



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

- IHI call 3 – topic 5

Before we start...

- We are recording this session and it will be published on the IHI website and B2Match platform.
- We will also publish the presentation slides.
- 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.

Today's session

- **Will cover:**

- Introduction to IHI programme
- IHI Call Topic
 - Challenge, need for public-private collaborative research
 - Scope, outcomes & impacts, budget
- Proposal submission, evaluation & preparation tips

- **Will not cover**

- rules and procedures
- how to prepare the financial proposal

Innovative Health Initiative

EU's new **partnership in health** between:

- the **European Union** represented by the European Commission
- &
- **Healthcare industry associations:**
 - **COCIR** (medical imaging, radiotherapy, health ICT and electromedical industries)
 - **EFPIA**, including **Vaccines Europe** (pharmaceutical and vaccine industries)
 - **EuropaBio** (biotechnology industry)
 - **MedTech Europe** (medical technology industry)

IHI's general objectives

- Turn health research and innovation into **real benefits for patients and society**
- Deliver safe, effective health innovations that **cover the entire spectrum of care** – from prevention to diagnosis and treatment – particularly in areas where there is an unmet public health need
- Make Europe's health industries globally **competitive**.

Strategic Research & Innovation Agenda

Focus

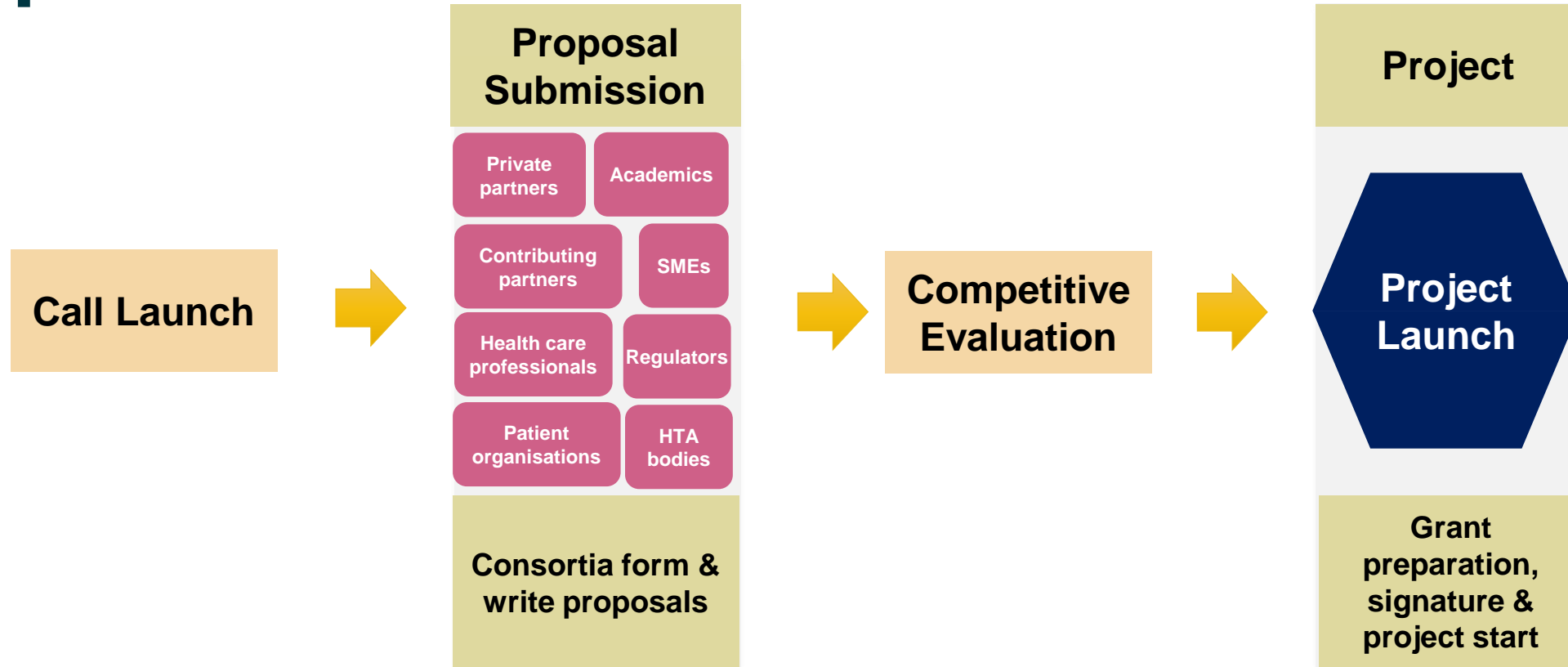
- **Cross-sectoral approaches** to facilitate creation of new products and services to **prevent, intercept, diagnose, treat and manage diseases** and foster recovery more efficiently.

Goal

- Lay foundations for development of **safer and more effective health care products or solutions** that respond to **unmet public health needs** and that can be implemented into healthcare systems.

Research supported by IHI should remain at precompetitive level

How does IHI work? single-stage procedure





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

IHI call 3 – topic 5

The challenge

- Mental health disorders represent an area of severe unmet public health need
- 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
- 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 might have the potential to address some of the challenges in the prevention, 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



Need for public-private, cross-sector collaboration

An appropriate multi-stakeholder and cross-sectorial, public-private platform, is needed to achieve the outcomes and impacts of this topic:

- For delivering learnings and sustainable outcomes of value across the ecosystem to foster the development, evaluation, and best use of DHT and
- to have people with mental disorders and their families/caregivers as active partners in all activities of such an initiative to ensure the results fit their needs for effective adoption and continued use.



Scope of the topic

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

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.

- 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).

- 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.

Expected outcomes

Applicants are expected to address all outcomes

- Robust evidence on the feasibility, acceptability, adherence, and personal satisfaction with digital health technologies (DHT) in people with mental disorders.
- A flexible digital platform usable across various conditions and scenarios to collect, analyse and integrate diverse multimodal clinical and patient data (including PROMs & PREMs), especially those generated by DHT.
- Effective and agreed guidelines for the development and implementation of DHT in clinical research and health and care, for more patient-centric interventions and better disease prevention.
- Robust knowledge for better understanding of mental disorders, their change over time and how all this relates to clinical outcomes.
- Robust data to enable the development of digital tools that optimise the engagement of people with mental disorders, caregivers and other relevant actors.
- Enhanced and more reliable tools and methods (e.g. analytical tools and algorithms) able to provide (near) real time feedback on the DHT.
- Robust evidence of how DHT may influence the treatment or behaviour of people with mental disorders.

Expected impact

- Enhanced cross-sectoral collaboration 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, earlier and more precise diagnosis, more clinically effective interventions and monitoring, better patient adherence, and reduced hospitalization.
- Demonstration of the added value of DHT for management and care and improved experience of people with mental disorders and their families/caregivers, 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'.
- Knowledge and learnings on mental disorders' long-term impact on physiology and physical health for better overall health & well-being of the population, especially for people with mental health disorders.



Budget

- Total of EUR 24 million public funding available for this topic
- IHI estimates that an IHI financial contribution of around EUR 6 000 000 to EUR 8 000 000 would allow a proposal to address the topic outcomes appropriately.
- At least 45% of the total budget of each project must be covered by contributions provided by IHI Private members & Contributing partners

Duration

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



Dissemination, exploitation and communication

- Importance to communicate and disseminate results throughout the full lifespan of the project
- Plan Dissemination & Exploitation measures to maximise the impact including elements in line with availability, accessibility and affordability (3A) provisions.
- Plan communication measures for promoting the project and its findings
- **Short description** of the Dissemination, Exploitation & Communication (D, E & C) activities, together with the impact pathways in the proposal. This is an **admissibility condition**.
- Full-fledged D, E & C plan to be submitted as a deliverable after the first 6 months of the project

Strategic planning of communication, dissemination and exploitation activities **already starts before the project** at the proposal stage.

Plans need to be constantly monitored, reviewed and potentially adjusted throughout the course of the project.

Exploitation of results

Dissemination of results

Communication of project *and* results

First Results

Further results may occur during the project – not only at the end

– that may initiate: a) dissemination activities, b) dissemination and linked communication actions, and/or c) exploitation measures.

Start

Project Implementation

End

Dissemination, exploitation and communication

SPECIFIC NEEDS
<p>What are the specific needs that triggered this project?</p> <p>Example 1</p> <p>Health solutions need to be better tailored to patients' needs. Novel approaches are needed to capture patients' needs and to involve them in the development a novel health technology.</p>

EXPECTED RESULTS
<p>What do you expect to generate by the end of the project?</p> <p>Example 1</p> <p>Patient-centric clinical development: Patients perspectives included in design of studies.</p> <p>Patients' perspective incorporated into the evidence generated for decision making.</p>


D & E & C MEASURES
<p>What dissemination, exploitation and communication measures will you apply to the results?</p> <p>Example 1</p> <p>Exploitation: Approach to include patients' perspectives is adopted by industry in their novel health technologies development programmes.</p> <p>Dissemination towards the scientific community and industry: Scientific publication of the results of the demonstration pilot</p> <p>Communication towards citizens: An event in a shopping mall to show how the outcomes of the action are relevant to our everyday lives.</p>

TARGET GROUPS
<p>Who will use or further up-take the results of the project? Who will benefit from the results of the project?</p> <p>Example 1</p> <p>Healthcare industry companies: pharmaceutical (including vaccine), biopharmaceutical, medical (and digital) technologies, etc.</p> <p>Scientific community (clinical research investigations, and testing activities of health solutions)</p> <p>End-user of the novel health technology: patients and citizens</p>

OUTCOMES
<p>What change do you expect to see after successful dissemination and exploitation of project results to the target group(s)?</p> <p>Example 1</p> <p>Healthcare industry partners: novel health technologies adapted to patients' needs.</p> <p>Use of the scientific results published (measured through the bibliometric indicators of the project publication).</p>

IMPACTS
<p>What are the expected wider scientific, economic and societal effects of the project contributing to the expected impacts outlined in the topic text?</p> <p>Example 1</p> <p>Scientific: New approach to patient engagement in the development of novel health technologies tailored to the patients needs.</p> <p>Economic/Technological: Health solutions designed with the patients in mind will facilitate the adoption of the health technology by the market / healthcare system</p> <p>Societal: Patients will benefit from truly patient-centric health technologies (designed from the start based on their needs)</p>

Make sure you reserve budget / resources for D, E & C activities



Proposal Submission & Evaluation



Proposal Template - Parts A, B & Annexes

- **Part A** of the proposal is **administrative data** that is entered in webforms through the Funding & Tenders Portal.
- **Part B** of the proposal is the **narrative part** that includes three sections:
 - Excellence
 - Impact
 - Quality and efficiency of the implementation
- **Read instructions** in proposal template **very carefully**
- **Annexes:**
 - Participant type
 - Budget details
 - Clinical studies template

Evaluation Criteria (1/2)

● Excellence

- Clarity and pertinence of the project's objectives, and the extent to which the proposed work is ambitious, and goes beyond the state of the art.
- Soundness of the proposed methodology, including the underlying concepts, models, assumptions, interdisciplinary approaches, appropriate consideration of the gender dimension in research and innovation content, and the quality of open science practices, including sharing and management of research outputs and engagement of citizens, civil society and end users where appropriate.

● Impact

- Credibility of the pathways to achieve the expected outcomes and impacts specified in the work programme, and the likely scale and significance of the contributions due to the project.
- Suitability and quality of the measures to maximise expected outcomes and impacts, as set out in the dissemination and exploitation plan, including communication activities.

Evaluation Criteria (2/2)

- **Quality and efficiency of the implementation**
 - Quality and effectiveness of the work plan, assessment of risks, and appropriateness of the effort assigned to work packages, and the resources overall
 - Capacity and role of each participant, and extent to which the consortium as a whole brings together the necessary expertise.



- Tips for applicants

Tips for applicants

- Read all the call-relevant material, especially the **topic text**
 - www.ih.europa.eu/apply-funding/open-calls
 - www.ih.europa.eu/apply-funding/future-opportunities
- Form your consortium **early**
 - Always think “public-private partnership“
 - Include partners bringing **in-kind contributions**
- Ensure that **all information requested in the call text and proposal template** is provided to allow the evaluation experts to easily assess your proposal against the evaluation criteria
- Consider & plan for the potential **regulatory impact** of results

Finding project partners

You'll need to build or join a consortium!

- Network with **your contacts & IHI Call Days participants:**
 - <https://ihi-call-days.ihi.b2match.io/>
 - Use EU Funding & Tenders portal **partner search tool:**
 - <https://europa.eu/!QU87Nx>
- Get in touch with your **IHI national contact point:**
 - <https://europa.eu/!D7jyMy>
- Network on social media:
 - www.twitter.com/IHIEurope
 - be.linkedin.com/company/innovative-health-initiative

How to book your meetings via the B2Match platform

Book your meetings in **4** easy steps

1. Make yourself available
2. Look for partner on the participants or organisation tab
3. Select date, time, attendees (up to eight per meeting), add message
4. Send the meeting request and wait for the reply

The platform will be available for meetings from the 22 November 2022 to 20 April 2023 and not only during the IHI Call Days

Step by Step guide on how to book meetings: <https://europa.eu/!fnJFFM>



- Additional Slides

Simplified example budget

Single-stage calls

Participant type	Total eligible costs + IKAA	Requested IHI funding Reimbursed eligible costs	In-kind contributions (IKOP, IKAA, FCs)
'Public' partners (Universities, hospitals, SMEs, patient orgs, regulators.....)	15 million	15 million	0
Private members & contributing partners (requested funding = 0)	15 million	0	15 million
Private members & contributing partners (“Hybrid”)	10 million	5 million	5 million
Total	40 million	20 million <u>(50%) public funds</u>	20 million <u>(50%) private funds</u>

Pitching Sessions

We are organising individual pitching sessions per call 3 topic
You can join the sessions via the B2Match platform

Monday, 12 December

15:30-16:30 (CET) Digital health technologies for the prevention, and personalised management of mental disorders and their long-term health consequences

Tuesday, 13 December

15:30-16:30 (CET) Strengthening the European ecosystem for Advanced Therapy Medicinal Products (ATMPs) and other innovative therapeutic modalities for rare diseases

Wednesday, 14 December

11:30-13:00 (CET) Screening platform and biomarkers for prediction and prevention of diseases of unmet public health need.

16:00-17:00 (CET) Patient input and patient generated evidence to improve patient outcomes, support decision making, and accelerate innovation

Thursday, 15 December

12:30-13:30 (CET) Combining hospital interventional approaches to improve patient outcomes and increase hospital efficiencies



Thank you for your attention

ihi.europa.eu



Questions time

If you want to ask a question please use the chat function on the right corner of your screen

