Getting Involved in the Innovative Health Initiative

Hugh Laverty 26.01.2022 • Introducing the Innovative Health Initiative: Europe's new partnership for health



Getting involved – Overview

- What is IHI?
 - Strategic Research and Innovation Agenda
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IHI IS EUROPE'S NEW PARTNERSHIP FOR HEALTH IHI is a **collaboration** between the EU and the biopharmaceutical, biotechnology, digital health and medical technology sectors, as well as academics, patients, regulators and other healthcare professionals. IHI will build on the extensive experience of IMI's 14 years and almost 200 projects

to build an interdisciplinary, sustainable, patient-centric health research partnership to help transform patients' lives. The industry members that make up the new partnership are:

COCIR EFPIA

EuropaBio

MedTech Europe

The public member in the partnership is the European Union, represented by the European Commission





- The way we're governed will change.
- The scope of the partnership is broader than IMI as it will cover the entire continuum of care.
- There will be new, specific objectives that align with the EU's latest health policy strategies.

- Funding comes equally from the public and industry partners.
- Calls for proposals will be open and competitive.
- Projects started under IMI will be managed by IHI.

- New Strategic Research and Innovation Agenda
- The Science and Innovation Panel
- One and two stage calls



Strategic Research and Innovation Agenda



IHI SRIA – background

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.



IHI's general objectives

IHI's objectives are set out in the legislation creating IHI. Our general objectives are to:

- 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.



IHI's specific objectives

Described in more detail in the Strategic Research and Innovation Agenda.

- Improve our **understanding of the factors that affect our health** and the development and treatment of certain diseases.
- Integrate fragmented health research and innovation efforts by bringing together health industry sectors and other stakeholders. This will enable the development of tools, data, platforms, technologies and processes that will in turn facilitate the prevention, diagnosis, treatment and management of diseases, especially in areas where there is an unmet public health need.
- Demonstrate the **feasibility of integrated healthcare solutions** that draw on various technologies from different sectors and address the needs of the people who will use them, such as patients and healthcare professionals.
- Make better use of **opportunities to gather health data** and use it in research and care, all while respecting relevant privacy legislation.
- Develop ways of **assessing the value of innovative, integrated health care** solutions to patients, carers, healthcare professionals and organisations, and
- 8 other stakeholders.



SRIA - IHI contributes to EU policies

On the policy front, IHI's projects are expected to contribute to EU policies, most notably:

- Horizon Europe (of which IHI is a part)
- Europe's Beating Cancer Plan
- The new Industrial Strategy for Europe
- The Pharmaceutical Strategy for Europe
- The European Health Data Space

IHI contributes to the UN Sustainable Development Goal 3 on ensuring healthy lives and promoting well-being for all at all ages.



IHI JU Budget

IHI will launch calls for proposals and select projects (actions) that contribute to reaching one or more of the objectives outlined in the SRIA.

IHI will work to reach its objectives with the following resources:

- up to EUR 1.2 billion provided by the European Union (Horizon Europe Health Cluster),
- at least EUR 1.0 billion provided by the member industry associations,
- up to EUR 200 million from Contributing Partners.





IHI Synergies

- IHI builds on lessons learned from the Innovative Medicines Initiative
- IHI is not meant to be a direct continuation of IMI. Rather, IHI will build on IMI's results and ongoing initiatives within a new platform with a broader scope, more partners and a wider stakeholder base.
- IHI will seek synergies with other Horizon Europe activities, including other European partnerships, as well as other EU and national programmes.





Science and Innovation Panel



Background

IHI requires **multi-stakeholder input** to fulfil its objectives and ensure it addresses **unmet public health needs**:

- Scientific & technological input relevant to the scope of IHI as in the SRIA.
- Input from other stakeholders in the healthcare system to ensure that its strategic design and activities address the needs of the health care systems and of the patients

The stakeholder input will be provided, amongst others, by a **Science and Innovation Panel** (SIP).



The SIP role

The SIP will provide science-based advice to the Governing Board, on scientific and technological matters such as:

- IHI's draft work programmes, and in particular the draft call topics;
- updates to the SRIA;
- the planning of additional activities;
- the set-up of advisory groups focused on specific scientific priorities;
- synergies with other Horizon Europe activities, including other European partnerships, other EU and national programmes.



SIP composition



SIP membership

Representatives of the Scientific Community (4 members)

Should provide the necessary know-how in scientific/technological areas relevant to the IHI objectives.

Representatives of Health Care Stakeholders (up to 6 members)

Experience in at least one of the following categories:

- Patients
- Health care professionals
- Health care providers
- Regulatory bodies
- Heath Technology Assessment bodies
- Health care payers



The **call for Expressions of Interest** (EoI) will establish a list of candidates for the IHI Governing Board.

- The selection will be based on the essential and advantageous criteria listed in the EoI Call.
- The IHI Governing Board will finalise the selection and appointment of the panellists ensuring a high level of expertise, balanced representation of **relevant know-how** and areas of interest in relation to IHI objectives, representative **geographical coverage** and **gender** balance.
- The selected permanent panelists will be appointed in their individual capacity and for a term of **3 years**.



Essential Criteria 1 – all candidates

- Proven experience in providing scientific and technical advice in the area(s) relevant to the IHI objectives;
- Very good command of written and spoken English.

Essential Criteria 2 – representatives scientific community

 Proven competence & expertise in health research and innovation and/or health care in scientific/technological areas relevant to the IHI objectives supported by a university qualification.



Essential Criteria 3 – representatives of health care stakeholders

- Proven competence and expertise in representing stakeholders involved in health care for at least one of the mentioned categories;
- Support from one or several organisations, groups or networks representing the interests of relevant stakeholders at European and/or international level.



Advantageous criteria – all candidates

- Record of previous participation in scientific and/or technological advisory bodies;
- Good understanding of the EU research & innovation environment (e.g. acquired through the participation in EU funded initiatives);
- Good understanding of industrial research & development environment;
- Scientific impact of relevance to the areas of IHI JU activities (representatives of the scientific community);
- Cross-sectoral experience & expertise (covering several technology areas).



Independence – Conflict of interest

- Selected permanent panelists shall not have financial or other interests in health-related industries which could affect their impartiality. They shall undertake to act in an independent manner.
- Selected permanent panelists shall not participate in proposals or projects funded under the IHI JU, either in their personal capacity or as a representative of the organisations to which they belong.
- Where discussions address proposals or projects in which their organisation is involved or where they have any advisory role, they shall inform the IHI JU Office and the SIP, and will be asked to leave the meeting for the discussion of the concerned item/subject.



Eol submission

• All information, the application form and list of documents to be included in a submission are available on the IHI website at:

ihi.europa.eu/about-ihi/who-we-are/science-and-innovation-panel

- Candidates may apply for one or both types of position as permanent panelists.
- In the case where a candidate applying for both types of position is shortlisted, the ultimate decision remains with the IHI JU Governing Board as to the final position offered.
- The deadline for submission of applications is:

21 February 2022, 23:59 CET

Become an evaluator/expert/independent observer

IHI appoints external independent experts to assist in the evaluation of grant applications and projects

If you have a high level of expertise in fields relevant to IHI please register on the Horizon Europe Funding & tender opportunities portal

ec.europa.eu/info/funding-tenders/opportunities/portal/screen/work-as-anexpert

and then send us an email at infodesk@ihi.europa.eu expressing your interest

If you already have a profile, please make sure that it is up-to-date.



Patient Pool

Identified patients/ patient informal carers interested in participating in IMI activities both at strategic and operational levels.

Drawing from this Patient Expert Pool, the Programme Office invited expert patients/patient informal carers with the most suitable profile to perform a variety of roles and tasks.

Later in the year we will re-open the patient pool to seek others who can contribute to shaping the IHI activities and improve the quality of IHI projects from a patient perspective through early and meaningful engagement.



Get involved - Contributing partners

- The contributing partner category was created to open IHI to a wide range of health stakeholders who may want to invest in IHI without becoming full members.
- Contributing partners invest their own resources or cash in a specific IHI project(s). Their contributions work in a similar way to those from industry partners.
- Under IMI over 30 associated partners from around the world including philanthropic organisations, patient groups, and companies.
- Any international organisation or legal entity can apply to become an IHI contributing partner.
- Those interested in becoming a contributing partner will require endorsement by the IHI Governing Board.

Interested? Contact the IHI office.



Call and Evaluation Planning



How does IHI work? single-stage procedure



How does IHI work? Two-stage procedure





Eligibility rules: funding for single-stage Calls





Any legal entity established in a Member State, Associated Country or Low and Middle Income Countries



See Horizon Europe programme guide



Eligibility rules: funding for two-stage Calls

Academic organisations institutions



For-profit legal entities (SME and larger enterprises with an annual turnover of less than EUR 500 million)

Any legal entity established in a Member State, Associated Country or

Low and Middle Income countries

See Horizon Europe programme guide

NOT eligible for funding:

Non-profit

- Pre-identified Industry Consortium
- Any legal entities which is:

(a) A for-profit legal entity with an annual turnover of EUR 500 million or more

(b) A for profit legal entity directly or indirectly controlling/or being controlled by for profit legal entities with an annual turnover of EUR 500 million or more.





Call 1 – single stage – Indicative timelines

April 2022	Publication of draft topics	
mid-June 2022	Launch of the Call	
end-September 2022	• Call Submission Deadline - Full Proposals (FP)	
October 2022	Scientific evaluation	
end-November 2022	 Information to the applicants - evaluation outcome 	
March 2023	 Grant Agreement Preparation (GAP) and GA signature 	• innovative health initiative

Call 2 - two-stage – Indicative timelines

April 2022	Publication of draft topics	
mid-June 2022	Launch of the Call	
end-September 2022	Call Submission Deadline - Short Proposals (SP)	
October 2022	Scientific evaluation - SP	
end-November 2022	 Information to the applicants - evaluation outcome 	
end-February 2023	Submission Deadline - Full Proposal (FP)	
March 2023	Scientific evaluation - FPs	
April 2023	 Evaluation Outcome letters to the applicants 	
July 2023	Grant Agreement Preparation (GAP) and GA signature	 innovative health initiative

Potential future topics

 IHI has published on its new website, indicative information on ideas that may be included in the first call for proposals.

• This first call should be launched by the end of Q2 2022



Call 1 – Ideas - Single-stage

Innovative patient-facing care pathways for patients with neurodegenerative diseases and comorbidities

2

Next generation imaging and image-guided diagnosis and therapy for cancer

3

Precision oncology: Innovative patient-centric, multi-modal therapies against cancer

4

Access and Integration of heterogeneous health data for improved health care in diseases areas of high unmet public health need



Call 2 – Ideas - Two-stage



New tools for prediction, prevention and monitoring of cardiometabolic diseases including secondary manifestations to enable timely intervention

2

Strengthening EU clinical development excellence and innovation attractiveness: Harmonised methodology to promote the uptake of early feasibility studies (EFS)



Brokerage events and information days

- Previous experience has shown that building a consortium to apply to an IHI call will probably be one of the bigger challenges that applicants face.
- Applicants with established networks have an advantage when it comes to building consortia.
- The need to broaden participation from a wider range of stakeholders will also be important.
- While IHI office has to remain impartial and cannot support the formation of a particular consortium, we will organise brokerage events and info-days to facilitate the networking and building of consortia.
- The aim is to have these events as F2F events.



Get Involved - Third party ideas

- At IHI, many ideas for call topics will come from our partners (the industry members and the European Commission) and from contributing partners. However, we also welcome ideas from the wider health and research community.
- All ideas will have to demonstrate how they would help IHI to achieve its goals; how they are aligned with the IHI SRIA; and why they need a cross-sectoral public-private partnership. Ideas will be assessed by the IHI Programme Office and governance bodies.
- We are working on a platform and procedures that will make it easy for people to submit call topic ideas.
- Once available, information will be placed on our website.



Getting involved in IHI

At programme/strategic level

 Join one of the industry trade associations who are IHI founding members (COCIR, EFPIA, EuropaBio, MedTech Europe, Vaccines Europe)

• Apply as an IHI contributing partner (similar to the status of IMI2 associated partner) <u>ihi.europa.eu/shape-our-future-</u> research/become-contributing-partner



Getting involved in IHI

• Apply to the Science and Innovation Panel:

ihi.europa.eu/about-ihi/who-we-are/science-and-innovation-panel

• Become an evaluation and review expert:

ec.europa.eu/info/funding-tenders/opportunities/portal/screen/work-as-an-expert

• Be part of the Patient Pool:

ihi.europa.eu/projects-results/health-spotlights/impact-patients-research

• Propose new ideas: <u>ihi.europa.eu/shape-our-future-research/propose-ideas</u>



Getting involved in IHI

- Apply to IHI calls:
 - IHI website: Future opportunities and Open calls

ihi.europa.eu/apply-funding/future-opportunities

ihi.europa.eu/apply-funding/open-calls

• Funding & tender opportunities Portal:

ec.europa.eu/info/funding-tenders/opportunities/portal/screen/home

 Participate in the brokerage events & info-days organised at Call launch



More information

Strategic Research and Innovation Agenda:

ihi.europa.eu/about-ihi/research-and-innovation-agenda

Horizon Europe General Model Grant Agreement

(Annex 5 - Specific rules for JU Actions):

ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/agrcontr/general-mga_horizon-euratom_en.pdf

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