the usability, efficacy/effectiveness, and long-term safety. Together, these enable healthcare professionals and providers to make more inclusive and efficient patient-centred decisions in collaboration with the people with mental disorders and their families.
- Robust evidence of how DHT may influence the treatment or behaviour of people with mental disorders. The inclusion of schools/social workers/psychologists in evidence generation should be considered where relevant.

## Scope

Mental health disorders represent an area of severe unmet public health need. This has been further negatively impacted by the COVID-19 pandemic, with a substantial increase in the number and severity of people affected for example by anxiety and depression<sup>18</sup>, which places substantial pressures on already strained mental health care systems. People with mental disorders have a reduced life expectancy compared to the general population, and this is linked to a greater risk of developing a range of chronic physical conditions<sup>19</sup>. The long-standing separation of psychiatry from other branches of medicine and the lack of specific training on this issue further contribute to the poor attention dedicated to management of comorbidities of mental health disorders.

Digital health technologies (DHT) applied via electronic devices such as wearable sensors, implanted equipment, and handheld instruments and smartphones have already shown significant promise for the prevention and disease management of chronic conditions (e.g. cardiovascular disease, diabetes, obesity). DHT, by making it possible to virtually perform medical activities that have traditionally been conducted in person, also have the potential to decrease the pressure on healthcare systems and their personnel. Thus, DHT might have the potential to address some of the challenges in the prevention,

<sup>18</sup> <https://www.who.int/news/item/02-03-2022-covid-19-pandemic-triggers-25-increase-in-prevalence-of-anxiety-and-depression-worldwide>

<sup>19</sup> <https://annals-general-psychiatry.biomedcentral.com/articles/10.1186/s12991-021-00374-y;>  
<https://www.nature.com/articles/s41569-020-00463-7>

prediction, monitoring and personalised management of mental disorders and their long-term health consequences, as well as to tackle some of the organisational issues in providing mental health care<sup>20</sup>.

The scope of this topic is to investigate how DHT might positively impact the healthcare pathway for people with mental disorders.

Applicants should demonstrate how DHT may enable:

1. better prevention and prediction of disorder onset or relapse;
2. better disease management;
3. tackling comorbidities;
4. addressing long-term health consequences (such as cardiovascular disease or diabetes).

The choice of the specific mental disorder should be justified based on unmet public health need, its impact on quality of life of people with mental disorders and their families/caregivers as well as the feasibility and preliminary evidence available on the use and value of DHT.

To contribute to breaking the silos between psychiatry and other medical branches and better address the impact of co-morbidities in people with mental disorders, applicants should consider relevant co-morbidity/ies where DHT data, learnings and technologies are already available and can be further developed/applied to mental disorders. Co-morbidities can significantly exacerbate mental health disorders, impacting quality of life and the development of long-term health consequences. The choice of comorbidity/ies must therefore be justified accordingly.

Ways of decreasing the burden on caregivers and families should be considered, and applicants should actively engage these actors as well as the people with mental disorders in addressing critical issues and research questions, including about (sustained) engagement with DHT<sup>21</sup>. Consortia should propose ways to foster the future integration of digital and clinical mental healthcare, as well as how DHT might enhance the outcomes of interventions by social and healthcare professionals while decreasing the burden on the healthcare system. Applicants should adequately describe how they plan to measure such burden.

Resources, and learnings from previous initiatives at European and national level (Innovative Medicines Initiative funded<sup>22</sup> among others) should be taken into consideration.

Applicants should aim to deliver robust evidence on how DHT may be:

- a. made easy to adopt and use in a sustained way for both people with mental disorders, their families/caregivers and health and care providers;
- b. effectively incorporated into clinical research and in clinician workflows.

Early engagement with regulators should be sought to ensure the future acceptance and usability of the results for example through scientific advice, qualification advice or qualification opinion.

Applicants are expected to implement activities to achieve all expected outcomes.

<sup>21</sup> <https://www.frontiersin.org/articles/10.3389/fdgth.2021.764079/full>

<sup>22</sup> [https://www.imi.europa.eu/projects-results/project-factsheets?keywords=digital+technology&status=All&call=All&programmes=All&disease\\_areas=All&products=All&tools=All;](https://www.imi.europa.eu/projects-results/project-factsheets?keywords=digital+technology&status=All&call=All&programmes=All&disease_areas=All&products=All&tools=All;)  
[https://www.imi.europa.eu/projects-results/project-factsheets?keywords=radar+cns&status=All&call=All&programmes=All&disease\\_areas=All&products=All&tools=All](https://www.imi.europa.eu/projects-results/project-factsheets?keywords=radar+cns&status=All&call=All&programmes=All&disease_areas=All&products=All&tools=All)

Applicants are expected to consider allocating appropriate resources to explore synergies with other relevant initiatives and projects.

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

Digital health technologies (DHT) have enormous potential to improve the prevention, prediction, diagnosis and treatment of health disorders, especially in areas of high unmet public health need such as mental disorders. To achieve this, all stakeholders — healthcare professionals and systems, academic researchers, including from the social sciences, technology developers, regulators, reimbursement authorities and, most of all, people with mental disorders, families and caregivers, and citizens need to be involved in the discussions. There is thus the need for an appropriate multi-stakeholder and cross-sectorial, public-private platform delivering learnings and sustainable outcomes of value across the ecosystem to foster the development, evaluation, and best use of DHT. IHI offers an ideal setting to bring the relevant stakeholders together and achieve the requested impacts.

People with mental disorders and their families/caregivers must be active partners in all activities of such an initiative to ensure the results fit their needs for effective adoption and continued use.

### **Indicative budget**

Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 24 000 000.

IHI estimates that an IHI financial contribution of between EUR 6 000 000 and EUR 8 000 000 would allow a proposal to address these outcomes appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

Applicant consortia must ensure that at least 45 % of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.

Additional activities from industry members and their constituent or affiliated entities may also contribute towards this 45 % threshold, providing these activities are related to the project. Contributing partners do not contribute additional activities.

### **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 calls management rules under "Specific conditions on availability, accessibility and affordability" apply<sup>23</sup>.

<sup>23</sup> See section 4.2.3.2 of the second amended Work Programme.